No. 23-12155

In the United States Court of Appeals for the Eleventh Circuit

AUGUST DEKKER, BRIT ROTHSTEIN, SUSAN DOE, by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., by and through his parent and next friend, JADE LADUE,

Plaintiffs-Appellees,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, *et al.*,

Defendants-Appellants.

On Appeal from the U.S. District Court for the Northern District of Florida, No. 4:22-cv-00325, Honorable Robert L. Hinkle, District Judge

APPELLEES' APPENDIX
VOLUME 8 OF 10 (Tabs 193-6 – 199-1)

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TABLE OF CONTENTS

Tab/Docket No.

VOLUME 1 OF 10

VOLUME 2 OF 10

VOLUME 3 OF 10

VOLUME 4 OF 10

VOLUME 5 OF 10

VOLUME 6 OF 10

VOLUME 7 OF 10

VOLUME 8 OF 10

VOLUME 9 OF 10

TAB 193-6 (continued)

although lesbian, gay, and bisexual populations are more vulnerable to suicide ideation overall, the evidence specifically on adult lesbian and bisexual women is unclear. Meyer did not include transgender populations in originating the hypothesis, and it remains a legitimate question to what extent and in what ways it might apply to gender identity.

72. Minority stress is associated, in large part, with being a visible minority. There is little evidence that transgender populations show the patterns suggested by the hypothesis. For example, the minority stress hypothesis would predict differences according to how visibly a person is discernable as a member of the minority, which often changes greatly upon transition. Biological males who are very effeminate stand out throughout childhood, but in some cases can successfully blend in as adult females; whereas the adult-onset transitioners blend in very much as heterosexual cis-gendered males during their youth and begin visibly to stand out in adulthood, only for the first time.

73. Also suggesting minority stress cannot be the full story is that the mental health symptoms associated with minority stress do not entirely correspond with those associated with gender dysphoria. The primary symptoms associated with minority stress are depressive symptoms, substance use, and suicidal ideation.[90] The symptoms associated with gender dysphoria indeed include depressive symptoms and suicidal ideation, but also include anxiety symptoms, Autism Spectrum Disorders, and personality disorders.

74. A primary criterion for readiness for transition used by the clinics demonstrating successful transition is the absence or resolution of other mental health concerns, such as suicidality. In the popular media, however, indications of mental health concerns are instead often dismissed as an expectable result caused by Sexual Minority Stress (SMS). It is generally implied that such symptoms will resolve

[90] Meyer, 2003.

upon transition and integration into an affirming environment.

V. Assessing Statements from Professional Associations

A. Understanding the Value of Statements from Professional Associations

75. The value of position statements from professional associations should be neither over- nor under-estimated. In the ideal, an organization of licensed health care professionals would convene a panel of experts who would systematically collect all the available evidence about an issue, synthesizing it into recommendations or enforceable standards for clinical care, according to the quality of the evidence for each alternative. For politically neutral issues, with relevant expertise contained among association members, this ideal can be readily achievable. For controversial issues with no clear consensus, the optimal statement would summarize each perspective and explicate the strengths and weaknesses of each, providing relatively reserved recommendations and suggestions for future research that might resolve the continuing questions. Several obstacles can hinder that goal, however. Committees within professional organizations are typically volunteer activities, subject to the same internal politics of all human social structures. That is, committee members are not necessarily committees of experts on a topic—they are often committees of generalists handling a wide variety of issues or members of an interest group who feel strongly about political implications of an issue, instead of scientists engaged in the objective study of the topic.

76. Thus, documents from professional associations may represent required standards, the violation of which may merit sanctions, or may represent only recommendations or guidelines. A document may represent the views of an association's full membership or only of the committee's members (or majorities thereof). Documents may be based on systematic, comprehensive reviews of the available research or selected portions of the research. In sum, the weight best placed

on any association's statement is the amount by which that association employed evidence versus other considerations in its process.

B. Misrepresentations of statements of professional associations.

77. In the presently highly politicized context, official statements of professional associations have been widely misrepresented. In preparing the present report, I searched the professional research literature for documentation of statements from these bodies and from my own files, for which I have been collecting such information for many years. I was able to identify statements from six such organizations. Although not strictly a medical association, the World Professional Association for Transgender Health (WPATH) also distributed a set of guidelines in wide use and on which other organizations' guidelines are based.

78. Notably, despite that all these medical associations reiterate the need for mental health issues to be resolved before engaging in medical transition, only the AACAP members have medical training in mental health. The other medical specialties include clinical participation with this population, but their assistance in transition generally assumes the mental health aspects have already been assessed and treated beforehand.

79. With the broad exception of the AAP, their statements repeatedly noted instead that:

- Desistance of gender dysphoria occurs in the majority of prepubescent children.
- Mental health issues need to be assessed as potentially contributing factors and need to be addressed before transition.
- Puberty-blocking medication is an experimental, not a routine, treatment.
- Social transition is not generally recommended until after puberty.

Although some other associations have published broad statements of moral support for sexual minorities and against discrimination, they did not include any specific standards or guidelines regarding medical- or transition-related care.

1. World Professional Association for Transgender Health (WPATH)

80. The WPATH standards as they relate to prepubescent children begin with the acknowledgement of the known rates of desistance among gender dysphoric children:

> [I]n follow-up studies of prepubertal children (mainly boys) who were referred to clinics for assessment of gender dysphoria, the dysphoria persisted into adulthood for only 6–23% of children (Cohen-Kettenis, 2001; Zucker & Bradley, 1995). Boys in these studies were more likely to identify as gay in adulthood than as transgender (Green, 1987; Money & Russo, 1979; Zucker & Bradley, 1995; Zuger, 1984). Newer studies, also including girls, showed a 12–27% persistence rate of gender dysphoria into adulthood (Drummond, Bradley, Peterson-Badali, & Zucker, 2008; Wallien & Cohen-Kettenis, 2008).[91]

81. That is, "In most children, gender dysphoria will disappear before, or early in, puberty."[92]

82. Although WPATH does not refer to puberty blocking medications as "experimental," the document indicates the non-routine, or at least inconsistent availability of the treatment:

> Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. If such treatment is offered, the pubertal stage at which adolescents are allowed to start varies from Tanner stage 2 to stage 4 (Delemarre-van de Waal & Cohen-Kettenis, 2006; Zucker et al., [2012]).[93]

83. WPATH neither endorses nor proscribes social transitions before puberty, instead recognizing the diversity among families' decisions:

> Social transitions in early childhood do occur within some families with early success. This is a controversial issue, and divergent views are held by health professionals. The current evidence base is insufficient to predict the long-term outcomes of completing a gender role transition during early childhood.[94]

84. It does caution, however, "Relevant in this respect are the previously described relatively low persistence rates of childhood gender dysphoria."[95]

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91 Coleman, *et al.*, 2012, at 172.
92 Coleman, *et al.*, 2012, at 173.
93 Coleman, *et al.*, 2012, at 173.
94 Coleman, *et al.*, 2012, at 176.
95 Coleman, *et al.*, 2012, at 176 (quoting Drummond, *et al.*, 2008; Wallien & Cohen-Kettenis, 2008).

85. The WPATH standards have been subjected to standardized evaluation, the Appraisal of Guidelines for Research and Evaluation ("AGREE II") method, as part of an appraisal of all published Clinical Practice Guidelines (CPGs) regarding sex and gender minority healthcare.[96] Utilizing community stakeholders to set domain priorities for the evaluation, the assessment concluded that the guidelines regarding HIV and its prevention were of high quality, but that "[t]ransition-related CPGs tended to lack methodological rigour and rely on patchier, lower-quality primary research."[97] The WPATH guidelines were recommended for use. Indeed, the WPATH guidelines received unanimous ratings of "Do not recommend."[98]

86. Finally, it should be noted that WPATH is in stark opposition to international standards: Public healthcare systems throughout the world have instead been ending the practice of medical transition of minors, responding to the increasingly recognized risks associated with hormonal interventions and the now clear lack of evidence that medical transition was benefitting most children, as opposed to the mental health counseling accompanying transition.

2. Endocrine Society (ES)

87. The 150,000-member Endocrine Society appointed a nine-member task force, plus a methodologist and a medical writer, who commissioned two systematic reviews of the research literature and, in 2017, published an update of their 2009 recommendations, based on the best available evidence identified. The guideline was co-sponsored by the American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Paediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society (PES), and the World Professional Association for Transgender Health (WPATH).

88. The document acknowledged the frequency of desistance among gender

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96 Dahlen, *et al.*, 2021.
97 Dahlen, *et al.*, 2021, at 6.
98 Dahlen, *et al.*, 2021, at 7.

dysphoric children:

> Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called "desisters"). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence. . . . In adolescence, a significant number of these desisters identify as homosexual or bisexual.[99]

89. The statement similarly acknowledges inability to predict desistance or persistence, "With current knowledge, we cannot predict the psychosexual outcome for any specific child."[100]

90. Although outside their area of professional expertise, mental health issues were also addressed by the Endocrine Society, repeating the need to handle such issues before engaging in transition, "In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues."[101] This ordering—to address mental health issues before embarking on transition—avoids relying on the unproven belief that transition will solve such issues.

91. The Endocrine Society did not endorse any affirmation-only approach. The guidelines were neutral with regard to social transitions before puberty, instead advising that such decisions be made only under clinical supervision: "We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional."[102]

92. The Endocrine Society guidelines make explicit that, after gathering information from adolescent clients seeking medical interventions and their parents, the clinician "provides correct information to prevent unrealistically high expectations [and] assesses whether medical interventions may result in unfavorable

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99 Hembree, *et al.*, 2017, at 3876.
100 Hembree, *et al.*, 2017, at 3876.
101 Hembree, *et al.*, 2017, at 3877.
102 Hembree, *et al.*, 2017, at 3872.

psychological and social outcomes."[103]

3. Pediatric Endocrine Society and Endocrine Society (ES/PES)

93. In 2020, the 1500-member Pediatric Endocrine Society partnered with the Endocrine Society to create and endorse a brief, two-page position statement.[104] Although strongly worded, the document provided no specific guidelines, instead deferring to the Endocrine Society guidelines.[105]

94. It is not clear to what extent this endorsement is meaningful, however. According to the PES, the Endocrine Society "recommendations include evidence that treatment of gender dysphoria/gender incongruence is medically necessary and should be covered by insurance."[106] However, the Endocrine Society makes neither statement. Although the two-page PES document mentioned insurance coverage four times, the only mention of health insurance by the Endocrine Society was: "If GnRH analog treatment is not available (insurance denial, prohibitive cost, or other reasons), postpubertal, transgender female adolescents may be treated with an antiandrogen that directly suppresses androgen synthesis or action."[107] Despite the PES asserting it as "medically necessary," the Endocrine Society stopped short of that. Its only use of that phrase was instead limiting: "We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being."[108]

4. American Academy of Child & Adolescent Psychiatry (AACAP)

95. The 2012 statement of the American Academy of Child & Adolescent Psychiatry (AACAP) is not an affirmation-only policy. It notes:

Just as family rejection is associated with problems such as depression,

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[103] Hembree, *et al.*, 2017, at 3877.
[104] PES, online; Pediatric Endocrine Society & Endocrine Society, Dec. 2020.
[105] Pediatric Endocrine Society & Endocrine Society, Dec. 2020, at 1; Hembree, *et al.*, 2017.
[106] Pediatric Endocrine Society & Endocrine Society, Dec. 2020, at 1.
[107] Hembree, *et al.* 2017, at 3883.
[108] Hembree, *et al.*, 2017 at 3872, 3894.

> suicidality, and substance abuse in gay youth, the proposed benefits of treatment to eliminate gender discordance in youth must be carefully weighed against such possible deleterious effects. . . . In general, it is desirable to help adolescents who may be experiencing gender distress and dysphoria to defer sex reassignment until adulthood, or at least until the wish to change sex is unequivocal, consistent, and made with appropriate consent.[109]

96. The AACAP's language repeats the description of the use of puberty blockers only as an exception: "For situations in which deferral of sex reassignment decisions until adulthood is *not clinically feasible*, one approach that has been described in case series is sex hormone suppression under endocrinological management with psychiatric consultation using gonadotropin-releasing hormone analogues."[110]

97. The AACAP statement acknowledges the long-term outcomes literature for gender dysphoric children: "In follow-up studies of prepubertal boys with gender discordance—including many without any mental health treatment—the cross gender wishes usually fade over time and do not persist into adulthood,"[111] adding that "[c]linicians should be aware of current evidence on the natural course of gender discordance and associated psychopathology in children and adolescents in choosing the treatment goals and modality."[112]

98. The policy similarly includes a provision for resolving mental health issues: "Gender reassignment services are available in conjunction with mental health services focusing on exploration of gender identity, cross-sex treatment wishes, counseling during such treatment if any, and *treatment of associated mental health problems*."[113] The document also includes minority stress issues and the need to deal with mental health aspects of minority status (*e.g.*, bullying).[114]

99. Rather than endorse social transition for prepubertal children, the AACAP

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[109] Adelson & AACAP, 2012, at 969.
[110] Adelson & AACAP, 2012, at 969 (italics added).
[111] Adelson & AACAP, 2012, at 963.
[112] Adelson & AACAP, 2012, at 968.
[113] Adelson & AACAP, 2012, at 970 (italics added).
[114] Adelson & AACAP, 2012, at 969.

indicates: "There is similarly no data at present from controlled studies to guide clinical decisions regarding the risks and benefits of sending gender discordant children to school in their desired gender. Such decisions must be made based on clinical judgment, bearing in mind the potential risks and benefits of doing so."[115]

5. American College of Obstetricians & Gynecologists (ACOG)

100. The American College of Obstetricians & Gynecologists (ACOG) published a "Committee Opinion" expressing recommendations in 2017. The statement indicates it was developed by the ACOG's Committee on Adolescent Health Care, but does not indicate participation based on professional expertise or a systematic method of objectively assessing the existing research. It includes the disclaimer: "This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed."[116]

101. Prepubertal children do not typically have clinical contact with gynecologists, and the ACOG recommendations include that the client additionally have a primary health care provider.[117]

102. The ACOG statement cites the statements made by other medical associations—European Society for Pediatric Endocrinology (ESPE),, PES, and the Endocrine Society—and by WPATH.[118] It does not cite any professional association of *mental* health care providers, however. The ACOG recommendations repeat the previously mentioned eligibility/readiness criteria of having no mental illness that would hamper diagnosis and no medical contraindications to treatment. It notes: "*Before* any treatment is undertaken, the patient must display eligibility and readiness (Table 1), meaning that the adolescent has been evaluated by a mental

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115 Adelson & AACAP, 2012, at 969.
116 ACOG, 2017, at 1.
117 ACOG, 2017, at 1.
118 ACOG, 2017, at 1, 3.

health professional, has no contraindications to therapy, and displays an understanding of the risks involved."[119]

103. The "Eligibility and Readiness Criteria" also include, "Diagnosis established for gender dysphoria, transgender, transsexualism."[120] This standard, requiring a formal diagnosis, forestalls affirmation-on-demand because self-declared self-identification is not sufficient for DSM diagnosis.

104. ACOG's remaining recommendations pertain only to post-transition, medically oriented concerns. Pre-pubertal social transition is not mentioned in the document, and the outcomes studies of gender dysphoric (prepubescent) children are not cited.

6. American College of Physicians (ACP)

105. The American College of Physicians published a position paper broadly expressing support for the treatment of LGBT patients and their families, including nondiscrimination, antiharassment, and defining "family" by emotional rather than biological or legal relationships in visitation policies, and the inclusion of transgender health care services in public and private health benefit plans.[121]

106. ACP did not provide guidelines or standards for child or adult gender transitions. The policy paper opposed attempting "reparative therapy;" however, the paper confabulated sexual orientation with gender identity in doing so. That is, on the one hand, ACP explicitly recognized that "[s]exual orientation and gender identity are inherently different."[122] It based this statement on the fact that "the American Psychological Association conducted a literature review of 83 studies on the efficacy of efforts to change *sexual orientation*."[123] The APA's document, entitled "Report of the American Psychological Task Force on appropriate therapeutic responses to

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[119] ACOG, 2017, at 1, 3 (citing the Endocrine Society guidelines) (italics added).
[120] ACOG, 2017, at 3 Table 1.
[121] Daniel & Butkus, 2015a, 2015b.
[122] Daniel & Butkus, 2015b, at 2.
[123] Daniel & Butkus, 2015b, at 8 (italics added).

sexual orientation" does not include or reference research on gender identity.[124] Despite citing no research about transgenderism, the ACP nonetheless included in its statement: "Available research does not support the use of reparative therapy as an effective method in the treatment of LGB*T* persons."[125] That is, the inclusion of "T" with "LGB" is based on something other than the existing evidence.

107. There is another statement,[126] which was funded by ACP and published in the Annals of Internal Medicine under its "*In the Clinic*" feature, noting that "'In the Clinic' does not necessarily represent official ACP clinical policy."[127] The document discusses medical transition procedures for adults rather than for children, except to note that "[n]o medical intervention is indicated for prepubescent youth,"[128] that a "mental health provider can assist the child and family with identifying an appropriate time for a social transition,"[129] and that the "child should be assessed and managed for coexisting mood disorders during this period because risk for suicide is higher than in their cisgender peers."[130]

7. American Academy of Pediatrics (AAP)

108. The policy of the American Academy of Pediatrics (AAP) is unique among the major medical associations in being the only one to endorse an affirmation-on-demand policy, including social transition before puberty without any watchful waiting period. Although changes in recommendations can obviously be appropriate in response to new research evidence, the AAP provided none. Rather, the research studies AAP cited in support of its policy simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing watchful waiting.[131] Moreover, of all

[124] APA, 2009 (italics added).
[125] Daniel & Butkus, 2015b, at 8 (italics added).
[126] Safer & Tangpricha, 2019.
[127] Safer & Tangpricha, 2019, at ITC1.
[128] Safer & Tangpricha, 2019, at ITC9.
[129] Safer & Tangpricha, 2019, at ITC9.
[130] Safer & Tangpricha, 2019, at ITC9.
[131] Cantor, 2020.

the outcomes research published, the AAP policy cited *one*, and that without mentioning the outcome data it contained.[132].

109. Immediately following the publication of the AAP policy, I conducted a point-by-point fact-check of the claims it asserted and the references it cited in support. I submitted that to the *Journal of Sex & Marital Therapy*, a well-known research journal of my field, where it underwent blind peer review and was published. I append that article as part of this report. *See* Appendix 2. A great deal of published attention ensued; however, the AAP has yet to respond to the errors I demonstrated its policy contained. Writing for *The Economist* about the use of puberty blockers, Helen Joyce asked AAP directly, "Has the AAP responded to Dr Cantor? If not, have you any response now?" The AAP Media Relations Manager, Lisa Black, responded: "We do not have anyone available for comment."

8. The ESPE-LWPES GnRH Analogs Consensus Conference Group

110. Included in the interest of completeness, there was also a collaborative report in 2009, between the European Society for Pediatric Endocrinology (ESPE) and the Lawson Wilkins Pediatric Endocrine Society (LWPES).[133] Thirty experts were convened, evenly divided between North American and European labs and evenly divided male/female, who comprehensively rated the research literature on gonadotropin-release hormone analogs in children.

111. The effort concluded that "[u]se of gonadotropin-releasing hormone analogs for conditions other than central precocious puberty requires additional investigation and cannot be suggested routinely."[134] However, gender dysphoria was not explicitly mentioned as one of those other conditions.

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[132] Cantor, 2020, at 1.
[133] Carel et al., 2009.
[134] Carel et al. 2009, at 752.

VI. International Health Care Consensus

1. United Kingdom

112. The National Health Service (NHS) of the United Kingdom centralizes gender counselling and transitioning services in a single clinic, the Gender Identity Development Service (GIDS) of the Tavistock and Portman NHS Foundation Trust. Between 2008 and 2018, the number of referrals to the clinic had increased by a factor of 40, leading to a government inquiry into the causes[135]. The GIDS was repeatedly accused of over-diagnosing and permitting transition in cases despite indicators against patient transition, including by 35 members of the GIDS staff, who resigned by 2019[136].

113. The NHS appointed Dr. Hilary Cass, former President of the Royal College of Paediatrics and Child Health, to conduct an independent review[137]. That review included a systematic consolidation of all the research evidence, following established procedures for preventing the "cherry-picking" or selective citation favouring or down-playing any one conclusion[138]. The review's results were unambiguous: "The critical outcomes for decision making are the impact on gender dysphoria, mental health and quality of life. The quality of evidence for these outcomes was assessed as very low"[139], again using established procedures for assessing clinical research evidence (called GRADE). The review also assessed as "very low" the quality of evidence regarding "body image, psychosocial impact, engagement with health care services, impact on extent of an satisfaction with surgery and stopping treatment"[140]. The report concluded that of the existing research, "The studies included in this evidence review are all small, uncontrolled observational studies, which are subject to bias and confounding….They suggest little change with GnRH analogues [puberty

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135 Marsh, 2020; Rayner, 2018.
136 BBC, 2021; Donnelly, 2019.
137 National Health Service, 2020, Sept. 22.
138 National Institute for Health and Care Excellence, 2020.
139 National Institute for Health and Care Excellence, 2020, p. 4.
140 National Institute for Health and Care Excellence, 2020, p. 5.

blockers] from baseline to follow-up"[141].

2. Finland

114. In Finland, the assessments of mental health and preparedness of minors for transition services are centralized by law into two research clinics, Helsinki University Central Hospital and Tampere University Hospital. The eligibility of minors began in 2011. In 2019, Finnish researchers published an analysis of the outcomes of adolescents diagnosed with transsexualism and receiving cross-sex hormone treatment[142]. That study showed that despite the purpose of medical transition to improve mental health: "Medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria. Appropriate interventions are warranted for psychiatric comorbidities and problems in adolescent development"[143]. The patients who were functioning well after transition were those who were already functioning well before transition, and those who were functioning poorly, continued to function poorly after transition.

115. Consistent with the evidence, Finland's health care service (Council for Choices in Health Care in Finland—COHERE) thus ended the surgical transition of minors, ruling in 2020 that "Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors" (COHERE, 2020). The review of the research concluded that "[N]o conclusions can be drawn on the stability of gender identity during the period of disorder caused by a psychiatric illness with symptoms that hamper development." COHERE also greatly restricted access to puberty-blocking and other hormonal treatments, indicating they "may be considered if the need for it continues *after* the other psychiatric symptoms have

141 National Institute for Health and Care Excellence, 2020, p. 13.
142 Kaltiala et al., 2020.
143 Kaltiala et al., 2020, p. 213.

ceased and adolescent development is progressing normally"[144]. The council was explicit in noting the lack of research needed for decision-making, "There is also a need for more information on the *disadvantages* of procedures and on people who regret them"[145].

3. Sweden

116. Sweden's national health care policy regarding trans issues has developed quite similarly to that of the UK. Already in place 20 years ago, Swedish health care policy permitted otherwise eligible minors to receive puberty-blockers beginning at age 14 and cross-sex hormones at age 16.) At that time, only small numbers of minors sought medical transition services. An explosion of referrals ensued in 2013–2014. Sweden's Board of Health and Welfare reported that, in 2018, the number of diagnoses of gender dysphoria was 15 times higher than 2008 among girls ages 13–17.

117. Sweden has long been very accepting with regard to sexual and gender diversity. In 2018, a law was proposed to lower the age of eligibility for surgical care from age 18 to 15, remove the requirement for parental consent, and lower legal change of gender to age 12. A series of cases of regret and suicide were reported in the Swedish media, leading to questions of mental health professionals failing to consider. In 2019, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) therefore conducted its own comprehensive review of the research[146]. Like the UK, the Swedish investigation employed methods to ensure the encapsulation of the all the relevant evidence[147].

118. The SBU report came to the same conclusions as the UK commission. From 2022 forward, the Swedish National Board or Health and Welfare therefore

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144 Council for Choices in Health Care in Finland, 2020; italics added.
145 Council for Choices in Health Care in Finland, 2020; italics added.
146 Orange, 2020, Feb 22.
147 Swedish Agency for Health Technology Assessment and Assessment of Social Services, 2019.

"recommends restraint when it comes to hormone treatment…Based on the results that have emerged, the National Board of Health and Welfare's overall conclusion is that the risks of anti-puberty and sex-confirming hormone treatment for those under 18 currently outweigh the possible benefits for the group as a whole"[148]. Neither puberty blockers nor cross-sex hormones would be provided under age 16, and patients ages 16–18 would receive such treatments only within research settings (clinical trials monitored by the appropriate Swedish research ethics board).

4. France

119. In 2022, the Académie Nationale de Médecine of France issued a strongly worded statement, citing the Swedish ban on hormone treatments. "[A] great medical caution must be taken in children and adolescents, given the vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available therapies can cause…such as impact on growth, bone fragility, risk of sterility, emotional and intellectual consequences and, for girls, symptoms reminiscent of menopause"[149]. For hormones, the Académie concluded "the greatest reserve is required in their use," and for surgical treatments, "[T]heir irreversible nature must be emphasized." The Académie did not outright ban medical interventions, but warned "the risk of over-diagnosis is real, as shown by the increasing number of transgender young adults wishing to "detransition". Rather than medical interventions, it advised health care providers "to extend as much as possible the psychological support phase." The Académie reviewed and emphasized the evidence indicating the very large and very sudden increase in youth requesting medical transition. It attributed the change, not to society now being more accepting of sexual diversity, but to social media, "underlining the addictive character of excessive consultation of social networks which is both

[148] Swedish National Board of Health and Welfare, 2022.
[149] Académie Nationale de Médecine, 2022, Feb. 25.

harmful to the psychological development of young people and responsible, for a very important part, of the growing sense of gender incongruence."

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APPENDICES

Appendix 1

The Outcomes Studies of Childhood-Onset Gender Dysphoria

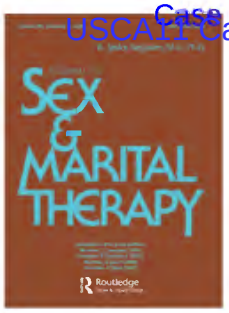
Appendix 2

Peer-reviewed article:

Cantor, J. M. (2020). Transgender and gender diverse children and adolescents: Fact-checking of AAP policy. *Journal of Sex & Marital Therapy, 46,* 307–313. doi: 10.1080/0092623X.2019.1698481

Prospective Outcomes Studies of Gender Dysphoric Children

2/16 4/16 10/16	gay trans-/crossdress straight/uncertain	Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. *American Journal of Psychiatry, 128,* 1283–1289.
2/16 2/16 12/16	trans- uncertain gay	Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. *Comprehensive Psychiatry, 19, 363–369.*
0/9 9/9	trans- gay	Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. *Journal of Pediatric Psychology, 4,* 29–41.
2/45 10/45 33/45	trans-/crossdress uncertain gay	Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. *Journal of Nervous and Mental Disease, 172,* 90–97.
1/10 2/10 3/10 4/10	trans- gay uncertain straight	Davenport, C. W. (1986). A follow-up study of 10 feminine boys. *Archives of Sexual Behavior, 15,*511–517.
1/44 43/44	trans- cis-	Green, R. (1987). *The "sissy boy syndrome" and the development of homosexuality*. New Haven, CT: Yale University Press.
0/8 8/8	trans- cis-	Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? *Medical Journal of Australia, 146,* 565–569.
21/54 33/54	trans- cis-	Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry, 47,* 1413–1423.
3/25 6/25 16/25	trans- lesbian/bi- straight	Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. *Developmental Psychology, 44*, 34–45.
47/127 80/127	trans- cis-	Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. *Journal of the American Academy of Child and Adolescent Psychiatry, 52,* 582–590.
17/139 122/139	trans- cis-	Singh, D., Bradley, S. J., and Zucker, K. J. (2021) A follow-up study of boys with gender identity disorder. Frontiers in Psychiatry, 12, 632784. doi: 10.3389/fpsyt.2021.632784



Journal of Sex & Marital Therapy

ISSN: 0092-623X (Print) 1521-0715 (Online) Journal homepage: https://www.tandfonline.com/loi/usmt20

Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy

James M. Cantor

To cite this article: James M. Cantor (2020) Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, Journal of Sex & Marital Therapy, 46:4, 307-313, DOI: 10.1080/0092623X.2019.1698481

To link to this article: https://doi.org/10.1080/0092623X.2019.1698481

Published online: 14 Dec 2019.

JOURNAL OF SEX & MARITAL THERAPY
2020, VOL. 46, NO. 4, 307–313
https://doi.org/10.1080/0092623X.2019.1698481

Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy

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ABSTRACT

The American Academy of Pediatrics (AAP) recently published a policy statement: *Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents*. Although almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping gender diverse (GD) children, the AAP statement instead rejected that consensus, endorsing *gender affirmation* as the only acceptable approach. Remarkably, not only did the AAP statement fail to include any of the actual outcomes literature on such cases, but it also misrepresented the contents of its citations, which repeatedly said the very opposite of what AAP attributed to them.

The American Academy of Pediatrics (AAP) recently published a policy statement entitled, *Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents* (Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, 2018). These are children who manifest discontent with the sex they were born as and desire to live as the other sex (or as some alternative gender role). The policy was quite a remarkable document: Although almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping transgender and gender diverse (GD) children, the AAP statement rejected that consensus, endorsing only *gender affirmation*. That is, where the consensus is to delay any transitions after the onset of puberty, AAP instead rejected waiting before transition. With AAP taking such a dramatic departure from other professional associations, I was immediately curious about what evidence led them to that conclusion. As I read the works on which they based their policy, however, I was pretty surprised—rather alarmed, actually: These documents simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing *watchful waiting*.

The AAP statement was also remarkable in what it left out—namely, the actual outcomes research on GD children. In total, there have been 11 follow-up studies of GD children, of which AAP cited one (Wallien & Cohen-Kettenis, 2008), doing so without actually mentioning the outcome data it contained. The literature on outcomes was neither reviewed, summarized, nor subjected to meta-analysis to be considered in the aggregate—It was merely disappeared. (The list of all existing studies appears in the appendix.) As they make clear, *every* follow-up study of GD children, without exception, found the same thing: Over puberty, the majority of GD children cease to want to transition. AAP is, of course, free to establish whatever policy it likes on

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whatever basis it likes. But any assertion that their policy is based on evidence is demonstrably false, as detailed below.

AAP divided clinical approaches into three types—conversion therapy, watchful waiting, and gender affirmation. It rejected the first two and endorsed *gender affirmation* as the only acceptable alternative. Most readers will likely be familiar already with attempts to use conversion therapy to change sexual orientation. With regard to gender identity, AAP wrote:

> "[C]onversion" or "reparative" treatment models are used to prevent children and adolescents from identifying as transgender or to dissuade them from exhibiting gender-diverse expressions. … Reparative approaches have been proven to be not only unsuccessful[38] but also deleterious and are considered outside the mainstream of traditional medical practice.[29,39–42]

The citations were:

38. Haldeman DC. The practice and ethics of sexual orientation conversion therapy. *J Consult Clin Psychol.* 1994;62(2):221–227.

29. Adelson SL; American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter on gay, lesbian, or bisexual sexual orientation, gender nonconformity, and gender discordance in children and adolescents. *J Am Acad Child Adolesc Psychiatry.* 2012;51(9):957–974.

39. Byne W. Regulations restrict practice of conversion therapy. *LGBT Health.* 2016;3(2):97–99.

40. Cohen-Kettenis PT, Delemarrevan de Waal HA, Gooren LJ. The treatment of adolescent transsexuals: changing insights. *J Sex Med.* 2008;5(8):1892–1897.

41. Bryant K. Making gender identity disorder of childhood: historical lessons for contemporary debates. *Sex Res Soc Policy.* 2006;3(3):23–39.

42. World Professional Association for Transgender Health. *WPATH De-Psychopathologisation Statement.* Minneapolis, MN: World Professional Association for Transgender Health; 2010.

AAP's claims struck me as odd because *there are no studies of conversion therapy for gender identity.* Studies of conversion therapy have been limited to *sexual orientation,* and, moreover, to the sexual orientation *of adults,* not to gender identity and not of children in any case. The article AAP cited to support their claim (reference number 38) is indeed a classic and well-known review, but it is a review of sexual orientation research *only.* Neither gender identity, nor even children, received a single mention in it. Indeed, the narrower scope of that article should be clear to anyone reading even just its title: "The practice and ethics of *sexual orientation* conversion therapy" [italics added].

AAP continued, saying that conversion approaches for GD children have already been rejected by medical consensus, citing five sources. This claim struck me as just as odd, however—I recalled associations banning conversion therapy for sexual orientation, but not for gender identity, exactly because there is no evidence for generalizing from adult sexual orientation to childhood gender identity. So, I started checking AAP's citations for that, and these sources too pertained only to sexual orientation, not gender identity (specifics below). What AAP's sources *did* repeatedly emphasize was that:

A. Sexual orientation of adults is unaffected by conversion therapy and any other [known] intervention;
B. Gender dysphoria in childhood before puberty desists in the majority of cases, becoming (cis-gendered) homosexuality in adulthood, again regardless of any [known] intervention; and
C. Gender dysphoria in childhood persisting after puberty tends to persist entirely.

That is, in the context of GD children, it simply makes no sense to refer to externally induced "conversion": The majority of children "convert" to cisgender or "desist" from transgender

regardless of any attempt to change them. "Conversion" only makes sense with regard to adult sexual orientation because (unlike childhood gender identity), adult homosexuality never or nearly never spontaneously changes to heterosexuality. Although gender identity and sexual orientation may often be analogous and discussed together with regard to social or political values and to civil rights, they are nonetheless distinct—with distinct origins, needs, and responses to medical and mental health care choices. Although AAP emphasized to the reader that "gender identity is not synonymous with 'sexual orientation'" (Rafferty et al., 2018, p. 3), they went ahead to treat them as such nonetheless.

To return to checking AAP's fidelity to its sources: Reference 29 was a practice guideline from the Committee on Quality Issues of the American Academy of Child and Adolescent Psychiatry (AACAP). Despite AAP applying this source to *gender identity,* AACAP was quite unambiguous regarding their intent to speak to sexual orientation and *only* to sexual orientation: "Principle 6. Clinicians should be aware that there is no evidence that *sexual orientation* can be altered through therapy, and that attempts to do so may be harmful. There is no established evidence that change in a predominant, enduring *homosexual* pattern of development is possible. Although sexual fantasies can, to some degree, be suppressed or repressed by those who are ashamed of or in conflict about them, sexual desire is not a choice. However, behavior, social role, and—to a degree—identity and self-acceptance are. Although operant conditioning modifies sexual fetishes, it does not alter *homosexuality*. Psychiatric efforts to alter *sexual orientation* through 'reparative therapy' *in adults* have found little or no change in *sexual orientation,* while causing significant risk of harm to self-esteem" (AACAP, 2012, p. 967, italics added).

Whereas AAP cites AACAP to support gender affirmation as the only alternative for treating GD children, AACAP's actual view was decidedly neutral, noting the lack of evidence: "Given the lack of empirical evidence from randomized, controlled trials of the efficacy of treatment aimed at eliminating gender discordance, the potential risks of treatment, and longitudinal evidence that gender discordance persists in only a small minority of untreated cases arising in childhood, further research is needed on predictors of persistence and desistence of childhood gender discordance as well as the long-term risks and benefits of intervention before any treatment to eliminate gender discordance can be endorsed" (AACAP, 2012, p. 969). Moreover, whereas AAP rejected watchful waiting, what AACAP recommended was: "In general, it is desirable to help adolescents who may be experiencing gender distress and dysphoria to defer sex reassignment until adulthood" (AACAP, 2012, p. 969). So, not only did AAP attribute to AACAP something AACAP never said, but also AAP withheld from readers AACAP's actual view.

Next, in reference 39, Byne (2016) also addressed only sexual orientation, doing so very clearly: "Reparative therapy is a subset of conversion therapies based on the premise that *same-sex attraction* are reparations for childhood trauma. Thus, practitioners of reparative therapy believe that exploring, isolating, and repairing these childhood emotional wounds will often result in reducing *same-sex attractions*" (Byne, 2016, p. 97). Byne does not say this of gender identity, as the AAP statement misrepresents.

In AAP reference 40, Cohen-Kettenis et al. (2008) did finally pertain to gender identity; however, this article never mentions conversion therapy. (!) Rather, in this study, the authors presented that clinic's lowering of their minimum age for cross-sex hormone treatment from age 18 to 16, which they did on the basis of a series of studies showing the high rates of success with this age group. Although it did strike me as odd that AAP picked as support against conversion therapy an article that did not mention conversion therapy, I could imagine AAP cited the article as an example of what the "mainstream of traditional medical practice" consists of (the logic being that conversion therapy falls outside what an 'ideal' clinic like this one provides). However, what this clinic provides is the very *watchful waiting* approach that AAP rejected. The approach

espoused by Cohen-Kettenis (and the other clinics mentioned in the source—Gent, Boston, Oslo, and now formerly, Toronto) is to make puberty-halting interventions available at age 12 because: "[P]ubertal suppression may give adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved" (Cohen-Kettenis et al., 2008, p. 1894).

Reference 41 presented a very interesting history spanning the 1960s–1990s about how feminine boys and tomboyish girls came to be recognized as mostly pre-homosexual, and how that status came to be entered into the DSM at the same time as homosexuality was being *removed* from the DSM. Conversion therapy is never mentioned. Indeed, to the extent that Bryant mentions treatment at all, it is to say that treatment is entirely irrelevant to his analysis: "An important omission from the *DSM* is a discussion of the kinds of treatment that GIDC children should receive. (This omission is a general orientation of the DSM and not unique to GIDC)" (Bryant, 2006, p. 35). How this article supports AAP's claim is a mystery. Moreover, how AAP could cite a 2006 history discussing events of the 1990s and earlier to support a claim about the *current* consensus in this quickly evolving discussion remains all the more unfathomable.

Cited last in this section was a one-paragraph press release from the World Professional Association for Transgender Health. Written during the early stages of the American Psychiatric Association's (APA's) update of the DSM, the statement asserted simply that "The WPATH Board of Directors strongly urges the de-psychopathologisation of gender variance worldwide." Very reasonable debate can (and should) be had regarding whether gender dysphoria should be removed from the DSM as homosexuality was, and WPATH was well within its purview to assert that it should. Now that the DSM revision process is years completed however, history has seen that APA ultimately retained the diagnostic categories, rejecting WPATH's urging. This makes AAP's logic entirely backwards: That WPATH's request to depathologize gender dysphoria was *rejected* suggests that it is *WPATH's* view—and therefore the AAP policy—which fall "outside the mainstream of traditional medical practice." (!)

AAP based this entire line of reasoning on their belief that conversion therapy is being used "to prevent children and adolescents from identifying as transgender" (Rafferty et al., 2018, p. 4). That claim is left without citation or support. In contrast, what is said by AAP's sources is "delaying affirmation should *not* be construed as conversion therapy or an attempt to change gender identity" in the first place (Byne, 2016, p. 2). Nonetheless, AAP seems to be doing exactly that: simply relabeling any alternative approach as equivalent to conversion therapy.

Although AAP (and anyone else) may reject (what they label to be) conversion therapy purely on the basis of political or personal values, there is no evidence to back the AAP's stated claim about the existing science on gender identity at all, never mind gender identity of children.

AAP also dismissed the watchful waiting approach out of hand, not citing any evidence, but repeatedly calling it "outdated." The criticisms AAP provided, however, again defied the existing evidence, with even its own sources repeatedly calling watchful waiting the current standard. According to AAP:

> [G]ender affirmation is in contrast to the outdated approach in which a child's gender-diverse assertions are held as "possibly true" until an arbitrary age (often after pubertal onset) when they can be considered valid, an approach that authors of the literature have termed "watchful waiting." This outdated approach does not serve the child because critical support is withheld. Watchful waiting is based on binary notions of gender in which gender diversity and fluidity is pathologized; in watchful waiting, it is also assumed that notions of gender identity become fixed at a certain age. The approach is also influenced by a group of early studies with validity concerns, methodologic flaws, and limited follow-up on children who identified as TGD and, by adolescence, did not seek further treatment ("desisters").[45,47]

The citations from AAP's reference list are:

45. Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Keo-Meier C. Prepubertal social gender transitions: what we know; what we can learn—a view from a gender affirmative lens. *Int J Transgend.* 2018;19(2):251–268

47. Olson KR. Prepubescent transgender children: what we do and do not know. *J Am Acad Child Adolesc Psychiatry.* 2016;55(3):155–156.e3

I was surprised first by the AAP's claim that watchful waiting's delay to puberty was somehow "arbitrary." The literature, including AAP's sources, repeatedly indicated the pivotal importance of puberty, noting that outcomes strongly diverge at that point. According to AAP reference 29, in "*prepubertal* boys with gender discordance—including many without any mental health treatment—the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance" (Adelson & AACAP, 2012, p. 963, italics added), whereas "when gender variance with the desire to be the other sex is present *in adolescence,* this desire usually does persist through adulthood" (Adelson & AACAP, 2012, p. 964, italics added). Similarly, according to AAP reference 40, "Symptoms of GID *at prepubertal ages* decrease or even disappear in a considerable percentage of children (estimates range from 80–95%). Therefore, any intervention in childhood would seem premature and inappropriate. However, GID persisting *into early puberty* appears to be highly persistent" (Cohen-Kettenis et al., 2008, p. 1895, italics added). That follow-up studies of prepubertal transition differ from postpubertal transition is the very meaning of non-arbitrary. AAP gave readers exactly the reverse of what was contained in its own sources. If AAP were correct in saying that puberty is an arbitrarily selected age, then AAP will be able to offer another point to wait for with as much empirical backing as puberty has.

Next, it was not clear on what basis AAP could say that watchful waiting withholds support—AAP cited no support for its claim. The people in such programs often receive substantial support during this period. Also unclear is on what basis AAP could already know exactly which treatments are "critical" and which are not—Answering that question is the very purpose of this entire endeavor. Indeed, the logic of AAP's claim appears entirely circular: It is only if one were already pre-convinced that gender affirmation is the only acceptable alternative that would make watchful waiting seem to withhold critical support—What it delays is gender affirmation, the method one has already decided to be critical.

Although AAP's next claim did not have a citation appearing at the end of its sentence, binary notions of gender were mentioned both in references 45 and 47. Specifically, both pointed out that existing outcome studies have been about people transitioning from one sex to the other, rather than from one sex to an in-between status or a combination of masculine/feminine features. Neither reference presented this as a reason to reject the results from the existing studies of complete transition however (which is how AAP cast it). Although it is indeed true that the outcome data have been about complete transition, some future study showing that partial transition shows a different outcome would not invalidate what is known about complete transition. Indeed, data showing that partial transition gives better outcomes than complete transition would, once again, support the watchful waiting approach which AAP rejected.

Next was a vague reference alleging concerns and criticisms about early studies. Had AAP indicated what those alleged concerns and flaws were (or which studies they were), then it would be possible to evaluate or address them. Nonetheless, the argument is a red herring: Because all of the later studies showed the same result as did the early studies, any such allegation is necessarily moot.

Reference 47 was a one-and-a-half page commentary in which the author off-handedly mentions criticisms previously made of three of the eleven outcome studies of GD children, but does not provide any analysis or discussion. The only specific claim was that studies (whether early or late) had limited follow-up periods—the logic being that had outcome researchers lengthened the follow-up period, then people who seemed to have desisted might have returned to the clinic as

cases of "persistence-after-interruption." Although one could debate the merits of that prediction, AAP instead simply withheld from the reader the result from the original researchers having tested that very prediction directly: Steensma and Cohen-Kettenis (2015) conducted another analysis of their cohort, by then ages 19–28 (mean age 25.9 years), and found that 3.3% (5 people of the sample of 150) later returned. That is, in long-term follow-up, the childhood sample showed 66.7% desistence instead of 70.0% desistance.

Reference 45 did not support the claim that watchful-waiting is "outdated" either. Indeed, that source said the very opposite, explicitly referring to watchful waiting as the *current* approach: "Put another way, if clinicians are straying from SOC 7 guidelines for social transitions, not abiding by the watchful waiting model *favored by the standards,* we will have adolescents who have been consistently living in their affirmed gender since age 3, 4, or 5" (Ehrensaft et al., 2018, p. 255). Moreover, Ehrensaft et al. said there are cases in which they too would still use watchful waiting: "When a child's gender identity is unclear, the watchful waiting approach can give the child and their family time to develop a clearer understanding and is not necessarily in contrast to the needs of the child" (p. 259). Ehrensaft et al. are indeed critical of the watchful waiting model (which they feel is applied too conservatively), but they do not come close to the position the AAP policy espouses. Where Ehrensaft summaries the potential benefits and potential risks both to transitioning and not transitioning, the AAP presents an ironically binary narrative.

In its policy statement, AAP told neither the truth nor the whole truth, committing sins both of commission and of omission, asserting claims easily falsified by anyone caring to do any fact-checking at all. AAP claimed, "This policy statement is focused specifically on children and youth that identify as TGD rather than the larger LGBTQ population"; however, much of that evidence was about sexual orientation, not gender identity. AAP claimed, "Current available research and expert opinion from clinical and research leaders … will serve as the basis for recommendations" (pp. 1–2); however, they provided recommendations entirely unsupported and even in direct opposition to that research and opinion.

AAP is advocating for something far in excess of mainstream practice and medical consensus. In the presence of compelling evidence, that is just what is called for. The problems with Rafferty, however, do not constitute merely a misquote, a misinterpretation of an ambiguous statement, or a missing reference or two. Rather, AAP's statement is a systematic exclusion and misrepresentation of entire literatures. Not only did AAP fail to provide compelling evidence, it failed to provide the evidence at all. Indeed, AAP's recommendations are *despite* the existing evidence.

Disclosure statement

No potential conflict of interest was reported by the author.

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Rafferty, J., AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. (2018). Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*, *142*(4), e20182162 doi:10.1542/peds.2018-2162

Steensma, T. D., & Cohen-Kettenis, P. T. (2015). More than two developmental pathways in children with gender dysphoria? *Journal of the American Academy of Child and Adolescent Psychiatry*, *52*, 147–148. doi:10.1016/j.jaac.2014.10.016

Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry*, *47*, 1413–1423. doi:10.1097/CHI.0b013e31818956b9

Appendix

Count	Group	Study
2/16 4/16 10/16	gay* trans-/crossdress straight*/uncertain	Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. *American Journal of Psychiatry, 128,* 1283–1289.
2/16 2/16 12/16	trans- uncertain gay	Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. *Comprehensive Psychiatry, 19,* 363–369.
0/9 9/9	trans- gay	Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. *Journal of Pediatric Psychology, 4,* 29–41.
2/45 10/45 33/45	trans-/crossdress uncertain gay	Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. *Journal of Nervous and Mental Disease, 172,* 90–97.
1/10 2/10 3/10 4/10	trans- gay uncertain straight	Davenport, C. W. (1986). A follow-up study of 10 feminine boys. *Archives of Sexual Behavior, 15,* 511–517.
1/44 43/44	trans- cis-	Green, R. (1987). *The "sissy boy syndrome" and the development of homosexuality*. New Haven, CT: Yale University Press.
0/8 8/8	trans- cis-	Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? *Medical Journal of Australia, 146,* 565–569.
21/54 33/54	trans- cis-	Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry, 47,* 1413–1423.
3/25 6/25 16/25	trans- lesbian/bi- straight	Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. *Developmental Psychology, 44,* 34–45.
17/139 122/139	trans- cis-	Singh, D. (2012). *A follow-up study of boys with gender identity disorder*. Unpublished doctoral dissertation, University of Toronto.
47/127 80/127	trans- cis-	Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. *Journal of the American Academy of Child and Adolescent Psychiatry, 52,* 582–590.

*For brevity, the list uses "gay" for "gay and cis-", "straight" for "straight and cis-", etc.

ATTACHMENT E

Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent

Quentin L. Van Meter, M.D.
May 17, 2022

Qualifications

I received my B.A. in Science at the College of William and Mary and my M.D. from the Medical College of Virginia, Virginia Commonwealth University. I am currently a pediatric endocrinologist in private practice in Atlanta, Georgia. I am the President of Van Meter Pediatric Endocrinology, P.C. I am on the clinical faculties of Emory University School of Medicine and Morehouse College of Medicine, in the role of adjunct Associate Professor of Pediatrics. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Georgia since 1991. I have been previously licensed to practice medicine in California, Louisiana, and Maryland.

I did my Pediatric Endocrine fellowship at Johns Hopkins Hospital from 1978-1980. The faculty present at that time had carried on the tradition of excellence established by Lawson Wilkins, M.D. Because of the reputation of the endocrine program as a center for exceptional care for children with disorders of sexual differentiation, I had well-above average exposure to such patients. As a Pediatric Fellow, I was also exposed to adults with Gender Identity Disorder, then called Trans-Sexuality, and received training from John Money, Ph.D., in his Psycho-hormonal Division. Over the past 44 years, I have closely followed the topic of incongruent gender in children adolescents and adults, but I am focusing in this document on working with children and adolescents. To get a more solid understanding of how male and female human beings develop in utero, it is important to start at the point when a sperm meets an egg.

Differentiation in the Fetus

From the moment of conception, a fetus is determined to be either a male (XY), female (XX), or in rare cases, to have a combination of sex-determining chromosomes, many of which are not compatible with life, and some of which are the cause of identifiable clinical syndromes. The presence of a Y chromosome in the developing fetus directs the developing gonadal tissue to develop as a testicle. The absence of a functional Y chromosome allows the gonadal tissue to develop as an ovary. Under the influence of the mother's placental hormones, the testicle will produce testosterone which directs the genital tissue to form a penis and a scrotum. Simultaneously, the testicle produces anti-Müllerian Hormone (AMH) which regresses development of the tissue that would otherwise develop into the uterus, fallopian tubes, and upper third of the vagina. This combination of actions in early fetal development is responsible for what we subsequently see on fetal sonograms, and what we observe at birth as male or female genitalia. It is only when the genital structures are ambiguous in appearance that sex determination is withheld until a thorough expert team evaluation has occurred.

For reasons most often occurring as random events, there are malfunctions of the normal differentiation. These aberrations of normal development are responsible for what we classify as Disorders of Sexual Differentiation (DSD), and they represent a very small fraction of the human population. The incidence of such circumstances occurs in 1:4500 to 1:5500 births.[1] Sex is binary, male or female, and is determined by chromosomal complement and corresponding reproductive role. The exceedingly rare DSDs are all medically identifiable deviations from this sexual binary norm. The 2006 consensus statement of the Intersex Society of North America and the 2015 revision of the Statement do not endorse DSD as a third sex.[2] DSD outcomes range from appearance of female external genitalia in an XY male (complete androgen insensitivity syndrome) to appearance of male external genitalia in an XX female (severe congenital adrenal hyperplasia).

As one would expect, there are variations of the degree of hormonally driven changes that create ambiguous genital development that prevent assigning of a specific classification as either male or female at birth. DSD patients are not "transgender"; they have an objective, physical, medically verifiable, physiologic condition. Transgender people generally do not have intersex conditions or any other verifiable physical anomaly. People who identify as "feeling like the opposite sex" or "somewhere in between" do not comprise a third sex. They remain biological men or biological women.

In some DSDs there exist more than one set of chromosomes. When there is a divergence of the appearance of the external genitalia from the chromosomally determined sex due to the presence of both an ovarian and testicular cell lines in a patient simultaneously, the patient is classified as having ovo-testicular DSD (formerly termed a true hermaphrodite). When there is a disruption in the development of genital structures but there is solely testicular tissue present in the chromosomal male or solely ovarian tissue in the chromosomal female, the term 46 XY DSD or 46 XX DSD is used instead respectively (formerly termed male pseudohermaphrodite or female pseudohermaphrodite).

The decision to assign a sex of rearing is complex and is specific to the diagnosis. Patients with complete androgen insensitivity (CAIS) are XY DSD but are never reared as a male. Because testosterone never influences development, they become happy, functional female adults with infertility. Females with severe congenital adrenal hyperplasia (CAH) are XX DSD but are not reared as males despite the male appearance of the genitalia at birth. Although these girls may show a tendency for male play behaviors as children, they generally assume a female sexual identity. Therapeutic interventions in the DSD individuals from infancy onward are aimed at what function can be expected from their disordered sexual anatomy in terms of function and fertility. Most often, the chromosomal sex aligns with the sex of rearing.

Gender Identity

"Gender" is a term that refers to the psychological and cultural characteristics associated with biological sex. It is a psychological concept and sociological term, not a biological one. The term gender possessed solely a linguistic meaning prior to the 1950s. This changed when sexologists of the 1950s and 1960s co-opted the term to conceptualize cross-dressing and transsexualism in their psychological practice. "Gender identity" is a term coined by my former endocrine faculty member John Money in the 1970s and has come to refer to an individual's mental and emotional sense of being male or female. The norm is for individuals to have a gender identity that aligns with one's biological sex.

Gender discordance (formerly Gender Identity Disorder) is used to describe a psychological condition in which a person experiences marked incongruence between his experienced gender and the gender associated with his biological sex. He will often express the belief that he is the opposite sex. Up until 2010, gender discordance occurred in 0.001% of biological females and in 0.0033% of biological males.[3] Exact numbers are hard to document since reporting is often anecdotal. Gender discordance is not considered a normal developmental variation.

"Gender Dysphoria" is a diagnostic term to describe the emotional distress caused by gender incongruity.[4] John Money played a prominent role in the early development of gender theory and transgenderism. He understood gender to be "the social performance indicative of an internal sexed identity."[5] He joined the Johns Hopkins faculty in 1951 specifically to have access to children diagnosed with DSD, hoping to prove his theory that gender was arbitrary and fluid. Money experimented with DSD infants by assigning them to the opposite biological sex through surgical revision, counseling, and hormonal manipulation during puberty. His mode of operation was to have a theory and then experiment with patients to see how his theory worked.

Ethics in Clinical Research on Human Subjects

It is important to discuss the need for ethics to play a role in the design of clinical studies involving human patients. To have a hypothesis, as did John Money, is not at issue. However, to clearly elucidate the potential for harm and balance that knowledge with the potential benefits is key and essential. After the travesties of open-ended experimentation in the Nazi concentration camps, international guidelines were established to protect human subjects from just such experimentation.[6] John Money ignored these guidelines as he assigned genders to infants and toddlers with ambiguous genitalia. There was no informed consent of the patients, who were infants and toddlers, and their parents were just told to follow the advice of Dr. Money and to trust that he had the correct information. There was no standardized protocol to follow, and no known outcome that could be guaranteed. This kind of endeavor did not anticipate or prevent adverse outcomes and was the antithesis of ethical science. Money never submitted his research proposals for review by an independent external review board. This left the patients unprotected and vulnerable to harm, and, indeed, in the case of the Reimer twins, to death due to drug addiction/overdose in one brother to and suicide in the other.[7]

Near the end of my fellowship training at Johns Hopkins, a male infant was sent to our clinic to assess the cause of his very small penis and testicles. My attending physician and I laid out a diagnostic work-up based on the known science which would help us understand whether the problem was due to a pituitary deficiency or an inability of tissue response to hormones. We purposely left John Money off the care "team," having some serious concerns about his tendency to dismiss science and to experiment. We sent the family home with their son and were quite surprised when the mother returned six weeks later with a baby wearing a pink dress and an eyelet bonnet. Without our knowledge, Dr. Money had intervened and told the family that our protocol was nonsense and the baby needed to be reared as female. On physical exam, there was clear evidence that not only was the baby able to produce testosterone, but his penis responded well, as expected, to the hormone production by his own body. The family was relieved but had not been spared suffering under the experimentation by Dr. Money. They had suffered deeply when they divulged to their extended family that their baby boy was actually a baby girl, and then they suffered even more when they recanted and resumed calling him a boy.

Because of his experience with infants, Money initially garnered support from endocrine colleagues and surgical colleagues, and Johns Hopkins became a renowned center for care of patients with DSD in the 1970s, receiving referrals from around the world. Follow-up studies on these infants later showed, however, that altering their natal sexual identity via social intervention could lead to severe psychological harm. Clinical case reports of children with DSD have revealed that gender identity is indeed not immune to environmental input.[8]

Meanwhile, Money had expanded into the field of adult patients with persistent gender identity disorder. This very small group of patients chose voluntarily, as adults, to enter a very precise protocol which began with living socially as the opposite sex for a year, eventually receiving hormonal therapy to change their physical appearance to some extent. The final step was surgical revision of the body structures that would otherwise be at odds with their desired gender identity. This small group of patients was followed for a number of years past their final surgical procedures and required continuous counseling. These patients expressed some degree of subjective satisfaction but showed no objective improvement in overall wellbeing.[9] The legacy of John Money fell into disrepute and the transsexual treatment program at Johns Hopkin was closed in the 1980s based on the lack of evidence that this protocol produced an effective cure.

Etiology of Gender Disorders

Transgender affirming professionals claim transgender individuals have a "feminized brain" trapped in a male body at birth and vice versa based upon various brain studies. Diffusion-weighted MRI scans have demonstrated that the pubertal testosterone surge in boys increases white matter volume. A study by Rametti and colleagues found that the white matter microstructure of the brains of female-to-male (FtM) transsexual adults, who had not begun testosterone treatment, more closely resembled that of men than that of women.[10] Other

diffusion-weighted MRI studies have concluded that the white matter microstructure in both FtM and male-to-female (MtF) transsexuals falls halfway between that of genetic females and males.[11] These studies, however, are of limited clinical significance due to the small number of subjects and failure to account for neuroplasticity.

Neuroplasticity is the well-established phenomenon in which long-term behavior alters brain microstructure. For example, the MRI scans of experienced cab drivers in London are distinctly different from those of non-cab drivers, and the changes noted are dependent on the years of experience.[12] There is no evidence that people are born with brain microstructures that are forever unalterable, but there is significant evidence that experience changes brain microstructure.[13,14] Therefore, any transgender brain differences would more likely be the result of transgender behavior than its cause.

Furthermore, infants' brains are imprinted prenatally by their own endogenous sex hormones, which are secreted from their gonads beginning at approximately eight weeks' gestation.[15,16,17] There are no published studies documenting MRI-verified differences in the brains of gender-disordered children or adolescents. The DSD guidelines also specifically state that current MRI technology cannot be used to identify those patients who should be raised as males or raised as females.[18] Behavior geneticists have known for decades that while genes and hormones influence behavior, they do not hard-wire a person to think, feel, or behave in a particular way. The science of epigenetics has established that genes are not analogous to rigid "blueprints" for behavior. Rather, humans "develop traits through the dynamic process of gene-environment interaction. ... [genes alone] don't determine who we are." [19]

Regarding transgenderism, twin studies of adults prove definitively that prenatal genetic and hormone influence is minimal. The largest twin study of transgender adults found that only 20 percent of identical twins were both transgender-identified.[20] Since identical twins contain 100 percent of the same DNA from conception and develop in exactly the same prenatal environment exposed to the same prenatal hormones, if genes and/or prenatal hormones contributed to a significant degree to transgenderism, the concordance rates would be close to 100 percent. Instead, 80 percent of identical twin pairs were discordant. This difference would indicate that at least 80 percent of what contributes to transgenderism as an adult in one co-twin consists of one or more non-shared post-natal experiences including but not limited to non-shared family experiences. These findings also mean that persistent GD is due predominately to the impact of nonshared environmental influences. These studies provide compelling evidence that discordant gender is not hard-wired genetically.

Gender Dysphoria vs. Gender Identity Disorder

Up until the recent revision of the DSM-IV criteria, the American Psychological Association (APA) held that Gender Identity Disorder (GID) was the mental disorder described as a discordance between the natal sex and the gender identity of the patient. Dr. Kenneth Zucker, who is a highly respected clinician and researcher from Toronto, carried on evaluation and

treatment of GID patients for forty years. His works, widely published, found that the vast majority of boys and girls with GID identify with their biological sex by the time they emerge from puberty to adulthood, through either watchful waiting or family and individual counseling.[21] His results were mirrored in studies from Europe.[22,23]

When the DSM-V revision of the diagnosis of GID was proposed by the APA committee responsible for revision, Dr. Zucker strongly opposed the change to the term Gender Dysphoria, which purposefully removed gender discordance as a mental disorder apart from the presence of significant emotional distress. With this revision, Gender Dysphoria describes the mental anguish which is experienced by the gender discordant patient. The theory that societal rejection is the root cause of Gender Dysphoria was validly questioned by a study from Sweden which showed that the dysphoria was not eliminated by hormones and sex reassignment surgery even with widespread societal acceptance.[24]

Treatment of Gender Dysphoria

The treatment of children and adolescents with gender discordance and accompanying gender dysphoria should include an in-depth evaluation of the child and family dynamics. This evaluation provides a basis on which to proceed with psychologic therapy. The entire biologic and social family should be involved in psychological therapy designed to assist the patient, if at all possible, to align gender identity with natal sex. Psychological support by competent counselors with an intent of resolving the gender conflict should be provided as long as the patient continues to suffer emotionally. Given the high degree of eventual desistance of gender discordance/dysphoria by the end of puberty, it would be ethical and logical to counsel the patient and family to rear the child in conformity with natal sex.

There should be no interruption of natural puberty. Natural pubertal maturation in accordance with one's natal sex is not a disease. It is designed to carry malleable, immature children forward to be healthy adults capable of conceiving their own progeny by providing either a sperm or an egg. Puberty affects physical changes, some of them painful, unique to the natal sex to reflect the laws of nature. Interruption of puberty has been reserved for children who begin puberty at an age much younger than normal in an effort to preserve final height potential and avoid the social consequences of precocious maturation.[25]

There are a number of physical changes that are a consequence of normally timed puberty that could be classified as disadvantageous: changes in body proportions can alter success with dance and gymnastics; acne can be severe and disfiguring; a boy soprano can suddenly hardly carry a tune. It has not been the ethical standard of care to stop puberty so that these changes can be circumvented. Erikson described the stage of adolescence as "Identity versus Role Confusion" during which the teen works at developing a sense of self by testing roles then integrating them into a single identity.[26] This process is often unpleasant regardless of the presence or absence of gender identity conflicts. The major benefit of enduring puberty in a GD patient is that it provides a strong likelihood of alignment of his gender identity with his

natal sex. There is no doubt that these patients need compassionate care to get them through their innate pubertal changes.

The light at the end of the tunnel is the proven scientific evidence that 80%- 95% of pre-pubertal children with GD will come to identify with their biological sex by late adolescence. Some will require lifelong supportive counseling while others will not.[27] Intervention at a young age with gonadotropin releasing hormone analogs (often referred to as puberty blockers) to either stop puberty early on or prevent it from starting before it naturally occurs is suggested by guidelines developed by WPATH without scientific basis. These guidelines are essentially nothing more than an open-ended experiment in the manner of John Money. They represent the ideas of their authors with clear admission that there is no long-term evidence that harm will exceed benefits as these patients grow to old age. There is evidence that bone mineral density is irreversibly decreased if puberty blockers are used during the years of adolescence.[28] To treat puberty as a pathologic state of health that should be avoided by using puberty blockers (GnRH analogs) is to interrupt a major necessary physiologic transformation at a critical age when such changes can effectively happen. We have definite evidence of the need for estrogen in females to store calcium in their skeleton in their teen years. That physiologic event can't be put off successfully to a later date. It is very difficult to imagine ethical controlled clinical trials that could elucidate the effects of delaying puberty until the age of consent.

The use of cross-sex hormones during this same time frame has no basis of safety and efficacy. The use of such treatment in adults raises scientifically valid concerns that were amply expressed in the 2009 Endocrine Society Guidelines on Transgender treatment. The next step in WPATH-recommended intervention is to use cross-sex hormone therapy during the time when the patient would naturally be experiencing endogenous pubertal changes. This too is not based on scientifically proven theories. The use of cross-sex hormones can cause permanent infertility.[29]

The final recommended step is so-called "sex reassignment surgery," which can include surgical removal of the breasts in natal females, or removal of the penis and scrotum in natal males. Each of these steps has adverse outcomes, some reversible and others not. Mastectomies leave scars, and there is great difficulty in creating a functional vaginal-like orifice, and certainly no success in creating an innervated erectile penis where none existed previously. Sex reassignment surgery is, by nature, permanent.

Recurrent Themes that Are Repeatedly Published

Puberty blockers are stated to be completely reversible in their effects on the adolescent who has entered puberty based on clinical studies in young children with precocious puberty who have been treated with these drugs. This is comparing apples to oranges. Precocious puberty, by definition, is defined as puberty which starts before the 8th birthday for a female child or the before the 9th birthday in a male child. The end of treatment is carefully timed so that resumption of puberty occurs at the average age for females (10.5 years) and males (11.5

years). This allows the necessary functions of puberty to prepare the body for reproduction and affects the bones, gonads, and brain, among other body systems. On the other hand, blocking puberty at the age of normal puberty prevents the needed accretion of calcium into the skeleton and prevents the maturation of the gonads. There is no long-term data that compares bone, gonad, and brain health in pubertal-aged patients who have had puberty interrupted and those who have not, as was noted as a concern in the Endocrine Society Guidelines. There are no such ongoing studies completed that guarantee the full reversibility of blocking puberty in this age group, but there is evidence that normal bone density can't be fully reestablished. Without any verifiable safety data, using the puberty blockers for interrupting normal puberty is not a sanctionable off-label use of these drugs and is therefore to be considered uncontrolled, non-consentable experimentation on children.

Advocates for the social, medical and surgical affirmation of gender incongruent children insist that they are only following established standards of care. There are no standards of care for transgender health. Standards of care established by broad consensus are reached by inclusion of the whole spectrum of opinions, clinical experience and published science in the formation thereof. The guidelines published by WPATH[30], the Endocrine Society,[29,31] the American Academy of Pediatrics[32], and the Pediatric Endocrine Society[33] are solely the opinions of like-minded practitioners who excluded any contrary opinion. The Endocrine Society Guidelines, as mentioned before, clearly stated that they are not to be considered standards of care. Before true consensus-driven standards of care are established for the treatment of transgender patients of all ages, following the current guidelines is risky experimentation in a manner reminiscent of John Money's tactics.

What We Do Know and Do Not Know

We do know that social affirmation of an incongruent gender tears the fabric of the patient's life into pieces- pitting family members against each other, ruining child friendships and it introduces the child to a fantasy world, much of it on the internet. Kenneth Zucker aptly documented the detrimental effects of such affirmation and the immense amount of work it takes to undo these effects when the child does come to realize they can't change their sex and wants to go back to identifying with their sex[34]. We do not know that social affirmation does anything other than push the child away from the proven, 80-90% effective, so-called watch-and wait treatment option. Embarrassingly unscientific short term convenience sample studies purport to show that all gender incongruent children who are socially affirmed have improved mental health and are therefore better off than those children who are not allowed to socially transition.[35]

We do know that blocking puberty during the age when puberty naturally happens lessens accretion of calcium into the skeleton and that this can't be regained by allowing puberty to resume or by using cross sex hormones. We do know that the ovary and testicle cease to mature with treatment. What we do not know is whether allowing puberty to resume will allow the ovary and testicle to fully mature and have full function in terms of fertility. We do

not know if brain development that is halted with puberty blockers can return to full . function once puberty is allowed to resume.

We do know that elevated levels of testosterone in females and of estrogen in males create significant medical morbidity. This knowledge comes from the evaluation and treatment of naturally occurring disease states in children and adults. Treatment of these conditions is aimed at returning hormone levels to normal, thereby avoiding cancers, heart disease, and stroke. We do not know that elevating testosterone in females and estrogen in males to levels ten-fold higher than these known disease states is safe, but common sense would say it can't possibly be safe.

The Myth of Increased Suicide

The affirmation advocates repeatedly refer to the established increased risk of suicide if any of the affirmation strategies are not followed to completion. They point to their own published studies touting dramatic improvement in mental health status of patients who are affirmed in all three ways, but they cite data from convenience sampling, which never should be sued to prove anything other than association, at best. Such studies can never prove causation. There are only two total population studies in the peer-reviewed medical literature.[24,36,37] They show that when every recorded case in the population of Sweden was analyzed, neither medical affirmation nor medical affirmation followed by surgical affirmation improved the mental health of the patients in the long run.

What of the Nearly Logarithmic Increase in Incidence of Gender Incongruence?

Data collection in this regard is subject to estimates based on surveys, which can easily alter the numbers upward or downward, depending on who designed the survey and to whom it was presented. Fear, self-loathing or suicide will necessarily lower the numbers of survey participants whose lives are made miserable by the choice to affirm an incongruent gender. Instant gratification, payback to strict parents, and current celebrity will draw survey participants to express euphoric satisfaction with their decision to affirm their incongruent gender, especially when the surveys are circulated by trans-activist organizations, such as the Trevor Project. What had been in 2010 a nearly invisible fraction of adults who admitted to living with an incongruent gender has exponentially increased in frequency to as many as one out of five students in a suburban Pittsburgh school district in 2021. After I completed my fellowship at Johns Hopkins in 1980, it was not until 1993 that a biologic male presented to my private practice office with a desire to be treated with estrogen to feminize his body so that he could appear to be a female and identify as such. There was nothing in published medical literature that I could find to guide my treatment options. I canvassed my broad contact pediatric endocrinology network across the United States, and nobody had heard of such a clinical case, and none had any suggestions about what I should do. In the ensuing 19 years, the number of transgender treatment centers have burgeoned from zero to several hundred between university-based centers and Planned parenthood. Minority stress theory is frequently used to cover this explosion in numbers, but that is utterly impossible. What does

explain this increase is online recruiting and grooming of vulnerable children and adolescents by a generously funded political movement aimed at dissolving the reality and birthright of biologic sex. This will not end well. By the time a plethora of legal action against those who promoted and engineered the social, medical, and surgical affirmation of incongruent gender knocks down this house of cards, millions of children and adolescents will have been medically, surgically, and mentally maimed as well sterilized.

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ATTACHMENT F

Florida Medicaid Project: Surgical Procedures and Gender Dysphoria

Patrick Lappert, M.D.

May 17, 2022

Florida Medicaid Project: Surgical Procedures and Gender Dysphoria

Patrick Lappert, M.D.

Overview

The "Gender Affirmation" care model for children who suffer from gender identity issues is experimental in nature because it is based in low to very low-quality scientific evidence. There is no body of quality scientific evidence to support the hypothesis that gender dysphoria with its associated problems of self-harm and suicide, is improved long-term by gender affirmation surgical procedures.

The best evidence available today demonstrates that transgender is not a single condition that can be explained by any single factor. There are vast differences in age of presentation, predominant sex, persistence into adulthood, and resolution during adolescent development. Moreover, there are numerous and common co-morbid conditions such as autism-spectrum disorder, major anxiety disorders, and clinical depression that severely affect any sense of certainty about the true cause of the child's dysphoria, as well as their capacity to understand and give assent to irreversible medical and surgical procedures that lead to permanent sterility, sexual impotence, and a lifetime of medical problems associated with affirmation care.

The process of obtaining medical informed consent as part of gender affirming surgery is morally indefensible, and likely legally indefensible as well. Parents of suffering children are led by medical professionals to believe that there is only one valid option of care (affirmation medicine and surgery), utterly concealing the historic reality that greater than 92% of children desist in their cross-sex self-identification when treated using the "watchful waiting" therapeutic strategy. Parents are told that if they do not consent to affirmation care, there is a high likelihood that their child will die from suicide. This is not informed consent, but rather consent under duress.

Gender identity is being presented as a fixed and unchanging, biologically determined, personal characteristic. It is not. The medical literature has consistently shown over many years that the vast majority of children with cross-sex gender identity resolve the issue during adolescence and adopt a gender identity that is congruent with their biological sex.

Because surgeons who perform gender affirmation surgeries have no diagnostic test to predict who among the self-identified transgender minors would have persisted in their cross-sex self-identification into adulthood, and who among those children would have desisted, they have no way to know, in any particular case if the irreversible surgery is being performed on a person who would have continued to self-identify in the cross-sex persona into adulthood. Given the historically well-known desistance rate, it is possible that as many as 90% of children are undergoing surgery based upon an incorrect diagnosis.

"Gender Affirming" breast surgery for self-identifying transgender minors is not medically and ethically equivalent to similar procedures performed for objectively identifiable medical conditions. Transgender breast surgery is always cosmetic (aesthetic) in nature because the indication is a hoped-for improvement in the interior emotional life of the patient. Transgender surgery is not based in any medical diagnosis and does not seek to restore any form or function that may have been lost due to trauma, disease, or developmental accident. It begins with normal structures and changes their appearance in order to achieve a subjective improvement and is therefore cosmetic surgery.

Because gender affirming surgery is cosmetic (aesthetic) in nature, such surgeries must never be offered if they are known to predictably produce an irreversible loss of function. To knowingly sacrifice a human capacity (breast feeding, capacity for sexual intimacy, fertility) in the pursuit of a cosmetic result in a minor who is incapable of giving informed consent, is morally indefensible. The hoped-for subjective improvement that is sought in transgender surgery is a short-lived improvement and is only supported by low to very low-quality scientific evidence. Long term longitudinal cohort studies that are based in level III evidence show that affirmation surgical care is of no benefit in reducing self-harm including suicide.

Problems with Informed Consent

The protection of children in situations requiring informed consent is a crucial problem that the state has a historic and abiding interest in. In the particular situation of self-identified transgender children, it becomes a most significant problem, given that they are being submitted for permanently life-altering interventions. In my opinion as a plastic and reconstructive surgeon, the life-altering nature of hormonal and surgical interventions needs to be addressed from the moment of the child's entry into the gender-transition system, given the fact that the overwhelming majority of children who first begin puberty blockade, go onto the physically altering and permanent changes produced by cross sex hormones, and many ultimately also pursue surgery, as is attested to by multiple papers, the content of which is examined below. Informed consent has several requirement that need to be met if such consent is to be deemed valid. These requirements include a thorough discussion of the details of the proposed procedure including risks, known complications, and some measure of the likelihood of a favorable outcome. The discussion must include alternative treatments, and their risks, known complications and their likelihood of a favorable outcome. In the case of the interventions associated with gender-transition medicine and surgery, the favorable outcomes should be evident over the lifetime of the patient, given that they are permanently sacrificing structures and capacities (breasts and breast-feeding, or genitals and fertility).

Because the commonly cited medical literature used in support of these surgeries is of low to very low quality, it must be recognized that such surgeries must be considered experimental in nature given the unknown long-term effects of treatment, and the vast uncertainty in the patient selection and diagnostic processes. Yet the experts who provide opinion in support of these surgeries speak with absolute certainty of their efficacy, and the absence of any alternative treatment. Considering these factors severally and together it becomes difficult to imagine a

more flawed consent process. It also becomes understandable how parents can be drawn into uninformed participation given the simultaneous presentation of dire consequences if gender dysphoria is left untreated, and the insistence that affirmation care including surgery is the only way to bring lasting happiness to the child.

Chest Masculinization" in Natal Females is Not Ethically Equivalent to Mastectomies for Breast Cancer

When mastectomy is performed for the management of breast cancer, or to mitigate the proven risk of developing breast cancer in women, it is done on the basis of objective diagnoses either by pathological examination of biopsy tissue, or as in the case of prophylactic mastectomy, on the basis of genetic analysis that shows known markers of increased risk of developing breast cancer. These tests (microscopic examination of tissue specimens, detection of cell surface markers with proven association with malignancy, and genetic screening of at-risk patients) have known positive predictive value for the diagnosis of breast cancer, and these tests have known error rates that can be used when obtaining informed consent for mastectomy. The validity of these tests has been proven using scientific methodologies that produce high quality evidence in longitudinal population studies with control populations, and very long follow up. As the result, when a woman gives consent for mastectomy to control or prevent the potentially lethal disease, it is with a clear and proven evaluation of the risks and benefits that consent is obtained. Mastectomy is being performed based upon an objective diagnosis of a potentially lethal condition, and the surgical procedure has proven benefit in management of that condition.

In stark contrast, this is not the case when mastectomy is performed to "masculinize" the chest of girls and women who self-identify as transgender or who self-report symptoms of dysphoria. In the self-identified transgender adolescent, breasts are being removed on the basis of a diagnosis that is made by the patient since there are no tests with known error rates that can be used to predict who will benefit from this disfiguring and irreversible surgery. The claim is made that chest masculinization has proven benefit in reducing dysphoria and the associated risk of suicide. But published studies that make this claim of benefit offer evidence that is low to very low quality, typically small case collections with self-selection bias, very short follow up, and no case controls.

The best data presently available on the long-term effects of medical and surgical transitioning are long-term, longitudinal, population-based studies. For example, Dehjne, et al., examined the putative long-term benefit of full transitioning (including hormonal and surgical treatments) found in the Swedish medical database. (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOSOne February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). That database includes all persons in the Swedish medical system, from pre-natal to death. It reports all episodes of care and all demographic information in a uniform vocabulary. Furthermore, Sweden has been on the forefront of "gender affirmation" long before the American medical

system seriously considered its claims. Because of the nature of Sweden's database, it is possible to study a cohort of patients that very closely matches the inquiry group with regards to age, sex, economic status, etc. It is possible to ask with great precision such questions as, "What is the likelihood that a fully transitioned transgender male will be hospitalized for psychiatric illness when compared to the age/sex matched control group?" Even more, one could urgently ask, "What is the relative risk of suicide in transgender persons, when compared to age/sex matched controls?"

Why are such longitudinal, population-based studies superior to the case-collection/case series methodology? Because confounding variables such as age, sex, and self-selection biases are removed. In the flawed case-collection methodology, the reported cases are typically only those who return for follow up. You have no way of knowing if the patient had a good outcome or didn't return for follow up because they were in a psychiatric hospital, were incarcerated, or committed suicide. In the Swedish longitudinal study, the suicide is in the same database, as are the other issues of hospitalization, incarceration, and addiction treatment, among other rates of comorbidity. Thus the longitudinal population study can give us what is called a "hazard ratio" for a particular study population (patients who have completed transgender transition in this case).

What this Swedish study shows us that the risk of completed suicide in all transgender persons is 19.1 times higher than in the control cohort. If you look only at patients who have transitioned — patients after "treatment" — from female to "male presentation," the risk of completed suicide is 40 times higher than in the general population. (Note: this finding is consistent with the historic Branstrom 10-year follow up study, which found no benefits to "transitioning treatments" but did note an increased risk of serious suicide attempts and anxiety disorders AFTER "treatment.") (Correction to Bränström and Pachankis, Am J Psychiatry 177:8, August 2020; see detailed citations in the "Notes" section of this report below).

Another cautionary note was added to the literature by the reputed Cochrane Review, a UK based international association of researchers who examine the quality of scientific evidence used in medical decision making. The Cochrane Review recently published findings concerning the medical evidence used to support the decision to give young women cross sex hormones as part of the transition process. The authors summarize the world literature review thus: "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition. This lack of studies shows a gap between current clinical practice and clinical research." (Does hormone therapy help transgender women undergoing gender reassignment to transition? See, Haupt C, Henke M, Kutschmar A, Hauser B, Baldinger S, Saenz SR, Schreiber G., Cochrane Review, 28 Nov 2020).

Similar issues of very poor, low quality scientific support for chest masculinization surgery can be seen in a recent article by Tolstrup et al. published in the journal Aesthetic Plastic Surgery (See Anders Tolstrup, Dennis Zetner, Jacob Rosenberg, Outcome Measures in Gender-Confirming Chest Surgery: A Systematic Scoping Review, Aesthetic Plast Surg 2020 Feb;44(1):219-228. doi: 10.1007/s00266-019-01523-1. Epub 2019 Oct 29). The article reports a

comprehensive review of the world literature concerning the efficacy of "gender confirming" chest surgery in transgender patients. The authors found 849 articles on the subject, published in peer reviewed medical journals. Of these 849 articles, only 47 could be included in the review. This means that only 5.5% of all the published, peer-reviewed transgender surgery articles demonstrated even rudimentary scientific rigor. Of those 47 articles, the authors report that only 29 of the articles addressed mental health outcomes (3.4% of all the articles). What is startling is that the mental health outcomes were judged only on the basis of uncorroborated, untested, and unassessed patient subjective reporting with descriptors that varied so widely from article to article that results could not even be compared. The authors summarize by saying, "Evaluation of outcomes in gender-confirming chest surgery showed large variations in reporting, and further streamlining of reporting is therefore required to be able to compare surgical outcomes between studies." None of these negligent articles even bothered to examine rates of psychiatric hospitalization, substance abuse, self-harm behaviors, and suicide. This tells us that the main reason for performing these surgeries (psychological distress and suicide risk) isn't even evaluated with regard to efficacy.

An example of an article with very low-quality data, reckless (now banned practices), and methodology, published in a "leading journal," and promoted as evidence for the efficacy of "chest masculinization" surgery makes this fact very clear. The lead author (Olson-Kennedy, a leading national advocate for the transgender treatment enterprise) is a board-certified pediatrician who leads the gender clinic for the Los Angeles Children's Hospital. The article appeared in 2018 (See J. Olson-Kennedy, J. Warus, MD1, et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults; Comparisons of Nonsurgical and Postsurgical Cohorts., JAMA Pediatr. 2018;172(5):431-436. doi:10.1001/jamapediatrics. 2017.5440. In their summary of findings, the authors reported that "chest dysphoria" is common among "trans males" (natal females seeking to present as males) and claimed that dysphoria is "decreased by surgery." They claim that regret for surgery is "rare." The article reports breast removal surgery on at least one girl aged 13 years. (Note that this reckless, experimental practice has now apparently been abandoned as unethical/experimentation on children by England, Sweden, and Finland. The average age of patients in the study was 19. Children were entered into the study through recruitment from among patients visiting the clinic and by telephone over a six-month period. The authors found that, of the patients recruited from among visitors to the clinic (convenience sampling), there was an over-representation of non-operated patients, so the authors were forced to reach out to all the post-surgical patients by phone. Twenty-six percent of the clinic's post-surgical patients could not be reached for various reasons including no working phone, or failure to respond to multiple messages. The 26% drop-out rate is never even questioned by these authors. Were surgical patients lost to follow up because of dissatisfaction, psychiatric hospitalization, or suicide? This problem is called "self-selection bias," and it is evidence of careless study design. Of the remaining 74% of patients, only 72% completed the survey. This is a second example of self-selection bias. Why would some post-surgical patients who had been successfully contacted, not complete the survey? The authors — demonstrating multiple levels of confirmation bias — do not even ask such essential questions. (See detailed citations in the "Notes" section of this report below).

In the study, dysphoria was evaluated using what the author called "a novel measure," which amounted to a series of subjective questions about happiness that was in part designed by the adolescent test subjects themselves. Essentially, the methodology used an entirely unvalidated ("junk science") test instrument, with no known error rates and no proven predictive power. Furthermore, the post-surgical patients were administered the survey at widely varying time intervals post-surgery. The longest interval between surgery and the satisfaction survey was 5 years, but children less than a year post-surgery were included in this obviously flawed sample, and yet the authors claim evidence of "negligible regret." This is a remarkable, misleading, and deceptive claim given that long-term, longitudinal population studies show that there is a dramatic rise in post-surgical problems such as depression, hospitalization, substance abuse, and suicide beginning at around seven years post-surgery (Ibid). Surely the authors are familiar with the world literature on transgender outcomes?

Having deceptively or negligently promised in the introduction to their paper that "chest dysphoria" is reduced by surgery, at the conclusion the authors confessed to the fact that the study design and execution produced very low-quality data that is not useful for patient selection, or prediction of outcomes. They even confessed that the study does not address the efficacy of surgery in improving outcomes regarding the single most compelling reason for performing the operation: mitigation of depression and suicide. The authors write, "An additional limitation of the study was the small sample size. The nonsurgical cohort was a convenience sample, recruited from those with appointments during the data collection period. There could be unknown imbalances between the nonsurgical and postsurgical cohorts that could have confounded the study findings."

Finally, the authors did not even bother to validate their "Chest Dysphoria Scale." Such a "made-up" scale is unlikely to accurately represent distress or correlate with properly validated measures of quality of life, depression, anxiety, or functioning. Their own analysis at the conclusion or the paper directly contradicts the deceptive claim made in their introduction.

This is the kind of "junk science" that is used to support transgender medicine and surgery. The paper is only a few years old. It was written by board certified physicians who practice in one of the nation's largest pediatric gender clinics and was published in a peer-reviewed medical journal. It is essentially useless in making any clinical decisions regarding who should be offered surgery, what is the likelihood they will benefit from it, and what is the likelihood they will regret their decision. Most importantly, it does not even measure the effect of therapy on suicide risk. The very morbidity (the risk of suicide) that they claim is improved by surgery is not even measured in their low-quality study.

Because of the very low-quality scientific support for mastectomy in the management of gender dysphoria, valid consent would demand that these procedures be described as experimental, would need the approval of ethics panels to monitor human experimentation, and would require the use of valid controls found in long-term, longitudinal population-based study models. These are the kinds of patient protections now endorsed in England, Sweden and Finland but still

ignored in the US environment where proper scientific critiques of such studies can get faculty "cancelled."

Even though the transgender treatment industry has been performing these surgeries for over 50 years, gender treatment centers continue to publish the same low quality, methodologically defective studies based upon collected cases that are degraded in value by self-selection bias, confirmation bias, and short-term follow-up, while continuing to deceptively claim that such defective research provides a sufficient scientific basis for performing irreversible, disfiguring, and ultimately sterilizing hormonal treatments and surgeries on children.

"Chest Masculinization" in Natal Females is Not Ethically Equivalent to Gynecomastectomy

Gynecomastectomy is the surgical treatment of gynecomastia, a fairly common condition in which males develop female-type breast gland tissue. Proponents of "masculinization" mastectomy in natal females erroneously equate the ethics of removing healthy breast tissue from gender dysphoric children with the removal of abnormal breast tissue in men (gynecomastia). In the case of gynecomastectomy in male patients, the operation is performed to remove the objectively diagnosed presence of female type glandular breast tissue present in a male patient. Physical examination demonstrates the presence of a dense retro-areolar mass which is tender and sometimes disfiguring. Pathological examination of the removed tissue will demonstrate the presence of female-type fibroglandular tissue in a male patient. This is an objectively abnormal condition. It should further be noted that the absence of such abnormal, female-type fibroglandular tissue in the submitted surgical specimen places the chest recontouring in the category of cosmetic surgery and is therefore not typically paid for by third-party payors.

A comprehensive literature review on the subject of gynecomastectomy and suicidal behavior conducted by Sollie in 2018 (Management of gynecomastia—changes in psychological aspects after surgery—a systematic review: Gland Surg. 2018 Aug; 7(Suppl 1): S70–76.doi: 10.21037/gs.2018.03.09) did not produce a single paper claiming improvement in suicide rate in patients who underwent this surgery. There were many reports concerning improvement in the pain that men with this objective condition suffer with. The remainder of the reported data was in the category of subjective "satisfaction survey". This tells us that the author did not distinguish between medically indicated and aesthetic surgeries. Nonetheless, no claim is made of decreased suicide rates in a suicidal population of male patients. This is because any male patient seeking removal of abnormal, female-type, breast tissue who reported suicidal ideation would be considered incompetent to give consent and would require a psychiatric evaluation and treatment to manage suicidal thinking before being considered for surgery. This kind of decision in favor of psychiatric support does not appear to be at work in the transgender affirmation world. There, and there alone, is suicidal thinking considered a qualification for a surgery.

"Chest Masculinization" in Natal Females is Not Ethically Equivalent to Breast Reduction

It should be obvious that "Chest Masculinization" surgery in natal females is not ethically equivalent to breast reduction surgery in non-transgender females. In the case of breast reduction for females with excessively large breasts (macromastia, or gigantomastia), the operation is performed to relieve a debilitating orthopedic complaint of neck, back, and shoulder pain associated with the postural/mechanical effects of the weight of the breasts. These patients experience significant activity restriction and chronic pain that is not relieved by medical management or physical therapy. Furthermore, there is voluminous actuarial data, based upon many years of longitudinal population-based study by medical insurance agencies that is used to predict who will benefit from surgery, and who will not. These physical, objective tests, based upon the actual measurement of the breasts, and the patient's overall body habitus, have known error rates that can be used to predict the likelihood that a breast reduction will relieve the orthopedic complaints of neck, back, and shoulder pain. When the tissue specimens are submitted to pathology, they are weighed in order to ensure that enough tissue has been removed so that there will be a very high likelihood that the surgery will relieve the orthopedic condition of neck, back, and shoulder pain (Accuracy of Predicted Resection Weights in Breast Reduction Surgery, Theodore A. Kung, MD, Raouf Ahmed, MBBS1 Christine O. Kang, MPH,1 Paul S. Cederna, MD, and Jeffrey H. Kozlow, MD; Plast Reconstr Surg Glob Open. 2018 Jun; 6(6): e1830.

Based upon that, adequate pre-operative consent can be obtained. The supporting data is based in very high-quality methodology. There is no quality research data, no pre-operative test or study, and no known error rates that can be used to predict the likelihood that any child suffering from gender dysphoria will benefit from the experimental procedures of mastectomy and chest "masculinization." As noted above, because of the very low quality data, transgender chest masculinization is at best experimental and at worst, should be viewed as a form of medical child abuse — it is important to note that Finland, Sweden, and the UK apparently now all agree with this analysis, as they have all retreated from such reckless surgical procedures for (See detailed citations in the "Notes" section of this report below).

It is crucial to remember that "chest masculinization-affirmation surgery" of healthy breast tissue results in a complete loss of function, that this loss is two-fold (breast feeding and erotic sensibility), and the cause of the loss is two-fold (gland removal and severing of the intercostal nerve). (See Breast Reduction with Use of the Free Nipple Graft Technique; Stephen R. Colen, MD; Aesthetic Surgery Journal, (Breast Reduction with Use of the Free Nipple Graft Technique; Stephen R. Colen, MD; Aesthetic Surgery Journal, Volume 21, Issue 3, May 2001, Pages 261–271, https://doi.org/10.1067/maj.2001.116439).

If a patient who undergoes "chest masculinization" should regret the surgery, they do have the option of breast reconstruction. However, all that will be produced is a counterfeit of a breast. The patient will have lost the function of breast feeding. Additionally, the most commonly performed "masculinization" surgery involves the removal of the nipples, and subsequent re-

attachment in the form of a nipple graft. Those nipples will have lost their native nerve connections that provoke erotic sensibility. All that can be hoped for is the eventual random ingrowth of local skin sensation, but there will never be erotic sensation because the particular branch of the fourth intercostal nerve which communicates with particular centers in the brain responsible for oxytocin release and erotic provocation will have been permanently severed. This means that breast function has been completely and irreversibly sacrificed for the sake of producing a cosmetic result (a masculine appearing chest). This is the exact opposite of the goals of any reconstructive surgery. It must therefore be understood that "chest masculinization" is a cosmetic procedure that has violated the most essential principle of cosmetic surgery: never sacrifice function for the sake of a cosmetic result.

Erroneous use of the word "Reconstructive" to describe Gender Affirmation Surgeries

The transgender treatment enterprise uses the word "reconstructive" to characterize a group of surgical treatments that seek to alter the sexed appearance of the person. It is important to understand that these procedures, because of the indications for surgery, the motivations for surgery, and the outcomes of surgery, are not reconstructive, but are to be properly understood to be cosmetic in nature.

Reconstructive surgeries are procedures that seek to establish or restore structures and their functioning that have been lost due to trauma, disease, in-utero developmental abnormalities, or surgical treatment for disease. Such reconstructive surgeries must begin with the objective characterization of the defect, including abnormalities of form, and associated loss of function. This process of defining the defect begins with a thorough understanding of normal human form and function and seeks to select, develop, and execute procedures that will restore both. In some cases function may be emphasized more than form, as when the mangled hand of a man is reconstructed. In other cases, reconstruction of form is all that is possible because as yet there are no techniques to restore function. An example of this is seen in the reconstruction of a woman's breast following cancer care. All that can be offered is the appearance of a breast; she will never be able to feed an infant through the reconstructed part.

This is to be contrasted with cosmetic, or aesthetic surgery in which the appearance of a structure is modified in order to produce a subjective (aesthetic) result for the patient. No functional restoration is addressed because no functional or structural loss exists. The object of the surgery is aesthetic. There is no lost form or function that needs to be reconstructed. It is aesthetic surgery because the motivation is aesthetic (subjective feelings about appearance). Further evidence for this is the fact that nearly the entirety of the outcome studies cited in support of these surgeries use subjective questionnaires which the patient fills out. The questions used are typical of those used to evaluate any aesthetic surgery. They are called "satisfaction surveys". Such surveys are prone to suffer from self-selection bias, confirmation bias, and high drop-out rates.

One of the key problems that the transgender treatment enterprise faces on a daily basis is the issue of third-party payment for services. No health insurance provider, including federal and state agencies will pay for cosmetic surgery. For this reason, it is necessary, in order for the business model to succeed, that providers characterize their services as reconstructive. This is doubly difficult given the intense political pressure that has been exerted upon the medical community to "de-pathologize" the condition of transgender. This is seen in the abandoning of the diagnostic nomenclature of "body dysmorphic disorder", and "gender identity disorder" in favor of the more recent DSM manual using the term "gender dysphoria". This leads transgender treatment providers into the difficult situation of claiming that transgender is not a pathology, while at the same time insisting that the services are medically necessary and describing the procedures as reconstructive without characterizing any physical/ functional defect.

As we consider the specific "gender affirming" surgical procedures we will see that comparison to medically indicated surgeries on both men and women actually serves to reinforce the evidence that these surgeries are essentially and fundamentally cosmetic.

Masculinizing and Feminizing Chest Surgeries are Not "Medically Necessary"

Supporters of "transitioning" treatments justify surgical treatment based upon "medical necessity." They claim that gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide. Yet with only a single exception, in the studies they cite no measures are made of the effects of surgery on what is claimed to constitute the "medical necessity" for these procedures.
In contrast, the Branstrom study[1] documented no reliable benefits for transgender surgery/hormonal treatments and no reduction in suicide and even an increase in serious suicide attempts requiring hospitalization in patients receiving surgery. These recent, long-term, published, peer reviewed, credible research findings are quite contrary to the claims of supporters of "transitioning treatments" — as are the National Science Reviews in this area from England-NICE, Sweden, and Finland. (See detailed citations in the Notes section in this declaration).

Scientific rigor would demand an examination of objective outcomes such as: rates of substance abuse, psychiatric hospitalization, self-harm, or suicide, and how they were changed by surgery. One paper does ask these crucial questions concerning efficacy is a very comprehensive, long term, longitudinal population cohort study which actually shows the opposite of what experts claim for these patient outcomes. When followed beyond eight years post operatively, this paper shows that patients receiving these treatments have the same alarmingly high rates of hospitalization, substance abuse, self-harm, and completed suicide as persons who have had no medical or surgical intervention.

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[1] *Correction of a key study: No evidence of "gender-affirming" surgeries improving mental health.* Home. (2020, August 30). Retrieved May 17, 2022, from https://segm.org/ajp_correction_2020

In summary, on the issue of the efficacy of these surgeries, the scientific support is very weak, while the scientific evidence rejecting the hypothesis of efficacy is remarkably strong (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885).

The surgical removal of the breasts, and the re-contouring of the chest through liposuction is a common procedure for women who seek to present as men. These operations are performed in both men and women, for a variety of reasons. They are generally very safe, and typically performed in the outpatient setting. It is important to understand that the only way of distinguishing cosmetic breast surgery from "medically necessary" surgery is based upon the diagnosis of underlying pathology. For example, breast reduction may be cosmetic, or it may be medically indicated. In both cases, the patient presents with a complaint that her breasts are too big. The distinction between cosmetic breast reduction and medically indicated breast reduction is based upon the presenting symptoms of orthopedic problems when working, such as chronic neck back and shoulder pain caused by the weight of the breasts. But even then, the weight of the removed tissue is factored into the objective verification that the surgery was "medically necessary." There is a vast body of medical and actuarial data that demonstrates the relationship between the weight of the breast tissue removed and the probability that back pain will be cured by performing a breast reduction.

The same issues are at stake in breast enhancement for men seeking to present as women. Cross-sex hormones will have caused varying degrees of gynecomastia (breast enlargement in men). Surgical enhancement procedures are exactly the same in both men and women.

Medically necessary surgery in women is based upon the diagnosis of an objective medical condition, such as Poland's syndrome (congenital absence of a breast), surgical absence of the breast following cancer care. In men, the objective diagnosis of gynecomastia might warrant surgery based upon medical necessity, but it would be the removal of tissue that has objective pathological features (breast gland proliferation in a man). A rare diagnosis of breast cancer in a man might warrant chest wall reconstruction after cancer care. On the other hand, cosmetic surgery of the breast is entirely about the subjective feelings of the patient, and that is all that we find in the case of the self-identified transgender patient.

In the case of transgender chest surgery, the diagnosis is based on the patient's subjective report of dysphoria, but the medical necessity is based on the expectation that surgery will relieve the patient of the risk of, among other things, major depression, self-harm behaviors, and suicide. None among the many papers typically cited by supporters of "transitioning treatments" address themselves to the question of medical necessity for either masculinizing surgery, or feminizing surgery. They only address technical issues, management of complications, and subjective outcomes that employ precisely the same language that is used to assess every

other cosmetic surgery of the breast. Such papers often begin with standard language about the suffering of self-identified transgender adolescents, and their risk of self-harm. They will claim that the reported surgeries somehow reduce the risk of suicide, or the frequency or severity of self-harm, but they never report actual results of improvement in the risk of suicide, or substance abuse, or cutting, or sexual risk taking. The claim of benefit is unsupported in the scientific literature.

In summary, the medical necessity of transgender chest surgery is not supported by scientific evidence and appears to be firmly in the category of cosmetic surgery. What is more, the surgeries when performed on natal females causes a life-long loss of function, placing those surgeries in the category of malpractice. No other cosmetic procedure is expected to produce major functional loss. Such a result would only be the result of a complication, or other surgical misadventure. To actually have a 100% certainty of loss when surgical consent is being obtained constitutes a complete neglect of one of the foundational principles in plastic surgery: Never sacrifice function for the sake of a cosmetic result.

About the Author

Education and Training: I received my Bachelor of Arts in Biological Sciences at the University of California, Santa Barbara, 1979. There I was engaged in research in cell membrane physiology with Dr. Philip C. Laris, studying stoichiometry of the sodium: potassium ATPase pump. I received my M.D., Doctor of Medicine degree at the Uniformed Services University of the Health Sciences, 1983 at Bethesda, Md. I served my General Surgery Residency at the Naval Hospital Oakland/UC Davis East Bay Consortium, 1987-1991 and served as Chief Resident, Department of Surgery, Naval Hospital Oakland, 1990-1991. I also served a Plastic Surgery Residency at the University of Tennessee-Memphis, 1992-1994. My professional background, experience, and publications are described in more detail in my curriculum vitae, which is attached as Exhibit A to this declaration.

Board Certifications in Medicine: I have been Board Certified in Surgery (American Board of Surgery, 1992), in Plastic Surgery (American Board of Plastic Surgery, 1997; American Board of Plastic Surgery, 2008).

Medical Staff Appointments: I served as the Staff General Surgeon at the Naval Hospital Oakland, CA 1991-1992 and as Associate Professor of Surgery, UC Davis-East Bay, 1991-1992. I also served as a Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, Virginia, 1994-2002 and as Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, Virginia, 1996-2002. I later served as Clinical Assistant Professor, Department of Surgery, Uniformed Services University of the Health Sciences, 1995-2002 and as Founding Director, Pediatric Cleft Palate and Craniofacial Deformities Clinic, Naval Hospital Portsmouth, Virginia, 1996-2002 also as the Founding Director, Wound Care Center, Naval Hospital Portsmouth, Virginia, 1995-2002. I have also served as a Staff Plastic Surgeon in Nebraska and Alabama.

U.S. Surgeon General Service: I served as a Specialty Leader, Plastic and Reconstructive Surgery, Office of the Surgeon General-USN, 1997-2002.

Faculty Appointments: I served as Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery, 1995-2002. I also served on the teaching faculty of the Via College of Osteopathic Medicine, 2017-2020.

Military Service: I served as an Aviation Officer Candidate, Naval Aviation Schools Command, NAS Pensacola, 1978 and was Commissioned an Ensign, MC, USNR 1979 and Commissioned as a Lieutenant, MC, USN 1983. I served as a Designated Naval Flight Surgeon, Naval Aerospace Medical Institute, 1985, and I was Assigned Marine Fighter/Attack Squadron-451, serving as Flight Surgeon, and serving as Radar Intercept Officer in the Marine F4S Phantom, accumulating 235 flight hours, and trained for qualification as an Air Combat Tactics Instructor. I was deployed to the Western Pacific as UDP forward deployed fighter squadron in Korea, Japan, and the Philippines. I served in the US Navy for 24 years, and I served in the USMC for 3 years. I retired with the rank of Captain, USN in 2002.

Publications - Peer Reviewed Medical Journals: Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep; 102(3):553-4; Toth B, Lappert P. Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning. J Plastic and Reconstructive Surgery. 1991; 87 (6): 1048-53; Lappert P. Patch Esophagoplasty. J Plastic and Reconstructive Surgery. 1993; 91 (5): 967-8; Smoot E C III, Bowen D G, Lappert P, Ruiz J A. Delayed development of an ectopic frontal sinus mucocele after pediatric cranial trauma. J Craniofacial Surg. 1995;6(4):327–331; Lappert PW. Scarless Fetal Skin Repair: "Unborn Patients" and "Fetal Material". J Plastic and Reconstructive Surgery. 1996 Nov; 98(6): 1125; Lappert PW, Lee JW. Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation. Plastic and Reconstructive Surgery 1998; 102(5): 1642-5.

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Operations and Clinical Experience: Consultations and Discussions: As a physician and surgeon, I have treated many thousands of patients in 7 states and 4 foreign nations. My practice has included Primary Care, Family Medicine, Aerospace Medicine, General Surgery, Reconstructive Surgery for combat injured, cancer reconstructive surgeries including extensive experience with microvascular surgery, Pediatric Congenital Deformity, and the care of chronic wounds. I have practiced in rural medicine, urban trauma centers, military field hospitals, university teaching hospitals, and as a solo private practitioner. In my private practice I have had occasion to treat many self-identified transgender patients for skin pathologies related to their use of high dose sex steroids, laser therapies for management of facial hair both in transitioners and detransitioners. I have performed breast reversal surgeries for detransitioning patients. My practice is rated as "LGBTQ friendly" on social media. I have consulted with families with children who are experiencing gender discordance. I have given many presentations to professional meetings of educators and counselors on the subject of transgender, and the present state of the science and treatment. I have discussed the scientific issues relevant to the case with many physicians and experts over a number of years and also discussed related issues with parents and others.

ATTACHMENT G

Florida Medicaid Project: Treatment for Transgender Children

Medical Experimentation without Informed Consent:

An Ethicist's View of Transgender Treatment for Children

G. Kevin Donovan, MD, MA
5-12-2022

Florida Medicaid Project: Treatment for Transgender Children

Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children

I. The Issue

Growing controversy attends the diagnosis and treatment of individuals identifying as transgender, particularly those who are still children or adolescents. As was recently pointed out, leading medical, mental health, and public health organizations support understanding gender-diverse youth and providing gender-affirming medical (hormonal) and other(surgical) care as the standard of care, including the American Academy of Pediatrics, American Psychological Association, Centers for Disease Control and Prevention, Society for Adolescent Health and Medicine, and the American Medical Association. Major nursing organizations—the American Nurses Association and the American Academy of Nursing— have made statements that young people's access to inclusive, safe, and competent health care is a human rights issue. (Wolfe, I., & Goepferd, A. "Child Abuse in Texas." *The Hastings Center*. 14 Mar. 2022) However, this widespread support is not going unchallenged, even by those who have been providing medical interventions for these children and adolescents.

Recently, questions have arisen about the appropriateness of both the diagnosis, and the safety and efficacy of these interventions that have been strongly encouraged up until now. Currently, less than half of state Medicaid programs provide gender affirming care. (Mallory, C., & Tentindo,W. "Medicaid coverage of gender-affirming care." Williams Institute, UCLA School of Law. Oct 2019). The Florida Surgeon General has said that minors should not undergo gender transition procedures, puberty blockers and hormone treatments. "Florida Department of Health Releases Guidance on Treatment of Gender Dysphoria for Children and Adolescents." 20220420-Gender-Dysphoria-Press-Release | Florida Department of Health.) In Texas, the state attorney general issued a decision that gender-affirming medical treatments such as puberty-suppressing hormones fall under the definition of child abuse in Texas state law. In fact, 34 states have introduced legislation to limit hormonal and surgical interventions for such transgender patients. This aligns with similar reassessments and limitations in the United Kingdom, Sweden, Finland, and France. A new position statement from the Royal Australian and New Zealand College of Psychiatrists (RANZCP) stresses the importance of a mental health evaluation for people with gender dysphoria — in particular for children and adolescents — before any firm decisions are made on whether to prescribe hormonal treatments to transition or to perform surgeries, often referred to as "gender-affirming care." "There is a paucity of quality evidence on the outcomes of those presenting with gender dysphoria. In particular, there is a need for better evidence in relation to outcomes for children and young people," the guidance states.

Given the legitimate concerns about the diagnosis, treatment, and the paucity of supportive, scientific studies in regard to the interventions being offered to minors who identify as transgender, I will offer a view of these from the perspective of an ethicist and pediatrician. This will be done in the face of strong and sometimes heated opposition to any variance from the currently prevailing recommendations. Each category of currently recommended or potential treatments will be briefly considered within this framework. The evidence base for these will be reviewed, and an overall argument made that such interventions must be considered as medical experimentation, subject to the requirements of research in childhood with informed consent. Finally, I will conclude with an examination of the fundamental flaw of the transgender project in childhood, and how it is leading to inevitable and controversial challenges.

In order to do this, we must review the ethical requirements for medical research in childhood and the elements of **informed consent**. Because of numerous abuses in the past, a strong system of regulations and oversight has been developed for the protection of human subjects in the United States. This began with the Belmont Report: (https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) The report not only described the ethical principles listed below, but led to guidelines for research protections that are now codified in Federal regulations (Code of Federal Regulations, or 'CFR') and monitored by the U.S. Department of Health and Human Services (DHHS). These led to the establishment of IRBs (Institutional Review Boards) which are responsible for the protection of human subjects in federally funded research—IRBs are the Federally mandated committees that review research activities for the protection of human subjects. The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the DHHS. The OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research. These measures have laid the ground rules for human research, in adults and children including the need for informed consent.

Although adults may be included in research, this should only be done with *fully informed consent*, and the requirements will differ for children and other vulnerable subjects. The bedrock of these protections lies in obtaining the informed consent from the participant. Informed consent to medical treatment and research involvement is fundamental to both ethics and law. The process requires that a *fully autonomous patient* have the ability to *understand relevant medical information* about the proposed interventions, including the *risks, benefits, if any, and alternatives* (including doing nothing/non-participation). and consent *voluntarily* without *coercion*. This is rooted in respect for the **ethical principles** of **autonomy**, **beneficence**, and **justice**.

Autonomy is derived from respect for persons, which requires that we not only respect those who are fully autonomous but protect those individuals that are not fully autonomous. Vulnerable subjects such as children cannot legally or ethically participate in the consent process due to their age and maturity level. The rules for their involvement are set out by the Code of Federal Regulations (46 CFR 401-409). While consent cannot be given for another person, parents or guardians can give "permission" and children can give assent to the extent that they are able. The process of obtaining assent should be appropriate to the age, maturity, and psychological development of the child. The consent process must contain three ethically required components: *information*, *comprehension*, and *voluntariness*. Deficiencies in any of these categories would invalidate the process. The main contention here is that deficiencies in *all* these categories can be found in the current approach to minors who identify as transgender, and current attempts at treatment should not proceed as they are now practiced.

Beneficence is reflected in the complementary expressions of (1) do no harm and (2) maximize possible benefits and minimize possible harms. An assessment of risks and benefits will depend heavily on the delivery of accurate and complete information as described above. An assessment of risk will include both the probability and the severity of envisioned harms, both physical and psychological.

Finally, ***justice*** requires fairness in distribution of risks and benefits. It suggests that not only should like cases be treated alike, but different approaches are appropriate for different circumstances. This is highly relevant in the selection process for those being subjected to the various interventions while still minors.

Thus the process of informed consent must proceed with a correct diagnosis, the nature and purpose of recommended interventions, the known burdens and benefits of all options, including doing nothing or forgoing the intervention. While not able to do an exhaustive review of these elements as they apply to the main treatment approaches recommended for transgender minors, we can briefly examine each category to assess for obvious deficiencies. The issue of deficient information will be significant in each category, and questions of comprehension and voluntariness will be addressed at the end.

II. The Interventions

Surgery

A variety of surgeries have been performed on transgender adults. These range from removal of both breasts (bilateral mastectomy) and associated chest reconstruction, nipple repositioning, dermal implant and tattooing, to gender surgery for trans men which includes construction of a penis (phalloplasty or metoidioplasty), construction of a scrotum (scrotoplasty) and testicular implants, or a penile implant. Removal of the womb (hysterectomy) and the ovaries and fallopian tubes (salpingo-oophorectomy) may also be considered. Surgery for trans women includes removal of the testes (orchidectomy), removal of the penis (penectomy), construction of a vagina (vaginoplasty), construction of a vulva (vulvoplasty), construction of a clitoris (clitoroplasty), as well as breast implants for trans women, facial feminisation surgery and hair transplants. Certainly there are multiple known risks to this long list of surgeries. These used to be described as "sex-change" operations: they are now termed "gender affirming surgeries." The semantic shift is important, as we will see.

Most, but not all, practitioners would delay undertaking these permanent alterations in minor children and adolescents. This may be as much for legal reasons as for medical considerations. However, the lack of sexual maturity in younger patients, especially if previously delayed by puberty blocking agents, makes the sparse tissue more difficult to work with and outcomes less favorable, with problems such as wound rupture more likely. These are not challenges that are routinely described to minors at the beginning of their treatment progression with puberty blocking agents or hormones. This deficit of information would be a major failing.

Hormonal Treatment

Treatment with cross-sex hormones is a mainstay of gender affirming care. These result in the changes in body habitus, facies, voice tone, and hair development that transgender patients seek. They are described as "gender affirming", "life-saving" and "a human right" by their proponents. They have been prescribed by Planned Parenthood clinics and others after a first visit for gender dysphoria (https://www.plannedparenthood.org/planned-parenthood-greater-texas/patient-resources/transgender-healthcare). Surely no one would argue that such a precipitous practice has been accompanied by a full psychological evaluation, or disclosure of medical risks. Chief among these is the fact that the resulting bodily changes will not disappear, even if the initial desire for them changes. And this change is no unlikely development – upwards of 80% of minors who identify as transgender will reverse this identity by the time they reach their mid-20's if left untreated, and revert to their previous identification, albeit possibly with a same-sex attraction. It is more than simply changes in one's body that are at risk; sex hormones have an important and lasting effect on brain development and adolescent psychology. To not fully appreciate this fact, or to not have it delineated in the first place, is an egregious failure of informed consent.

Puberty Blockers

Perhaps the greatest failure of informed consent, and non-disclosure of human experimentation outcomes, is found in the supposedly benign use of puberty blocking agents in minors. They are routinely and widely prescribed with the thought that this will "buy time" for those questioning their gender as minors. Children and their supportive parents are assured that they are a benign intervention whose effects are easily reversible, just in case the child decides not to transition. Some potential effect on the development of bone density may be mentioned. The extent of this danger is just now being appreciated, with severe and disabling osteoporosis described in at least one child in Sweden. This led to new guidelines for gender-affirming care issued in February by the National Board of Health and Welfare. It stated that, based on current knowledge: "the risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits, and that the treatments should be offered only in exceptional cases." However, the effect of puberty blocking agents (started in early adolescent development) on long-term sexual function seems to be largely unstudied. Current guidelines recommend starting puberty blockers at the earliest stage of sexual maturation in children (Tanner two). These will not only prevent the enlargement of penile tissue, it will desensitize the orgasmic potential for tissues later exposed to cross-sex hormones. Simply put, transgender adults treated in early adolescence with puberty blockers may never experience orgasm. When children with gender dysphoria are given these powerful hormones (around age 11) they are too young to appreciate the implications of what will happen.

It is not simply a matter of chronology. As children mature into adolescents and adults, their brains are also being formed and reformed under the influence of sex hormones. There is evidence for structural changes, and these are likely to be demonstrated in cognitive and behavioral changes. In fact, the development of the adolescent brain and the maturation of its rational and executive functions does not typically complete until one's early 20s. Although the deleterious effects on sexual development and function in adulthood from puberty blockers may be predicted, no one is entirely certain of the effects on other critical areas such as brain development and bone density. Carefully constructed and monitored studies have not been done. *Until they are, these off-label treatments with puberty blockers and cross sex hormones can only be considered experimental.* Experimental interventions should be done as carefully as any other research, and fully informed consent is the only ethical way to enter into such studies. Clearly, this is not the current practice.

III. The Fundamental Flaw

There appears to have been a headlong rush in the past decade towards the process of gender affirming care described above. After close scrutiny, it can only be seen as off label experimentation, despite the fact that informed consent practices do not conform to this reality. Given this, we must ask ourselves: how can experienced and ethical physicians so mislead others or be so misled themselves? In 2013, the American Psychiatric Association published their update of the Diagnostic and Statistical Manual of Mental Disorders, the DSM-5. In it the diagnosis of "gender identity disorder" was replaced with "gender dysphoria." This was done to "avoid stigma and ensure clinical care for individuals who see and feel themselves to be a different gender" other than the one to which they were born. The APA stated that "it is important to note the gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition." Dysphoria is a state of uneasiness, unhappiness, or dissatisfaction. With this change in terminology there was also a shift from seeking or correcting the underlying cause of the dysphoria, and a focus on transitioning to the preferred gender.

This revision has probably done more harm than good by accepting a self-diagnosis characterized by the belief that the patient (or their essence) is "trapped in the wrong body." This concept relies on the Cartesian duality, a body-self dichotomy. It reverts to the fallacious "ghost in the machine" concept. In reality, we cannot be trapped in the wrong body; we **are** our bodies, which are an integral and inseparable part of ourselves. To assert that there is a female self inside a male body (or the reverse), is to fail to achieve a full understanding that we are embodied persons, unified body and mind, if you will. A generation ago, sex and gender were taken to be synonyms for the same phenomena. Even now, a transgender female, no matter how much or how long of a hormonal therapeutic regimen they undergo, is still genetically male. Ignoring this fact has led to a contradiction, where sympathetic practitioners recommend "holistic care" while insisting on a fragmented concept of the self. This approach has been warmly embraced, even insisted upon, by many practitioners while viewed as nonsensical and even ludicrous by many laypersons.

Inevitably this has led to added difficulties. Even young patients are encouraged to begin puberty blockers and then hormones based on a self-diagnosis. Self-diagnosing psychiatric conditions is always fraught with the possibility of error. In this case, there can be no confirmatory lab tests, radiologic exams, or genetic findings. Moreover, the dysphoria can only be diagnosed and opened to treatment if it is causing significant trauma to the individual. The clinically significant distress manifests itself in underlying psychiatric diagnoses such as depression and suicidality. It is argued that embarking on affirmative treatment as early as possible is urgently needed to prevent further psychiatric complications, a contested assertion. Studies have shown that adult transgender persons continue to have evidence of depression and suicidality following treatment. The rate of suicide among post-operative transgender adults in a study from Sweden found an incidence 20 times greater than that of the general population. Such treatment may not be urgently needed to protect adolescents; it may not even be effective protection for their adult counterparts.

The claim of urgency coupled with an impulse toward nonjudgmental empathy for the disturbed patients has led to a frantic insistence on a single approach that may seem almost cult like in its insularity and opposition to outside challenges. Both parents (Trinko, K.(Nov. 19, 2018 "What It's Like to Lose Your Children to the 'Transgender Cult,' From a Mom Who Knows." *The Daily Signal*, 30 Oct. 2019) and teachers (Manning, M. for The Mail on Sunday. "Whistleblower Teacher Makes Shocking Claim That 'Most Are Autistic'." *Daily Mail Online*, Associated Newspapers, 19 Nov. 2018, https://www.dailymail.co.uk/news/article-6401593/Whistleblower-teacher-makes-shocking-claim-autistic.html.) report that their children or students are being wrongly encouraged at school to think of themselves as transgender. Sometimes this is the result of overenthusiastic acceptance or "love bombing". Sometimes it appears to influence the susceptible, as in autistic children. Sometimes transgender counseling is taking place even without the parents' knowledge, and this troubling approach has been supported in the literature with statements that adolescents should be legally empowered to obtain puberty-blocking without parental consent (Priest, M. Transgender Children and the Right to Transition: Medical Ethics When Parents Mean Well but Cause Harm. Am J Bioeth. 2019 Feb;19(2):45-59).

Inevitably, this has resulted in complications and conflicts. The media have been replete with reports of such things as contested accessibility of transgender females to such things as domestic abuse shelters, female prisons, and female sports competitions. Similar issues regarding bathroom accessibility in schools recently came to a boil in Virginia, when it came to light that a sexual assault by a self-described trans- female (with a penis) was repeated in another school after the perpetrator was transferred. (Poff, J. "Loudoun superintendent failed to inform state of school sexual assault." Washington Examiner, 4 May 2022.) These issues are far from any resolution by debate, discussion, or legislation. In fact, both sides of the debate have doubled down with insistence that the opposing viewpoint must not only be rejected but considered unethical and made illegal.

Some disturbing trends have developed resulting not only from this dichotomy of opinion about the proper treatment approach, but ultimately based in the acceptance of the mind-body dichotomy. There has been a change in the diagnosed population. As Abigail Schrier pointed out:

> For the nearly 100-year diagnostic history of gender dysphoria, it overwhelmingly afflicted boys and men, and it began in early childhood (ages two to four). According to the DSM-V, the latest edition of the historical rate of incidence was 0.01 percent of males (roughly one in 10,000).
>
> For decades, psychologists treated it with "watchful waiting" — that is, a method of psychotherapy that seeks to understand the source of a child's gender dysphoria, lessen its intensity, and ultimately help a child grow more comfortable in her own body. Now such an approach is disdained by the term "conversion therapy", and labelled as unethical, and even made illegal.

She continues:

> Since nearly seven in 10 children initially diagnosed with gender dysphoria eventually outgrew it, the conventional wisdom held that, with a little patience, most kids would come to accept their bodies. The underlying assumption was children didn't always know best. But in the last decade, watchful waiting has been supplanted by "affirmative care," which assumes children do know what's best. Affirmative care proponents urge doctors to corroborate their patients' belief that they are trapped in the wrong body. The family is pressured to help the child transition to a new gender identity — sometimes having been told by doctors or activists that, if they don't, their child may eventually commit suicide. From there, pressures build on parents to begin concrete medical steps to help children on their path to transitioning to the "right" body. That includes puberty blockers as a preliminary step. Typically, cross-sex hormones follow and then, if desired, gender surgery. (Shrier, A. "Top Trans Doctors Blow the Whistle on 'Sloppy' Care." Emmaus Road Ministries, 5 Oct. 2021)

These pressures apply not only to parents, but to the children themselves because of the strong emphasis on affirmative support for anyone declaring themselves transgender. As one mother described: "A lot of these kids have concurrent mental health issues, and they find a place to fit in because as soon as you say that you're trans, you get love-bombed," she reflects. "You get love-bombed online, you get love-bombed on at school … As soon as you say you're trans, you turn into a star. And kids are thirsty for that kind of affirmation." (Trinko, 2019)

Two phenomena may be associated with this. Strong affirmation for the diagnosis and hormonal treatment may be altering the natural course of the phenomenon in childhood. It may not only be easier to identify as transgender in today's environment; it may be more difficult to turn ones back on the diagnosis. This may help explain a recent report that found that an average of 5 years after their initial social transition, 7.3% of youth had retransitioned (changed gender identity) at least once. At the end of this period, most youth identified as binary transgender youth (94%), including 1.3% who retransitioned to another identity before returning to their binary transgender identity. 2.5% of youth identified as cisgender and 3.5% as nonbinary. Later cisgender identities were more common amongst youth whose initial social transition occurred before age 6 years; the retransition often occurred before age 10. Unlike previous studies of transgender youth, males were not predominant, but were outnumbered by 2 to 1. Moreover, this is a direct contradiction of previous data showing a high rate of reversion towards a sex/gender coherence in children as they mature. (Olson, Kristina R., Durwood, Lily, Horton, Rachel, Gallagher, Natalie M., & Devor, Aaron; Gender Identity 5 Years

After Social Transition. Pediatrics 2022; 10.1542/peds.2021-056082) We must ask if this represents a shift towards being trapped in a wrong diagnosis, rather than a child being trapped in a wrong body.

In fact, there has been another shift. Unlike in the past, we now see increased numbers of females identifying as transgender, and later in their adolescence. Sometimes this occurs in large cohorts within a single school or peer group, a phenomenon labelled "rapid onset gender dysphoria." Both these phenomena call into question the underlying cause for the concept of gender dysphoria. Rather than approaching it as an accurate self-diagnosis that must be affirmed and treated to change the outward sexual appearance, isn't there a better model? We may be making a fundamental mistake in approaching transgender phenomena, not as a disease or disorder, but at most a dysphoria that is a cause for affirmation. This contrasts with our approach to similar conditions claiming a mind- body divergence, such as anorexia nervosa or body integrity identity disorder. The former is familiar to most Americans. The latter is a rare mental disorder characterized by a desire to have a physical disability, claiming discomfort with being able-bodied and often resulting in a request for amputation of the body part that makes them uncomfortable. People with this condition may refer to themselves as "trans abled."

In all three of these conditions there is a claim for a mismatch between one's mental bodily image and physical body. All tend to find an onset in prepubescence and are frequently associated with other mental disturbances. "Affirmative care" is the only recommended standard for transgender patients. It is horribly disturbing to contemplate amputation of a healthy limb because of a mental disorder (although this has been done). No one would seriously consider surgery to limit caloric intake or weight gain for a patient with anorexia nervosa, in order to support and affirm her distorted body image. Nevertheless, sex change operations have been recast as "gender affirming surgeries". The change in language reflects the change in attitude that distorts the approach to treatment for a psychiatric, not medical/surgical, disorder.

Finally, what are we to make of this situation, as a medical profession, and as a society? This question cannot be answered until both the affected people and profession can overcome our collective hubris. It is not enough to admit we don't know all the answers. We must see that we are not yet certain of all the questions that must be answered. In such a situation, competing interests must not pretend to take the moral high ground when no one can be certain where it will be located. First and foremost, we must back off from our current approaches until questions can be answered with proper studies, done with sufficient patients, and sufficient controls, over a sufficient period of time. Any insistence on a single course of therapy without this information could prove to be the same type of morally unacceptable interventions that caused formal research protections to be created in the first place.

In the meantime, we must adopt a more respectful tone with those whom we disagree. As John Milton said, "Where there is much desire to learn, there of necessity will be much arguing, much writing, many opinions; for opinion in good men is but knowledge in the making." Most important of all, in order to protect the current and future well-being of these affected children, we must rely on the ancient principal of medical ethics "In the first place, do no harm." Until we can demonstrate the efficacy and safety of any proposed treatment or intervention, its usage must properly be considered a medical experimentation and require fully informed consent. Anything less is a betrayal of both our principles and our progeny.

About the author: *Dr. Donovan's observations flow from his professional experience. He has been a Board-certified pediatrician for over 40 years, as an academic physician who rose to Vice-chair of the Department of Pediatrics and ultimately interim Chair at the University of Oklahoma in Tulsa. His professional role and interests expanded in the 1990's after he took a sabbatical in medical ethics at*

Georgetown University under the world-famous Dr. Edmund Pellegrino, a founding father of modern bioethics. He subsequently went on to earn a master's degree in Bioethics and founded the first bioethics center in his home university, where he was responsible for ethics training and education for students and physicians. He also served as clinical ethics consultant for three teaching hospitals. He was chair of the Section on Bioethics for the American Academy of Pediatrics (AAP) for three years and then their first liaison member of the AAP Committee on Bioethics. He has also served as the chair for a hospital Intuitional Review Board for 17 years. Finally, he was asked to become Director for the Center for Clinical Bioethics at Georgetown University School of Medicine, where he served from 2012-2020. His duties included teaching, consultation, publishing papers and speaking on bioethics extensively at the local, national, and international level on four continents. He has been interviewed and quoted on National Broadcasting Company (NBC), National Public Radio (NPR), Eternal Word Television Network (EWTN), and Al Jazeera, as well as the New York Times and the Washington Post, among others. He was awarded the Humanism in Medicine award from the Gold Foundation, which recognizes physicians to have successfully integrated humanism into the delivery of care to their patients and families. He has also offered formal testimony on bioethical issues before state legislatures and the U.S. Congress.

TAB 199

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	CASE NO. 4:22-cv-00325-RH-MAF

PLAINTIFFS' TRIAL BRIEF

TABLE OF CONTENTS

INTRODUCTION

Plaintiffs August Dekker, Brit Rothstein, Susan Doe, and K.F. submit this trial brief pursuant to this Court's Scheduling Order (ECF 67) to apprise the Court of the relevant issues of fact and law involved at trial in the above-captioned case and to explain why Plaintiffs should prevail at trial.

STATEMENT OF FACTS

I. The Parties

A. The Plaintiffs

1. Brit Rothstein

Plaintiff Brit Rothstein is a 20-year-old transgender man who is completing his junior year of college at the University of Central Florida. (ECF 11-7, Decl. of B. Rothstein ¶¶ 3, 5 ("Rothstein").) Mr. Rothstein has been enrolled in Medicaid since he was a child and receives his health insurance coverage through Sunshine Health. (*Id.* ¶ 4; *see* Ex. 1, Defs.' Admission No. 6 (ECF 175-1).)[1]

Mr. Rothstein was incorrectly assigned the sex female at birth, but his gender identity is male, a fact of which he has been aware since the third grade. (*Id.* ¶¶ 6-7.) His gender dysphoria intensified over time, and he sought therapy for his

[1] Plaintiffs will use "Ex." to refer to Plaintiffs' trial exhibits filed at ECF 175-184 and also identify the exhibits by ECF number. Attached to this brief are also deposition transcripts which were not filed as exhibits; those will be referred to as "Br. Ex."

dysphoria in seventh grade. (*Id.* ¶ 8-9.) At age 14, in July 2016, Mr. Rothstein received a formal diagnosis of gender dysphoria. (*Id.*, ¶ 11; *see* Ex. 1, Defs.' Admission No. 5 (ECF 175-1).)

At age 17, Mr. Rothstein began receiving medically necessary hormone therapy at Joe DiMaggio hospital under the care of a pediatric endocrinologist with expertise in the treatment of gender dysphoria. (*Id.* ¶ 12.) Access to hormone therapy, in the form of testosterone, has impacted Mr. Rothstein's life in so many positive ways, including, among other things, the changes to his physical body, his mental and emotional health, and his self-confidence. (*Id.* ¶ 13.)

Because Mr. Rothstein and his twin sister were born premature and have medical conditions that have followed them throughout life, his treating providers have closely monitored his labs and levels to ensure his treatment is safe and medically indicated. *See* Ex. 16, Shumer Rebuttal Rep. ¶ 72 ("Shumer Rebuttal") (ECF 175-16); Ex. 234, Rothstein Medical Records (ECF 180-32).)

In May of 2022, after many years of debilitating dysphoria, particularly significant dysphoria related to his chest, a surgeon recommended that Mr. Rothstein undergo masculinizing chest surgery to align his appearance with his gender identity. (ECF 11-7, Rothstein ¶¶ 15-17.) Access to masculinizing chest surgery, sometimes referred to as "top surgery," was necessitated by his dysphoria and the harm he

experienced as the result of wearing a binder for 10-12 hours every day, causing discomfort, irritations, bruising on his ribcage, and even hospitalization. (*Id.* ¶ 16.)

Finding a surgeon with expertise in gender-affirming top surgery, not to mention a provider that accepted Medicaid, was an arduous task given the dearth of providers in Florida. (*Id.* ¶ 16-17.) Mr. Rothstein was elated when, after waiting months for his consultation with Dr. Danker at the University of Miami, Medicaid issued prior authorization approving his top surgery on August 11, 2022, and the University of Miami providers scheduled his long-awaited surgery for December 22, 2022. (*Id.* ¶ 17-18.) Upon learning that AHCA promulgated a rule categorically banning coverage of medically necessary treatment for gender dysphoria for all transgender Medicaid beneficiaries in Florida, Mr. Rothstein's feelings of devastation came as swiftly as his feelings of elation had mere days prior when he learned that Medicaid approved his surgery. (*Id.* ¶ 18.) Due to Mr. Rothstein's income, and the income of his family – which is what qualifies him for Medicaid – he could not afford to pay out of pocket for the surgery. (*Id.* ¶¶ 19-20.) He also cannot afford to pay out of pocket for his testosterone prescriptions. (*Id.*)

Mr. Rothstein's health insurance coverage through Medicaid had covered all of his gender-affirming care, including puberty blocking medication, testosterone, therapy, blood tests, and office visits, prior to the enactment of the Challenged Exclusion. (*Id.* ¶¶ 4, 12.) The Challenged Exclusion will cause Mr. Rothstein to

continue to suffer harm, including impacts on his mental health, and will subject him to increased risk of discrimination, harassment, and violence. (*Id.* ¶ 21; *see also* Ex. 16, Shumer Rebuttal ¶ 71 (ECF 176-16) ("Mr. Rothstein's mental health would deteriorate if unable to receive gender-affirming care.").)

2. Susan Doe

Plaintiff Susan Doe is 13-year-old transgender adolescent girl; Jane and John Doe are Susan's parents. (*See* ECF 11-8, Decl. of J. Doe ("Doe") ¶¶ 2-3.) They adopted Susan out of medical foster care when she was two years old, which entitles her to Medicaid coverage until age 18. (*Id.* ¶¶ 8-9; *see* Ex. 1, Defs.' Admission No. 6 (ECF 175-1).)

Susan first realized she was a girl at age 3. (*Id.* ¶ 10.) The summer before starting second grade, Susan told her parents clearly: "I need to be a girl." (*Id.* ¶ 13.) Thereafter, Susan saw a therapist, who diagnosed her with gender dysphoria. (*Id.* ¶ 13; *see* Ex. 1, Defs.' Admission No. 5 (ECF 175-1).) The therapist recommended that Susan consult with a pediatric endocrinologist (*id.* ¶ 16), and Susan established care with Dr. Bethel Steindel-Spargo at Joe DiMaggio Children's Hospital. (*Id.* ¶ 17.) In July 2020, after Susan began puberty, Dr. Steindel-Spargo prescribed her the puberty-delaying medication GnRHa (Lupron) as medically necessary treatment for her gender dysphoria. (*Id.* ¶19.) Florida Medicaid covered the medication. (*Id.*) Dr.

Steindel-Spargo has been monitoring Susan to determine when it would be medically appropriate for her to begin hormone therapy. (*Id*. ¶ 21.)

Without Medicaid coverage of the care that Susan needs, her parents will have no choice but to try to pay for the treatment out-of-pocket. (*Id*. ¶ 29.) Based on their research, the retail price for a single Lupron injection is roughly $11,000, a prohibitively high cost for a family of four living on a single income. (*Id.* ¶ 29.) Should Susan have to stop taking Lupron and go through endogenous puberty, she would be devastated. (*See id.* ¶ 26.) She has been living as a girl in every aspect of her life since 2017. (*Id.)* Without Lupron, Susan's mental health would suffer as endogenous puberty would be torture for her. (*Id*; Ex. 16, Shumer Rebuttal ¶ 74 (ECF 175-16) (finding that S.D. "has received appropriate care and would likely have a deterioration in health if this care were discontinued").)

3. August Dekker

Plaintiff August Dekker is a 28-year-old transgender man who lives in Hernando County, Florida. (ECF 11-6, Decl. of A. Dekker ¶ 3 ("Dekker").) Mr. Dekker does not work but receives Supplemental Security income due to rheumatoid arthritis. (*Id*. ¶ 4.) He has been a Medicaid beneficiary since 2014. (*Id*. ¶ 5; *see* Ex. 1, Defs.' Admission No. 6 (ECF 175-1).)

As early as age 5, Mr. Dekker experienced symptoms of gender dysphoria, which continued into and through adolescence. *(Id*. ¶ 8) Despite Mr. Dekker's

awareness of his male gender identity, he was forced to hide who he was because of his family's religious beliefs. (*Id.* ¶ 10.) After graduating high-school and gaining independence, he felt free to live openly and, in 2015, began to socially transition to his male identity. Mr. Dekker also sought out mental health care support and in 2017, he received a formal diagnosis of gender dysphoria. (*Id.* ¶ 12; *see* Ex. 1, Defs.' Admission No. 5 (ECF 175-1).) Mr. Dekker then began hormone therapy at the recommendation of his medical providers, which he continues to receive today. (ECF 11-6, Dekker ¶¶ 13, 15.) Mr. Dekker was advised by his rheumatologist about the risks of receiving hormone therapy along with medications he takes to manage his rheumatoid arthritis, but he works closely with his rheumatologist to avoid those risks, including monitoring of his liver function every 8 weeks. (Br. Ex. 1, Dekker Dep. at 12:13-22; 17: 15-18.) Mr. Dekker has been on testosterone therapy without interruption since 2019 and while he is aware of the risks associated with his medications, when he is receiving testosterone therapy, he is the most stable and happy that he has ever been. (Br. Ex. 1, Dekker Dep. at 29:5-10.)

As additional treatment for gender dysphoria, Mr. Dekker received masculinizing chest surgery in April 2022. (ECF 11-6, Dekker ¶16.) Mr. Dekker described the first birthday he celebrated after receiving top-surgery as an afternoon of joy and laughter, where he was able to be shirtless in public, like other men. (*Id.* ¶ 20.) Mr. Dekker describes that obtaining hormone therapy and top surgery helped

to align his body with his identity and brought him a "great deal of relief and comfort," and allowed him to be the version of himself that he pictured growing up to be. (*Id.* ¶18-19.) All of Mr. Dekker's gender-affirming care to date has been covered by Medicaid as medically necessary. (*Id.* ¶ 17.)

Mr. Dekker continues to need hormone therapy to treat his gender dysphoria. (*Id.* ¶ 26.) The gender-affirming care he has received allows him to live without the symptoms of gender dysphoria in his day-to-day life. (*Id.* ¶¶ 18-19.) Under the Challenged Exclusion, Medicaid will no longer cover this care, and because Mr. Dekker cannot afford to pay out-of-pocket for it, he will lose access to hormone therapy, which would result in myriad negative outcomes for him. (*Id.* ¶¶ 23.) Mr. Dekker has lived without testosterone for a period of time and the mental health effects were significant, including overwhelming social anxiety because he was afraid to go outside or leave his house for fear of not being perceived as male. (Br. Ex. 1, Dekker Dep. at 30:2-15.) Stopping this treatment will cause him to undergo physical changes that will cause him psychological distress and increase his risk of discrimination and violence. (ECF 11-6, Dekker ¶¶ 23, 26-27; *see also* Ex. 16, Shumer Rebuttal ¶ 76 (ECF 175-16) (Mr. Dekker "would be at high risk for negative health outcomes if his care were discontinued.").)

4. K.F.

Plaintiff K.F. is a 13-year-old transgender boy who receives Medicaid coverage due to his family's income. (ECF 11-9, Decl. of J. Ladue ¶ 8 ("Ladue"); Ex. 1, Defs.' Admission No. 6 (ECF 175-1).) From a very young age, K.F. knew that his sex assigned at birth did not match his gender identity. (ECF 11-9, Ladue ¶¶ 9-10.) K.F. has never wavered about his gender identity. (*Id.* ¶ 10.) When K.F. came out at age 7, his parents arranged for him to see a mental health professional, who diagnosed K.F. with gender dysphoria after a thorough evaluation. (*Id.* ¶ 13.) He later established care with the Gender Multispecialty Service (GeMS) Program at Boston Children's Hospital, the first pediatric and adolescent transgender health program in the country. (*Id.* ¶¶ 13, 16; *see also* Ex. 11, Karasic Rebuttal Rep. ¶ 64 ("Karasic Rebuttal") (ECF 175-11).)

K.F.'s initial consult at GeMS was with a psychologist and lasted over two hours. (ECF 11-9, Ladue ¶ 16; Ex. 11, Karasic Rebuttal ¶ 63 (ECF 175-11).) GeMS then started him with a pediatric nurse practitioner, Sarah Pilcher, who monitored K.F.'s hormone levels for the onset of puberty. (ECF 11-9, Ladue ¶ 16.)[2] In June 2020, Pilcher determined that it was medically necessary for K.F. to start on puberty

[2] *See also* Ex. 11, Karasic Rebuttal ¶ 64 (ECF 175-11) (noting that the NP was "providing care as part of a team led by a Harvard pediatric endocrinologist"); Ex. 16, Shumer Rebuttal ¶ 69 (ECF 175-16) (stating that NPs, including the provider who K.F. saw, "are qualified to provide excellent, thoughtful and evidence-based care").

delaying medication; he and his mother discussed the risks and benefits of the medication with Pilcher, and K.F. then received a Supprelin implant, which the Massachusetts Medicaid program covered. (*Id.* ¶ 17; Ex. 11, Karasic Rebuttal ¶ 66 (ECF 175-11).)

Upon moving to Florida in August 2020, K.F. enrolled in Medicaid and established care with Florida-based specialists at the Johns Hopkins Gender Clinic. (ECF 11-9, Ladue ¶¶ 8, 19-20.) There, he saw a provider with a Doctorate in Nursing Practice. (*Id.* ¶ 20; Ex. 11, Karasic Rebuttal ¶ 65 (ECF 175-16).) In April 2022, after again discussing the risks and benefits of Supprelin with a pediatric urologist, K.F. received his second implant. (ECF 11-9, Ladue ¶ 20; Ex. 11, Karasic Rebuttal ¶ 66 (ECF 175-11).) His Florida Medicaid managed care plan, Humana, covered the treatment. (ECF 11-9, Ladue ¶ 20.)

K.F.'s treating specialists have indicated that he will likely need to begin hormone therapy when he is fourteen years old. (*Id.* ¶ 24.) Whatever course K.F.'s treatment takes, his family will be unable to afford it without Medicaid coverage. (*Id.* ¶ 30.)

Gender-affirming care created a "night and day" change in K.F. His persistent anxiety and issues functioning at school significantly improved, and he is now "thriving." (*Id.* ¶ 25.) He is doing well academically, socially, and athletically. (*Id.* ¶ 34.) Without access to this care through Medicaid, K.F.'s mental health will suffer

tremendously. (*Id.* ¶¶ 22, 28; Ex. 16, Shumer Rebuttal ¶ 69 (ECF 175-16) ("K.F.'s mental health would deteriorate precipitously if he were unable to continue to receive [gender-affirming] care").)

B. The Defendants

1. Defendant Jason Weida

Jason Weida is sued in his official capacity as Secretary of AHCA, the "single state agency authorized to manage, operate, and make payments for medical assistance and related services under Title XIX of the Social Security Act [Medicaid]." (ECF 1, Compl., at ¶ 17; ECF 65, Ans. at ¶ 17 (admitted).) *See* Fla. Stat. §§ 409.902, 409.963 (2022); *see also* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10. Weida is responsible for the enforcement of the Challenged Exclusion. (ECF 1, Compl., at ¶ 17; ECF 65, Ans. at ¶ 17 (admitted).) Weida is responsible for ensuring that the operation of Florida's Medicaid program complies with the United States Constitution and the Medicaid Act and its implementing regulations. (*Id.*) Defendant Weida's official place of business is located in Tallahassee, Leon County, Florida. (*Id.*)

2. Defendant Agency for Healthcare Administration

AHCA is the single state agency in Florida that is responsible for administering and implementing Florida's Medicaid program consistent with the requirements of federal law. (ECF 1, Compl., at ¶ 18; ECF 65, Ans. at ¶ 18

(admitted).) *See* Fla. Stat. § 409.902; 42 U.S.C.§ 1396a(a)(5); 42 C.F.R. § 431.10. AHCA receives federal funding to support the Florida Medicaid Program. (ECF 1, Compl, at ¶ 18; ECF 65, Ans at ¶ 18 (admitted).) AHCA uses the funds it receives from the federal government in part to cover health care services for persons enrolled in the Florida Medicaid Program. *Id.* Moreover, AHCA oversees the promulgation of all Medicaid rules, fee schedules, and coverage policies into the Florida Administrative Code. *Id*; *see also* Fla. Stat. § 409.919 (2022).

II. The History of Discrimination Against Transgender People

Transgender people have faced a long history of discrimination in this country. For much of the nineteenth and twentieth centuries, expression of a person's gender identity, when it did not align with their assigned sex at birth, was criminalized through cross-dressing laws. *See* Jennifer Levi & Daniel Redman, *The Cross-Dressing Case for Bathroom Equality*, 34 Seattle U. L. Rev. 133, 152-53, 171 (2010).

In more recent decades, Congress explicitly excluded gender diverse and transgender people from no less than four civil right laws, including the Fair Housing Act (excluding "transvestites"), the Americans With Disabilities Act ("ADA") (excluding gender identity disorder, "transsexualism," and "transvestism"), the Rehabilitation Act (including an exclusion identical to the ADA exclusion, thereby stripping transgender people of rights they held for almost two decades), and the

ADA Amendments Act (maintaining the prior transgender exclusions while expanding the definition of "disability" under the ADA and Rehabilitation Act for all other impairments). Kevin M. Barry et al., *A Bare Desire to Harm: Transgender People and the Equal Protection Clause*, 57 B.C. L. Rev. 507, 556 (2016).[3]

This discrimination extends well beyond federal legislation. According to a report issued by the U.S. Commission on Civil Rights ("USCCR"), "90 percent of transgender employees report experiencing some form of harassment or mistreatment" in the workplace. (Ex. 131, U.S. Commission on Civil Rights Briefing Report, *Working for Inclusion: Time for Congress to Enact Federal Legislation to Address Workplace Discrimination Against Lesbian, Gay, Bisexual, and Transgender Americans* (2017) ("USCCR Rep."), at 11 (ECF 178-11).) That same report relies on studies indicating that transgender people were three times as likely to be unemployed and more than twice as likely to live in poverty as compared to the general population in the United States. (*See id.* at 15; *see also id.* at 19 (citing survey noting that, of transgender respondents that were employed in the past year, 77-percent reporting "hid[ing] their gender identity, delay[ing] their transition, or quit[ting] their job, due to fear of negative repercussions").) Overall, transgender

[3] To be sure, many of those exclusions were unconstitutional and some, like those in the ADA, are inoperative because they were based on since-obsolete diagnoses pathologizing identity. *See Williams v. Kincaid*, 45 F.4th 759, 769 (4th Cir. 2022). "[A]s a matter of statutory construction, gender dysphoria is not a gender identity disorder." *Id.*

people in the United States are also more likely to lack health insurance or have a disability, and discrimination and a lack of access to care are major drivers of these inequities. (*See* Ex. 6, Decl. of Baker ¶ 28 ("Baker") (ECF 175-6).)

This discrimination, and the relative political powerlessness of transgender people, continue into the present day. "A wave of discriminatory State laws is targeting transgender youth, terrifying families and hurting kids who are not hurting anyone" and "epidemic of violence against transgender women and girls, in particular women and girls of color, has taken lives far too soon." (Ex. 77, U.S. Presidential Proclamation, Transgender Day of Visibility, 2023 (ECF 176-37).)

In 2016, the USCCR issued a statement condemning a spate of state laws and pending bills targeting the transgender community, among others. (*See* Ex. 69, April 18, 2016 USCCR Statement (ECF 176-29).) One year later, in 2017, the Trump Administration indicated that it would ban transgender people from serving in the military. (*See* Ex. 70, August 18, 2017 USCCR Statement (ECF 176-30); *see also* Presidential Memorandum of August 25, 2017: Military Service by Transgender Individuals, 82 Fed. Reg. 167 (Aug. 30, 2017).)

In the past two years alone, "hundreds of anti-transgender bills in States were proposed across America, most of them targeting transgender kids." (Ex. 76, U.S. Presidential Proclamation, Transgender Day of Visibility, 2022 (ECF 176-36).) Indeed, more than 110 anti-trans bills were proposed in states across the country in

2021,[4] and more than 500 such bills have been introduced and/or passed in the first months of 2023 alone.[5] "These bills … to criminalize supportive medical care for transgender kids, to ban transgender children from playing sports, and to outlaw discussing LGBTQI+ people in schools undermine [transgender people's] humanity and corrode our Nation's values." (*Id.*) They are also "damaging to the mental health and wellbeing of transgender youth, putting children and their families at greater risk of bullying and discrimination." (*Id.*)

Florida is no exception. At present, the Florida legislature is currently considering a slew of additional legislation specifically targeting transgender people. *See, e.g.*, Fla, S.B. 254/H.B. 1421 (2023) (criminalizing doctors for providing gender-affirming care to minors and prohibiting gender marker amendments on Florida birth certificates); Fla. H.B. 1223/S.B. 1320 (2023) (redefining "sex" to exclude the existence of transgender people, mandating the use of pronouns corresponding to sex assigned at birth, and banning classroom instruction relating to sexual orientation and gender identity in schools through the 8th grade); Fla. S.B.

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[4] *See* Sam Levin, "In an extraordinary attack on trans rights, conservative state lawmakers proposed more than 110 anti-trans bills this year," Guardian (June 14, 2021), *available at* https://www.theguardian.com/society/2021/jun/14/anti-translaws-us-map.

[5] American Civil Liberties Union, *Over 120 Bills Restricting LGBTQ Rights Introduced Nationwide in 2023 So Far* (Jan. 19, 2023), available at https://www.aclu.org/press-releases/over-120-bills-restricting-lgbtq-rights-introduced-nationwide-2023-so-far.

1674/H.B. 1521 (2023) (prohibiting gender-inclusive restrooms and changing facilities in schools, private businesses, public shelters, and healthcare facilities); Fla. S.B. 954/H.B.1265 (officially titled the "Reverse Woke Act," it would punish companies for providing affirming health insurance policies by holding employers liable in perpetuity for any future "detransition" treatment an employee may ever seek if they provide health insurance coverage for gender-affirming healthcare).

Within the last year, Florida officials have adopted several additional measures targeting LGBTQ people and more specifically, transgender people for disparate treatment. For example, on June 2, 2022, the same day the GAPMS Report was issued, the State Surgeon General urged the Florida Boards of Medicine to adopt a rule prohibiting physicians from providing this well-established medically necessary care to treat minors with gender dysphoria.[6] In response, the Florida Boards of Medicine promulgated a set of rules banning physicians from providing gender-affirming care to transgender minors. *See* Fla. Admin. Code R. 64B8-9.019 (effective March 16, 2023); Fla. Admin. Code R. 64B15-14.014 (effective March 28, 2023).

Around the same time, Florida enacted its infamous "Don't Say Gay" law, Florida Statute § 1001.42(8)(c) (2022), which prohibits "[c]lassroom instruction … on sexual orientation or gender identity" and has since been expanded by the Florida

[6] https://s3.documentcloud.org/documents/22050967/board-letter.pdf

Board of Education through the rulemaking process to apply to students in Kindergarten through 12th grade. Fla. Admin. Code. R. 6A-10.081 (2022). Enforcement of the "Don't Say Gay" law included sending letters from the Senior Chancellor of the Florida Department of Education to school districts whose LGBTQ+ Critical Support Guides, which outline best practices for creating a safe and affirming environment for LGBTQ+ students, were out of compliance with the law.[7] The impacts of these cruel measures are pushing parents of LGBTQ+ youth to move out of Florida to protect their children.[8]

Florida's Governor even removed a state attorney from office for, in part, saying that "transgender people are 'some of the most vulnerable Americans' and that attacks on them 'will deeply harm public safety.'" *Warren v. DeSantis*, No. 4:22CV302-RH-MAF, 2023 WL 345802, at *13 (N.D. Fla. Jan. 20, 2023).[9] And the Florida Department of Business and Professional Regulation lodged a public nuisance complaint against a bar catering to transgender persons when that bar had a drag queen reading event.[10]

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[7] December 14, 2022 - Meeting Agenda (fldoe.org) at https://www.fldoe.org/policy/state-board-of-edu/meetings/2022/2022-12-14/

[8] https://williamsinstitute.law.ucla.edu/wp-content/uploads/Dont-Say-Gay-Impact-Jan-2023.pdf

[9] *See also* https://www.flgov.com/wp-content/uploads/2022/08/Executive-Order-22-176.pdf.

[10] https://images.newrepublic.com/ce24ef552cdf7d41f1371580f1fb4163900f063c.pdf; https://www.myfloridalicense.com/viewcomplaint.asp?SID=&licid=5619209.

Indeed, Florida officials and their spokespersons have made a litany of public statements by denigrating transgender persons.[11] On April 24, 2023, Representative Randy Fine, sponsor of the bill that would impose felony penalties upon physicians who provide evidence-based medical care to transgender minors, began issuing subpoenas to "Florida-based organizations that recommend, endorse, or otherwise promote the [WPATH] standard of care[.]"[12]

Despite this historical and presently ongoing discrimination, being transgender, or receiving a diagnosis of gender dysphoria, has no bearing on an individual's ability to contribute to their community or society at large, especially when transgender people receive effective treatment to manage their symptoms of gender dysphoria (*See* Ex. 7, Karasic ¶¶ 26, 35 (ECF 175-7) ("People who are transgender have no impairment in their ability to be productive, contributing members of society simply because of their transgender status.") (ECF 175-7); *see*

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[11] https://twitter.com/JeremyRedfernFL/status/1558932733153402881?s=20&t=-RT4y02Czo48_y2JU3I6PA; https://twitter.com/GovRonDeSantis/status/1559646179595407362?s=20&t=55DYjYGjIIotEUZx-AY7Og; https://twitter.com/ChristinaPushaw/status/1560750173814689794?s=20&t=ReChkHaAQNRRoiwNfPSCkw.

[12] Florida House of Representatives, Memorandum "Authorization to commence Investigation"; *see also* https://twitter.com/VoteRandyFine/status/1650589678414733314?cxt=HHwWhICxvaekiegtAAAA ("I just signed subpoenas to the Florida Psychiatric Society, a branch of the @APApsychiatric and the Florida Chapter of the @AmerAcadPeds demanding production of all materials justifying their recommendation that castrating and mutilating children is "gender affirming care.")

also, *e.g.*, ECF 11-7 Rothstein ¶¶ 3, 5 (Mr. Rothstein describing how he attends the University of Central Florida on a full scholarship, and is pursuing degree in digital media full-time and participating in a federal work study program); ECF 11-9 ¶¶ 10, 34 (plaintiff K.F. is an intelligent, well-grounded young man who is immersed in his community, participates in golf and baseball, and loves his friends, family, and teammates).)

"Transgender Americans shape our Nation's soul—proudly serving in the military, curing deadly diseases, holding elected office, running thriving businesses, fighting for justice, raising families, and much more." (Ex. 77, U.S. Presidential Proclamation, Transgender Day of Visibility, 2023 (ECF 176-37); *see also* Ex. 76, U.S. Presidential Proclamation, Transgender Day of Visibility, 2022 (ECF 176-36).) Indeed, like other people with medical conditions managed by individualized treatment, many transgender people are highly accomplished and contribute to society in myriad ways. (*See* Brief of Elliot Page, Major Griffin-Gracy, Gwendolyn Herzig, Jazz Jennings, and Fifty-Four Others as Amicus Curiae In Support of Plaintiffs-Appellees in Brandt v. Rutledge 4:21-cv-00450-JM), *available at* https://www.aclu.org/cases/brandt-et-al-v-rutledge-et-al?document=Amicus-Brief-of-Trans-Adult-Voices#legal-documents).

III. Gender Identity & Gender Dysphoria

A. Gender Identity

Gender identity is a person's internal sense of being male or female. (Ex. 7, Decl. of Karasic ¶ 23 ("Karasic") (ECF 175-7); Ex. 8, Decl. of Olson-Kennedy at 8 ¶ 1 ("Olson-Kennedy")[13] (ECF 175-8); Ex. 9, Decl. of Shumer ¶ 26 ("Shumer") (ECF 175-9); Ex. 17, Janssen Rebuttal Rep. ¶ 36 ("Janssen Rebuttal") (ECF 175-17).) Gender identity is a well-understood and accepted concept in medicine and science that has a strong biological basis, is not a product of external influence, and cannot be changed. (Ex. 8, Olson-Kennedy at 8 ¶¶ 1-2 (ECF 175-8); Ex. 9, Shumer ¶ 29-33 (ECF 175-9); Ex. 7, Karasic ¶ 23 (ECF 175-7).) Indeed, "[e]fforts to change or suppress a person's … gender identity are grounded in the belief that being [transgender] is abnormal" and "are dangerous, discredited, and ineffective practices." (Ex. 74, SAMHSA, *Ending Conversion Therapy* (Oct. 2015) (ECF 176-33), at 8; *see also* Ex.7, Karasic ¶ 37 (ECF 175-7); Ex. 8, Olson-Kennedy, at ¶¶ 14-16 (ECF 175-8); Ex. 9, Shumer ¶ 28; Ex. 17, Janssen Rebuttal ¶ 41 (ECF 175-17).)

Everyone has a gender identity, and it does not always align with a person's "sex assigned at birth." (Ex. 7, Karasic ¶ 23 (ECF 175-7); Ex. 8, Olson-Kennedy at 8 ¶ 1 (ECF 175-8); Ex. 17, Janssen Rebuttal ¶¶ 35, 39 (ECF 175-17).)

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[13] Olson-Kennedy's Expert Declaration has two sets of paragraphs 1-19 due to a numbering error. Where necessary, her Declaration will be referred to by both a page number and paragraph number for clarity.

Sex assigned at birth refers to the sex designation given to a person when they are born, typically based on the appearance of external genital characteristics. (Ex. 7, Karasic ¶ 22 (ECF 175-7); Ex. 8, Olson-Kennedy at 9 ¶ 4 (ECF 175-8).) "Sex" as a concept in science and medicine is complicated and multifactorial – there are multiple sex characteristics, including genitalia, gonads, chromosomal makeup, endogenous hormones, gender identity, and variations in brain structure and function. (Ex. 7, Karasic ¶ 22 (ECF 175-7); Ex. 8, Olson-Kennedy at 9 ¶ 5 (ECF 175-8); Ex. 9, Shumer ¶ 25 (ECF 175-9); Ex. 17, Janssen Rebuttal ¶ 41 (ECF 175-17).)

The term "transgender" refers to a person whose gender identity does not align with their sex assigned at birth. (Ex. 8, Olson-Kennedy at 8 ¶ 3 (ECF 175-8); Ex. 17, Janssen Rebuttal ¶ 35 (ECF 175-17).)

B. Gender Dysphoria

Gender dysphoria is a serious medical condition experienced by many transgender people characterized by the distress due to the incongruence between their sex assigned at birth and their gender identity. (Ex. 8, Olson-Kennedy at 10 ¶ 7 (ECF 175-8); Ex. 10, Decl. of Schechter ¶ 20 ("Schechter") (ECF 175-10); Ex. 7, Karasic ¶ 24 (ECF 175-7); Ex. 17, Janssen Rebuttal ¶¶ 48-49 (ECF 175-17).) The diagnosis is contained in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* ("DSM-5"). (Ex. 7, Karasic ¶

25 (ECF 175-7); Ex. 17, Janssen Rebuttal ¶ 49 (ECF 175-17); Ex. 8, Olson-Kennedy at 10-11 ¶¶ 7-8 (ECF 175-8); Ex. 10, Schechter ¶ 20 (ECF 175-10); *see also* Ex. 33, DSM 5 Gender Dysphoria (ECF 175-33).) The *International Classification of Diseases* (World Health Org., 11th rev.) also recognizes the diagnosis of "gender incongruence." (Ex. 8, Olson-Kennedy at 11 ¶ 8 (ECF 175-8); Ex. 10, Schechter ¶ 20 (ECF 175-10).)Gender dysphoria is characterized by clinically significant distress or impairment in social, occupational, or other important areas of functioning and often manifests as intense and persistent discomfort with the primary or secondary characteristics of a person's sex assigned at birth. (Ex. 7, Karasic ¶ 25 (ECF 175-7); Ex. 17, Janssen Rebuttal ¶ 49 (ECF 175-17); Ex. 8, Olson-Kennedy at 11 ¶ 9 (ECF 175-8); Ex. 9, Shumer ¶ 36 (ECF 175-9); Ex. 10, Schechter ¶ 21 (ECF 175-10).)

Without appropriate treatment, gender dysphoria may cause debilitating anxiety, severe depression, self-harm, and even suicidality. (Ex. 7, Karasic ¶¶ 26, 36, 68 (ECF 175-7); Ex. 8, Olson-Kennedy ¶¶ 57, 122 (ECF 175-8); Ex. 17, Janssen Rebuttal ¶¶ 54, 83 (ECF 175-17); Ex. 9, Shumer ¶ 41 (ECF 175-9); Ex. 10, Schechter ¶ 21 (ECF 175-10); Ex. 15, Edmiston Rebuttal Rep. ¶¶ 34-35 ("Edmiston Rebuttal") (ECF 175-15).)

C. Treatment for Gender Dysphoria

Gender dysphoria is treatable, and interventions are supported by well-established guidelines and decades of research and clinical practice evidence. (*See*

Ex. 9, Shumer ¶ 41 (ECF 175-9); Ex. 5, Decl. of Antommaria ¶ 17 ("Antommaria") (ECF 175-5); Ex. 8, Olson-Kennedy at 12-13 ¶¶ 10-12 (ECF 175-8); Ex. 10, Schechter ¶¶ 24-26 (ECF 175-10); Ex. 7, Karasic ¶¶ 27-28, 33, 56-59 (ECF 175-7); Ex. 142, Nat'l Academies of Sciences, Engineering, and Medicine, *Understanding the Well-Being of LGBTQI+ Populations* ("Nat'l Academies Rep.") (ECF 178-22).)

Treatment seeks to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. (Ex. 7, Karasic ¶ 36 (ECF 175-7); Ex. 10, Schechter ¶ 22 (ECF 175-10).) Treatment is generally referred to as "gender-affirming care" and may include counseling, puberty-delaying medication, hormone therapy, surgery, or other medically necessary treatments. (*See* Ex. 7, Karasic ¶ 40 (ECF 175-7); Ex. 8, Olson-Kennedy at 12 ¶ 10 (ECF 175-8); Ex. 10, Schechter ¶ 22 (ECF 175-10).)

Gender-affirming medical care is recognized to be medically necessary, safe, and effective treatment that improves the short and long-term health and quality of life outcomes for transgender people. (Ex. 17, Janssen Rebuttal ¶¶ 23-27, 133 (ECF 175-17); Ex. 7, Karasic ¶¶ 53-60, 100 (ECF 175-7); Ex. 8, Olson-Kennedy ¶¶ 24-48, 76, 121 (ECF 175-8); Ex. 12, Olson-Kennedy Rebuttal ¶¶ 73-74 (ECF 175-12); Ex. 10, Schechter ¶¶ 23, 34, 36-43, 81 (ECF 175-10); Ex. 9, Shumer ¶¶ 82, 86, 88, 89 (ECF 175-9).) The medical community does not consider these treatments to be experimental or investigational. (Ex. 5, Antommaria, ¶¶ 32-33 (ECF 175-5); Ex. 14,

Antommaria Rebuttal ¶¶ 21-36 (ECF 175-14); Ex. 17, Janssen Rebuttal ¶ 23 (ECF 175-17); Ex. 8, Olson-Kennedy ¶ 73 (Ex. 175-8); Ex. 10, Schechter ¶¶ 44-46 (ECF 175-10); Ex. 9, Shumer ¶ 89 (ECF 175-9).) Moreover, there is no established safe and effective alternative to gender-affirming care for gender dysphoria. (*See* Ex. 10, Schechter ¶ 58 (ECF 175-10); Ex. 7, Karasic ¶ 37 (ECF 175-7); Ex. 11, Karasic Rebuttal ¶¶ 23-24, 47 (ECF 175-11).)

1. Puberty-Delaying Medications

For adolescents with gender dysphoria who experience severe distress with the onset of puberty, puberty-delaying medications, also known as gonadotropin-releasing hormone agonists ("GnRHa") or "puberty blockers," may be indicated. (Ex. 7, Karasic, ¶ 42 (ECF 175-7); Ex. 8, Olson-Kennedy ¶¶ 22-23 (ECF 175-8); Ex. 9, Shumer ¶ 46 (ECF 17-9); Ex. 17, Janssen Rebuttal Rep. ¶ 89 ("Janssen Rebuttal") (ECF 175-17).) Puberty-delaying medications work by pausing endogenous puberty when the treatment begins, thus limiting the influence of a person's endogenous hormones on their body. (Ex. 8, Olson-Kennedy ¶¶ 23-24 (ECF 175-8); Ex. 7, Karasic ¶ 42 (ECF 175-7); Ex. 9, Shumer ¶ 63 (ECF 175-9).) Such interventions afford the adolescent time to better understand their gender identity while delaying the development of secondary sex characteristics, which can cause severe distress when incompatible with an adolescent's gender identity. (Ex. 8, Olson-Kennedy ¶¶ 23-24 (ECF 175-8); Ex. 12, Olson-Kennedy Rebuttal Rep. ¶ 81 ("Olson-Kennedy

Rebuttal") (ECF 175-12); Ex. 9, Shumer ¶ 66 (ECF 175-9); Ex. 17, Janssen Rebuttal ¶ 92 (ECF 175-17).)

Puberty-delaying medications may be indicated when an adolescent with gender dysphoria enters puberty, at what is called Tanner Stage 2. (Ex. 9, Shumer ¶ 62 (ECF 175-9); Ex. 8, Olson-Kennedy ¶ 24 (ECF 175-8).) Tanner Stage 2 refers to the stage in puberty when the physical effects of testosterone or estrogen are apparent upon physical exam and usually occurs between age 9-14 for individuals assigned male at birth and between age 8-12 for individuals assigned female at birth. (Ex. 9, Shumer ¶ 62 (ECF 175-9).) The treatment is reversible, meaning that if an adolescent discontinues the treatment, puberty will resume. (Ex. 7, Karasic, ¶ 42 (ECF 175-7); Ex. 8, Olson-Kennedy ¶ 24 (ECF 175-8); Ex. 9, Shumer ¶ 65 (ECF 175-9).)

When used to treat gender dysphoria, puberty-delaying medication does not delay puberty beyond the typical age range for puberty, as the protocols use to treat transgender adolescents would cease the provision of puberty-delaying medication without the provision of gender-affirming hormones at about the latter third of typical puberty. (Ex.12, Olson-Kennedy Rebuttal ¶ 23 (ECF 175-12).)

2. Hormone Therapy

For some adolescents and adults with gender dysphoria, hormone therapy (utilizing testosterone for transgender males and testosterone suppression and estrogen for transgender females) may be medically necessary. (Ex. 17, Janssen

Rebuttal ¶ 96 (ECF 175-17); Ex. 8, Olson-Kennedy ¶ 32 (ECF 175-8); Ex. 7, Karasic ¶ 43 (ECF 175-7), Ex. 9, Shumer ¶¶ 46, 72 (ECF 175-9).) Hormones are administered to attain the appropriate masculinization or feminization to align with the patient's gender identity. (Ex. 7, Karasic ¶ 43 (ECF 175-7).) Gender-affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible, while others are not. (Ex. 7, Karasic ¶ 43 ECF 175-7); Ex. 8, Olson-Kennedy ¶ 32 (ECF 175-8).) Hormone therapy allows for a physical appearance more closely aligning with gender identity and helps to alleviate gender dysphoria. (Ex. 9, Shumer ¶¶ 60, 71 (ECF 175-9).) Laboratory testing ensures proper dosing and hormone levels. (Ex. 9, Shumer ¶¶ 74, 84 (ECF 175-9).)

3. Gender Confirming Surgeries

Gender confirming surgery may be medically indicated for some transgender adults and older adolescents to align their primary and secondary sex characteristics with their gender identity. (Ex. 8, Olson-Kennedy ¶ 42 (ECF 175-8); Ex. 10, Schechter ¶ 22 (ECF 175-10).) Surgical care can include, but is not limited to, mastectomy, breast augmentation, hysterectomy, oophorectomy, orchiectomy, vaginoplasty, and phalloplasty. (Ex. 7, Karasic ¶ 44 (ECF 175-7); Ex. 8, Olson-Kennedy ¶ 42 (ECF 175-8); Ex. 10, Schechter ¶ 28 (ECF 175-10).) Surgeons regularly perform these procedures to treat conditions other than gender dysphoria.

(Ex. 10, Schechter ¶ 38 (ECF 175-10).)

IV. Gender-Affirming Care is the Standard of Care to Treat Gender Dysphoria

A. History of Gender-Affirming Medical Care

Gender-affirming medical care dates back almost a century. (Ex. 5, Antommaria ¶ 32 (ECF 175-5), Ex. 10, Schechter ¶ 46 (ECF 175-10).) The first gender confirming surgeries were performed in the 1920s at Magnus Hirschfeld's Institute for Sexual Science. (Ex. 143, Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding 48-49 (The National Academies Press 2011) ("Inst. of Medicine Rep.") (ECF 178-23).) Many of the surgical techniques currently used in phalloplasties and vaginoplasties were developed over 30 years ago. (Ex. 10, Schecter ¶ 46 (ECF 175-10).) Hormone treatment for gender dysphoria began after estrogen and testosterone became commercially available in the 1930s. (Ex. 5, Antommaria, ¶ 32 (ECF 175-5); Ex. 11, Karasic Rebuttal ¶ 32 (ECF 175-11); Ex. 12, Olson-Kennedy Rebuttal ¶ 27 (ECF 175-12); *see also* Ex. 143, Inst. of Medicine Rep., at 49 (ECF 178-23) ("During the 1930's, endocrinologist Harry Benjamin became one of the first physicians in the United States to routinely administer hormone therapy to individuals desiring to change their sex.").) The first United States clinics providing gender affirming medical care to transgender patients were opened in the 1960s and 1970s. (Ex. 8, Olson-Kennedy ¶ 71 (ECF 175-8); Ex. 11,

Karasic Rebuttal ¶ 32 (ECF 175-11); Ex. 142, Nat'l Academies Rep. at 360 (ECF 178-22).) And puberty delaying medications have been used since at least the late 1990s to prevent the development of irreversible secondary sex traits that may exacerbate adolescents' gender dysphoria. (Ex. 5, Antommaria ¶ 32 (175-5); Ex. 8, Olson-Kennedy ¶ 24 (ECF 175-8); Ex. 142, Nat'l Academies Rep., at 364 (ECF 178-22).)

As research and clinical experience evolved, the medical paradigm related to gender nonconformity began to shift, and, instead of encouraging transgender individuals to conform to gender expectations, clinical management instead began to focus on "ameliorating the negative effects of stigma" and "assisting transgender individuals in finding a gender expression that is comfortable and consistent with their gender identity." (*See* Ex. 143, Inst. of Medicine Rep., at 51-52 (ECF 178-23).) In 1979, an interdisciplinary group of physicians, therapists, and researchers created the Harry Benjamin International Gender Dysphoria Association, now known as the World Professional Association for Transgender Health ("WPATH"). (*Id.* at 50.)

In 2013, the American Psychiatric Association replaced the former diagnosis of "gender identity disorder" contained in prior iterations of the DSM with the new and distinct diagnosis of "gender dysphoria" in the DSM-5. (Ex. 8, Olson-Kennedy at 10 ¶ 7 (ECF 175-8); Ex.7, Karasic ¶ 35 (ECF 175-7); Ex. 11, Karasic Rebuttal ¶ 26 (ECF 175-11); Ex. 9, Shumer ¶¶ 36-37 (ECF 175-9); Ex. 142, Nat'l Academies

Report, at 362 (ECF 178-22).) The DSM-5 defined gender dysphoria to "emphasize[] the clinically significant distress and impairment that can accompany incongruence between assigned sex and gender identity" rather than to pathologize a person's gender incongruence as disordered. (Ex. 17, Janssen Rebuttal ¶ 53 (ECF 175-17); Ex. 7, Karasic ¶ 35 (ECF 175-7); Ex. 11, Karasic Rebuttal ¶ 26 (ECF 175-11); Ex. 8, Olson-Kennedy at 10 ¶ 7 (ECF 175-8); Ex. 12, Olson-Kennedy Rebuttal ¶ 15 (ECF 175-12); Ex. 9, Shumer ¶¶ 36-37 (ECF 175-9); Ex. 10, Schechter ¶ 20 (ECF 175-10); Ex. 142, Nat'l Academies Rep., at 362 (ECF 178-22).) That is because "being transgender is widely accepted as a variation in human development and is not considered a mental illness." (Ex. 7, Karasic ¶ 35 (ECF 175-7); Ex. 17, Janssen Rebuttal ¶ 53 (ECF 175-17); *see also* Ex. 74, SAMHSA, *Moving Beyond Change Efforts* (2023) at 9 (ECF 176-34).)

The World Health Organization has similarly replaced transsexualism and gender identity disorder with the diagnosis of gender incongruence and moved it to a new chapter on sexual health from the chapter on mental and behavioral disorders. (Ex. 8, Olson-Kennedy at 11 ¶ 8 (ECF 175-8); Ex. 10, Schechter ¶ 20 (ECF 175-10); Ex 7, Karasic ¶ 35 (ECF 175-7); Ex. 142, National Academies Report, at 362 (ECF 178-22).)

For more than four decades, medical organizations have studied the treatment of gender dysphoria and created evidence-based standards for the medical treatment

of transgender patients. For example, WPATH first published its standards of care for the treatment of gender dysphoria in 1979, which have been continuously maintained and are now in their eighth version (*See* Ex. 7, Karasic ¶ 27 (ECF 175-7); Ex. 8, Olson-Kennedy at 12 ¶ 10 (ECF 175-8); Ex. 9, Shumer ¶ 48 (ECF 175-9); Ex. 10, Schechter ¶ 24 (ECF 175-10); Ex. 17, Janssen Rebuttal ¶ 55 (ECF 175-17); Ex. 142, Nat'l Academies Rep., at 361 (ECF 178-22); *see also* Ex. 34, E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,* 23 Internat'l J. of Transgender Health S1 (2022) ("WPATH Standards of Care 8") (ECF 175-34).)

B. Current Guidelines for the Provision of Gender-Affirming Care

The WPATH Standards of Care 8 are based on the best available evidence and professional consensus. (Ex. 5, Antommaria ¶ 29 (ECF 175-5); Ex. 7, Karasic ¶ 28 (ECF 175-7); Ex. 8, Olson-Kennedy at 12 ¶ 10 (ECF 175-8); Ex. 9, Shumer ¶ 48 (ECF 175-9); Ex. 10, Schechter ¶¶ 8, 24 (ECF 175-10); Ex. 17, Janssen Rebuttal ¶ 56 (ECF 175-17); Ex. 142, Nat'l Academies Rep., at 361 (ECF 178-22); *see also* Ex. 34, WPATH Standards of Care 8, at S8, S247-S251 ("Methodology") (ECF 175-34).) Major medical organizations like the American Medical Association ("AMA"), the Endocrine Society American Academy of Pediatrics ("AAP"), American Psychiatric Association, American Psychological Association, Pediatric Endocrine Society, the American College of Physicians, the American Academy of Family

Physicians ("AAFP"), and the American Academy of Child and Adolescent Psychiatry ("AACAP") have joined WPATH in recognizing that gender-affirming care is medically necessary for transgender people and endorse the WPATH Standards of Care 8. (Ex. 5, Antommaria ¶ 30 (ECF 175-5); Ex. 7, Karasic ¶ 34 (ECF 175-7); Ex. 8, Olson-Kennedy at 12 ¶¶ 10-11 (ECF 175-8), 31 ¶ 48; Ex. 9, Shumer ¶¶ 54-55 (ECF 175-9); Ex. 10, Schechter ¶ 27 (ECF 175-10); Ex. 17, Janssen Rebuttal ¶ 60 (ECF 175-17); Ex. 142, Nat'l Academies Rep., at 361 (ECF 178-22).)[14]

The Endocrine Society's clinical practice guidelines, first published in 2009 and later revised in 2017, are largely consistent with the WPATH Standards of Care 8 and were developed using rigorous scientific methods. (*See* Ex 5, Antommaria ¶¶ 17-18 (ECF 175-5); Ex. 7, Karasic ¶¶ 31-33 (ECF 175-7); Ex. 8, Olson-Kennedy 13 ¶ 12 (ECF 175-8); Ex. 9, Shumer ¶ 53 (ECF 175-9); Ex. 10, Schechter ¶ 26 (ECF

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[14] *See, e.g,* Ex. 36, AACAP, *Statement Responding to Efforts to Ban Care* (ECF 175-36); Ex. 37, AAFP, *Care for Transgender Patients* (ECF 175-37); Ex. 38, Am. Acad. of Peds., *Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents* (ECF 175-38); Ex. 41, Am. Coll. of Physicians, *LGBT Health Disparities Policy* (ECF 176-1);Ex. 45, Am. Psychol. Ass'n., *Guidelines for Psyhoclogical Practice with Transgender and Gender Non-confirming People* (ECF 176-5); Ex. 47, Am. Psychia. Ass'n, *Position Statement on Treatment of Transgender and Gender Diverse Youth* (ECF 176-7); Ex. 48, Am. Psychia. Ass'n, *Position Statement on Access to Care* (ECF 176-8); Ex. 49, Endocrine Soc., *Transgender Health Position Statement* (ECF 176-9); Ex. 50, Ped. Endocrine Soc., *Opposition to Bills that Harm Transgender Youth* (ECF 176-10); Ex. 42, AMA, *Letter to Nat'l Gov. Ass'n* (ECF 176-2); Ex. 43, AMA, *Issue Brief: Health Insurance Coverage for Gender-Affirming Care* (ECF 176-3); Ex. 44, AMA, *Resolution H-185.950* (ECF 176-4).

175-10); Ex. 17, Janssen Rebuttal ¶¶ 57-58 (ECF 175-17); Ex. 142, Nat'l Academies Rep., at 361 (ECF 178-22); *see also* Ex. 123, Wylie Hembree et al., *Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An EndocrineSociety Clinical Practice Guideline*, 102 J. Clin Endocrinol Metab. 3869 (2017) ("Endocrine Soc. Guidelines") (ECF 178-3).)

The WPATH Standards of Care 8 and the Endocrine Society Guidelines provide for medical interventions that are individualized based on patient needs and may include pubertal suppression, hormone therapy, or surgeries. (*See* Ex. 8, Olson-Kennedy at 12 ¶ 10 (ECF 175-8); Ex. 7, Karasic ¶ 40 (ECF 175-7); Ex. 9, Shumer ¶ 57 (ECF 175-9); Ex. 10, Schechter ¶ 25 (ECF 175-10); *see generally* Ex. 34, WPATH Standards of Care 8 (ECF 175-34); Ex. 123. Endocrine Soc. Guidelines (ECF 178-3).) Treatment protocols and recommendations differ depending on whether the patient is an adolescent (minors who have started puberty) or an adult. (Ex. 17, Janssen Rebuttal ¶ 59 (ECF 175-17); *see also* Ex. 34, WPATH Standards of Care 8, at S32, S48, S111, S129 (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3878, Table 5 (ECF 178-3).)

Neither WPATH nor the Endocrine Society Guidelines recommend any medical, pharmaceutical, or surgical interventions prior to the onset of puberty. (Ex. 8, Olson-Kennedy at 17 ¶ 18 (ECF 175-8); Ex. 7, Karasic ¶ 41 (ECF 175-7); Ex. 9, Shumer ¶ 44 (ECF 175-9); Ex. 17, Janssen Rebuttal ¶¶ 25, 59 (ECF 175-17); see

also Ex. 34, WPATH Standards of Care 8, at S69, Endocrine Society Guidelines, at 3870, Recommendation 1.3 (ECF 175-34).) Medical interventions are only indicated once a person experiencing gender dysphoria has begun puberty. (Ex. 9, Shumer ¶ 44, 58 (ECF 175-9); Ex. 17, Janssen Rebuttal ¶ 62 (ECF 175-17).)

1. Assessment and Diagnosis of Gender Dysphoria

The diagnosis of gender dysphoria in adults can generally be made by a health care provider with relevant expertise and training in identifying gender dysphoria as well as co-existing mental health and psychosocial concerns, including a psychiatrist, psychologist, social worker, or therapist. (*See* Ex. 7, Karasic ¶ 49 (ECF 175-7); *see also* Ex. 34, WPATH Standards of Care 8, at S32 (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3870 (ECF 178-3).) The diagnostic criteria for gender dysphoria in the DSM 5 require that "the marked incongruence between one's experienced/expressed gender and assigned gender" last least six months duration, (Ex. 7, Karasic ¶ 25 (ECF 175-7); Ex. 8, Olson-Kennedy at 11 ¶ 9 (ECF 175-8); Ex. 9, Shumer ¶ 36 (ECF 175-9); *see also* Ex. 33, DSM 5 (ECF 175-33).)

For minors, WPATH Standards of Care 8 recommend that health care professionals working with transgender and non-binary adolescents be licensed, hold a postgraduate degree in relevant clinical field, have received training and developed expertise in working with children and adolescents, including those with autism spectrum disorder, and have received training and developed expertise in

gender identity and diversity in youth, and in the ability of youth to assent/consent to care (Ex. 7, Karasic ¶ 47 (ECF 175-7); *see also* Ex. 34, WPATH Standards of Care 8, at S48 (ECF 175-34).) The Endocrine Society Clinical Practice Guideline states that for the assessment and diagnosis of gender dysphoria in children and adolescents that only "[mental health professionals] who ha[ve] training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis," which usually includes "a complete psychodiagnostic assessment." (Ex. 7, Karasic ¶ 52 (ECF 175-7); *see also* Ex. 123, Endocrine Society Guidelines, at 3870 (ECF 178-3).) Because gender dysphoria may be accompanied with psychological or psychiatric conditions, clinicians involved in diagnosis and psychological assessment must meet specific competency requirements and undertake or refer patients for appropriate psychological or psychiatric treatment as necessary. (Ex. 7, Karasic ¶ 52 (ECF 175-7).) Children and adolescents diagnosed with gender dysphoria are recommended to engage with a multidisciplinary team of mental health and medical professionals to formulate a treatment plan, in coordination with the parent(s) or guardian(s), with a goal of reduction of gender dysphoria. (Ex. 9, Shumer ¶ 38 (ECF 175-9).)

2. Criteria for Gender-Affirming Medical Interventions

Adults

Gender-affirming medical interventions may be considered for transgender

adults whose gender dysphoria is "marked and sustained" when other possible causes of gender incongruence are excluded, mental or physical health conditions that could negatively impact the outcome of treatment are assessed, and the adult has the capacity to understand the risks and benefits of treatment and provide consent. (Ex. 7, Karasic ¶ 49 (ECF 175-7); Ex. 9, Shumer ¶ 73 (ECF 175-9); Ex. 10, Schecter ¶ 29 (ECF 175-10); *see also* Ex. 34, WPATH Standards of Care 8, at S35-S39, Statement 5.3 (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3878. Table 4 (ECF 178-3) (requiring "persistent, well-documented gender dysphoria/gender incongruence").) A qualified provider must recommend initiation of the treatment. (Ex. 10, Shechter ¶ 29 (ECF 175-10); *see also* Ex. 34, WPATH Standards of Care 8, at S33-S35, Statement 5.1 (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3878, Table 5 (ECF 178-3).) Before any gender-affirming care is provided, impacts on fertility and fertility preservation options be discussed thoroughly with the patient. (Ex. 7, Karasic ¶ 50 (ECF 175-7); Ex. 9, Shumer ¶ 39 (ECF 175-9); *see also* Ex. 34, WPATH Standards of Care 8, at S39, Statement 5.3g (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3878, Table 5 (ECF 178-3)). And, prior to any genital reconstruction surgery, the patient must have received a minimum of six months of hormone therapy "as appropriate to their gender goals." (Ex. 10, Schechter ¶ 29 (ECF 175-10); *see also* Ex. 34, WPATH Standards of Care 8, at S132, Statements 13.5-13.6 (ECF 175-34).)

Adolescents

Similarly, the treatment guidelines require that an adolescent's gender dysphoria be "marked and sustained over time" for medical interventions to be considered. (Ex. 9, Shumer ¶ 72 (ECF 175-9); Ex. 17, Janssen Rebuttal ¶ 99 (ECF 175-17); *see also* Ex. 34, WPATH Standards of Care 8, at S60-S61, Statement 6.12b (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3878, Table 5 (requiring "the persistence of gender dysphoria") (ECF 178-3).)

Prior to offering medical interventions, which are only indicated for individuals who have begun puberty, it is recommended that providers determine that the adolescent has the emotional and cognitive capacity to provide assent for treatment, and that other mental health concerns "that may interfere with diagnostic clarity and capacity to consent have been addressed." (Ex. 9, Shumer ¶ 72 (ECF 175-9); Ex. 17, Janssen Rebuttal ¶ 99 (ECF 175-17); *see also* Ex. 34, WPATH Standards of Care 8, at S62-S63, Statement 6.12(d) (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3878, Table 5 (ECF 178-3).) The WPATH Standards of Care recommend that parent(s)/guardian(s) be involved in the assessment and treatment process for minors. (Ex. 9, Shumer ¶ 72 (ECF 175-9); *see also* Ex. 34, WPATH Standards of Care 8, at S57-S58, Statement 6.11 (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3878, Table 5 (ECF 178-3).)

Some surgical procedures, primarily chest masculinization and breast

augmentation, "can be considered in minors when clinically and developmentally appropriate as determined by a multidisciplinary team experienced in adolescent and gender development." (Ex. 10, Schechter ¶ 30 (ECF 175-10); Ex. 8, Olson-Kennedy ¶ 46 (ECF 175-8); *see also* Ex. 34, WPATH Standards of Care 8, at S133, Statement 13.7 (ECF 175-34).)

Prior to initiating any medically necessary medical or surgical intervention" for gender dysphoria an adolescent will have had a comprehensive biopsychosocial assessment that will include gender identity development, social development and support, diagnostic assessment of co-occurring mental health or developmental concerns, and capacity for decision making. (Ex. 7, Karasic ¶ 48 (ECF 175-7); Ex. 17, Janssen Rebuttal ¶ 77 (ECF 175-17); *see also* Ex. 34, WPATH Standards of Care 8 at S50-S51, Statement 6.3 (ECF 175-34); Ex. 123, Endocrine Society Guidelines, at 3877 (ECF 178-3)). The goals of this assessment are to develop a deep understanding of the young person's experience with gender identity, to consider whether the child or adolescent meets criteria for a diagnosis of gender dysphoria, and to understand what options may be desired and helpful for the adolescent (Ex. 9, Shumer ¶ 43 (ECF 175-9); *see also* Ex. 34, WPATH Standards of Care 8, at S50-S51, Statement 6.3 (ECF 175-34).)

Affirming care for transgender youth means supporting them through their period of exploration of gender expression and increasing self-awareness of their

identity, not steering them in any particular direction. (Ex. 7, Karasic ¶ 51 (ECF 175-7); *see also* Ex. 34, WPATH Standards of Care 8, at S50, Statement 6.2 (ECF 175-34). It is recommended that health professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular outcome is favored and that for some youth, obtaining gender-affirming medical care is important while for others it is not necessary. (*Id.*)

C. Gender-Affirming Care Is Safe and Effective

Gender-affirming medical care is recognized to be medically necessary, safe, and effective treatment that improves the short and long-term health and quality of life outcomes for transgender people. (Ex. 17, Janssen Rebuttal ¶¶ 23-27, 133 (ECF 175-17); Ex. 7, Karasic ¶¶ 53-60, 100 (ECF 175-7); Ex. 8, Olson-Kennedy, ¶¶ 24-48, 76, 121 (ECF 175-8); Ex. 12, Olson-Kennedy Rebuttal ¶¶ 73-74 (ECF 175-12); Ex. 10, Schechter, ¶¶ 23, 34, 36-43, 81 (ECF 175-10); Ex. 9, Shumer ¶¶ 82, 86, 88, 89 (ECF 175-9).) The medical community does not consider these treatments to be experimental or investigational. (Ex. 5, Antommaria ¶¶ 32-33 (ECF 175-5); Ex. 14, Antommaria Rebuttal ¶¶ 21-36 (ECF 175-14); Ex. 17, Janssen Rebuttal ¶ 23 (ECF 175-17); Ex. 8, Olson-Kennedy ¶ 73 (ECF 175-8); Ex. 10, Schechter ¶¶ 44-46 (Ex 175-10); Ex. 9, Shumer, ¶ 89 (ECF 175-9).). Moreover, there is no established safe and effective alternative to gender affirming care for gender dysphoria. (*See* Ex. 10,

Schechter ¶ 58 (ECF 175-10); Ex. 7, Karasic ¶ 37 (ECF 175-7); Ex. 11, Karasic Rebuttal ¶¶ 23-24, 47 (ECF 175-11).)

1. Puberty-delaying medications

Puberty-delaying medications have been used exclusively in pediatrics for several decades to treat precocious puberty. (Ex. 8, Olson-Kennedy ¶ 24 (ECF 175-8); Ex. 16, Shumer Rebuttal ¶ 64 (ECF 175-16).) For both indications, the side effects of these medications are comparable and easily managed, and the risks are greatly outweighed by the benefits of treatment. (Ex. 9, Shumer ¶ 68 (ECF 175-9); Ex. 8, Olson-Kennedy ¶¶ 103-105 (ECF 175-8).) These medications are not experimental merely because they are not FDA-approved for the specific application of treating gender dysphoria. (Ex. 5, Antommaria ¶ 34 (ECF 175-5); Ex. 17, Janssen Rebuttal ¶ 107 (ECF 175-17); Ex. 7, Karasic ¶ 66 (ECF 175-7).) There are other conditions for which puberty-delaying medications may be prescribed that are off label, yet not considered experimental. (Ex. 9, Shumer ¶ 69 (ECF 175-9).) Off-label prescribing is both legal and common and does not impact the safety or efficacy of these medications. (Ex. 5, Antommaria ¶¶ 34-37 (ECF 175-5); Ex. 7, Karasic ¶ 66 (ECF 175-7), Ex. 8, Olson-Kennedy ¶¶ 92-93 (ECF 175-8); Ex. 9, Shumer ¶ 69 (ECF 175-9).)

The clinical guidelines require that potential risks and benefits of treatment with puberty-delaying medications are discussed with adolescent patients and their

families. (Ex. 5, Antommaria ¶ 50 (ECF 175-5); Ex. 9, Shumer ¶ 66 (ECF 175-9); Ex. 16, Shumer Rebuttal ¶¶ 41, 48, 51 (ECF 175-16); Ex. 17, Janssen Rebuttal ¶ 93 (ECF 175-17).) The treatment is reversible, meaning that if an adolescent discontinues the treatment, puberty will resume. (Ex. 7, Karasic, ¶ 42 (ECF 175-7); Ex. 8, Olson-Kennedy ¶¶ 24 (ECF 175-8); Ex. 9, Shumer ¶ 65 (ECF 175-9).) These medications do not have any long-term implications on fertility or sexual function, and there is no evidence that they impact brain development, emotional regulation, or cognition. (Ex. 15, Edmiston Rebuttal Rep. ¶¶ 21-33 ("Edmiston Rebuttal") (ECF 175-15); Ex. 12, Olson-Kennedy Rebuttal ¶¶ 17-23 (ECF 175-12); Ex. 9, Shumer ¶ 73 (ECF 175-9).) And the medical and scientific literature has established that puberty-delaying medication is safe and effective to treat gender dysphoria in adolescents. *See* Ex. 5, Antommaria ¶ 32 (ECF 175-5); Ex. 9, Shumer ¶¶ 63, 78-82 (ECF 175-9); Ex. 8, Olson-Kennedy ¶¶ 25-29, 99-101 (ECF 175-8); Ex. 16, Shumer Rebuttal ¶¶ 51-54 (ECF 175-16); Ex.12; Olson-Kennedy Rebuttal ¶¶ 73-74 (ECF 175-12).)

Many studies have demonstrated that this medication is effective. (*See, e.g.,* Ex. 165, P.T. Cohen-Kettenis & S.H. van Goozen, *Pubertal Delay as an Aid in Diagnosis and Treatment of a Transsexual Adolescent*, 7 Eur Child Adolesc Psychiatry 246, 248 (1998) (ECF 179-5) ("pubertal delay [i]s an additional tool in the diagnosis and treatment of young adolescents with . . . a life-long consistent and

extreme GID [for whom] it may be a physical and psychological beneficial way to intervene"); Ex. 141, Annelou L.C. de Vries et al., *Puberty Suppression in Adolescents With Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. Sex. Med. 2276, 2278 (2011) (ECF 178-21) (while not resolving gender dysphoria, puberty-delaying medication "relieves the acute distress accompanying gender dysphoria"); Ex. 168, Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696, 703 (2014) (ECF 179-8) ("[A] treatment protocol including puberty suppression leads to improved psychological functioning of transgender adolescents."); Ex. 167, Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12 J. Sex. Med. 2206, 2213 (2015) (ECF 179-7) ("This study confirms the effectiveness of puberty suppression for [gender dysphoric] adolescents.").)

The literature has also established that treatment with puberty-delaying medication is safe. (*See, e.g.,* Ex. 163, Polly Carmichael et al., *Short-term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLoS ONE e0243894, at *21, *17 (2021) (ECF 179-3) (concluding that "[t]reatment of young people with persistent and severe [gender dysphoria] aged 12–15 years with [puberty-delaying medication] was efficacious in suppressing pubertal progression. . . . and there were no

unexpected adverse events," and noting that "[a]ll adverse events were minor and anticipated .... [and] less common after 12 months of treatment").)

Puberty-delaying medications have been used in pediatrics for several decades to treat precocious puberty. (Ex. 8, Olson-Kennedy ¶ 24 (ECF 175-8); Ex. 16, Shumer Rebuttal ¶ 64 (ECF 175-16).) For both indications, the side effects of these medications are comparable and easily managed, and the risks are greatly outweighed by the benefits of treatment. (Ex. 9, Shumer ¶ 68 (ECF 175-9); Ex. 8, Olson-Kennedy ¶ 103-105 (ECF 175-8); *see also, e.g.,* Ex. 172, Erica A. Eugster, *Treatment of Central Precocious Puberty*, 3 J. Endocrine Soct'y 965, 965, 967 (2019) (ECF 179-12) (puberty-delaying medications are the "gold-standard treatment of central precocious puberty . . . and have an enviable track record of safety and efficacy").)

For example, while there is a risk of lower bone mineral density with prolonged use of puberty-delaying medications, it can be mitigated by screening for, and treating, vitamin D deficiency when present, and by limiting the number of years of treatment based on a patient's clinical course. (Ex. 204, Stephen M. Rosenthal, *Approach to the Patient: Transgender Youth: Endocrine Considerations*, 99 J. Clin. Endocrine Metab. 4379 (2014) (ECF 180-4).) In addition, studies show that with removal of the puberty-delaying medication or addition of gender-affirming hormone therapy, bone mineral density begins to improve. (Ex. 219, M. C. Vlot,

Effect of Pubertal Suppression and Cross-Sex Hormone Therapy on Bone Turnover Markers and Bone Mineral Apparent Density (BMAD) in Transgender Adolescents, 95 Bone 11 (2020) (ECF 180-19); Ex. 184, Daniel Klink et al., *Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents with Gender Dysphoria*, 100 J. Clin. Endocrine Metab. E270 (2015) (ECF 179-24); *cf.* Ex. 172, Eugster, *supra*, at 967 (ECF 179-12) (reviewing use of puberty-delaying medications for treatment of central precocious puberty and noting that "follow-up of patients several years after cessation of therapy reveals bone mineral accrual to be within the normal range compared with population norms").)

Puberty-delaying treatment does not have long-term implications on fertility. (Ex. 137, Federica Guaraldi et al., *Long-term Outcomes of the Treatment of Central Precocious Puberty*, 14 Eur. Soct'y Endocrinology R79, R83 (2016) (ECF 178-17); Ex. 138, Laetitia Marinerie et al., *Fertility of Women Treated during Childhood with Triptorelin (Depot Formulation) for Central Precocious Puberty*, 93 Horm. Res. Paediatrics 529 (2021) (ECF 178-18).) Adult patients who have had previous treatment with GnRHa followed by hormone therapy could withdraw the hormones and allow pubertal progression if fertility is desired. (*See* Ex. 191, Caitlin E. Martin et al., *Successful Oocyte Cryopreservation Using Letrozole as an Adjunct to Stimulation in a Transgender Adolescent after GnRH Agonist Suppression*, 116

Fertility & Sterility 522 (2021) (ECF 179-31); Ex. 205, Stephanie S. Rothenberg et al., *Oocyte Cryopreservation in a Transgender Male Adolescent*, 380 N. Eng. J. Med. 886 (2019) (ECF 180-5).) Assistive reproduction could be employed if needed. (Ex. 212, Guy T'Sjoen, et al., *Endocrinology of Transgender Medicine*, 40 Endocrine Rev. 97, 105 (2018) (180-12).) Still, standards of care recommend discussing a potential loss of fertility and fertility preservation prior to initiation of puberty-delaying medications. (Ex. 5, Antommaria ¶ 50 (ECF 175-5); Ex. 9, Shumer Rebuttal ¶ 48 (ECF 175-9).)

There is no evidence that the provision of puberty-delaying medications has negative effects on brain development in adolescents. (Ex. 15, Edmiston Rebuttal ¶¶ 26-29, 38 (ECF 175-15); Ex. 16, Shumer Rebuttal ¶¶ 53, 54 (ECF 175-16).) To the contrary, the studies that do exist looking into brain structure and function of transgender adolescents receiving GnRHa treatment have not found any significant effects of treatment on the brain. (Ex. 15, Edmiston Rebuttal ¶ 29 (ECF 175-15).)

2. Hormone Therapy

Hormone medications are approved for the treatment of other conditions and have been used for nearly a century to treat gender dysphoria, supporting their safety and efficacy. (Ex. 7, Karasic ¶ 66 (ECF 175-7); Ex. 8, Olson-Kennedy ¶¶ 106-110 (ECF 175-8); Ex. 9, Shumer ¶ 84 (ECF 175-9).) Hormone therapy is provided only when medically indicated and, after thorough mental health evaluation, in

coordination with the individual's mental health provider. (Ex. 8, Olson-Kennedy ¶ 32 (ECF 175-8); Ex. 9, Shumer ¶¶ 38, 57 (ECF 175-9).) Like with puberty-delaying medications, the fact that hormone treatments may be prescribed off-label does not mean they are untested or unsafe. (Ex. 5, Antommaria ¶¶ 34-37 (ECF 175-5); Ex. 7, Karasic ¶ 66 (ECF 175-7); Ex. 8, Olson-Kennedy ¶¶ 92-93 (ECF 175-8); Ex. 17, Janssen Rebuttal ¶ 107 (ECF 175-17).)

Risks and benefits of hormone treatment are discussed with patients, and their families if the patient is a minor. (Ex. 5, Antommaria ¶¶ 46-50 (ECF 175-5); Ex. 8, Olson-Kennedy ¶ 32 (ECF 175-8); Ex. 9, Shumer, ¶ 74 (ECF 175-9); Ex. 12, Olson-Kennedy Rebuttal ¶ 39 (ECF 175-12); Ex. 17, Janssen Rebuttal ¶¶ 98, 110 (ECF 175-17).) Side effects of hormone therapy are rare and usually related to overtreatment, which can be minimized with monitoring. (Ex. 9, Shumer ¶ 84 (ECF 175-9).) Laboratory testing ensures proper dosing and hormone levels. (Ex. 9, Shumer ¶¶ 74, 84 (ECF 175-9).)

The scientific literature has established that hormone treatment is safe and effective to treat gender dysphoria in adolescents and adults. (*See* Ex. 9, Shumer ¶¶ 86-88 (ECF 175-9); Ex. 8, Olson-Kennedy ¶¶ 34-40 (ECF 175-8); Ex. 17, Janssen Rebuttal ¶¶ 101-102 (ECF 175-17).) The literature demonstrating that hormone treatment is effective to treat gender dysphoria is robust and well-established. (Ex. 8, Olson-Kennedy ¶ 40 (ECF 175-8).) Numerous longitudinal studies document

improvement in gender dysphoria and associated distress. (*See, e.g.,* Ex. 166, Marco Colizzi et al., *Hormonal Treatment Reduces Psychobiological Distress in Gender Identity Disorder, Independently of the Attachment Style*, 10 J. Sex. Med. 3049 (2013) (ECF 179-6); Ex. 173, Alessandra D. Fisher et al., *Cross-Sex Hormone Treatment and Psychobiological Changes in Transsexual Persons: Two-Year Follow-Up Data*, 101 J. Clin. Endo. & Metabolism 4260, 4267 (2016) (ECF 179-13); Ex. 180, Gunter Heylens, et al., *Effects of Different Steps in Gender Reassignment Therapy on Psychopathology*, 11 J. Sex. Med. 119, 124 (2014) (ECF 179-20); *see also, e.g.,* Ex. 221, Katrien Wierckx et al., *Cross-Sex Hormone Therapy in Trans Persons Is Safe and Effective at Short-Time Follow-Up*, 11 J. Sex. Med. 1999 (2014) (ECF 180-21).)

Further, hormone treatment has been shown to have other positive health outcomes when used to treat gender dysphoria. (*See, e.g,* Ex. 156, Kellan E. Baker et al., *Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review*, 5 J. Endo. Soct'y 1, 13 (2021) (ECF 178-36) ("[G]ender-affirming hormone therapy is likely associated with improvements in QOL, depression, and anxiety. No studies showed that hormone therapy harms mental health or quality of life among transgender people."); Ex. 197, Anna Nobili et al., *Quality of Life of Treatment-Seeking Transgender Adults*, 19 Rev. Endo. & Metabolic Disorders 199, 218 (2018) (ECF 179-37) (finding that quality of life

generally improved after the initiation of hormone treatment for gender dysphoria); Ex. 164, Diane Chen et al., *Psychosocial Functioning in Transgender Youth after 2 Years of Hormones*, 388 New England J. Med. 240 (2023) (ECF 179-4) (hormone treatment for adolescents correlates to reductions in depression and anxiety); Ex. 176, Amy E. Green, *Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, 70 J. Adol. Health 643 (2022) (ECF 179-16) ("Findings support a relationship between access to [gender-affirming hormone treatment] and lower rates of depression and suicidality.").)

The literature further demonstrates that satisfaction with hormone treatment is high. (*See, e.g.,* Ex. 195, T.O. Nieder et al., *Individual Treatment Progress Predicts Satisfaction with Transition-Related Care for Youth with Gender Dysphoria*, 18 J. Sex. Med. 632 (2021) (ECF 179-35) (among a group of 75 adolescents with gender dysphoria, satisfaction improved the further along the treatment course had progressed); Ex. 164, Chen et al., *supra*¸ at 240 (ECF 179-4) (in study following 315 adolescents for two years after initiation of hormone therapy, life satisfaction increased); Ex. 212, T'Sjoen et al., *supra* at 101 (ECF 180-12) (summarizing various studies and concluding "[o]verall satisfaction after gender-affirming [hormone] treatment is high").)

The literature similarly shows that hormone treatment is safe and has a low

risk of side effects or adverse events. (Ex. 221, Wierckx et al., *supra,* at 1999 (ECF 180-21) (hormone therapy to treat gender dysphoria "carried a low risk for side effects and adverse events at short-time follow-up); Ex. 212, T'Sjoen et al., *supra* at 98 (ECF 180-12)("Long-term estrogen and androgen-lowering medications may be associated with increased risk of thromboembolism, which can be mitigated by changing the formulation and route of estrogen therapy [and t]estosterone treatment in transgender men is seen as safe regarding cardiovascular and oncological disease in the short-term and mid-term.").) Side effects of hormone therapy are rare and usually related to overtreatment, which can be minimized with monitoring. (Ex. 9, Shumer ¶ 84 (ECF 175-9).)

In addition, the literature suggests that long-term hormone treatment does not necessarily impair fertility. (*See, e.g.,* Ex. 225, I. Yaish et al., *Functional Ovarian Reserve in Transgender Men Receiving Testosterone Therapy*, 36 Hum. Reproduction 2753 (2021) (ECF 180-25); Ex. 162, Mirte R. Caanen et al., *Effects of Long-Term Exogenous Testosterone Administration on Ovarian Morphology, Determined by Transvaginal (3D) Ultrasound in Female-to-Male Transsexuals*, 32 Hum. Reproduction 1457 (2017) (ECF 179-2).) Furthermore, the literature shows that withdrawal of hormone therapy is successful in achieving fertility when it is desired. (Ex. 188, Alexis D. Light, et al., *Transgender Men Who Experienced Pregnancy After Female-to-Male Gender Transitioning*, 124 Obstet. Gynecol. 1120

(2014) (ECF 179-28); Ex. 185, Gail Knudson & Petra De Sutter, *Fertility Options in Transgender and Gender Diverse Adolescents*, 97 Acta Obstetricia et Gynecologica Scandinavica 1269 (2017) (ECF 179-25).)

3. Surgery

Gender confirming surgeries use accepted techniques that are well established and used in other surgeries. (Ex. 10, Schechter, ¶ 45 (ECF 175-10).) The use of these techniques does not become experimental merely when used to treat gender dysphoria. (Ex. 10, Schecter, ¶ 45 (ECF 175-10).) The risks of gender confirming surgical procedures are well-known and well-documented in the literature and are no different when used to treat gender dysphoria rather than other health conditions. (Ex. 10, Schecter ¶¶ 37-38, 60 (ECF 175-10); Ex. 13, Schechter Rebuttal Report ¶ 26 ("Schechter Rebuttal") (ECF 175-13).) Though not all transgender people require gender-affirming surgical care, such care is necessary when medically indicated. (Ex. 10, Schechter ¶¶ 23, 25, 31-32 (ECF 175-10); Ex. 13, Schechter Rebuttal ¶ 27 (ECF 175-13).)

The literature shows that surgery is an effective treatment for gender dysphoria. (*See* Ex. 10, Schechter ¶¶ 40-42, 46 (ECF 175-10); Ex. 8, Olson-Kennedy ¶¶ 44-45 (ECF 175-8); Ex. 5, Antommaria ¶ 32 (ECF 175-5).) For example, in a 1998 meta-analysis, Pfafflin and Junge reviewed data from 80 studies, from 12 countries, spanning 30 years. (Ex. 202, Friedemann Pfäfflin & Astrid Junge, *Sex*

Reassignment. Thirty Years of International Follow-up Studies After Sex Reassignment Surgery: A Comprehensive Review, 1961-1991 (1998) (ECF 180-2).) They concluded that "reassignment procedures were effective in relieving gender dysphoria. There were few negative consequences and all aspects of the reassignment process contributed to overwhelmingly positive outcomes." (*Id.*) Subsequent studies confirm this conclusion. Researchers reporting on a large-scale prospective study of 325 individuals in the Netherlands concluded that after surgery there was "a virtual absence of gender dysphoria" in the cohort and "results substantiate previous conclusions that sex reassignment is effective." (Ex. 208, Yolonda L. Smith, et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals*, 35 Psych. Med. 89, 94, 89 (2005) (ECF 180-8).) The authors of that study concluded that the surgery "appeared therapeutic and beneficial" across a wide spectrum of factors and "[t]he main symptom for which the patients had requested treatment, gender dysphoria, had decreased to such a degree that it had disappeared." (*Id.* at 96.) Another study of transgender women found that surgical interventions were highly correlated with alleviating gender dysphoria. (Ex. 178, Jochen Hess et al., *Satisfaction with Male-to-Female Gender Reassignment Surgery*, 111 Deutsches Arzteblatt Int'l 795, 795 (2014) (ECF 179-18).) A recent study of 30 transmasculine youth whose gender dysphoria was treated with chest surgery found that "[a]ll post-[surgery] youth reported near or total

resolution of chest dysphoria." (Ex. 192, Jamie E. Mehringer et al, *Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine Youth*, 147 Pediatrics e2020013300, *6 (2021) (ECF 179-32); *see also* Ex. 198, Johanna Olson-Kennedy et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 431 (2018) (ECF 179-38) (finding that transmasculine youth whose dysphoria was treated surgically reported less dysphoria compared to youth who were not treated surgically).) Similarly, a 2019 study found that 100% of transgender women who underwent breast augmentation reported improvement in their gender dysphoria and "would undergo the operation again." (Ex. 193, Travis J. Miller et al, *Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes*, 21 JPRAS Open, 63, 64 (2019) (ECF 179-33).)

Decades of research demonstrate that gender confirmation surgery leads to positive outcomes for patients. (Ex. 8, Olson-Kennedy ¶¶ 44-46 (ECF 175-8); Ex. 12, Olson-Kennedy Rebuttal, ¶¶ 46-47 (ECF 175-12); Ex. 10, Schechter, ¶¶ 37-43 (ECF 175-10).) The scientific literature clearly demonstrates that people whose gender dysphoria is surgically treated experience other positive health outcomes, including improvements to mental health, sexual function, and psychosocial wellbeing and quality of life. *(See, e.g.,* Ex. 154, Anthony N. Almazan et al.,

Association Between Gender-Affirming Surgeries and Mental Health Outcomes, 156 JAMA Surgery 611, 611 (2021) (ECF 178-34) (finding that "undergoing 1 or more types of gender-affirming surgery was associated with lower past-month psychological distress . . ., past-year smoking . . ., and past-year suicidal ideation"); Ex. 192, Mehringer et al., *supra*, at *6 (ECF 179-32) ("Youth [treated with surgery] reported improvements in mood, confidence, self-esteem, and interpersonal relationships[and] decreased anxiety."); Ex. 177, Miriam Hadj-Moussa et al., *Feminizing Genital Gender-Confirmation Surgery*, 63 Sex. Med. Rev. 457 (2018) (ECF 179-17) (recent literature review concluded that in appropriately selected individuals, gender confirmation surgery is effective at improving sexual functioning, quality of life, and overall happiness in in transgender women who are diagnosed with gender dysphoria); Ex. 220, Romain Weigert et al., *Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male-to-Female Transsexuals*, 132 Plastic & Recon. Surgery 1421 (2013) (ECF 180-20) (finding among transgender women treated with chest surgery that sexual and psychosocial well-being improved significantly at 4 months postoperatively and later); Ex. 181, Sophie E.R. Horbach et al., *Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques*, 12 J. Sex. Med. 1499 (2015) (ECF 179-21) (peer-reviewed study of transgender women who had vaginoplasty found that study participants' mean

improvement in quality of life after surgery was 7.9 on a scale from one to ten); Ex. 201, Nikolaos A. Papadopulos et al., *Male-to-Female Sex Reassignment Surgery Using the Combined Technique Leads to Increased Quality of Life in a Prospective Study*, 140 Plastic & Recon. Surgery 286 (2017) (ECF 180-1) (recent post-operative and six-month follow-up survey of transgender female patients found improvements in quality of life in a significant majority of patients); Ex. 155, Mona Ascha et al., *Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults*, 176 JAMA Pediatrics 1115 (2022) (ECF 178-35) (transmasculine and nonbinary adolescents and young adults who were treated with chest surgery experienced improved body image satisfaction).)

The scientific literature also establishes that surgery to treat gender dysphoria is safe. (*See* Ex. 10, Schechter ¶¶ 23, 36-38 (ECF 175-10).) The risks of gender confirming surgical procedures are well-known and well-documented in the literature and are no different when the same procedures are used to treat other health conditions. (Ex. 10, Schecter ¶¶ 37-38, 60 (ECF 175-10); Ex. 13, Schechter Rebuttal ¶ 26 (ECF 175-13).) For example, one study found that transgender men who received chest reconstruction experienced few clinical complications. (Ex. 174, Michael J. Frederick et al., *Chest Surgery in Female to Male Transgender Individuals*, 78 Ann. Plastic Surg. 249, 253 (2017) (ECF 179-14).) These findings were confirmed by a 2022 study finding that in transgender and nonbinary

adolescents and young adults, top surgery is associated with low complication rates. (Ex. 155, Ascha et al., *supra*, at 1115 (ECF 178-35).) A study of over 1000 gender-affirming surgeries in the United States found that "[c]omplications of all gender-affirming procedures was 5.8%." (Ex. 148, Megan Lane et al., *Trends in Gender-affirming Surgery in Insured Patients in the United States*, 6 Plast. Surg. Global Open e1738 (2018) (ECF 178-28).) Further, the evidence that shows that surgical interventions are safe to treat gender dysphoria is the same evidence that supports these interventions as safe to treat other conditions, such as congenital conditions, cancer, or traumatic injury since they use the same techniques. (*See* Ex. 5, Antommaria ¶¶ 52-53 (ECF 175-5); Ex. 10, Schechter ¶¶ 36-38 (ECF 175-10).)

In addition, the literature establishes that patient satisfaction with gender-affirming surgery is very high. For example, multiple studies have found that transmasculine people who receive chest reconstruction are overwhelmingly satisfied with their surgical outcomes. (Ex. 174, Frederick et al., *supra*, at 253 (ECF 179-14); Ex. 160, Valeria P. Bustos, et al., *Transgender and Gender-Nonbinary Patient Satisfaction after Transmasculine Chest Surgery*, 9 Plastic & Recon. Surgery e3479 (2021) (ECF 178-40).) Similarly, a study of genital surgeries for transgender women found that patients were overwhelmingly satisfied with their surgical outcomes. (Ex. 181, Horbach et al., *supra,* at 8 (ECF 179-21); *see also* Ex. 178, Jochen Hess, *supra,* at 800 (ECF 179-18) (same).)

In contrast, regret rates for gender-affirming surgeries are quite low.[15] (Ex. 10, Schechter ¶¶ 63-67 (ECF 175-10).) A study of 209 gender-affirming mastectomies in transmasculine adolescents aged 12-17, performed at Kaiser Permanente Northern California from 2013 to 2020, showed a regret rate of 1%. (Ex. 210, Annie Tang et al., *Gender-Affirming Mastectomy Trends and Surgical Outcomes in Adolescents*, 88 Ann. Plastic Surg. S325 (2022) (ECF 180-10).) A pooled review across multiple studies of 7,928 adult patients receiving gender-affirming surgery also showed a regret rate of 1%. (Ex. 161, Valeria P. Bustos, et al., *Regret after Gender-affirmation Surgery: A Systematic Review and Metaanalysis of Prevalence*, 9 Plastic & Recon. Surgery e3477 (2021) (ECF 179-1).) Over 50 years of gender-affirming surgery in Sweden, the regret rate, as measured by legal gender change reversal, was 2%. (Ex. 169, Cecilia Dhejne et al., *An Analysis of All Applications for Sex Reassignment Surgery in Sweden, 1960-2010: Prevalence, Incidence, and Regrets*, 42 Arch. Sex. Behav. 1535 (2014) (ECF 179-9).) These are very low regret rates for surgery. For example, 47% of women expressed at least some regret after reconstructive breast

[15] Defendants are also imprecise in defining what they mean by "regret." One recent study found that not only is regret after gender-affirming surgery very low overall, but that "true gender-related regret" defined as a situation where "a person having undergone a transition in gender . . . then desires to return to their assigned sex at birth or a different gender identity," represented less than half of all cases of regret. (*See* Ex. 194, Sasha Karan Narayan et al, *Guiding the Conversation—Types of Regret after Gender-Affirming Surgery and Their Associated Etiologies*, 9 Ann. Translational Med. 605, *7 (2021) (ECF 179-34).)

surgery following mastectomy for breast cancer. (Ex. 208, Joanne Sheehan et al., *Regret Associated with the Decision for Breast Reconstruction*, 23 Psychology & Health 207, 213 (2008) (ECF 180-1).)

4. Levels of Evidence

The quality of the evidence supporting medical and surgical interventions as treatment for gender dysphoria is comparable to that from studies supporting other, well-established treatments and procedures. (*See, e.g.,* Ex 8, Olson-Kennedy ¶¶ 70-90 (ECF 175-8); Ex 5, Antommaria ¶¶ 18-28 (ECF 175-5); Ex 7, Karasic ¶ 55, 83 (ECF 175-7); Ex 10, Schechter ¶ 52-54 (ECF 175-10); Ex 17, Janssen Rebuttal ¶ 106 (ECF 175-17).) Scientific ratings of evidence generally employ extremely high standards that are not satisfied for many commonly prescribed treatments and procedures. The fact that there are not randomized-control trials of surgical procedures, for example, "is to be expected since a randomised controlled study for this scenario would be impossible to carry out." (Ex. 206, Royal College of Psychiatrists, *Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria* 50 (2014) (ECF 180-6).) Indeed, one recent article concluded that "only a minority of outcomes for health care interventions are supported by high-quality evidence." (Ex. 182, Jeremy Howick et al., *The Quality of Evidence for Medical Interventions Does Not Improve or Worsen: A*

Metaepidemiological Study of Cochrane Reviews, 126 J. Clin. 154, 154 (2020) (ECF 179-22).)

The fact that a treatment is not supported by high-quality evidence does not mean that the treatment is unsupported in the literature and clinical practice, or that it is not medically necessary; on the contrary, the literature shows that the provision of appropriate gender affirming medical care dramatically improves the health, mental health, and well-being of transgender persons. (Ex. 6, Baker ¶ 31 (ECF 175-6); Ex. 7, Karasic ¶¶ 71-76 (ECF 175-7); Ex. 8, Olson-Kennedy ¶¶ 25-41, 98-101, 107 (ECF 175-8); Ex. 9, Shumer, ¶ 35, 42, 82-83 (ECF 175-9); Ex. 10, Schechter ¶¶ 36-43, 81 (ECF 175-10); Ex. 17, Janssen, ¶ 105 (ECF 175-17).)

D. Psychotherapy alone is not an effective treatment for gender dysphoria.

The literature demonstrates that the consequences of untreated gender dysphoria are dire, including higher levels of stigmatization, discrimination, and victimization, contributing to negative self-image and the inability to function effectively in daily life. (*See* Ex. 6, Baker ¶ 30 (ECF 175-6); Ex. 7, Karasic ¶ 68 (ECF 175-7); Ex. 8, Olson-Kennedy at ¶¶ 48, 122 (ECF 175-8); Ex. 9, Shumer ¶ 41, 90 (ECF 175-9); Ex. 10, Schechter ¶ 82 (ECF 175-10); Ex. 17, Janssen Rebuttal ¶¶ 54, 123-124, 126-132 (ECF 175-17).) There is no established safe and effective alternative to gender-affirming medical care for treating gender dysphoria. (Ex.10, Schechter ¶ 58 (ECF 175-10); Ex.7, Karasic ¶ 37 (ECF 175-7); Ex.11, Karasic

Rebuttal ¶¶ 23-24, 47 (ECF 175-11).)

Alternative approaches to treatment for gender dysphoria suggested by persons opposed to gender affirming care such as "reparative" or "corrective" therapy, which attempts to change sexual orientation or gender identity, and "wait and see" or "watchful waiting" which is inapplicable to adolescents and adults,[16] have been determined to be harmful and put children at risk for symptomatic behaviors. (Ex. 8, Olson-Kennedy, ¶ 14-17 (ECF 175-8).)

The evidence is quite clear that withholding proven gender-affirming medical services from transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. (*See* Ex. 7, Karasic ¶¶ 37, 101 (ECF 175-7); Ex. 17, Janssen Rebuttal Report ¶¶ 27-29, 123-27 (ECF 175-17); Ex. 10, Schecter Report ¶ 82 (ECF 175-10); *see also, e.g.,* Ex. 200, Ashli Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J. Sex. Med. 591, 591 (2018) (ECF 179-40)

[16] As described in the literature, "watchful waiting" recommends that caregiver prohibit prepubertal social transition but may allow cross-gender play and clothing within the home, followed by medical care if gender dysphoria persists into adolescence. (Ex. 8, Olson-Kennedy ¶ 17 (ECF 175-8); *see also* Ex. 170, Ehrensaft, *Gender Nonconforming Youth: Current Perspectives*, 2017 (ECF 179-10).)

("Withholding or delaying [gender-affirming care] until depression or anxiety have been treated may not be the optimal treatment course given the benefits of reduced levels of distress after undergoing these interventions"); Ex. 215, Jack Turban et al., *Access to Gender-Affirming Hormones during Adolescence and Mental Health Outcomes Among Transgender Adults*, 17 PLos ONE e0261039, *2 (2022) (ECF 180-15) (those who had access to gender-affirming hormone therapy in adolescence had better mental health outcomes in adulthood, compared to individuals who desired but could not access hormonal interventions); Ex. 152, Zoë Aldridge et al., *Long-Term Effect of Gender-Affirming Hormone Treatment on Depression and Anxiety Symptoms in Transgender People*, 9 Andrology 1808, 1813 (2020) (ECF 178-32) ("These findings do confirm, once again, the high levels of possible anxiety and depressive disorders before [gender-affirming hormone treatment] and the benefit that this treatment brings. It highlights the need to facilitate the expedited use of [gender-affirming hormone treatment] to aid the reduction of poor mental health symptoms in the transgender population, when possible and appropriate."); Ex. 211, Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 2 JAMA Network Open e220978 (2022) (ECF 180-11) (provision of puberty-delaying medications and gender-affirming hormones for transgender youth decreases depression); Ex. 176, Green, et al., *supra*, at 647 (provision of puberty-delaying medications and gender-affirming hormones

for transgender youth decreased depression and suicidality) (ECF 179-16).)

ACHA mischaracterizes "watchful waiting" as withholding all medical treatment for an indefinite period. (Ex. 18, GAPMS Report, at 12, 20-22 (ECF 175-18).) The authoritative medical and scientific literature does not support this approach, which, as discussed above, results in depriving people of needed care and the potential for serious harms to health. (Ex. 16, Shumer Rebuttal, ¶ 37 (ECF 175-16).) Rather, under the "watchful waiting" model of treatment for gender diverse youth, as supported by the scientific and clinical literature:

> If a child's cross-gender identifications and affirmations are persistent over time, interventions are made available for a child to consolidate a transgender identity, once it is assessed, through therapeutic intervention and psychometric assessment, as in the best interests of the child. These interventions include social transitions (the shift from one gender to another, including possible name change, gender marker change, and gender pronoun changes), puberty blockers, and later hormones and possible gender-affirming surgeries.

(Ex. 170, Diane Ehrensaft, *Gender Nonconforming Youth: Current Perspectives*, 8 Adol. Health, Med. & Ther. 57 (2017) (ECF 179-10).) While it is true that under this model, "a young child's demonstration of gender nonconformity, be it in identity, expressions, or both, is not to be manipulated in any way, but observed over time" once the child reaches puberty, medical interventions are made available. (*Id.*) This is because "young adolescents who had been carefully diagnosed show persisting gender dysphoria into late adolescence or young adulthood." (Ex. 141, de Vries (2011), *supra*, at 2281 (ECF 178-21).) Notably, however, the Challenged Exclusion

does not allow for any medical interventions for gender dysphoria for anyone and thus is not consistent with the "watchful waiting" approach. *See* Fla. Admin. Code R. 59G-1.050(7) (2022).

The other option Defendants present is psychotherapy alone as an alternative but have offered no evidence to support that claim. While behavioral health interventions are an important component of gender-affirming care for many, the literature has established for decades that mental health interventions alone are insufficient to treat gender dysphoria. (Ex.7, Karasic ¶ 37 (ECF 175-7); Ex.11, Karasic Rebuttal ¶ 48 (ECF 175-11); Ex.17, Janssen Rebuttal ¶ 91 (ECF 175-17); Ex.8, Olson-Kennedy ¶112 (ECF 175-8); Ex. 10, Schechter ¶ 58 (ECF 175-10); *see also* Ex. 158, Harry Benjamin, *The Transsexual Phenomenon* (1966), at 13 (ECF 178-38).) Indeed, the literature has established for decades that mental health interventions alone are insufficient to treat gender dysphoria. As far back as 1966, Harry Benjamin noted in that:

> The desire to change sex has been known to psychologists for a long time. . . . Beyond some attempts with psychotherapy in a (futile) effort to cure them of their strange desires, nothing was or could be done for them medically. . . . Only because of the recent great advances in endocrinology and surgical techniques has the picture changed.

(Ex. 158, Harry Benjamin, *supra*, at 13 (ECF 178-38).)

Moreover, a study just last year compared mental health outcomes for people who accessed gender-affirming hormone therapy as adolescents to those who

accessed treatment as adults, and concluded that "participants who accessed [gender-affirming hormone therapy] earlier had better mental health outcomes, . . . [which] argue[s] against waiting until adulthood to offer [gender-affirming hormone therapy] to transgender adolescents and suggest that doing so may put patients at greater mental health risk." (Ex. 215, Turban (2022), *supra*, at *11 (ECF 180-15).) In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people.

Nor is "conversion therapy," also known as "reparative therapy" or "gender identity change efforts," an alternative to treatment. As noted above, gender identity cannot be changed. (Ex. 8, Olson-Kennedy at 8 ¶¶ 1-2 (ECF 175-8); Ex. 9, Shumer ¶ 29-33 (ECF 175-9); Ex. 7, Karasic ¶ 23 (ECF 175-7).) But, just last month (March 2023), a report by the U.S. detailed how "[e]fforts to change or suppress a person's sexual orientation or gender identity are grounded in the belief that being LGBTQI+ is abnormal" and therefore "are dangerous, discredited, and ineffective practices." (Ex. 74, SAMHSA, *Moving Beyond Change Efforts* (2023), at 8 (ECF 176-34); *see also* Ex. 73, SAMHSA, Ending Conversion Therapy (Oct. 2015), at 46 (ECF 176-33).) As such, major medical groups have condemned conversion therapy as an intervention to treat gender dysphoria. (*See* Ex. 190, Mallory et al., *supra*, at 2, 4 (ECF 179-30); Ex 8, Olson-Kennedy at 13 ¶ 14 (ECF 175-8); Ex 7, Karasic ¶ 37 (ECF 175-7).)

The scientific literature shows such efforts to be not only ineffective but to also increase the risk for mental health symptoms, including suicide. (*See, e.g.,* Ex. 158, Benjamin (1966), *supra*, at 76, 130 (ECF 178-38) ("Psychotherapy with the aim of curing transsexualism, so that the patient will accept himself as a man, it must be repeated here, is a useless undertaking," and "[p]sychotherapy with the purpose of having the patient accept herself as a woman is as useless in female transsexualism as it is in male"); Ex. 214, Jack L. Turban et al., *Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults*, 77 JAMA Psychiatry 68 (2020) (ECF 180-14); Ex. 190, Christy Mallory et al., *Conversion Therapy and LGBT Youth* 2 (2019 ed.) (collecting studies) (ECF 179-30).)

V. The Medicaid Program

A. Federal Requirements

The Medicaid Act, Title XIX of the Social Security Act of 1965 creates a joint federal-state program that provides health care services to specified categories of low-income individuals. 42 U.S.C. §§ 1396-1396w-6. Medicaid is designed to "enabl[e] each State, as far as practicable...to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and

individuals attain or retain capability for independence and self-care....” 42 U.S.C. § 1396-1. States are not required to participate in the Medicaid program—but all states do. States that choose to participate must comply with the Medicaid Act and its implementing regulations. *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 433 (2004) (“[O]nce a State elects to join the program, it must administer a state plan that meets federal requirements.”). In return, the federal government reimburses each participating state for a substantial portion of the cost of providing medical assistance. *See* 42 U.S.C. §§ 1396b(a), 1396d(b), 1396(c).

The Medicaid Act requires each participating state to designate a single state agency charged with administering or supervising the state’s Medicaid program. *Id.* § 1396a(a)(5). Under the Medicaid Act, a participating state must provide medical assistance to certain eligibility groups, *id.* § 1396a(a)(10)(A)(i), including children and adolescents under age 18 whose household income is below 133% of the federal poverty level, *id.* §§ 1396a(a)(10)(A)(i)(VI)-(VII), 1396a(l). Another mandatory eligibility category is individuals with a disability who receive Supplemental Security Income or meet separate disability and financial eligibility standards established by the state. *Id.* §§ 1396a(a)(10)(A)(i)(II), 1396a(f). States have the option to cover additional eligibility groups. *Id.* §§ 1396a(a)(10)(A)(ii). The Medicaid Act also requires each participating state to cover certain health care services, *id.* §§ 1396a(a)(10)(A), 1396d(a)(4), including Early and Periodic

Screening, Diagnostic, and Treatment (EPSDT) services for beneficiaries under age 21, *id.* §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r), 1396a(a)(43). States may cover additional services. *See id.* §§ 1396a(a)(10)(A), 1396d(a)(4). In addition, States must ensure that "the medical assistance made available to any individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. §1396a(a)(10)(B)(i). States must administer Medicaid in "the best interests of recipients." *Id.* § 1396a(a)(19).

B. Florida's Medicaid Program and the GAPMS Process

The State of Florida participates in the federal Medicaid program. Fla. Stat. §§ 409.901-409.9205. Florida regulations require AHCA to cover health care services that are medically necessary. *See* Fla. Admin. Code R. 59G-1.035(6), 59G-1.010 (2022). To qualify as medically necessary, a service must meet several conditions. *See* Fla. Admin. Code R. 59G-1.010 (2022), incorporating by reference AHCA Definitions Policy at 2.83 (2017) (defining medically necessary care). For one, the service must be consistent with generally accepted professional medical standards and not experimental or investigational. *Id.*; Fla. Admin. Code R. 59G-1.035 (2022).

"Generally accepted professional medical standards" ("GAPMS") are defined by regulations as "standards based on reliable scientific evidence published in peer-reviewed scientific literature generally recognized by the relevant medical

community or practitioner specialty associations' recommendations." Fla. Admin. Code R. 59G-1.035(1)(a) (2022). To determine whether a particular service is consistent with generally accepted professional medical standards, AHCA must consider: (a) evidence-based clinical practice guidelines; (b) published reports and articles in the authoritative medical and scientific literature related to the health service (published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations); (c) effectiveness of the health service in improving the individual's prognosis or health outcomes; (d) utilization trends; (e) coverage policies by other creditable insurance payor sources; (f) recommendations or assessments by clinical or technical experts on the subject or field." *Id*. § 59G-1.035(4). After considering those factors, AHCA must submit a report with recommendations to the Deputy Secretary for Medicaid for review, and the Deputy Secretary makes a final determination as to whether the health service is consistent with generally accepted professional medical standards and not experimental or investigational. *Id*. § 59G-1.035(5).

The GAPMS process is used to determine whether to cover a new service, not whether to exclude an existing service. (ECF 120-6, Brackett Feb. 8 Dep. at 93:13-21; Ex. 302, English email to Cogle (ECF 183-4) (stating "[t]he GAPMS process exists to determine whether the service/device requested for coverage is

experimental/investigational" or "medically necessary"); Br. Ex. 2, English Dep. at 41:6-14.)

VI. Defendants' Categorical Exclusion of Medical Services to Treat Gender Dysphoria

A. Florida Medicaid Coverage of Gender-Affirming Medical Care

Until the Challenged Exclusion, Defendants provided Medicaid coverage for the gender-affirming medical care at issue, that is, puberty-delaying medications, hormone therapy, and gender-affirming surgeries, for adolescents and adults for whom it was medically necessary to treat gender dysphoria since at least 2017. (ECF 120-6, Brackett Feb. 8 Dep. at 66:25-68:17, 74:18-75:9, 84:2-18, 243:4-15; Ex. 257, GnRHa Pharmacy Policy (ECF 181-24); Ex. 317, AHCA FY17-21 Gender Affirming Care Coverage Data Charts ("Coverage Data Charts") (ECF 183-20).) For example, AHCA covered over 6,000 prescriptions for hormone therapy on behalf of Medicaid beneficiaries between 2017 and 2021. (Ex. 317, Coverage Data Charts (ECF 183-20); ECF 120-6, Brackett Feb. 8 Dep. at 66:25-68:17, 243:10-12.) AHCA authorized surgeries to treat gender dysphoria, covering at least 67 surgeries to treat gender dysphoria on behalf of Medicaid beneficiaries between 2017 and 2021. (Ex. 317, Coverage Data Charts (ECF 183-20); Br. Ex. 2, Bracket 2/8/23 Dep. at 84:2-18, 243:13-15.) AHCA also covered puberty-delaying medication, or GnRHa, for Medicaid beneficiaries who met AHCA's internal criteria starting in September 2016; between 2017 and 2021, it covered 405 such prescriptions. (Ex. 317, Coverage

Data Charts (ECF 183-20); Ex. 257, GnRHa Pharmacy Policy (181-24); ECF 120-6, Brackett Feb. 8 Dep. at 74:18-75:9, 243:7-9.)

In fact, as a result of a GAPMS process in 2016, AHCA adopted an explicit policy to cover puberty-delaying medications in 2016 resulted from a GAPMS process which determined that puberty suppression to treat gender dysphoria was consistent with generally accepted professional medical standards. (Ex. 254, Elliot 8/29/2016 email (ECF 181-21); Ex. 240, 2016 GAPMS for Puberty Suppression Therapy (ECF 181-4).) The 2016 GAPMS Report explicitly relied on the clinical practice guidelines of the Endocrine Society and the AAP consensus statement in its review of evidence-based clinical practice guidelines. (Ex. 240, 2016 GAPMS for Puberty Suppression Therapy, at 6 (ECF 181-4).) After this determination was made, AHCA again considered the Endocrine Society Guidelines as it implemented a pharmacy policy setting forth the criteria for coverage of GnRHa medication to treat gender dysphoria. (Ex. 257, GnRHa Pharmacy Policy (ECF 181-24); Ex. 255, Borgert email (181-22); ECF 120-6, Brackett Feb. 8 Dep. at 74:18-75:9.)

In practice, and except for the above, AHCA did not have a policy expressly providing for coverage for gender-affirming medical services (i.e., the services at issue in this case), but instead considered whether the service was medically necessary for a particular Medicaid beneficiary on a case-by-case basis. (*See* Ex. 240, 2016 GAPMS for Puberty Suppression Therapy, at 9 (ECF 181-4)

(recommending that any individualized request for [puberty suppression therapy] be reviewed as a part of the "Agency's" special services process"); Ex. 264, Bouquio 6/12/2018 email (ECF 181-31) ("Florida Medicaid does not expressly cover or deny coverage for gender confirmation surgery but does reimburse for procedures typically performed during gender confirmation surgeries"); Ex. 318, List of Appeals for Denial of Hormone Therapy (ECF 183-21) (overturning denials of hormones and GnRHa medications as medically necessary).

Each Plaintiff has been receiving coverage for their medically necessary gender affirming-medical care for many years. (Br. Ex. 2, Brackett 2/8/23 Dep. at 243:16-245:10, 246:15-247:6, 247:9-20; ECF 11-6, Dekker ¶ 17; ECF 11-7, Rothstein ¶ 12; ECF 11-8, Doe ¶ 19; ECF 11-9, Ladue ¶ 20.) And there is no dispute that Defendants cover each of the relevant medical treatments when necessary to treat at least one condition other than Gender Dysphoria. (Ex. 1, Defs' Admissions Nos. 8-12 (ECF 175-1); Ex. 4, Pltfs' Reqs for Admissions, at Definitions ¶ 13 (ECF 175-4).)

Thus, until August 21, 2022, Florida Medicaid covered and deemed medically necessary the full range of gender-affirming treatments, including puberty delaying medication, hormone therapy, and surgical care.

B. Defendants' Promulgation of the Challenged Exclusion

1. The Lead Up to the Challenged Exclusion

On March 2, 2022, the U.S. Department of Health and Human Services' (HHS) Office of Civil Rights issued guidance on gender-affirming care, stating that HHS "stands with…the significant majority of expert medical associations" in "unequivocally stating that gender affirming care for minors, when medically appropriate and necessary, improves their physical and mental health." (ECF 120-2, HHS Notice and Guidance on Gender Affirming Care.) Later that month, HHS issued additional guidance on gender-affirming care, finding that it "yield[s] lower rates of adverse mental health outcomes, build[s] self-esteem, and improve[s] overall quality of life for transgender and gender diverse youth." (ECF No. 120-3, HHS Fact Sheet: Gender Affirming Care and Young People.)

Sensing political opportunity, Governor DeSantis's administration decided it wanted to rebut these guidance documents, notwithstanding that Florida Medicaid already covered such medical care. Thus, immediately thereafter, the Florida state administration took steps to rebut the federal government's position. Following the HHS Guidance and HHS Factsheet, a meeting was convened involving the governor's office, the Florida Department of Health, and select AHCA staff including now-Secretary Jason Weida in early April to assess how to respond. there was at least one meeting between the governor's office, the Florida Department of

Health, and Secretary Jason Weida in early April. (ECF 120-6, Brackett Feb. 8 Dep. at 88:12-89:19.)

During this time, AHCA's in-house counsel Andrew Sheeran and then-Assistant Deputy Director Jason Weida began actively seeking out and hiring these activists to bolster the Agency's unscientific position. (*See* Ex. 273, April 11, 2022, email from Sheeran to Weida regarding a call with James Cantor (ECF 182-4); Ex. 274, April 14, 2022 email from Andrew Sheeran scheduling a call with Miriam Grossman (ECF 182-5); Ex. 275, April 18, 2022, email between Sheeran and Brignardello-Petersen about her role in the "GAPMS process" (ECF 182-6); Ex. 279, April 21, 2022 email between Sheeran and Michelle Cretella (ECF 182-11).)[17]

Seven consultants were retained all together: Miriam Grossman, Andre Van Mol, Quentin Van Meter, G. Kevin Donovan, James Cantor, Patrick Lappert and Romina Brignardello-Peterson—all notable critics of gender-affirming care.[18] (ECF

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[17] Notably, AHCA's corporate representative, Matthew Brackett, who was also the purported author of the June 2022 GAPMS Report, testified that no work on this process began prior to April 20, 2022. (ECF 120-6, Brackett Feb. 8 Dep. at 95:19-96:7.) The extensive communications between Weida, Sheeran, and the consultants prior to April 20, 2022, make clear that is not true.

[18] James Cantor, *Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy* (2020); Andre Van Mol, *Testimony Please Oppose SB 923 Gender-Affirming Care*; Andre Van Mol, *Testimony: Please Support HB 2649, Missouri Save Adolescents from Experimentation (SAFE) ACT*; Jennifer Bilek, *The Billionaires Behind the LGBT Movement*, firththings.com, Jan. 21, 2020; Jennifer Bilek, *LGBTQ+: A Front for the Techno-Medical Complex* (January 26); Jennifer Bilek, *Who Are the Rich, White Men Institutionalizing Transgender Ideology?*, the federalist.com, Feb. 20, 2018; Jennifer Bilek, *Stryker Corporation and the Global*

120, at 10-11.) Several of the consultants sent articles to Weida and Brackett that took the same hostile position towards gender affirming care, some written by the consultants themselves. (Ex. 273, Email from Ashley Lukis dated April 18, 2022 (ECF 182-4); Ex. 284, Email from Andre Van Mol dated May 6, 2022 (ECF 182-21); Pls' Ex. 285, Email from Andre Van Mol dated May 7, 2022 (ECF 182-22).) AHCA had never hired outside consultants to advise on a particular GAPMS process before. (ECF 120-6, Brackett Feb. 8 Dep. at 137:10-12, 139:17-140:3; Br. Ex. 2 English Dep., at 51:15-19; 138:22-139:4). But ACHA hired these consultants because "it was a unique experience for this case." (ECF 120-6, Brackett Feb. 8 Dep. at 180:23-24). AHCA hired only consultants who were known critics of gender-affirming care and had spoken out against such care in public forums and prior court proceedings.[19] Not a single consultant supporting the provision of gender affirming

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Drive for Medical identities (January 26). Jennifer Bilek, *The ACLU Gets Fat on Pharma and Tech Funding, Part 2* (Mach 4); James Kirkup, *The document that reveals the remarkable tactics of trans lobbyists*, Spectator (December 2, 2019).

[19] Some of these consultants' opinions had been rejected by courts around the country. A Texas court had previously barred Van Meter from providing expert testimony regarding medical treatment for gender dysphoria. *See* Stephen Caruso, *A Texas Judge Ruled That This Doctor Was Not an Expert*, PENNSYLVANIA CAPITAL-STAR (Sept. 15, 2020) (reporting on the now-sealed case) (Pls' Ex. 104). Cantor's opinion regarding gender-affirming care was also given little weight by a federal judge due to his lack of experience in this field. *Eknes-Tucker v. Marshall*, Case No. 2:22-CV-184, 2022 WL 1521889, at *5 (M.D. Ala. May 13, 2022). A federal judge later disqualified Lappert from testifying regarding aspects of gender-affirming care, citing the lack of scientific support for his opinions and "evidence that calls Dr. Lappert's bias and reliability into serious question." *Kadel*

care was hired to advise AHCA; none were even considered. (ECF 120-6, Brackett Feb. 8 Dep. at 135:10-15).

Following this, the FDOH issued a set of guidelines on April 20, 2022, titled "Treatment of Gender Dysphoria for Children and Adults" ("FDOH Guidelines"). (ECF No. 120-7.) The FDOH recommended against prescribing puberty-delaying medication and hormone treatments to children and adolescents. (*Id.*) It also recommended against surgery as a treatment for gender dysphoria as well. (*Id.*)

That same day, AHCA's then-Secretary Simone Marstiller purported to instruct by letter Deputy Secretary Tom Wallace to initiate a GAPMS process to review treatments for gender dysphoria. (Ex. 19, Letter from Marstiller to Wallace (ECF 175-19).) However, the process to create a report and adopt the Exclusion was already long underway. (*See* Ex. 273, April 11, 2022, email from Sheeran to Weida regarding a call with James Cantor (ECF 182-4); Ex. 274, April 14, 2022 email from Andrew Sheeran scheduling a call with Miriam Grossman (ECF 182-5); Ex. 275, April 18, 2022, email between Sheeran and Brignardello-Petersen about her role in

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v. Folwell, Case No. 1:19-CV-272, 2022 WL 3226731, *9 (M.D.N.C. Aug. 10, 2022). Others are affiliated with groups founded specifically to oppose gender-affirming care. For example, Dr. Brignardello-Petersen is affiliated with and "has conducted research for the Society for Evidence-Based Gender Medicine," which "is actually an activist group that opposes standard medical care for gender dysphoria" and is known for "present[ing] a cherry-picked collection of studies and narrative content that is full of scientific errors." (Ex. 324, Yale Public Comment, at 8-9 (ECF 183-27).)

the "GAPMS process" (ECF 182-6).) The letter also misstated that Florida Medicaid did "not have a policy on whether to cover" treatments for gender dysphoria, (Letter from Marstiller to Wallace (ECF 175-19)), when in fact it did—its policy was to cover these treatments on a case-by-case basis, when determined medically necessary. *See* Statement of Facts § VI(A), *supra*. Moreover, although AHCA had already reviewed puberty-delaying medications under a prior GAPMS and determined that they were not experimental, the agency embarked upon a new GAPMS process. (*See* Ex. 240, 2016 GAPMS for Puberty Suppression Therapy (ECF 181-4).) Notably, this was the first time the GAPMS process was used to review services already covered by Florida Medicaid. (ECF 120-6, Brackett Feb. 8 Dep. at 93:13-21; Br. Ex. 2, English Dep. at 41:6-14.).

2. The 2022 GAPMS Review Process and Proposed Rule

Also on April 20, 2023, AHCA formally tasked an agency employee named Matthew Brackett with conducting the GAPMS review, with assistance from two other employees, Devona Pickle and Nai Chen. (ECF 120-9, Dalton Dep. at 83:24-84:3; ECF 120-6, Brackett Feb. 8 Dep. at 96:6-15.) Brackett was not part of the normal GAPMS review team at the time. (ECF 120-9, Dalton Dep. at 84:11-85:19.) He and his two colleagues were part of the unrelated Canadian Prescription Drug Importation Plan team. (ECF 120-9, Dalton Dep. at 83:19-84:3.) In choosing Brackett, Pickle, and Chen, AHCA leadership entirely bypassed the AHCA

employees responsible for GAPMS determinations at the time, (ECF 120-9, Dalton Dep. at 85:7-19, 90:12-19; 24:5-14),[20] who are also the employees most knowledgeable about the GAPMS process. (*Id.* at 78:20-79:1; 151:9-13; *see also* Br. Ex. 2, English Dep. at 148:5-149:15 (Mr. English was kept off the project, despite being the "GAPMS guy," due to the understanding that he would be unwilling to participate because this "particular GAPMS was a conclusion in search of an argument.").) During this same time, AHCA staff worked with five of the agency's retained consultants—Cantor, Brignardello-Petersen, Van Meter, Lappert, and Donovan—to draft separate supporting reports that would be used as attachments. (ECF 120-6, Brackett Feb. 8 Dep. at 111:12-113:16; 110:5-10; 132:13-21.)

Aside from the fact that the GAPMS process had never before been used to

[20] Indeed, Van Mol appears to have been the true architect of the GAPMS Report that Brackett claims he solely drafted. (ECF 120-6, Brackett Feb. 8 Dep. at 97:16-19, 98:3-8). Brackett testified that he was the only one involved in reviewing the literature and writing the GAPMS Report, and that nobody else provided an outline or assisted with the drafting. He acknowledged only "verbal consultations" with the outside consultants. (*See* ECF 120-6, Brackett Feb. 8 Dep. at 96:11-97:19, 98:3-21; 104:8-20; 111:4-11, 145:14-146:24.) Van Mol wrote a document to be used in the GAPMS review process, which he sent to Weida and Brackett in early May. (Exs. 328, 328A 5/1/22 email from Van Mol with attachment (ECF 183-31 to 183-32).) AHCA used this document as guidance in drafting the main report. (*Compare* Ex. 328A, attachment to 5/1/22 email (ECF 183-32), *with* Ex. 18, June 2022 GAPMS Report report (ECF 175-18).) Van Mol also provided Brackett and Weida with additional sources throughout the process. (Exs. 284; 290; 347, emails from Van Mol to Weida (ECF 182-21, 182-29, 184-12).) And after the GAPMS report was drafted, Van Mol provided seven pages of corrections to the draft. (Exs. 286, 286A-B, email from Andre Van Mol dated May 13, 2022 with attachment (ECF 182-23 to 182-25).)

evaluate continued coverage of services already covered by Florida Medicaid, the GAPMS process and the June 2022 GAPMS Report that served as the basis for the Challenged Exclusion at issue in this case bore little resemblance to the GAPMS processes and reports that came before them. For one, the GAPMS process is typically used to analyze "a single service or good." (Ex. 321, Request Form authorizing payment to Van Mol (stating that service coverage analysis "requests *typically are for a single service or good,* this particular request called for a simultaneous analysis of three distinct services") (emphasis added) (ECF 183-24).) The June 2022 GAPMS process, however, reviewed three distinct treatments: "puberty blockers," "cross-sex hormones," and "sex reassignment surgery." (Ex. 18, AHCA GAPMS June 2022, at 39 (ECF 175-18).) The June 2022 GAPMS determination also differs from earlier GAPMS determinations in its consideration of the factors the Agency is required to consider in making its GAPMS Determination. *See* Fla. Admin. Code R. 59G-1.035(4); *see* Legal Argument § I, *infra*.

Indeed, the GAPMS process utilized to exclude coverage of gender affirming medication care "did not come through the traditional channels and was not handled through the traditional GAPMS process," and was so divergent from that the AHCA employee who was responsible for GAPMS determinations at the time, Jeff English, felt compelled to stand up for the "true credibility of the GAPMS process" by

informing the AHCA's Chief Medical Officer that the June 2022 GAMPS Report "does not present an honest and accurate assessment of the status of the current evidence and practice guidelines as I understand them to be in the existing literature." (Ex. 302, email from English to Cogle (ECF 183-4); *see also* Br. Ex. 2, English Dep. at 154:6-13 (the GAPMS process veered from process in terms of ""the quality of the studies included" and "the dismissal" of the "professional organizations and experts that we had frequently cited before."); *id.* at 137:11-138:17 (prior to the June 2022 GAPMS, the "relevant professional medical organizations" AHCA relied on included the American Academy of Pediatrics, American Psychological Association, and American Medical Association, among others); *id.* at 154:6-164:17 ("I would be hard-pressed to envision a scenario where I would second-guess [the Endocrine Society] without, you know, really. really good cause.").

Meanwhile, in addition to their work on the GAPMS Report and supporting documents, AHCA engaged these consultants to perform tasks related to publicizing and defending the agency's policy position. For example, on May 12, 2022, now-Secretary Weida asked Cantor to prepare a short video summarizing his position against gender-affirming care, which "would be posted on the Agency's website along with a copy of the Agency's GAPMS report and other resources on the topic." (Ex. 350, email between Weida and Cantor (ECF 184-15).) And ACHA paid two of

the other consultants, Van Mol and Grossman, not to write a report or review the GAPMS Report based on their knowledge and expertise, but instead to provide evidence and testimony to defend AHCA's position. (Ex. 290 (Weida asks Van Mol for help finding Florida-based people who would say that they regret gender-affirming treatment and doctors who will say they don't provide gender-affirming treatment anymore and reminds him to bill his time) (ECF 182-29); Ex. 303 (email from Grossman seeking feedback on remarks for July 8th hearing) (ECF 183-5); Ex. 307 (email from Grossman stating she expected to be challenged at the July 8th hearing) (ECF 183-9); Ex. 334 (email from Grossman to Van Mol regarding the July 8th hearing: "Can't wait to see you take them apart Andre." (ECF 183-38); Br. Ex. 2, Brackett 2/8/23 Dep., at 137:21-24 (stating that AHCA allocated $35,000 for each "consultant," for a total of $245,000).) Further, AHCA created a "slogan" for the rule promulgation process at issue here, which is something they have never done before. (ECF 120-6, Brackett Feb. 8 Dep. at 181:1-23; 184:9-11; Br. Ex. 2, English Dep., at 117:24-118:20.) The slogan, "Let Kids Be Kids," was featured on the website that was created specifically for the June 2022 GAPMS.[21]

Once the GAPMS report and the consultant reports were finalized, they had to be reviewed and approved by agency leadership. (Ex. 297, AHCA routing and

[21] The use of the phrase is peculiar given that the Challenged Exclusion applies across the board, excluding coverage for the treatments needed for transgender minors and adults. (ECF 120-6, Brackett Feb. 8 Dep. at 185:4-186:17.)

tracking form for June 2022 GAPMS (ECF 182-37).) All the reviewers approved the GAPMS report the day they received it, June 1, 2022. (*Id.*) On June 2, 2022, the GAPMS report was published, and on June 3, 2022, a proposed rule implementing the Challenged Exclusion was published, initiating a statutorily required 21-day comment period. *See* Notice of Proposed Rule, 59G-1.050 (June 3, 2022); *see* also Fla. Stat. 120.54(2).

3. Public Comment on the Proposed Rule

Upon receiving requests for public hearing from the public, AHCA scheduled the statutorily required public hearing, *see* Fla. Stat. § 120.54(3)(c), on the Proposed Rule that would become the Challenged Exclusion on July 8, 2022. This public hearing was the one and only occasion during which the public was able to engage with the agency promulgating this rule, ask questions, and provide oral input on the rule. (*See* ECF 120-9, Dalton Dep. at 118:22-119:3.)

The public hearing was presented before a panel of not only AHCA staff, Jason Weida, Cole Gearing, Matt Brackett, and Sheena Grant, but also outside counsel and consultants, Mohammad Jazil, Gary Perko, Dr. Andre Van Mol, Dr. Quentin Van Meter, and Dr. Miriam Grossman. (*See* Ex. 305, AHCA Rule 59G-1.050 Hearing Brief.) It was highly unusual for AHCA to rely on outside consultants not employed by AHCA, to pay those consultants to attend the public hearing, and to arrange and pay for their travel and transportation. (ECF 120-6, Brackett Feb. 8

Dep. at 177:14-20; *see also id.* at 180:12-25 (stating, when asked about the involvement of "consultants" like Grossman, Van Mol, and Van Meter, that "it was a unique experience for this case, but we generally don't have contracted consultants at our hearings.").) While AHCA is required by rule to have a "subject matter expert" at the public hearing, they had never before relied on outside individuals not employed by AHCA. (*See* ECF 120-9, Dalton Dep. at 120:13-121:10 (when asked about subject matter attendance at the public hearing, Dalton explained that "the subject matter expert for all of our coverage policies are individuals employed by the agency").) Moreover, at the hearing stickers featuring AHCA's slogan "Let Kids Be Kids" were handed out to all participants. (ECF 120-6, Brackett Feb. 8 Dep., 181:1-10). As an email from Grossman summarizing her experience at the July 8th hearing makes clear, this hearing was not an opportunity for AHCA to consider public comment, but rather a stage for AHCA's activist consultants to promote their views in opposition to gender affirming care (Ex. 307, 7/10/23 email from Grossman to to Weida, Van Mol, and Meter (ECF 183-9) ("I was prepared to be challenged and put on the spot but the clock ticked and ticked and…nothing. Where did all the opposition go? Weren't you expecting a bigger turnout? That one church really brought a lot of people! I was smiling ear to ear by the end.")

In addition to the oral public comments made at the hearing, AHCA accepted written comments. Indeed, thousands of written comments were submitted in

opposition to the Proposed Rule, including comments from the Endocrine Society (Ex. 323 (ECF 183-26)), the American Academy of Pediatrics (Ex. 325 (ECF 183-28)), and a team of legal and medical experts from various academic institutions. (Ex. 324 (ECF 183-27).) Together, these comments made it clear that: (1) the Proposed Rule would cause unnecessary harm and suffering; (2) the GAPMS Memo was significantly flawed and contrary to established standards of care; and (3) the Proposed Rule was illegal. (*See* Exs. 323-325 (ECF 183-26 to 183-28).)

Notwithstanding these comments, Defendants filed to adopt the Proposed Rule a mere three weeks after the close of the comment period. (*See* 59G-1.050, Rule History, *available at* https://www.flrules.org/gateway/ruleno.asp?id=59G-1.050.) The final version was identical to the Proposed Rule and went into effect on August 21, 2022. *Id.*

C. The Variance and Waiver Process Is Not Available to Obtain Coverage for Gender-Affirming Care

State statute and regulations provide a process by which a person can seek a variance and waiver from the "unreasonable, unfair, and unintended results" of agency rule requirements. Fla. Stat. § 120.542 (2022); *see also* Fla. Admin. Code R. 28-104.001-28.104.006. Under the statute, a variance is granted when: 1) "the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person;" and 2) "application of a rule would create a substantial hardship or would violate principles of fairness." Fla. Stat. §

120.542. Thus, by its own terms, the process cannot be used to request Medicaid coverage of a service that has been determined experimental under the regulations.

Defendants have provided no plausible explanation as to how Medicaid beneficiaries in need of services subject to the Challenged Exclusion could possibly satisfy the first requirement. Matthew Brackett, who testified as AHCA's corporate representative, suggested that a person could qualify for a waiver or variance by showing that the excluded services are not experimental to treat their gender dysphoria. (Br. Ex. 2, Brackett 2/8/23 Dep. at 42:19-43:18.) But that suggestion is nonsensical. AHCA made a categorical determination that the services are experimental – that determination is not dependent on the circumstances of a particular individual. (*See id.* at 41:22-42:4.)

And indeed, no variance has ever been granted for services that had been deemed experimental and categorically excluded from coverage (*Id.* at 240:1-241:18.) Brackett also acknowledged that this complex process was practically unavailable for pro se individuals, noting that due to "the complexities of request and legalities of it" a person would need legal assistance or representation to complete the process. (*Id.* at 241:19-242:13.) Accordingly, the variance and waiver process is not a viable option for individual Medicaid beneficiaries to obtain

coverage for gender-affirming care.[22]

LEGAL ARGUMENT AND AUTHORITIES

The Challenged Exclusion targets only transgender persons , including Plaintiffs Dekker, Rothstein, Doe, and K.F., and, accordingly, it violates the Fourteenth Amendment's Equal Protection Clause and Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116. There is nothing experimental about the medical treatment (known as gender-affirming care) for gender dysphoria. To the contrary, gender-affirming care is supported by scientific evidence and recognized as safe, effective, and medically necessary. There is no rational basis, let alone the exceedingly persuasive justification or compelling interest, necessary for the implementation of the Challenged Exclusion. Defendants' abrupt deviation from the status quo has caused and will continue to cause irreparable harm to Plaintiffs, who will no longer be able to access medically necessary care, endangering their health and wellbeing.

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[22] Even if the variance process could result in coverage (which it cannot), requiring beneficiaries to use the process to obtain coverage of services subject to the Challenged Exclusion could run afoul of federal due process requirements. *See* 42 U.S.C. § 1396a(a)(3) (requiring states to grant an opportunity for a fair hearing before the state Medicaid agency to beneficiaries whose claim for services is denied); 42 C.F.R. §§ 431.200 to 431.246 (setting forth detailed notice and fair hearing requirements for states). (*Cf.* Ex. 229 (ECF 180-28) (template notice of adverse benefit determination providing no mention of the variance process); Ex. 231 (ECF 180-30) (sample AHCA final fair hearing order providing no mention of the variance process).)

I. Defendants' Determination That the Treatments at Issue Are Experimental Is Unreasonable

This Court, relying on *Rush v. Parham*, 625 F.2d 1150 (5th Cir. 1980), articulated as a controlling question in this case "whether, based on current medical knowledge, the state's determination that these [gender-affirming medical] treatments are experimental is reasonable."[23] AHCA's determination is not reasonable.

Here, Defendants' *own* regulations set forth the six specific criteria that govern whether a service is consistent with generally accepted professional medical standards, as opposed to experimental or investigational, for purposes of Medicaid coverage. *See* Fla. Admin. Code R. 59G-1.035(4); *see also K.G. ex rel. Garrido v.*

[23] Of note, the decision in *Rush* turns on the "reasonable standards" provision of the Medicaid Act, 42 U.S.C. § 1396a(a)(17), whereas Plaintiffs are claiming that the Challenged Exclusion violates the EPSDT and comparability provisions of the Medicaid Act. (*See* ECF No. 1, Compl., at ¶¶ 275-80.) Nevertheless, Plaintiffs agree that if the relevant treatments are experimental, the Challenged Exclusion does not violate the EPSDT requirements. (*See* Ex. 62, *EPSDT – A Guide for States*, at 24-25 (2014) (EPSDT does not require coverage of treatments, services, or items that are experimental or investigational. . . . The state's determination of whether a service is experimental must be reasonable and should be based on the latest scientific information available.").); *K.G. ex rel. Garrido v. Dudek*, 864 F. Supp. 2d 1314, 1321 (S.D. Fla. 2012), *aff'd in part, rev'd in part sub nom. Garrido v. Dudek*, 731 F.3d 1152 (11th Cir. 2013). That said, Plaintiffs contend the Exclusion could violate the Medicaid Act's comparability requirement, Section 1557 of the ACA, and the Equal Protection Clause even if Defendants' conclusion was reasonable, and the Court has acknowledged the possibility of such circumstances. (*See* ECF No. 64, at 4 (recognizing discrimination could occur where a state covers experimental services for some conditions and not others).)

Dudek, 864 F. Supp. 2d 1314, 1321 (S.D. Fla. 2012), *aff'd in part, rev'd in part sub nom. Garrido v. Dudek*, 731 F.3d 1152 (11th Cir. 2013). Consideration of each of these six factors clearly shows that the excluded services are not experimental.

AHCA's skewed and incomplete consideration of the GAPMS factors underscores that its determination otherwise was not reasonable.[24] *See K.G.*, 864 F.Supp.3d at 1322 (finding that AHCA's use of an "arbitrary, capricious, and unreasonable" process to determine whether a service is experimental shows that its conclusion was equally unreasonable).

A. Evidence-based clinical practice guidelines

Two long-standing professional medical associations – WPATH and the Endocrine Society – have published clinical practice guidelines recommending gender-affirming care, including puberty-delaying medications, hormone therapy, and surgery, for the treatment of gender dysphoria in adolescents and adults who meet specific criteria.[25] (*See* Ex. 34, WPATH Standards of Care 8 (ECF 175-34);

[24] The fact that AHCA even initiated the GAPMS process for these services reveals that the process was a sham, as the process is not used for services that the agency already covers. Ex. 30 (3/22/23 email from Pickle to English (ECF 175-30) (noting that per the state regulation, the GAPMS process is for requesting coverage, not disputing it); Br. Ex. 2, English Tr. at 41:6-41:14 (stating that the GAPMS process is not initiated to assess existing coverage of Medicaid services); (ECF 120-6, Brackett Feb. 8 Dep. at 93:13-93:21 (stating that the June 2022 GAPMS was the first time AHCA used the GAPMS process to eliminate coverage of a service).)

[25] In addition, the University of San Francisco Center for Excellence in Transgender Care has published Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People that recommend the use of the excluded

Ex. 123, Endocrine Soc. Guidelines (ECF 178-3).) These guidelines establish authoritative protocols for health care providers working with transgender patients. (Ex. 7, Karasic ¶ 39 (ECF 175-7); ¶ 39; Ex. 9, Shumer ¶¶ 48-49, 56 (ECF 175-9); Ex. 10, Schechter ¶ 24 (ECF 175-10); *see* Ex. 324, Yale Public Comment re: Proposed Medicaid Rule 59G-1.050(7) ("Yale Comment") (ECF 183-27), at 4.) Most major medical associations in the country, including the American Academy of Pediatrics, American Medical Association, the American Psychiatric Association, the American Psychological Association, the American College of Physicians, the American Academy of Family Physicians, and the American Academy of Child and Adolescent Psychiatry, among others, have endorsed these guidelines. *See* Statement of Facts § IV(B), n.14, *supra.* In reaching its conclusion, AHCA did not consider any of these views or positions and did not give any credit to any of them. (*See* Ex. 18, GAPMS Report, at Works Cited (ECF 175-18); ECF 120-6, Brackett Feb. 8 Dep. at 117:21-120:7.) There are no published clinical practice guidelines that recommend the use of psychotherapy alone to treat adolescents or adults with gender dysphoria, notwithstanding that AHCA presumably covers it. (*See* Ex. 9, Shumer Rebuttal ¶ 14 (ECF 175-9).)

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services. (*See* https://transcare.ucsf.edu/guidelines; Ex. 12, Olson Kennedy Rep. ¶ 12 (ECF 175-12); Ex. 7, Karasic Rep. ¶ 32 (ECF 175-7).)

Defendants' argument that the WPATH and Endocrine Society guidelines are biased and not evidence-based, *see* ECF 120 at 19-23, is without merit. First, it is *de rigeur* for professional medical associations to advocate on behalf of health care providers and their patients. (Ex. 14, Antommaria Rebuttal ¶¶ 54-56 (ECF 175-14).)[26] That does not undermine—let alone, invalidate—their published clinical practice guidelines. Second, the fact that members of WPATH drafted the Standards of Care does not reflect bias or a conflict of interest, but rather that clinicians and researchers with the requisite expertise in the field of transgender medicine drafted the guidelines. (*See* Ex. 12, Olson-Kennedy Rebuttal. ¶ 42 (ECF 175-12); Ex. 5, Antommaria ¶¶ 9-11 (ECF 175-5).) Third, the WPATH and Endocrine Society guidelines are based on a rigorous review of the peer-reviewed published literature, as well as extensive clinical experience. (*See* Ex. 17, Janssen Rebuttal ¶¶ 55-58 (ECF 175-17); Ex. 5, Antommaria ¶¶ 18-24, 29 (ECF 175-5); Ex. 7, Karasic ¶¶ 28, 33 (ECF 175-7); *see also* Ex. 34, WPATH Standards of Care 8 at Appx. A (ECF 175-34); Ex. 123, Endocrine Soc. Guidelines at 3872-73 (ECF 178-3).)

What is more, the guidelines themselves were published in medical journals and subjected to peer-review. "That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is

[26] *See, also, e.g.*, AMA, Health Care Advocacy, https://www.ama-assn.org/health-care-advocacy; American Society of Plastic Surgeons, Advocacy, https://www.plasticsurgery.org/for-medical-professionals/advocacy.

a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995).

And, as described more fully below, the level of evidence supporting the WPATH and Endocrine Society guidelines mirrors the level of evidence supporting many treatments that AHCA does not characterize as experimental. (*See* Ex. 10, Schechter ¶¶ 52-54 (ECF 175-10); Ex. 13, Schechter Rebuttal ¶¶ 7-10 (ECF 175-13); Ex. 17, Janssen Rebuttal ¶ 106 (ECF 175-17); Ex. 5, Antommaria ¶ 24 (ECF 175-5).)

Defendants' attempt to discredit the existing clinical practice guidelines for the treatment of gender dysphoria is even more remarkable in light of AHCA's usual treatment of such guidelines during GAPMS processes. When noting the presence of clinical practice guidelines and describing their recommendations, previous GAPMS reports do not even comment on the organization that developed the guidelines, much less delve into the inner workings of the organization to try to assess if the recommendations could be subject to bias. (*See, e.g.*, Ex. 330, Specially Modified Foods GAPMS (ECF 183-34); Ex. 331, Scleral Contact Lenses GAPMS (ECF 183-35); Ex. 332, Fractional Exhaled Nitric Oxide GAPMS (ECF 183-36); Ex. 333, Breast Pump GAPMS (ECF 183-37).). And indeed, AHCA has relied on guidelines and recommendations published by other organizations with an advocacy

mission to find that services are not experimental. (*See, e.g.*, Ex. 333, Breast Pump GAPMS (ECF 183-37) (referring to recommendations of AAP, AAFP, and others in determining that breast pumps are not experimental); Ex. 331 Scleral Contact Lenses GAPMS (ECF 183-35) (referring to retrospective review by American Academy of Ophthalmology in determining that scleral contact lenses are not experimental).) Tellingly, the 2016 GAPMS report on puberty suppression therapy included the Endocrine Society guidelines without any suggestion that they were somehow invalid. (*See* Ex. 240, 2016 GAPMS for Puberty Suppression Therapy (ECF 181-4).)

B. Published reports and articles in the authoritative medical and scientific literature

As detailed in Section IV(C), Statement of Facts, *supra*, there is an abundance of "peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations" examining the use of puberty delaying medications (GnRHa), hormone therapy, and surgery to treat gender dysphoria. *See* Fla. Admin. Code R. 59G-1.035(4)(b) (2022). The peer-reviewed literature on gender-affirming surgery dates back to the 1960s, and researchers have been evaluating the safety and efficacy of hormone therapy and puberty delaying medications for decades. *See, e.g.*, Statement of Facts § IV(C), *supra*.

In drafting the GAPMS Report, AHCA ignored virtually all of the large body of peer-reviewed literature on gender-affirming care. (*See* ECF 120-6, Brackett

2/8/23 Dep. at 147:12-147:25; ECF No. 84-1, Decl. of Matthew Brackett, at ¶ 4.) Indeed, Dr. Brignardello-Peterson and Dr. Wiercioch, the AHCA consultants who purported to conduct a review of the relevant literature, included just 27 studies published between 2020 and 2022 in their review. (*See* Ex. 324, Yale Comment, at 10-11, 31-32 (ECF 183-27).) They also only considered studies that included participants under age 25, while many patients who receive gender-affirming surgery are 25 or older. (Ex. 7, Karasic ¶ 81 (ECF 175-7).) In addition, they searched only one non-governmental organization website for research: the Society for Evidence-Based Gender Medicine, which is a small group founded recently specifically in opposition to gender-affirming care. (*Id.* ¶ 80 (noting that this decision "raises a concern for bias").) Their review of the relevant literature was far from comprehensive. (Ex. 324, Yale Comment, at 10-11 (ECF (183-27); Ex.7, Karasic ¶¶ 80-81 (ECF 175-7).)

The GAPMS Report and Defendants' experts attempt to discount the literature that they did consider, arguing that the studies are low quality. That claim is highly misleading, however. (Ex. 324, Yale comment at 11-12, 32-33 (ECF 183-27); *see also* Ex. 5, Antommaria ¶¶ 19-22 (ECF 175-5) (explaining how scientific evidence is rated).) While randomized trials are usually rated as high-quality evidence and observational studies as low-quality evidence (Ex. 5, Antommaria ¶20 (ECF 175-5)), for ethical and practical reasons, it is not possible to conduct randomized trials

involving the use of puberty delaying medications, hormone therapy, or surgery to treat gender dysphoria. (Ex. 8, Olson-Kennedy ¶¶ 74-85 (ECF 175-8); Ex. 10, Schechter ¶¶ 52-53 (ECF 175-10); Ex. 5, Antommaria ¶¶ 27-28 (ECF 175-5); Ex. 9, Shumer ¶ 17 (ECF 175-9); Ex. 7, Karasic ¶ 83 (ECF 175-7).)

The lack of randomized trials does not mean the existing research is insufficient to inform clinical decision making. (Ex. 14, Antommaria Rebuttal ¶ 30 (ECF 175-14); Ex., 10, Schechter ¶ 56 (ECF 175-10); Ex. 13, Schechter Rebuttal ¶ 8 (ECF 175-13); Ex. 8, Olson-Kennedy ¶¶ 73, 88-90 (ECF 175-8); *see also* Ex. 324, Yale Comment at 13, 33-34 (ECF 173-27).) In fact, the level of evidence supporting gender-affirming care is no different than the level of evidence supporting any number of very common medical interventions. (Ex. 10, Schechter ¶¶ 52-54 (ECF 175-10); Ex. 13, Schechter Rebuttal ¶¶ 7-11 (ECF 175-13); Ex. 17, Janssen Rebuttal ¶ 106 (ECF 175-17); Ex. 5, Antommaria ¶ 24 (ECF 175-5); Ex. 8, Olson-Kennedy ¶¶ 86, 124 (ECF 175-8); Ex. 7, Karasic ¶ 55 (ECF 175-7); *see also* Ex. 324, Yale Comment at 12-13, 34-36 (ECF 183-27) (noting that the evidence supporting the use of statins, screening mammograms, and routine surgical procedures have a similar evidence base).)

What is more, while the GAPMS Report and Defendants' experts criticize the methodology of individual studies, they fail to acknowledge that the entire body of literature, taken as a whole, provides strong evidence in support of puberty delaying

medications, hormone therapy, and surgery. (*See* Ex. 10, Schechter ¶¶ 73 (ECF 175-10); Ex. 8, Olson-Kennedy ¶¶ 98-99 (ECF 175-8); Ex. 16, Shumer Rebuttal ¶ 11 (ECF 175-16); Ex. 17, Janssen Rebuttal ¶¶ 26, 105 (ECF 175-17); *see also* Ex. 324, Yale Comment at 14-15, 36 (ECF 183-27).) Indeed, "the safety and efficacy in medicine is not and cannot be measured by any single study," as "*every study has limitations.*" (Ex. 12, Olson-Kennedy Rebuttal ¶ 73 (ECF 175-12).) "***To determine whether a treatment is safe and effective, and whether it is experimental or investigational, we look at the whole body of research and clinical experience.***" (*Id.*). "By this measure, gender-affirming medical care as treatment for gender dysphoria has been shown to be safe, effective, and is not experimental or investigational." (*Id.*).

Finally, while attempting to undermine the large body of peer-reviewed literature in support of gender-affirming care, Defendants rely on articles published in websites or other outlets – not peer-reviewed scientific literature. (*See* Ex. 18, GAPMS Report, at Works Cited (ECF 175-18); Ex. 324, Yale Comment at 13-15 (ECF 183-27).) This is not reliable evidence, which "means, in relevant part, 'only published reports and articles written in the authoritative medical and scientific literature.'" *K.G.*, 839 F.Supp.2d at 1265 (quoting Fla. Admin. Code R. 59G-1.010(84)(b)).

C. Effectiveness in improving prognosis or health outcomes

The peer-reviewed literature shows that puberty delaying medications, hormone therapy, and surgery are: 1) safe and effective for the treatment of gender dysphoria; and 2) when used for that purpose, are correlated additional positive health outcomes, including improved quality of life, mental health, and psychosocial functioning. *See* Statement of Facts § IV(C), *supra*. In determining whether a particular medical intervention is safe and effective, providers look at both the peer-reviewed literature and clinical experience and expertise. (Ex. 8, Olson-Kennedy ¶¶ 88-90 (ECF 185-8); Ex. 16, Shumer Rebuttal ¶ 21 (ECF 175-16); Ex. 10, Schechter ¶ 56 (ECF 175-10).) The clinical experience of providers who have treated thousands of patients with gender dysphoria supports the safety and effectiveness of gender-affirming medical care. (Ex. 9, Shumer ¶¶ 42, 46 (ECF 175-9); Ex. 8, Olson-Kennedy ¶¶ 30-31, 41 (ECF 175-8); Ex. 7, Karasic ¶¶ 26, 59 (ECF 175-7); Ex. 10, Schechter ¶ 36, 43 (ECF 175-10); Ex. 17, Janssen Rebuttal. ¶¶ 94-95, 101-102 (ECF 175-17).)

While Defendants argue that mental health services alone are equally effective in treating gender dysphoria, they provide absolutely no evidence to support that conclusion. *See* Statement of Facts § IV(D), *supra.* (*See also* Ex. 7, Karasic ¶ 37 (ECF 175-7); Ex. 11, Karasic Rebuttal ¶ 48 (ECF 175-11); Ex. 17, Janssen Rebuttal ¶ 91 (ECF 175-17); Ex. 8, Olson-Kennedy ¶ 112 (ECF 175-8); Ex. 10, Schechter ¶

58 (ECF 175-10).) In fact, research and clinical experience have proven that efforts to use talk therapy, and even aversive therapy, to try to "cure" transgender individuals are ineffective and harmful. (Ex. 17, Janssen Rebuttal ¶¶ 41-43 (ECF 175-17); Ex. 7, Karasic ¶¶ 30, 95 (ECF 175-7); Ex. 8, Olson-Kennedy at 10 ¶ 6, 13-15 ¶¶ 14-16 (ECF 175-8).) Similarly, while Defendants argue that many patients come to regret receiving gender-affirming care, the peer-reviewed literature, as well as the clinical experience of providers, demonstrates otherwise. (Ex. 10, Schechter ¶¶ 63-67 (ECF 175-10); Ex. 9, Shumer ¶ 75 (ECF 175-9); Ex. 7, Karasic ¶¶ 58, 62-64 (ECF 175-7).)

D. Utilization trends

The GAPMS Report makes no mention of this factor. There has been a notable increase in the utilization of gender-affirming medical care over the last three decades. (Ex. 5, Antommaria ¶¶ 39-40 (ECF 175-5).) AHCA's own data shows that the number of Medicaid beneficiaries accessing puberty-delaying medication (GnRHa), hormone therapy, and surgery has increased since 2017. (*See* Ex. 317, Coverage Data Charts (ECF 183-20); *see also* Ex. 6, Baker ¶ 59 (ECF 175-6).) Paradoxically, AHCA appears to view that rise in utilization as a reason to implement the Challenged Exclusion. (*See* Ex. 335, Juarez email 8/29/2022 re Medicaid data (ECF 183-39).) But, in fact, such data shows the opposite: that the services are commonly used and not experimental. *See Rush*, 625 F.2d at 1156 n.11

(contrasting a service that is "generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used" with a service or treatment that "is rarely used, novel, or relatively unknown").

E. Other coverage policies

AHCA's coverage exclusion is an outlier among health plans. The vast majority of health plans, in Florida and elsewhere, do not have categorical transgender-specific exclusions. (*See* Ex. 6, Baker ¶¶ 40 (state employee plans), 41 (plans offered by private employers), 42 (federal employee plans), 44-46 (plans sold through the federal Marketplace, including in Florida) (ECF 175-6); *see also id*. ¶ 35 (highlighting that 25 states and D.C. prohibit such exclusions in state-regulated individual and group plans); Ex. 5, Antommaria ¶ 42 (ECF 175-5).) In drafting the GAPMS report, AHCA did not even review private insurance coverage policies. (ECF 120-6, Brackett Feb. 8 Dep. at 149:2-152:6.)

Likewise, Medicare has covered gender-affirming surgical care since 2014. (*See* Ex. 71, Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2576 at 20 (May 30, 2014) (ECF 176-31) (invalidating the exclusion of gender-affirming surgery given the "consensus among researchers and mainstream medical organizations that [gender-affirming] surgery is an effective, safe and medically necessary treatment").) The 2016 decision memo that Defendants

rely on (*see* ECF 120 at 6, 7) did not change that policy. HHS simply declined to issue national standards governing when gender-affirming surgery is medically necessary, allowing local Medicare contractors to continue determining medical necessity on an individual basis. (Ex. 64, Ctrs. for Medicare & Medicaid Servs., Decision Memo for Gender Dysphoria and Gender Reassignment Surgery at 2 (Aug. 30, 2016) (ECF 176-24).) That decision was not unusual, as many widely accepted surgical procedures do not have national coverage standards under Medicare.[27] (Ex. 10, Schechter ¶ 79 (ECF 175-10).) Medicare also covers gender-affirming medications. (Ex. 5, Antommaria ¶ 41 (ECF 175-5).)

As for Medicaid, only 9 of the 56 states and territories operating a Medicaid program exclude coverage of gender-affirming care. (Ex. 6, Baker ¶¶ 54, 57 (ECF 175-6).) Even among those jurisdictions, Florida's exclusion stands apart for its breadth and scope.[28] (*Id.* ¶¶ 55-57 (noting that three of the exclusions are limited to

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[27] What is more, HHS only concluded that the evidence was "inconclusive for the Medicare population," which consists primarily of people over age 65. The conclusion is not transferable to other population groups. (Ex. 10, Schechter ¶ 79 (ECF 175-10).) For that reason, CMS has made clear that Medicare guidance is not determinative of whether a service is experimental for individuals under age 21. (Ex. 62, Ctrs. for Medicare & Medicaid Servs., *EPSDT – A Guide for States* 25 (2014) (ECF 176-22).)

[28] AHCA's evaluation of Medicaid coverage policies in the GAPMS report was flawed. It involved only an online search for state policies, (*see* ECF 120-6, Brackett Feb. 8 Dep. at 152:7-155:12), while a comprehensive evaluation would involve state statutes, regulations, operative guidance, managed care organizations' policies, and administrative and court decisions. (Ex. 6, Baker ¶ 56 (ECF 175-6).)

surgery, one is limited to minors, and one appears to be inoperative).) Perhaps most remarkably, Florida Medicaid covered puberty-delaying medications, hormone therapy, and surgical care prior as treatment for gender dysphoria prior to the implementation of the Challenged Exclusion. (Ex. 317, Coverage Data Charts (ECF 183-20); ECF 120-6, Brackett Feb. 8 Dep. at 74:18-75:9; 66:25-68:17, 81:14-84:18.) What is more, the insurers with which AHCA contracts to deliver services to Medicaid enrollees cover gender-affirming care under their own policies. (*See, e.g.*, Ex. 57 (Aetna Coverage of GnRHa) (ECF 176-17); Ex. 56 (Aetna Coverage of Gender Confirming Surgery) (ECF 176-16); Ex. 54 (Humana Coverage of Testosterone) (ECF 176-14); Ex 58 (Humana Coverage of Gender Confirming Surgery) (ECF 176-18); Ex 60 (Molina Coverage of Gender Confirming Surgery) (ECF 176-20); Ex 59 (Molina Coverage of Hormone Therapy) (ECF 176-19); Ex 61 (United Coverage of Gender Dysphoria Treatment) (ECF 176-21).)

While other nations' coverage policies have never before factored into the GAPMS process, Defendants argue that their determination regarding puberty delaying medications, hormone therapy, and surgery reflects an "international consensus" on the issue. (ECF 120, at 24-25.) But that is wrong. First, Defendants have not conducted a comprehensive review of other countries' policies regarding gender-affirming care. (*See* Ex. 18, GAPMS Report, at 35 (ECF 175-18) (citing to guidelines in only 3 European nations).) Second, the statements Defendants cite do

not even address treatment for adults, but Florida has excluded coverage of gender-affirming care for Medicaid beneficiaries of all ages. *Id.* Third, Defendants have misrepresented those nations' policies with respect to minors.[29] (Ex. 14, Antommaria Rebuttal ¶¶ 73-82 (ECF 175-14).) For example, Defendants ignore that the United Kingdom, Sweden, and Finland continue to provide gender-affirming care for minors in some cases, as do many other developed nations. (*See id*. ¶¶ 77-79; Ex. 7, Karasic ¶¶ 94-95.) Neither Australia nor New Zealand have changed their policies, and other countries like Denmark, Germany, Spain, and Mexico have adopted policies explicitly providing this care. (ECF 142-11, at 13-20.)

F. Recommendations or assessments by clinical or technical experts on the subject or field

This factor calls for the views "by clinical or technical experts *on the subject or field*." Fla. Admin. Code R. 59G-1.035(4)(f) (emphasis added). Recognized clinical and technical experts in the field of transgender medicine agree that gender-affirming medical care services in the form of puberty-delaying medications, hormone therapy, and surgery are safe and effective treatments for gender dysphoria. (Ex. 8, Olson-Kennedy ¶ 121 (ECF 175-8); Ex. 9, Shumer ¶ 89 (ECF 175-9); Ex. 7, Karasic ¶¶ 53-54, 100 (ECF 175-7); Ex. 17, Janssen Rebuttal ¶¶ 23, 133 (ECF 175-

[29] In the GAPMS report itself, AHCA included maps purporting to show the age at which an individual can receive hormone therapy or surgery "without consent of parents or of a public authority" in various European nations. (Ex. 18, GAPMS Report, at 37-38 (ECF 175-18).) That information is irrelevant.

17); Ex. 10, Schechter ¶¶ 23, 43, 81 (ECF 175-10); *see also* Ex. 324, Yale Comment at 4-5, 24-25 (ECF 183-27).) Because Defendants were determined to terminate Medicaid coverage for these services, AHCA did not seek recommendations or assessments from recognized experts or individuals with actual experience in the field of transgender medicine.

Instead, in preparing the GAPMS report, AHCA asked a handful of select, vocal opponents of gender-affirming care to serve as consultants. The process began with the Department of Health pointing AHCA staff to Dr. Michelle Cretella – a former President of the American College of Pediatricians, which has taken extreme positions on a number of LGBTQ issues and opposes the provision of gender-affirming care – who then pointed AHCA to other consultants. (ECF 120-6, Brackett Feb. 8 Dep. at 104:21-106:8, 110:5-110:25). Dr. Cretella then connected AHCA with Dr. Andre Van Mol, touting his credentials as "Chair of the Adolescent Sexuality Committee of the American College of Pediatricians and a spokesperson for the Christian Medical and Dental Associations." (Ex. 279, 4/21/22 email between Sheeran and Michelle Cretella (ECF 182-11).) Dr. Van Mol appears to promote fringe theories about gender-affirming care. (Ex. 284, 5/6/22 email from Van Mol to Weida (ECF 182-21) (sharing online articles about "financing the [transgender] movement and its tactics" including "Who Are the Rich, White Men Institutionalizing Transgender Ideology"); Ex. 285, 5/7/22 email from Van Mol to

Weida, Brackett and Pickle (ECF 182-22) (sharing additional online articles purporting to establish "the connection to big pharma/biotech/philanthropy profiteering in the clothes of being rights advocates").)

AHCA also retained Dr. Miriam Grossman as a consultant to assist with the GAPMS process. (ECF 120-6, Brackett Feb. 8 Dep. at 104:6-20, 111:4-11.) Dr. Grossman is a psychiatrist and transgender denier who "currently focuses on gender-confused young people and their parents" and "believes that every child is born in the right body." (Ex. 32, Grossman Biography (ECF 175-32).) She was very eager to support Defendants' efforts, as well as other similar restrictions. (*See, e.g.*, Ex. 334 7/7/22 Grossman email (ECF 183-38) (telling Dr. Van Mol before the July 8, 2022 hearing on the Challenged Exclusion that she "[c]an't wait to watch you take [AAP] apart Andre"); Ex. 307, 7/10/22 Grossman email (ECF 183-9) (after the hearing, stating that she "loved how [the people speaking in favor of the regulation] cheered each time de Santis was mentioned" and expressed her eagerness to see similar measures enacted in other states).)

It is no surprise then, that the so-called "experts" that AHCA retained to complete assessments to include in the GAPMS Report have no expertise in the field and have been shown to be unreliable or biased.

Romina Brignardello-Petersen. Despite claiming to have "no research interests in medical care for transgender youth," Dr. Brignardello-Peterson conducts

research for an organization (SEGM) that opposes gender-affirming care. (*See* Ex. 324, Yale Comment, at 8 (ECF 183-27).) That organization (SEGM) "is actually an activist group that opposes standard medical care for gender dysphoria" and is known for "present[ing] a cherry-picked collection of studies and narrative content that is full of scientific errors." (*Id.*, at 8-9.)

James Cantor. Dr. Cantor is a psychologist who has never diagnosed a child or adolescent with gender dysphoria nor treated a child or adolescent for the condition. *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1142-43 (M.D. Ala. 2022) (giving "his testimony regarding the treatment of gender dysphoria in minors very little weight").

Quentin Van Meter. Dr. Van Meter is a pediatric endocrinologist who has never provided treatment for gender dysphoria, (ECF 144-3, Van Meter Dep. at 37:13-25), nor conducted any original, peer-reviewed research on gender identity, transgender people, or gender dysphoria. (*Id.* at 28:6-23.) The Past President of American College of Pediatricians,[30] he believes that being transgender is a choice

[30] The American College of Pediatricians ("ACPeds"), a Florida-headquartered group to which several of Defendants' experts and consultants belong (including Dr. Van Meter, Dr. Van Mol, Dr. Zanga, Dr. Hruz, and Michelle Cretella) is well-known for pushing anti-LGBTQ policies across the country and internationally. ACPeds was founded by "dissenting members of the AAP" who "disagree[d] with the AAP's point of view on gay parenting" and their "pro-homosexual stance," according to founding member Dr. Joseph Zanga. (ECF 117; *see also* ECF 112.) Since that time, ACPeds has campaigned widely against same-sex attraction (ECF 116 (claiming that "defenders and promoters of

and "is not normal," (*id*. at 197:24-198:2, 191:25-192:2), and considers gender affirmation to be "medical abuse." (*Id*. at 186:12-15.) (*See generally* ECF No. 144, Memo. in Support of Mot. to Exclude Expert Testimony of Dr. Quentin Van Meter.)

Patrick Lappert. Dr. Lappert, a retired surgeon, concedes that he has never provided and is not an expert in gender-affirming care. (*See* ECF 127-5, Lappert Dep. at 151, 168; ECF 127-4, *Brandt v. Rutledge* Trial Tr. at 1042:13-15.) He has characterized surgical treatment for gender dysphoria as an "intentional mutilation," (ECF 127-5, Lappert Dep. at 59-60), and "diabolical in every sense of the word." (*Id*. at 464-65; ECF 127-10 (Lifesite article).) *See also Kadel v. Folwell*, Case No. 1:19cv272, 2022 WL 3226731, *12 (M.D.N.C. Aug. 10, 2022) (finding "evidence that calls Dr. Lappert's "bias and credibility into serious question"). (*See generally* ECF 127, Mot. to Partially Exclude Expert Testimony of Dr. Patrick W. Lappert.)

G. Kevin Donovan. Dr. Donovan, a bioethicist and pediatric gastroenterologist, has never provided an ethical consult regarding the care of a transgender patient, has never treated a transgender patient, and is categorically

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homosexuality try to cover up the scientifically documented serious promiscuity...and psychological and medical illnesses associated with the lifestyle")), and even allege that "divorce and single parenting" are "harmful to children." (ECF 118.) Further, ACPeds has published official position statements endorsing conversion therapy for homosexual youth. (ECF 111; *see also,* ECF 116.) ACPeds founder, and Defendants' expert witness Dr. Zanga, has said "a child can no more make him or herself someone of the opposite sex than they could become a chimpanzee." (ECF 105.)

opposed to any gender-affirming medical treatment. (Br. Ex. 3, Donovan Dep. at 128:15-130:8, 118:6-120:14.) Despite proffering Donovan as an expert in their Rule 26(a)(2) disclosures, Defendants have elected not to call him as an expert, or even as a fact witness at trial. (ECF 197-2.)

The additional individuals that AHCA retained to serve as expert witnesses for this case are equally unqualified and unreliable. Like the consultants hired during the GAPMS process, their opposition to gender-affirming care is not based on the scientific and medical evidence, but rather their ideological views about sex and gender. (*See generally* ECF 136, Mot. to Exclude Expert Testimony of Dr. Paul W. Hruz; ECF 133, Mot. to Exclude Expert Testimony of Michael Laidlaw; ECF 119, Mot. to Exclude Expert Testimony of Sophie Scott, Ph.D.; ECF 138, 139, Mot. to Exclude Expert Testimony of Dr. Kristopher Kaliebe and Memo. in Support; ECF 142, Mot. to Exclude Expert Testimony of Joseph Zanga, M.D.)

In sum, a sober look at the GAPMS factors reveals that when used to treat gender dysphoria, puberty-delaying medication, hormone therapy, and surgery are consistent with generally accepted professional medical standards and are not experimental. Defendants' contrary conclusion is not reasonable.

II. The Challenged Exclusion Violates the EPSDT and Comparability Provisions of the Medicaid Act

A. The EPSDT and Comparability Provisions of the Medicaid Act Are Enforceable Pursuant to 42 U.S.C. § 1983.

The Court should reject Defendants' argument that Plaintiffs do not have a private cause of action to enforce their Medicaid Act claims. (*See* ECF 120, at 28.) For more than 20 years, the Supreme Court has required lower courts to apply a three-prong test to determine whether a statutory provision gives rise to a federal right under 42 U.S.C. § 1983. *See Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002); *Blessing v. Freestone*, 520 U.S. 329 (1997). *Blessing* requires courts to evaluate three elements: first, Congress must intend the provision in question to benefit the plaintiff; second, the right contained in the provision must not be so "vague and amorphous" that its enforcement would strain judicial competence; and third, the statute must unambiguously impose a binding obligation on the state. 520 U.S. at 340-41 (citations omitted). *Gonzaga* clarified the first prong of the test, instructing that the provision in question must contain unambiguous "right- or duty-creating language," as opposed to language with an aggregate, rather than individual, focus. 536 U.S. at 284 n.3; *see also* 42 U.S.C. §§ 1320a(2), (10) (stating congressional intent that provisions of the Social Security Act, of which Medicaid is a part, are privately enforceable).[31]

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[31] Citing *Collins v. City of Harker Heights*, 503 U.S. 115, 119 (1992), Defendants argue that the EPSDT and comparability provisions do not create enforceable rights because § 1983 "does not provide a remedy for abuses that do not violate federal law." (ECF 120 at 28.) *Collins*, which did not involve a federal law, is inapposite. There, the Supreme Court held that even if the allegations in the complaint were true, there was no constitutional violation. 503 U.S. at 125-30. Defendants have made no such argument here, and in fact, this Court has found that if Defendants'

Blessing also instructs plaintiffs to plead their complaints in "manageable analytic bites" and courts to determine whether "each separate claim" satisfies the test. *Blessing*, 520 U.S. at 342; *id*. at 340. Here, Count III of Plaintiffs' complaint alleges that the Challenged Exclusion violates the EPSDT provisions, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r)(5), and 1396a(a)(43)(C), and Count IV alleges that the Challenged Exclusion violates the comparability requirements, 42 U.S.C. § 1396a(a)(10)(B). (*See* ECF 1, Compl., at ¶¶ 275-80.)

Every federal appellate court to have considered whether the EPSDT provisions are enforceable by Medicaid beneficiaries through section 1983 has applied the three-prong test and concluded that they are. *See S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 602-07 (5th Cir. 2004); *Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs.*, 293 F.3d 472, 477-79 (8th Cir. 2002); *Miller v. Whitburn*, 10 F.3d 1315, 1319-20 (7th Cir. 1993). *See also Waskul v. Washtenaw Co. Cmty. Mental Health,* 979 F.3d 426, 445-48 (6th Cir. 2020) (finding § 1396a(a)(10)(A) enforceable in case involving coverage of services other than EPSDT); *Bontrager v. Ind. Fam. & Soc. Servs. Admin,* 697 F.3d 604, 606-07 (7th Cir. 2012) (same); *Watson v. Weeks*, 436 F.3d 1152, 1159-62 (9th Cir. 2006) (same).

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determination that the excluded treatments are experimental was unreasonable, Defendants have violated the Medicaid Act. (ECF 64, at 3-6.)

Defendants' argument that these courts failed to grasp the nature of a federal right under *Gonzaga* is unfounded. (*See* ECF 120, at 28.) Take, for example, *S.D. ex rel. Dickson v. Hood*. There, a teenage Medicaid beneficiary with spina bifida alleged that Louisiana's refusal to cover incontinence supplies necessary to help treat his condition violated the EPSDT provisions. Assessing the first *Blessing*/*Gonzaga* prong, the Fifth Circuit concluded that section 1396a(a)(10)(A) – which requires that the state plan "must provide for making medical assistance available, including at least the care and services listed in paragraph (1) through (5), (17) and (21) of section 1396d(a) of this title, to all individuals" who meet the eligibility criteria – contains "precisely the sort of 'rights-creating' language identified in *Gonzaga* as critical to demonstrating a congressional intent to establish a new right." *S.D.*, 391 F.3d at 603 (explaining that EPSDT services are listed in § 1396d(a)(4), which then refers to § 1396d(r)). The Court also found that the EPSDT provisions do not have an aggregate focus but rather are "'concerned with whether the needs of [particular individuals] have been satisfied.'" *Id*. at 604 (quoting *Gonzaga*, 536 U.S. at 275). Turning to the second prong of the test, the Court found that enforcement of the EPSDT provisions does not "'strain judicial competence;' it is the sort of work in which courts engage

every day." *S.D.*, 391 F.3d at 605.[32] As for the third prong, the Court concluded that the provisions impose binding requirements on participating states. *Id*. at 605-06.

Similarly, two circuits have addressed whether the comparability provision is enforceable through section 1983, and both concluded that it is.[33] *See Waskul*, 979 F.3d at 446-48; *Davis v. Shah*, 821 F.3d 231, 255 n.12 (2d Cir. 2016).[34] In *Waskul*, the Sixth Circuit found that the comparability provision – which requires that "the medical assistance made available to any individual described" must "not be less in

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[32] While Defendants claim otherwise (*see* ECF 120 at 30), district courts are clearly capable of determining whether particular health care services are "necessary" under section 1396d(r)(5). *See, e.g.*, *K.G.*, 981 F.Supp.2d at 1291-92 (concluding that applied behavioral analysis therapy "is necessary to correct or ameliorate the condition of Autism Spectrum Disorder" and AHCA violated EPSDT by excluding coverage of the therapy for beneficiaries under age 21 with ASD); *C.R. ex rel. Reed v. Noggle*, 559 F. Supp. 3d 1323, 1337 (N.D. Ga. 2021) (finding state denied plaintiff speech and feeding therapy services "that were medically necessary to ameliorate her conditions" in violation of EPSDT).

[33] In *Harris v. James*, 127 F.3d 993 (11th Cir. 1997), the Eleventh Circuit held that a federal regulation, standing alone, cannot create an enforceable right under section 1983. *Id.* at 1008. In reaching its decision, the Court looked at whether a Medicaid regulation requiring transportation to and from providers could be reasonably understood to be part of the content of various statutory provisions, including the comparability provision, and concluded that it could not. *Id*. at 1011-12. In reaching its decision, the Court made clear that it was not deciding the issue of whether the comparability provision could give rise to any other federal right. *Id*. at 1011. As such, *Harris* has no bearing on the issue before this Court. *See Doe v. Chiles*, 136 F.3d 709, 714-15 (11th Cir. 1998) (discussing limits of *Harris* holding).

[34] Following similar reasoning, a number of district courts have held that the comparability provision is enforceable under Section 1983. *See, e.g.*, *Cruz v. Zucker*, 116 F.Supp.3d 332, 345-46 (S.D.N.Y. 2015); *Women's Hosp. Found. v. Townsend*, 2008 WL 2743284 (M.D. La. July 10, 2008); *Michelle P. v. Holsinger*, 356 F.Supp.2d 763, 767-68 (E.D. Ky. 2005).

amount, duration, or scope than the medical assistance made available to any other such individual," 42 U.S.C. § 1396a(a)(10)(B) – contains "the kind of individually focused terminology that unambiguously confers an individual entitlement under the law." *Id.* at 447 (cleaned up). Turning to the second and third *Blessing* factors, the Court determined that the provision is "amenable to judicial remedy," as it "sets forth criteria for determining whether . . . services are equitably provided," and that the provision is "couched in mandatory rather than precatory language." *Id.* at 448 (cleaned up).

As this case law demonstrates, the EPSDT and comparability provisions create individual federal rights for Medicaid beneficiaries. Thus, these provisions are "presumptively enforceable by § 1983." *See Gonzaga Univ.*, 536 U.S. at 284. The State may rebut this presumption by making the "difficult showing" that Congress expressly prohibited reliance on section 1983 or that it provided a comprehensive remedial scheme intended to preclude individual suits. *See Blessing*, 520 U.S. at 346. Congress has not done so here. *See Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 521-22 ("The Medicaid Act contains no . . . provision for private judicial or administrative enforcement . . . generalized powers . . . to audit and cut off federal funds [are] insufficient to foreclose reliance on § 1983 to vindicate federal rights."); *see also City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113, 121-22 (2005)

(Scalia, J.) (citing *Wilder* and listing Medicaid as a statute whose enforcement is not foreclosed).

Finally, contrary to Defendants' argument, *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320 (2015), does not implicate Plaintiffs' ability to enforce Medicaid's EPSDT and comparability provisions pursuant to section 1983. *See* Defs.' Br. at 29-30. *Armstrong* concerned a Medicaid payment provision (not EPSDT or comparability) that health care providers (not Medicaid enrollees) were seeking to enforce under the Supremacy Clause (not section 1983). *See* 575 U.S. at 323-34. Unlike the provisions at issue in this case, the provision at issue in *Armstrong*, 42 U.S.C. § 1396a(a)(30)(A), had been found unenforceable pursuant to section 1983 by most courts, including this one. *See Fl. Pharmacy Ass'n v. Cook*, 17 F.Supp.2d 1293 (N.D. Fla. 1998). The relevant reasoning from *Armstrong* did not reflect a majority of the Court, but only a plurality, and it did not involve and certainly did not overrule the section 1983 enforcement test. *See, e.g.*, *BT Bourbonnais Care, LLC v. Norwood*, 866 F.3d 815, 820 (7th Cir. 2017) (concluding *Armstrong* does not preclude plaintiffs from enforcing the Medicaid Act through section 1983); *Legacy Cmty. Health Servs., Inc. v. Smith*, 881 F.3d 358, 373 (5th Cir. 2018), *as revised* (Feb. 1, 2018) (same); *see also*, *e.g.*, *O.B. v. Norwood*, 170 F. Supp. 3d 1186, 1090-93 (N.D. Ill. 2016) (holding EPSDT provisions enforceable under section 1983 and distinguishing *Armstrong*); *William v. Horten*, 2016 WL 6582682

(N.D. Ga. Nov. 7, 2016) (same, collecting cases); *J.E. v. Wong*, 125 F. Supp. 3d 1099, 1105-08 (D. Haw. 2015) (same).

The Court should hold that Plaintiffs have the right to enforce the EPSDT and comparability provisions of the Medicaid Act.

B. The Challenged Exclusion Violates the Medicaid Act's EPSDT Requirements.

As described in detail above, puberty delaying medications, hormone therapy, and surgery are not experimental. As such, Florida must cover the services when they are medically necessary for beneficiaries under age 21.

The fundamental purpose of the EPSDT requirements is to ensure that Medicaid recipients under age 21 receive the "health care they need when they need it." *M.H. v. Berry*, No. 15-cv-1427, 2021 WL 1192938, *6 (N.D. Ga. March 29, 2021) (quoting Ex. 62, Ctrs. for Medicare & Medicaid Servs., *EPSDT – A Guide for States* (2014) (ECF 176-22)). Specifically, the EPSDT provisions require each state Medicaid program to cover any service that is allowable under § 1396d(a) if "necessary . . . to correct or ameliorate" illnesses or conditions regardless of whether the state covers the service for adults. 42 U.S.C. §§ 1396d(r)(5), 1396a(a)(10)(A), 1396d(a)(4)(B); *see, e.g., Moore ex rel. Moore v.* Reese, 637 F.3d 1220, 1233-34 (11th Cir. 2011); *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 589-593 (5th Cir. 2004). "The EPSDT obligation is thus extremely broad." *Katie A., ex rel. Ludin v. L.A. County*, 481 F. 3d 1150, 1154 (9th Cir. 2007); *see also Smith v. Benson*, 703 F.

Supp.2d 1262, 1269-70 ("the Centers for Medicare and Medicaid Services ("CMS"), has made the broad mandate of EPSDT program abundantly clear."). And "there is a very strong inference to be inclusive rather than exclusive" when determining the meaning of "correct or ameliorate." *Ekloff v. Rodgers*, 443 F.Supp.2d 1173, 1180 (D. Ariz. 2006). Further, states must take the proactive step of ensuring that services determined to be medically necessary for a particular beneficiary are actually arranged for. 42 U.S.C. § 1396a(a)(43)(C); *Katie A.*, 481 F. 3d at 1158-59.

Here, the EPSDT provisions require Defendants to cover the gender-affirming services that are the subject of the Challenged Exclusion. Puberty-delaying medications, hormone therapy, and surgery fall within the scope of benefits listed in § 1396d(a). *See* 42 U.S.C. § 1396d(a)(1) (inpatient hospital services), (2)(A) (outpatient hospital services), (5)(A) (physicians' services), (12) (prescribed drugs).[35] And, for many transgender young people, the services are "necessary . . . to correct or ameliorate" their gender dysphoria. *Id.* § 1396d(r)(5).

[35] While the Medicaid Act allows states to place certain limited restrictions on coverage of prescribed drugs for adults, *see* section III below, EPSDT requires coverage of all "prescribed drugs" for beneficiaries under age 21 when medically necessary. *See* 42 C.F.R. § 440.120 (defining prescribed drugs). (*See also* Ex. 63, Ctrs. for Medicare & Medicaid Servs., *CMCS Informational Bulletin* 2 (July 21, 2022) (ECF 176-23) (noting that "any prescribed drug covered under Medicaid EPSDT requirements is eligible for federal financial participation (FFP) regardless of the applicability of [42 U.S.C. 1396r-8]).

As described in detail above, there is broad consensus within the medical community that puberty-delaying medications (GnRHa), hormone therapy, and surgery may be medically necessary for transgender adolescents and young adults, based on their individual needs. *See* Facts § V, *supra.* Prior to implementing the Challenged Exclusion, AHCA reached the same conclusion, covering each of these services for a significant number of transgender Medicaid beneficiaries under age 21. (*See* Ex. 317, AHCA FY17-21 Gender Affirming Care Coverage Data Charts.) Indeed, the agency covered puberty delaying medications for K.F. and S.D. (ECF 120-6 (Brackett Feb.8 Dep.) at 247:9-247:20; ECF 11-8, Doe ¶ 19; ECF 11-9, Ladue ¶ 20), and hormone therapy for Mr. Rothstein. (ECF 120-6 (Brackett Feb.8 Dep.) at 246:15-247:6; ECF 11-7, Rothstein ¶ 12.)[36] While AHCA's policy regarding coverage of the services has changed, Plaintiffs' medical need for the services and the general consensus of the medical community regarding the services have not. *See* Statement of Facts §§ I(A), IV(B)-(C), *supra*.

Given that the services are not experimental, *see* Statement of Facts § IV(C), *supra*, AHCA cannot escape its obligation to cover them when necessary for a particular individual who is under age 21, including for Plaintiffs K.F., S.D., and Mr. Rothstein. *See S.D.,* 391 F.3d at 592 ("[T]he plain words of the [Medicaid Act] and

[36] AHCA also prior authorized coverage of a mastectomy for Mr. Rothstein. (*See* Ex. 319, List of Surgery Requests (showing Rothstein mastectomy approved).)

the legislative history make evident that Congress intended that the health care, services, treatment and other measures that must be provided under the EPSDT program be determined by reference to federal law, not state preferences.").

C. The Challenged Exclusion Violates the Medicaid Act's Comparability Requirement.

The Medicaid Act requires AHCA to ensure that the "medical assistance made available to any [categorically needy] individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240. Federal regulations make clear that states "may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c).

Courts repeatedly hold that the comparability requirement "prohibits discrimination among individuals with the same medical needs stemming from different medical conditions." *Davis v. Shah*, 821 F.3d 231, 258 (2d Cir. 2016) (finding state policy covering prescription orthopedic footwear and compression stockings for beneficiaries with certain listed conditions, but not for those with equal need for the services due to other conditions, violated comparability requirement); *see also White v. Beal*, 555 F.2d 1146, 1148 (3d Cir. 1977); *Cota v. Maxwell-Jolly*, 688 F. Supp. 2d 980, 993 (N.D. Cal. 2010).

With the Challenged Exclusion, however, AHCA is doing just that. For example, for many transgender people, various surgical procedures are medically necessary to treat their gender dysphoria. *See* Facts § IV(C)(3), *supra*. While AHCA refuses to cover these surgeries when necessary to treat gender dysphoria, the agency covers the same surgeries when necessary to treat other conditions. (*See* Ex. 1, Defs' Admissions Nos. 8-12 (ECF 175-1); Ex. 4, Pltfs' Reqs for Admissions at Definitions ¶ 13 (ECF 175-4).) Multiple federal courts have held that such a policy violates the comparability requirement by discriminating on the basis of diagnosis.[37] *Flack v. Wis. Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1019 (W.D. Wis. 2019); *Fain v. Crouch*, 618 F.Supp.3d 313 (S.D. W. Va. 2022), *appeal filed*, No. 22-1927, 2022 WL 3051015 (4th Cir. 2022), *reh'g en banc granted*, 2023 WL 2908815 (4th Cir. Apr. 12, 2023).

The same reasoning applies to the categorical exclusion of hormone therapy, which is medically necessary for many transgender people. *See* Statement of Facts § IV(C)(2), *supra*. For example, pursuant to the Challenged Exclusion, AHCA does not cover testosterone or estrogen when necessary to treat gender dysphoria but

[37] Defendants argue that there is no "equivalence between" a mastectomy performed to treat gender dysphoria and a mastectomy performed to treat breast cancer because in the breast cancer context, "diseased breast tissue is removed from the body." (ECF 120 at 28.) Defendants do not explain why that distinction is meaningful and ignore that a mastectomy is routinely performed (and covered by AHCA) in patients whose breast tissue is not "diseased." (*See* Ex. 13, Schechter Rebuttal ¶ 14, 24 (ECF 175-13).)

covers the same prescription drugs when necessary to treat other conditions. (*See* Ex. 1, Defs' Admissions ¶¶ No. 8 (ECF 175-1); Ex. 4, Pltfs' Reqs for Admissions at Definitions ¶ 13 (ECF 175-4).) While Defendants argue that these uses are not equivalent for purposes of Medicaid coverage, (*see* ECF 120, Defs.' Mot. for Summ. J. and Mem. of Law, at 28), the prescription drug provision of the Medicaid Act indicates otherwise. The statute requires states to cover all FDA-approved drugs when they are prescribed for a "medically accepted indication," subject to certain limited exceptions not at issue here.[38] 42 U.S.C. §§ 1396r-8(k)(2), 1396r-8(d)(1)(B). (*See* Ex. 63, Ctrs. for Medicare & Medicaid Servs., *CMCS Informational Bulletin* 2 (July 21, 2022) (ECF 176-23) ("covered outpatient drugs that are prescribed for a medically accepted indication must be covered" by Medicaid); *see also Edmonds v. Levine,* 417 F. Supp. 2d 1323, 1338 (S.D. Fla. 2006) (Congress designed a "statutory scheme, which sets forth very specific criteria and means by which a state may exclude coverage for specific drugs or use of such drugs"). A "medically accepted indication" is a use that is FDA-approved or "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the Medicaid Act. 42 U.S.C. § 1396r-8(k)(6); *see also id*. § 1396r-8(g)(1)(B)(i) (listing three compendia, one of which is DRUGDEX). Thus, for purposes of determining

[38] Conversely, nothing in the Medicaid Act prohibits states from covering FDA-approved drugs when they are prescribed for a use that is not FDA-approved or supported by citation in a compendium.

medical need for a prescription drug under the Medicaid Act, a use that is FDA-approved stands on equal footing with a use that is supported by citation in a compendium. *See Edmonds v. Levine*, 417 F. Supp. 2d at 1337 (holding that AHCA cannot "substitute its own judgment for that of Congress" and deny coverage for uses of a prescription drug that are supported by citation in a compendium).

Here, citations in DRUGDEX support the use of various forms of testosterone (testosterone, testosterone cypionate, testosterone enanthate, and testosterone undecanoate) and estrogen (estradiol, estradiol cypionate, estradiol valerate) to treat gender dysphoria. (Ex. 25, DRUGDEX, Testosterone, at 18-21, 23-26, 29-36 (ECF 175-25); Ex. 26, DRUGDEX, Estradiol, at 23-25, 27-28, 34-35 (ECF 175-26).) *See Dobson v. Sec'y of Health & Hum. Servs.*, 2022 WL 424813 at *7 (11th Cir. 2022) (interpreting the phrase "supported by one or more citations" in § 1396r-8(k)(6) to mean a citation "tend[s] to show or help[s] prove the efficacy and safety of the prescribed off-label use"). But while that use is on par with any FDA-approved use for purposes of Medicaid coverage, Florida only covers testosterone for FDA-approved indications. (*See* Ex. 27, AHCA, *Prior Authorization Criteria, Testosterone (non-injectable formulations)* (revised March 13, 2023) (ECF 175-27) (limiting coverage to beneficiaries with hypogonadism); Ex. 25, DRUGDEX, Testosterone, at 10-11 (listing the FDA-approved indication as hypogonadism).) What is more, as a matter of practice, AHCA covers testosterone cypionate,

testosterone enanthate, and estrogen for ***absolutely any use*** – whether the use is FDA-approved, supported by citation in a compendium, or not – other than to treat gender dysphoria. (*See* AHCA, Preferred Drug List Effective Jan. 1, 2023, *available at* https://ahca.myflorida.com/content/download/8681/file/ PDL.pdf (indicating that AHCA does not require prior authorization for testosterone cypionate, testosterone enanthate, or any form of estradiol); Ex. 28, Agency Responses to Plaintiffs' Questions (3/1/2023) (ECF 175-28) (indicating that for drugs that do not require prior authorization, AHCA "does not verify the diagnosis" prior to providing coverage).) Thus, AHCA is excluding coverage for only one "medically accepted indication" (gender dysphoria) and providing coverage for every other indication, even those that are not medically accepted. By failing to provide "comparable services for individuals with comparable needs," AHCA is plainly violating the Medicaid Act. *Cota*, 688 F.Supp.2d at 993.

III. The Challenged Exclusion violates Section 1557 of the Affordable Care Act.

An "important component of the ACA's effort to ensure the prompt and effective provision of health care to all individuals . . . is the statute's express anti-discrimination mandate" in Section 1557. *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F.Supp.3d 1, 11 (D.D.C. 2020), *appeal dismissed*, No. 20-5331, 2021 WL 5537747 (D.C. Cir. Nov. 19, 2021). Accordingly, Section 1557 requires, in relevant part, that "[a]n individual shall not, on the ground

prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), … be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). It is "an affirmative obligation not to discriminate in the provision of health care." *Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 955 (9th Cir. 2020).

"To state a claim under this provision, a plaintiff is required to show that he or she (1) was a member of a protected class, (2) qualified for the benefit or program at issue, (3) suffered an adverse action, and (4) the adverse action gave rise to an inference of discrimination." *Griffin v. Gen. Elec. Co.*, 752 F. App'x 947, 949 (11th Cir. 2019). Plaintiffs address each element in turn.

A. The Challenged Exclusion Discriminates Against Plaintiffs Based on Sex.

As noted above, Section 1557 prohibits discrimination "the ground prohibited under … title IX." 42 U.S.C. § 18116(a). Under Title IX, "[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under … [a] program or activity receiving Federal financial assistance." 20 U.S.C. § 1681.

Here, the Challenged Exclusion discriminates based on sex in three distinct ways. First, the Challenged Exclusion speaks in explicit gendered terms and *facially discriminates* based on sex. Second, the Challenged Exclusion discriminates based

on sex stereotypes relating to a person's sex assigned at birth. And third, the Challenged Exclusion discriminates based on sex because it discriminates based on transgender status.

1. The Challenged Exclusion facially discriminates based on sex.

On its face, the Challenged Exclusion discriminates based on sex. The Challenged Exclusion explicitly precludes Medicaid coverage for "services for the treatment of *gender* dysphoria," including "*[s]ex* reassignment surgeries" and any "procedures that alter primary or secondary *sexual* characteristics." Fla. Admin. Code. R. 59G-1.050(7)(2022). "A facial inquiry is what it sounds like: a review of the language of the policy to see whether it is facially neutral or deals in explicitly racial or gendered terms.'" *Kadel v. Folwell*, 2022 WL 3226731, at *18 (M.D.N.C. Aug. 10, 2022) (cleaned up).

Here, one cannot "'try writing out instructions' for which treatments are excluded 'without using the word[] … sex (or some synonym).'" *Kadel*, 2022 WL 3226731, at *19 (quoting *Bostock*, 140 S. Ct. at 1746). "It can't be done." *Bostock*, 140 S. Ct. at 1746. It is impossible to determine whether a particular treatment is for "*gender* dysphoria,"[39] leads to ""*[s]ex* reassignment," or "alter[s] primary or secondary *sexual* characteristics"—and thus, whether the Exclusion applies—

[39] Gender dysphoria necessarily considers an individual's sex assigned at birth. *See* Statement of Facts § III(A)-(B)

without comparing the member's sex assigned at birth before the treatment to how it might be impacted by the treatment. *Kadel*, 2022 WL 3226731, at *19. Moreover, when "the trigger for application of the Exclusion and a denial of coverage [is] a diagnosis of 'gender dysphoria,'" the Exclusion facially discriminates based on sex. *C.P. by & through Pritchard v. Blue Cross Blue Shield of Illinois*, 2022 WL 17788148, at *6 (W.D. Wash. Dec. 19, 2022). "Gender dysphoria cannot be understood without referencing sex or a synonym." *Kadel v. Folwell*, 2022 WL 11166311, at *4 (M.D.N.C. Oct. 19, 2022).

This result is supported by a barrage of case law looking at similar exclusions. *See*, *e.g.*, *Fain v. Crouch*, 618 F.Supp.3d 313, 327 (S.D.W. Va. 2022); *Fletcher v. Alaska*, 443 F.Supp.3d 1024, 1027, 1030 (D. Alaska 2020); *Flack v. Wisconsin Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1019-22 (W.D. Wis. 2019); *Boyden v. Conlin*, 341 F.Supp.3d 979, 1002-03 (W.D. Wis. 2018). *Cf. Brandt by & through Brandt v. Rutledge*, 2022 WL 3652745, at *2 (8th Cir. Aug. 25, 2022) (finding a state law banning gender-affirming care for minors discriminates on the basis of sex).

Take *Kadel v. Folwell*, for example. In *Kadel*, the plan at issue "exclude[d] "[t]reatment or studies leading to or in connection with *sex* changes or modifications and related care." 2022 WL 3226731, at *19 (emphasis in original). As such, the court concluded that the plan's exclusion "facially discriminate[s] based on sex" and

"necessarily rests on a sex classification because it cannot be stated or effectuated without referencing sex." *Kadel*, 2022 WL 3226731, at *19.

Or *Fletcher v. Alaska*, 443 F.Supp.3d 1024 (D. Alaska 2020), for example. In *Fletcher*, the Court concluded that the "defendant's policy of excluding coverage for medically necessary surgery such as vaginoplasty and mammoplasty for employees, such a[s] plaintiff, whose natal sex is male while providing coverage for such medically necessary surgery for employees whose natal sex is female is discriminatory on its face and is direct evidence of sex discrimination." *Id.* at 1030. The court found that a health plan that covers one "surgery if it reaffirms an individual's natal sex, but denies coverage for the same surgery if it diverges from an individual's natal sex … is discrimination because of sex and makes … [the] policy … facially discriminatory." *Id.*

The court in *C.P.* came to a similar conclusion. There, the health plan excluded coverage "for treatment, drugs, therapy, counseling services and supplies for, or leading to, gender reassignment surgery." *C.P.*, 2022 WL 17788148, at *2. The court found that such policy constituted sex discrimination under Section 1557. *Id.* at *6.

The Eleventh Circuit's decision in *Adams by & through Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791 (11th Cir. 2022) (en banc), does not affect this straightforward analysis. In *Adams*, the Eleventh Circuit was concerned not with

whether the policy at issue discriminated based on sex but "whether discrimination based on biological sex necessarily entails discrimination based on transgender status." *Id.* at 809. Indeed, in *Adams*, the Eleventh Circuit found that a "bathroom policy requir[ing] 'biological boys' and 'biological girls'—in reference to their sex determined at birth—to use either bathrooms that correspond to their biological sex or sex-neutral bathrooms," *id.* at 801, facially "classifie[d] on the basis of biological sex." *Id.* at 803.[40]

Because a Medicaid beneficiary's sex (however, one defines it) plays "an unmistakable and impermissible role in the" decision to deny Medicaid coverage under the Challenged Exclusion, the Exclusion facially discriminates based on sex. *Hammons v. Univ. of Maryland Med. Sys. Corp.*, No. CV DKC 20-2088, 2023 WL 121741, at *8 (D. Md. Jan. 6, 2023) (citing *Kadel*, 2022 WL 3226731, at *28).

2. The Exclusion discriminates based on sex because it discriminates based on sex stereotypes.

The Challenged Exclusion also discriminates based on sex because it is premised on the belief that a person's *sexual* characteristics must be aligned with the person's *sex* assigned at birth. In other words, "the Exclusion implicates sex

[40] Section 1557 only incorporated the grounds and enforcement mechanisms of Title IX, not any of its exemptions or carve-outs. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F.Supp.3d 1, 43 (D.D.C. 2020). Thus, unlike Title IX, Section 1557 lacks express statutory and regulatory carve outs. *Adams* firmly recognizes this textual distinction. 57 F.4th at 811.

stereotyping by limiting the availability of medical transitioning, if not rendering it economically infeasible, thus requiring transgender individuals to maintain the physical characteristics of their natal sex." *Boyden*, 341 F. Supp. 3d at 997.

But excluding coverage for gender-affirming medical care because it "*alter[s]* primary or secondary *sexual* characteristics," Fla. Admin. Code R. 59G-1.050(7)(a)(4), "entrenches" the sex-stereotyped "belief that transgender individuals must preserve the genitalia and other physical attributes of their [sex assigned at birth] sex over not just personal preference, but specific medical and psychological recommendations to the contrary." *Boyden*, 341 F.Supp.3d at 997. This is a "form of sex stereotyping where an individual is required effectively to maintain his or her natal sex characteristics." *Id.*; *see also Flack*, 328 F.Supp.3d at 951 ("the Challenged Exclusion feeds into sex stereotypes by requiring all transgender individuals … to keep … sex characteristics consistent with their natal sex no matter how painful and disorienting it may prove for some"). It "is textbook sex discrimination." *Kadel*, 2022 WL 3226731, at *19.

Accordingly, courts throughout the country have found similar discrimination against transgender people to be rooted in impermissible sex stereotyping. *See*, *e.g.*, *Kadel v. Folwell*, 446 F.Supp.3d 1, 14 (M.D.N.C. 2020) (exclusion "tethers Plaintiffs to sex stereotypes which, as a matter of medical necessity, they seek to reject"); *Toomey v. Arizona*, 2019 WL 7172144, at *6 (D. Ariz. Dec. 23, 2019)

("Discrimination based on the incongruence between natal sex and gender identity—which transgender individuals, by definition, experience and display—implicates … gender stereotyping.").

This principle is also in keeping with longstanding Eleventh Circuit precedent that "[a]ll persons, whether transgender or not, are protected from discrimination on the basis of [a sex stereotype]." *Adams,* 57 F.4th at 813 (quoting *Glenn v. Brumby,* 663 F.3d 1312, 1318-19 (11th Cir. 2011)). *Adams* does not change this result. In *Adams*, the Court found the sex stereotyping claim not viable because "bathroom policy does not depend in any way on how students act or identify" and the "bathroom policy separates bathrooms based on biological sex, which is not a stereotype." *Adams*, 57 F.4th at 809. Here, by contrast, the Challenged Exclusion hinges on prohibiting coverage for procedures that "*alter* primary or secondary *sexual* characteristics," Fla. Admin. Code R. 59G-1.050(7)(a)(4), and "services for the treatment of *gender* dysphoria," Fla. Admin. Code, *id.* at (7)(a), which by definition refers to the psychological distress that results from an *incongruence between one's sex assigned at birth and one's gender identity*. (See Ex. 7, Karasic ¶¶ 24-25 (ECF 175-7); Ex. 8, Olson-Kennedy at 10-11 ¶¶ 7-9 (ECF 175-8); Ex. 9, Shumer ¶ 36 (ECF 175-9); Ex. 10, Schechter ¶ ¶ 20-21 (ECF 175-10); *see also* Ex. 33, DSM 5 Gender Dysphoria (ECF 175-33).)

3. The Exclusion discriminates based on sex because it discriminates based on transgender status.

In *Bostock*, the Supreme Court explained that "it is impossible to discriminate against a person for being … transgender without discriminating against that individual based on sex." 140 S.Ct. at 1741. And it is settled law that a policy that discriminates based on conduct or characteristics that either define or are closely correlated with a particular group facially discriminates against that group. *See*, *e.g.*, *Christian Legal Soc'y v. Martinez*, 561 U.S. 661, 689 (2010) (holding that a club's exclusion of people because they engaged in same-sex conduct was discrimination based on sexual orientation); *Lawrence v. Texas*, 539 U.S. 558, 583 (2003) (O'Connor, J., concurring) (stating that a law targeting conduct "closely correlated with being homosexual" is "directed toward gay persons as a class").

Here, not only is gender dysphoria exclusively suffered by transgender people, *see* Statement of Facts § III(A)-(B), *supra*; *Fain*, 618 F. Supp. 3d at 325 ("[A] person cannot suffer from gender dysphoria without identifying as transgender."); *see also C.P.*, 2022 WL 17788148, at *6; *Kadel II*, 2022 WL 11166311, at *4, but the medical care singled out by the Exclusion—treatment to "*alter* primary or secondary *sexual* characteristics," Fla. Admin. Code R. 59G-1.050(7)(a)(4)—is medical care that only transgender people need or seek. *See Fain*, 618 F.Supp.3d at 327 ("Only individuals who identify as transgender would seek 'transsexual surgery'"); *Toomey*, 2019 WL 7172144, at *6 (finding that similar

exclusion "singles out transgender individuals for different treatment" because "transgender individuals are the only people who would ever seek gender reassignment surgery"); *Flack*, 328 F.Supp.3d at 950 ("expressly *singles out* and bars a medically necessary *treatment solely for transgender people*" (emphasis added)).

It should therefore come as no surprise that courts have held that "[d]iscrimination against individuals suffering from gender dysphoria is also discrimination based on sex and transgender status." *Kadel*, 2022 WL 3226731, at *20; *C.P.*, 2022 WL 17788148, at *6. Thus, the Challenged Exclusion discriminates based on transgender status and as such, discriminates based on sex.

B. As Medicaid beneficiaries, Plaintiffs qualified for the health program at issue: Medicaid.

Each plaintiff is enrolled in Medicaid and has received coverage for medically necessary gender-affirming medical services. (ECF 120-6, Brackett Feb. 8 Dep. at 243:16-245:10, 246:15-247:6, 247:9-20; ECF 11-6, Dekker ¶ 17; ECF 11-7, Rothstein ¶ 12; ECF 11-8, Doe ¶ 19; ECF 11-9, Ladue ¶ 20.) And lest there be any doubt, Section 1557 unquestionably applies to AHCA, who receives federal financial assistance from HHS. (ECF 197, at 6 ¶ 4.) Indeed, multiple courts have applied Section 1557 to state-administered Medicaid programs. *See, e.g.*, *Fain*, 618 F. Supp. 3d at 331; *Flack*, 328 F.Supp.3d at 949; *Cruz v. Zucker*, 195 F.Supp.3d 554, 571 (S.D.N.Y. 2016).

C. Plaintiffs have suffered an adverse action, that gives rise to an inference of discrimination.

As to the third element, Plaintiffs suffered an "adverse action" due to the Challenged Exclusion. Because of the Challenged Exclusion, Plaintiffs have lost Medicaid coverage for necessary medical treatment recommended by their doctors that would otherwise be covered. (*See* ECF 11-6, Dekker ¶ 23; ECF 11-7, Rothstein ¶¶ 19-20; ECF 11-8, Doe ¶ 29; ECF 11-9, Ladue ¶ 30.) *See also C.P.*, 2022 WL 17788148, at *6.

As to the fourth element, Defendants promulgated the Challenged Exclusion with discriminatory intent to achieve a discriminatory effect. The Challenged Exclusion bans coverage of medically necessary care for the treatment of gender dysphoria, which only transgender persons experience. *See also Kadel*, 2022 WL 3226731, at *20.

Moreover, where the state "intentionally penalizes a person identified as male at birth for . . . actions that it tolerates in [someone] identified as female at birth"—here, pursuing medical intervention to affirm a female identity—"sex plays an unmistakable and impermissible role." *Bostock*, 140 S.Ct. at 1741-42. Put another way, whether coverage is prohibited turns explicitly on a person's sex assigned at birth.

IV. Defendants' Challenged Exclusion Violates Equal Protection.

When government differentiates, as the State has done here, based on sex and/or transgender status, its line-drawing triggers heightened scrutiny.

A. The Challenged Exclusion Classifies Based on Sex.

As articulated above, the Challenged Exclusion (1) *facially discriminates* based on sex; (2) discriminates based on sex stereotypes relating to a person's sex assigned at birth; and (3) discriminates based on sex because it discriminates based on transgender status. *See* Legal Argument § III(A), *supra*.

The fact that one sex is not categorically treated worse than another does not change the fact that the law discriminates based on sex for purposes of equal protection. "[T]he Equal Protection Clause, extending its guarantee to 'any person,' reveals its concern with rights of individuals, not groups." *J.E.B.* v. *Alabama ex rel. T.B.*, 511 U.S. 127, 152 (1994) (Kennedy, J., concurring) (cleaned up); *see also Loving v. Virginia*, 388 U.S. 1, 8 (1967) (rejecting "the notion that the mere 'equal application' of a statute containing racial classifications is enough to remove the classifications from the Fourteenth Amendment's proscription of all invidious racial discriminations"); *Waters v. Ricketts*, 48 F.Supp.3d 1271, 1282 (D. Neb. 2015) ("The 'equal application' of [bans on same-sex marriage] to men and women as a class does not remove them from intermediate scrutiny"), *aff'd on other grounds*, 798 F.3d 682 (8th Cir. 2015).

Defendants have argued that the law does not facially classify on the basis of sex or transgender status, citing the Supreme Court's decision in *Geduldig* v. *Aiello*, 417 U.S. 484 (1974). But Defendants' reliance on *Geduldig* is misplaced for three distinct reasons:

First, the Exclusion explicitly and facially classifies based on sex. *See Fletcher*, 443 F.Supp.3d at 1027, 1030; *see also Whitaker v. Kenosha Unified Sch. Dist. No.1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017). Every person to whom the Challenged Exclusion applies is therefore discriminated against because of sex.

Second, *Geduldig* only held that an exclusion of pregnancy from a disability benefits program with no showing of "pretext" is not *per se* "discrimination against the members of one sex." 417 U.S. at 496 n.20. But "[s]ome activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). Here, the Exclusion was designed to categorically exclude gender-affirming care from coverage—care "which is only sought by transgender individuals." *Brandt v. Rutledge*, 2021 WL 3292057, at *2 (E.D. Ark. Aug. 2, 2021). That is precisely what *Geduldig* and *Bray* prohibit: a pretextual classification designed to effectuate discrimination.

Third, the centrality of gender transition to transgender identity distinguishes this case from *Geduldig*. Unlike the pregnancy exclusion in *Geduldig*, the Exclusion here is based on a characteristic that defines membership in the excluded group. Pregnancy is not the defining characteristic of a woman. Living in accord with one's gender identity rather than birth-assigned sex is the defining characteristic of a transgender person. *See*, *e.g.*, *Glenn*, 663 F.3d at 1316.

Defendants have also argued that that *Adams* held that "sex-based discrimination is discrimination based on biological sex" and that the Exclusion "does not make a distinction based on biological sex." (ECF 120 at 32.) Not so, *see supra*. But even when viewed in that (incorrect) framing, the Exclusion discriminates based on sex. That is because the Exclusion prohibits coverage of procedures that ""*alter* primary or secondary *sexual characteristics*." Fla. Admin. Code R. 59G-1.050(7). Such characteristics are biological.

Defendants further argue that rational basis applies because the Exclusion purportedly discriminates not based on sex, but on "medical diagnosis." (ECF 120 at 32.) But this does not save the Challenged Exclusion, either. Federal courts have rejected Defendants' attempt "to frame the Exclusion as one focused on medical diagnoses, not … gender." *Kadel*, 446 F.Supp.3d at 18. And only transgender people need coverage for "services and treatment for *gender dysphoria*" because

only transgender people are diagnosed with gender dysphoria. *See C.P.*, 2022 WL 17788148, at *6; *Kadel II*, 2022 WL 11166311, at *4; *Fain*, 618 F.Supp.3d at 325.

B. The Challenged Exclusion Classifies Based on Transgender Status and Therefore Independently Triggers Heightened Scrutiny.

As articulated above, the Challenged Exclusion discriminates based on transgender status. *See* Legal Argument § III(A)(3), *supra*. Such discrimination based on transgender status is separately entitled to, at least, heightened scrutiny. *See Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 607 (4th Cir. 2020), as amended (Aug. 28, 2020); *see also Karnoski v. Trump*, 926 F.3d 1180, 1200 (9th Cir. 2019).

In identifying whether a classification is suspect or quasi-suspect, courts consider whether: (a) the class has historically been "subjected to discrimination," *Bowen v. Gilliard*, 483 U.S. 587, 602 (1987); (b) the class's defining characteristic "bears [any] relation to ability to perform or contribute to society," *City of Cleburne,* 473 U.S. at 440-41; (c) the class exhibits "obvious, immutable, or distinguishing characteristics that define them as a discrete group," *Gilliard*, 483 U.S. at 602; and (d) the class is "a minority or politically powerless." *Id.*

All indicia are present for transgender people. "[T]ransgender people as a class have historically been subject to discrimination or differentiation; … they have a defining characteristic that frequently bears no relation to an ability to perform or contribute to society; … as a class they exhibit immutable or distinguishing

characteristics that define them as a discrete group; and … as a class, they are a minority with relatively little political power." *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 288 (W.D. Pa. 2017).[41]

History of discrimination. "There is no doubt that transgender individuals historically have been subjected to discrimination on the basis of their gender identity, including high rates of violence and discrimination in education, employment, housing, and healthcare access." *Grimm*, 972 F.3d at 611 (citation omitted). As the Fourth Circuit detailed in *Grimm*, there is extensive data documenting the staggering discrimination that transgender people face in all aspects of life. *Id.* at 611-12. This pattern of discrimination is long-standing, including through formal governmental action. Expression of a person's transgender identity was criminalized for much of the nineteenth and twentieth centuries through cross-dressing laws. *See* Jennifer Levi & Daniel Redman, *The Cross-Dressing Case for Bathroom Equality*, 34 SEATTLE U. L. REV. 133, 152-53, 171 (2010). More recently, Congress explicitly excluded transgender people from protection under four civil rights statutes over the past thirty years. *See* Kevin M. Barry et al., *A Bare Desire to*

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[41] Although there is record evidence related to some of these factors, when courts decide the legal question of what level of equal protection scrutiny applies to a classification, they are not confined to record evidence presented by the parties. *See, e.g., Frontiero v. Richardson*, 411 U.S. 677, 684-86 (1973) (referencing diverse sources including history books and law review articles in its analysis supporting its conclusion that classifications based on sex are inherently suspect); *Grimm*, 972 F.3d at 611-12 (referencing congressional records and law review articles).

Harm: Transgender People and the Equal Protection Clause, 57 B.C. L. REV. 507, 556-57 (2016). The record is replete with evidence of this discrimination. *See* Statement of Facts § II, *supra*.

Defining characteristic that bears no relation to the ability to contribute to society. Transgender people have a defining characteristic that "bears no relation to ability to perform or contribute to society." *See Cleburne*, 473 U.S. at 441. The relevant question is not whether every person in the class is the same but rather whether they share a characteristic that "tend[s] to be irrelevant to any proper legislative goal." *Plyler* v. *Doe*, 457 U.S. 202, 216 n.14 (1982). Transgender people share the defining characteristic of having a gender identity that does not align with their birth-assigned sex. *See* Statement of Facts, § III(A)-(B), *supra*. And "[s]eventeen of our foremost medical, mental health, and public health organizations agree that being transgender implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." *Grimm*, 972 F.3d at 612 (quotation marks omitted). (*See also* Ex. 7, Karasic ¶¶ 26, 35 (ECF 175-7).)

Obvious, immutable, or distinguishing characteristics. There is no requirement that a characteristic be immutable in a literal sense in order to trigger heightened scrutiny. For example, heightened scrutiny applies to classifications based on alienage and "illegitimacy" even though both classifications are subject to change. *Windsor*, 699 F.3d at 183 n.4; *see Nyquist* v. *Mauclet*, 432 U.S. 1, 9 n.11

(1977) (rejecting argument that alienage did not deserve strict scrutiny because it was mutable). "Rather than asking whether a person *could* change a particular characteristic, the better question is whether the characteristic is something that the person *should* be required to change [in order to avoid government discrimination] because it is central to a person's identity." *Wolf* v. *Walker*, 986 F.Supp.2d 982, 1013 (W.D. Wis. 2014) (emphasis in original), *aff'd sub nom*, *Baskin* v. *Bogan*, 766 F.3d 648 (7th Cir. 2014); *see also Latta* v. *Otter*, 771 F.3d 456, 464 n.4 (9th Cir. 2014). "A transgender person's awareness of themselves as male or female is no less foundational to their essential personhood and sense of self than it is for those [who are not transgender]." *Grimm*, 972 F.3d at 624 (Wynn, J., concurring). A person's gender identity is a core part of who they are is not something that can be changed voluntarily or by external forces. (*See* Ex. 8, Olson-Kennedy at 8 ¶¶ 1-2 (ECF 175-8); Ex. 9, Shumer ¶ 29-33 (ECF 175-9); Ex. 7, Karasic ¶ 23 (ECF 175-7).)

Political powerlessness. The final factor concerns whether the class of persons is "in a position to adequately protect themselves from the discriminatory wishes of the majoritarian public." *Windsor*, 699 F.3d at 185. As evidenced by the over 500 legislative bills targeting them for discrimination in the first few months of 2023 alone,[42] transgender people are not in such a position.

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[42] Trans Legislation Tracker, 2023 anti-trans bills tracker, https://translegislation.com/ (last visited Apr. 28, 2023).

As such, numerous courts have reached the conclusion that classifications based on transgender status are subject to, at least, heightened scrutiny. *See, e.g.*, *Grimm*, 972 F.3d at 607; *Karnoski*, 926 F.3d at 1200; *Flack*, 328 F.Supp.3d at 951–53; *M.A.B. v. Bd. of Educ. of Talbot Cnty.*, 286 F.Supp.3d 704, 718–22 (D. Md. 2018); *Evancho*, 237 F.Supp.3d at 288; *Norsworthy v. Beard*, 87 F.Supp.3d, 1104, 1119 (N.D. Cal. 2015).

Defendants argue that *Adams* precludes this conclusion. They are wrong. Defendants misconstrue the reach of the *Adams* case again in their assertion that the court "explained what constitutes unconstitutional discrimination based on transgender status." (Mot. at 32.) But the *Adams* court did no such thing. True, the *Adams* court expressed in *dicta* "doubt that transgender persons constitute a quasi-suspect class" because "the Supreme Court has rarely deemed a group a quasi-suspect class." 57 F.4th at 803 n.5. But that does not mean that "[t]ransgender individuals [] aren't entitled to heightened constitutional review per se." (ECF 120 at 33.)

"The novelty of an issue does not doom it to failure," however. *Nonhuman Rts. Project, Inc. v. Breheny*, 197 N.E.3d 921, 937 (2022) (Wilson, J., dissenting). Indeed, "a novel habeas case freed an enslaved person" and "a novel habeas case removed a woman from the subjugation of her husband." *Id.* The argument "'this has never been done before' … is an argument against all progress, one that flies in

the face of legal history." *Id.* "The correct approach is not to say, 'this has never been done' and then quit, but to ask, 'should this now be done even though it hasn't before, and why?'" *Id.*

C. Defendants Engaged in Purposeful Discrimination.

Defendants must "treat all persons similarly situated alike" or "avoid all classifications that … that reflect a 'bare desire to harm a politically unpopular group.'" *Glenn*, 663 F.3d at 1315 (quoting *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 446-47 (1985)).

While a showing of intentional discrimination is unnecessary in this case given that the Challenged Exclusion is facially discriminatory, *see Cmty. Servs., Inc. v. Wind Gap Mun. Auth.*, 421 F.3d 170, 177 (3rd Cir. 2005), here, the Challenged Exclusion purposefully discriminates against transgender people.

Determining discriminatory intent is guided by an eight-factor test. *See League of Women Voters of Fla., Inc. v. Fla. Sec'y of State*, 32 F.4th 1363, 1373 (11th Cir. 2022) (cleaned up). Here, most of the factors are either met or there is a genuine dispute of material fact as to their presence.

- *The impact of the challenged law*: "[T]he Exclusion impacts only transgender individuals—that provides some circumstantial evidence of intentional discrimination." *Lange v. Houston Cnty., Georgia*, 608 F.Supp.3d 1340, 1355 (M.D. Ga. 2022) ("*Lange II*"). *See also supra*.

- *The historical background:* Here, Florida Medicaid covered medical treatment for gender dysphoria, until 2022, when Florida's government enacted or adopted a blizzard of anti-LGBTQ laws. This includes restrictions on the coverage and provision of gender-affirming care, "Don't Say or Trans" laws, banning of books discussing LGBTQ identities, bans on drag performances, and more. *See* Statement of Facts § II, *supra*. (ECF 1, Compl. at ¶¶126(a)-(f).)
- *The specific sequence of events leading up to its passage:* Plaintiffs have laid out circumstantial evidence concerning this factor, including the coordination with the Governor's Office, FDOH, and anti-transgender activists. *See* Statement of Facts § VI(B), *supra*;
- *Procedural and substantive departures:* Plaintiffs have documented a litany of procedural and substantive departures, including but not limited to AHCA: (1) hiring of outside consultants, which AHCA had never done for a GAPMS (ECF 120-6, Brackett Feb. 8 Dep., at 137:10-12, 139:17-138:3), and all of the consultants retained opposed gender-affirming care (Ex. 324, Yale Comment, at 7-9 (ECF 183-27); (2) not enlisting or even considering any consultant supporting the provision of gender-affirming care (ECF 120-9, Dalton Dep., at 112:5-23); (3) employing a GAPMS process for a treatment already covered, which was unprecedented (ECF

120-6, Brackett Feb. 8 Dep. at 93:13-21); (4) bypassing the employees typically tasked with conducting GAPMS processes (ECF 120-9, Dalton Dep. at 85:16-19); (5) "dismiss[ing] the professional organizations and experts that [AHCA] frequently cited before" (Br. Ex. 2, English Dep. at 154:6-13); and (6) closely coordinating with and having the process originate from other agencies like FDOH and the Governor's Office. (ECF 120-6, Brackett Feb. 8 Dep., at 89:18-19, 90:25-91:1, 92:2-4; Br. Ex. 2, English Dep. at 154:8-19; Ex. 302, 6/27/2022 email from English to Cogle (ECF 183-4).)

- *The contemporary statements and actions of key legislators:* Plaintiffs have pointed to some of these disturbing and offensive statements. Statement of Facts § II, *supra*. (ECF 1, Compl., ¶126(g).)
- *The foreseeability of the disparate impact and knowledge of that impact:* Not only was the impact on transgender Medicaid beneficiaries foreseeable, but it was also communicated to Defendants during the notice-and-comment process. (Ex. 323, Endocrine Soc. Comment, at 6 (ECF 183-26); Ex. 324, Yale Comment, at 2 (ECF 183-27); Ex. 325, AAP Public Comment, at 3-4 (ECF 183-28).)[43]

[43] *See also* NHELP Public Comment, *available at* https://static1.squarespace.com/static/6283b20d7013340d81fd360f/t/644c7c3e38b786135741e3f0/1682734142446/FHJP+%2B+NHeLP+Comments+on+Rule+59G-1050.pdf; Lamba Legal Public

- *The availability of less discriminatory alternatives*: "There is no evidence [Defendants] considered less discriminatory alternatives." *Lange II*, 608 F.Supp.3d at 1356.

Thus, when it comes to whether Defendants engaged in purposeful discrimination, "the facts are hotly disputed," at least. *Lange II*, 608 F.Supp.3d at 1356.

D. The Challenged Exclusion Cannot Survive Heightened Scrutiny

The Challenged Exclusion targeting transgender Medicaid beneficiaries demands meaningful review. Arguably, it is subject to the onerous strict scrutiny standard, wherein Defendants must show that the Challenged Exclusion is narrowly tailored to advance a compelling state interest. *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 227 (1995). Even under the heightened scrutiny required for all sex-based classifications, Defendants carry the heavy burden of showing that the Challenged Exclusion is substantially related to an important government interest, and that they had an "exceedingly persuasive" justification for it. *Glenn*, 663 F.3d at 1321; *see also, e.g.*, *VMI*, 518 U.S. at 533. Under both standards, the "burden of justification is demanding and [] rests entirely on the State," and constitutionality is

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Comment, *available at* https://static1.squarespace.com/static/6283b20d7013340d81fd360f/t/644c7c560af479331dbb642b/1682734166584/Lambda+Legal+Comments+Regarding+Changes+to+Florida+Medicaid+Coverage+2022.07.08+-+Copy.pdf ; Southern Legal Counsel Public Comment, *available at* https://static1.squarespace.com/static/6283b20d7013340d81fd360f/t/644c7c11c861fa5a60881a4d/1682734097281/SLC+Final+Comment+-+Medicaid+Proposed+Rule.pdf.)

judged based on the "the actual state purposes, not rationalizations for actions in fact differently grounded." *VMI*, 518 U.S. at 533, 535-36.

Here, the Challenged Exclusion cannot meet either standard. To the extent that Defendants contend the Challenged Exclusion is justified because gender-affirming care is allegedly "experimental" and "investigational," that conclusion is contradicted by the evidence. *See* Statement of Facts § IV(C), *supra*; Legal Argument § I, *supra*. The Court cannot simply accept Defendants' *ipse dixit* that gender-affirming medical treatments are "experimental" and "investigational" because "[t]he Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake." *Gonzales* v. *Carhart*, 550 U.S. 124, 165 (2007).

As articulated above (Facts § IV(C)(4), *supra*), Defendants cannot carry their burden to justify the Challenged Exclusion based on purported concerns about the quality of the evidence concerning treatment. While Defendants baldly assert that this well-established treatment is "experimental," the medical and scientific evidence in the record shows the opposite and Plaintiffs refer the Court to Section I of the Argument where they articulate why under *Rush*.

Defendants rely on a claimed absence of long-term longitudinal studies and randomized clinical trials assessing safety and efficacy of gender-affirming care. These kinds of studies are not the only type of studies upon which the medical

profession relies on to determine the safety and efficacy of treatments. (Ex. 12, Olson-Kennedy ¶¶ 70-90 (ECF 175-12).) In the context of pediatric medicine, the body of research is less likely to use randomized trials than is clinical research for adults, and, at times, it is unethical to conduct such randomized trials.[44] (Ex. 5, Antommaria, ¶¶ 24-27 (ECF 175-5); Ex. 12, Olson-Kennedy, ¶¶ 74-77 (ECF 175-12).) For similar reasons, researchers rarely use randomized clinical trials for surgical treatments. (Ex. 13, Schechter ¶ 8 (ECF 175-13).) Thus, if AHCA were to exclude from Medicaid coverage all treatment unsupported by randomized clinical trials, it would have to exclude much of pediatric medicine and many surgical procedures.

If limiting Medicaid coverage to treatments supported by certain kinds of medical research, such as randomized clinical trials, somehow advanced a government interest in individual patients' well-being, then Defendants would have to require that standard to be met for all treatments, but it does not. *See Eisenstadt*, 405 U.S. at 452. AHCA cannot provide any rational explanation—much less an

[44] Requiring use of randomized trials to justify a medical intervention would be unethical because it would require doctors to disregard substantial evidence demonstrating the safety and efficacy of medical treatments and deny patients treatments that are known to provide relief for their medical conditions. Moreover, even if this demand were legitimate, an exclusion of coverage for treatment would prohibit any additional research, thereby undermining any purported desire for further study.

"exceedingly persuasive" one—to justify subjecting only gender-affirming care to this unique burden. *VMI*, 518 U.S. at 533.

Indeed, Defendants cannot establish any reputable scientific or medical support for the Challenged Exclusion, let alone an "exceedingly persuasive" justification, *VMI*, 518 U.S. at 531, or one "narrowly tailored to a compelling state interest." *Adarand*, 515 U.S. at 235.

The Challenged Exclusion cannot even withstand deferential "rational basis" review. Under rational basis, the classification must be rationally related to a legitimate state interest. *City of Cleburne*, 473 U.S. at 440. States must "avoid all classifications that are arbitrary or irrational and those that reflect a bare … desire to harm a politically unpopular group." *Glenn*, 663 F.3d at 1315 (cleaned up). Here, as articulated in Section IV(C) of the Argument, Defendants have chosen to exclusively single out transgender Medicaid beneficiaries for exclusion of coverage. The Challenged Exclusion targets only transgender beneficiaries and their medical care alone for unequal treatment. *See Kadel*, 2022 WL 3226731, at *20 ("Discrimination against individuals suffering from gender dysphoria is also discrimination based on sex and transgender status."); *Toomey*, 2019 WL 7172144, at *6 (noting exclusion "singles out transgender individuals for different treatment" because "transgender individuals are the only people who would ever seek gender reassignment surgery").

As such, the Challenged Exclusion violates the Equal Protection Clause.

CONCLUSION

For the foregoing reasons, the record shows that Plaintiffs should prevail on the merits of each of their statutory and constitutional claims and are entitled to a declaratory judgment and permanent injunctive relief against the Challenged Exclusion.

Respectfully submitted this 28th day of April 2023.

/s/ Chelsea Dunn
Chelsea Dunn

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of April 2023, a true copy of the foregoing has been filed with the Court utilizing its CM/ECF system, which will transmit a notice of electronic filing to counsel of record for all parties in this matter registered with the Court for this purpose.

/s/ Chelsea Dunn
Counsel for Plaintiffs

TAB 199-1

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION
CASE NO.: 4:22-CV-00325-RH-MAF

AUGUST DEKKER, et al.,

Plaintiff,

vs.

JASON WEIDA, et al.,

Defendant.
_____/

REMOTE ZOOM-RECORDED DEPOSITION OF

AUGUST DEKKER

VOLUME 1
Pages 1 through 35

Thursday, January 26, 2023

10:02 a.m. - 10:54 p.m.

Location: Phipps Reporting
20 N. Orange Avenue, Suite 700
Orlando, Florida 32801

STENOGRAPHICALLY REPORTED BY
SANDRA NARUP
RPR, RSA, FPR-C

Job No.: 291657

Q. And have you taken Prednisone?
A. Yes.
Q. You still take it?
A. No.
Q. What about tocilizumab, T-O-C-I-L-I-Z-U-M-A-B?
MR. CHARLES: Sorry. Gary, can you spell that again more slowly?
MR. PERKO: Sure. T-O-C-I-L-I-Z-U-M-A-B.
A. I believe that's my Actemra, so, yes.
BY MR. PERKO:
Q. You still take it?
A. Yes.
Q. Did the provider at Metro Inclusive Health, or whoever prescribed these drugs, advise you of any essential adverse effects of taking these medications at the same time as testosterone?
A. No. But I worked closely with my rheumatologist to avoid these risks.
Q. So your rheumatologist explained the risks associated with taking these medications at the same time as testosterone?
A. Yes, I was made aware of it.
Q. Have you been told by any of your healthcare providers that celecoxib increases the risk of cardiovascular disease?

A. I believe so.
Q. Do you happen to know the M.D.'s name?
A. No, I do not.
Q. When you were prescribed -- first prescribed testosterone, were you advised of the risks and benefits of taking that hormone?
MR. CHARLES: Objection. Asked and answered.
You can answer.
A. Yes, I was.
BY MR. PERKO:
Q. Had you been informed by any of your healthcare providers that the warning label for testosterone says that it may cause liver problems?
A. No.
Q. Do you know if your liver tests are being monitored by the prescriber of testosterone?
A. They're being monitored by my rheumatologist every eight weeks.
Q. Have you been told that doses of testosterone used to treat gender dysphoria can lead to high red blood cell counts?
MR. CHARLES: Sorry. Can you say that again, Gary? I couldn't hear you.
MR. PERKO: Sure.
BY MR. PERKO:

A. Benefits included increased body hair, deepened voice, enlargement of the clitoris, increased body and facial hair, increased muscle tone. Probably a few other things I'm forgetting.

Q. Okay. What benefits have you experienced from taking testosterone?

A. My mental health has significantly improved since I -- well, whenever I'm on testosterone, I no longer have any suicidal ideations, I am generally the most stable and happy I have ever been.

Q. Earlier today, Mr. Perko asked about a hospital visit in January of 2019. Is that correct?

A. Yes.

Q. And you responded -- I'm paraphrasing here -- that that was related to an unsupportive, abusive partner. Is that correct?

A. Yes.

Q. Were there other reasons that caused your experience of suicidal ideation at that time?

A. My situation was complicated by the fact that I -- this was the same partner who convinced me to stop my testosterone treatment, and I was experiencing mental health issues due to not having my medication.

Q. By medication, are you referring to testosterone?

A. Yes.

Q. Earlier today -- I'm paraphrasing here -- you told Mr. Perko that there were negative effects to stopping testosterone. Is that correct?

A. Yes.

Q. Were there negative mental health effects that you experienced as well?

A. Yes.

Q. And what were some of those?

A. My social anxiety specifically was very, very high. I did not want to go outside or to leave the house because, afraid of being perceived as female.

My depression also worsened significantly, and that contributed to me not wanting to interact with the outside world.

MR. CHARLES: Okay. Unless you have anything else, Gary, I think we're okay.

MR. PERKO: I don't have anything else.

Mr. Dekker, you have the right to review the transcript of the deposition to identify any transcription errors. Would you like to do that?

THE WITNESS: Yes.

MR. PERKO: I have nothing further. Thank you for your time, Mr. Dekker.

THE CERTIFIED STENOGRAPHER: Okay. And --

No. 23-12155

In the United States Court of Appeals for the Eleventh Circuit

AUGUST DEKKER, BRIT ROTHSTEIN, SUSAN DOE, by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., by and through his parent and next friend, JADE LADUE,

Plaintiffs-Appellees,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, *et al.*,

Defendants-Appellants.

On Appeal from the U.S. District Court for the Northern District of Florida, No. 4:22-cv-00325, Honorable Robert L. Hinkle, District Judge

APPELLEES' APPENDIX
VOLUME 9 OF 10 (Tabs 199-2 – 230-4)

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TABLE OF CONTENTS

Tab/Docket No.

VOLUME 1 OF 10

VOLUME 2 OF 10

VOLUME 3 OF 10

VOLUME 4 OF 10

VOLUME 5 OF 10

VOLUME 6 OF 10

VOLUME 7 OF 10

VOLUME 8 OF 10

VOLUME 9 OF 10

TAB 199-2

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

CASE NO. 4:22-cv-00325-RH-MAF

AUGUST DEKKER, et al.,
Plaintiffs,
vs.
SIMONE MARSTILLER, et al.,
Defendants
_____/

DEPOSITION OF:	JEFFREY ENGLISH
AT THE INSTANCE OF:	THE PLAINTIFF
DATE:	JANUARY 23, 2023
TIME:	COMMENCED: 10:00 A.M.
LOCATION:	AGENCY FOR HEALTH CARE ADMINISTRATION 2727 MAHAN DRIVE TALLAHASSEE, FLORIDA 32308
REPORTED BY:	DANA W. REEVES Court Reporter and Notary Public in and for State of Florida at Large

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INDEX TO WITNESS

PLAINTIFF'S INDEX TO EXHIBITS

DEFENDANT'S INDEX TO EXHIBITS

NO.	DESCRIPTION	MARKED
Exhibit D1	Computer-assisted musculoskeletal surgical navigational orthopedic GAPMS	166
Exhibit D2	Blue Cross Blue Shield of Rhode Island document	167

*Uh-uh is a negative response
*Uh-huh is a positive response

that is on our fee schedule and it is --

Q Can I stop you there? When you say multiple things checked off, do you mean yes or no?

A Yes -- well, let me double-check that. Yeah. You know, if something gets checked off as a yes, you know, especially overwhelmingly so, then that would be something that we would, you know, give a really serious consideration of coverage for. And if we looked at it, and it was, you know, potentially experimental investigational, and then that's the GAPMS. And if it's, you know, yes, we should cover this, what -- you know, why don't we have this on our fee schedule kind of thing, then that would be a decision point.

Q Okay. Does a yes answer to any of these questions imply that a service is not experimental?

MR. PERKO: I'm going to object to form. You can answer.

THE WITNESS: Do answer or --

MR. PERKO: Do answer.

THE WITNESS: Okay. Well, through this form, we would discover that it's -- you know, if it's something that's already on the fee schedule that we already covered, then that would -- that would end the process immediately and we would just notify the provider, hey, we already pay for this

and move on to the next thing.
BY MS. DeBRIERE::
Q So if it was on AHCA's fee schedule --
A Then it's not and then someone -- I guess the presumption is that someone or someone somewhere along the way determined that AHCA would cover it, and that it was not a -- you know, it was not experimental investigational.
Q I'm sorry, Mr. English. Hold on one second. Just a real basic question. I see here an email address, healthserviceresearch@AHCA.myflorida.com inbox?
A Yes. That's a -- that's a -- the requesters will send in -- that's the email address to inquire about making a GAPMS request or a coverage request.
Q Who can submit a GAPMS request via the email?
A Anybody, I believe.
Q Okay. Other than the three entities you listed that typically trigger a traditional GAPMS --
A I would think of it other than the weird one with Beth and the bionic pancreas, most of the other requests would come in through health service research, you know, the provider or the manufacturer. And from time to time, you would get a phone call, usually from a salesperson and they'd want to set up a meeting. And they -- you know, they have sort of regional travel

schedules, they want to hit you up on their way through. But health service research is sort of, I guess, the basic -- getting the process started way of contacting us.

Q To your knowledge, have you ever had a request to initiate come from another state agency?

A I do not -- I'll just point out, again, I inherited a queue and I don't necessarily know where all the projects that I inherited originated.

Q So, to your knowledge --

A No.

Q And to your knowledge, has a request ever come from a member of the public?

A I'm unclear how you define that.

Q Fair.

A I mean, technically, isn't everyone a member of the public?

Q Yes. Absolutely. Have you ever had a request come in from a Medicaid recipient, to your knowledge?

A I can't say for certain. It sounds familiar, but I can't say for certain. And what I might actually be remembering is a provider requesting on behalf of Medicaid patient.

Q Okay. How about request from a political figure?

A No. That's bill analysis. That's a -- that's a different -- that's a different task.

Q Okay. To your knowledge, have you ever not used the decision tree for a traditional GAPMS request?

A When I first started, you know, but I only have -- it might have been one or two. There was a stretch where I was working with what was already in the queue, and so I don't know that this had been performed for those. I think some of them because I think Chris -- Christina, like, in order to sort of workshop this, we went through and we're like, well, this one would, you know, and this one, but it was pretty much like the newer requests going forward, and then Nick was assigned with backtracking with this, and I don't know if he got every single one in the queue or not, so that's theoretical there are GAPMS that -- for which this was not performed.

Q After the checklist was developed and it was consistently -- after December of 2020 --

A Yes.

Q -- when traditional GAPMS request was received by AHCA, did you ever not use the checklist?

A It was part of the -- it was part of the standard process. I can't say for sure that, you know, when we were working from home -- I think I had meetings

with supervisors for them, but I don't know for certain that every single request that came in went through that or not. I can't say.

Q You said it was the standard process?

A It is.

Q Okay. Is GAPMS ever initiated with respect to services that AHCA is covering -- already covering?

A In my experience, no, that would -- that would be determined through the checklist and that would be deemed not a GAPMS.

Q Kind of the same question asked a little differently. Is it ever initiated to assess existing coverage of Medicaid services?

A Not in my experience.

Q I asked some of these. I don't want to ask them again, so I'm going to blow through them real quick.

MR. PERKO: Would now be time for a break?

MS. DeBRIERE: Yeah, let's do it.

(Brief recess.)

BY MS. DeBRIERE::

Q So did you speak to anybody during the break about the deposition?

A I did not.

Q Okay. And I just want to go back quickly to

what I believe we marked as Exhibit 2. Is that -- no, Exhibit 3, excuse me, which is the GAPMS decision tree checklist. I needed to ask one more question about that. If something was -- so when you receive the request, and you're going through the checklist, if something was on Medicaid's fee schedule, and therefore covered by Florida Medicaid, would you initiate the GAPMS process?

A No.

Q What types of Medicaid services are assessed using the GAPMS process?

A Treatments, I guess, for lack of a better way for shorthand. Typically, it's -- can I answer the question by giving you an example of GAPMS?

Q Absolutely. You can answer the question however you would like to?

A There's, you know, specially modified low-protein foods for inborn errors of metabolism. There's negative-pressure wound therapy, which is a medical device for wound healing. There's low-intensity pulsed ultrasound, which is a medical device for healing fractures. There's a procedure with sort of a proprietary technology called transcervical fibroid ablation that's kind of a cross between a procedure and the type of bead that's used in the procedure that

Q Who's involved in the -- who was involved in the GAPMS process when you were doing it?

A Primarily myself. There was, from time to time if we got it -- you know, if I got along in the process and was determining that, you know, this had a potential, that it would be recommending coverage -- because everything has to be budget-neutral, we would -- I would reach out to Medicaid, the fiscal folks, and they would put together a fiscal analysis of what the cost would be, or any potential cost savings. So from time to time, not every GAPMS, if I didn't reach out to them, if it was something that it was clear that we weren't going to cover, because the time wasn't -- it's pointless to take up their time. My supervisor -- I had weekly regular weekly meetings with my immediate supervisor, you know, to go over what was in the queue, what was I working on, what was the status.

I frequently had scheduled meetings with the Bureau Chief, but those didn't often come off, but it was understood that, you know, typically, along, you know, the course of time, you know, they would get, you know, an update on what was going on, and if it was one where, you know, I had written it, my supervisor had signed off on it, and then the next step was, you know, to get the bureau chief to sign off on it in order for

it to go to the Medicaid director. And then Nick -- Nick was doing the checklist. But I mean, it was -- it was kind of a joke with my, you know, with my co-workers, I was kind of like the one-end game.

Q Okay. Okay. So can you describe that line of approval. So it started with you.

A It started with me. I would write a report. I would submit it to either, at the time Christina, or Jesse, whoever was my immediate supervisor. They would review it, they may or may not have some edits to send back, and then it would -- once they had, you know, signed off on it and said, you know, this can advance to the bureau chief, and then, you know, the bureau chief would sign off on it, yay or nay, and then the next step is to go to the Medicaid director.

Q Okay. And who currently is the Medicaid director?

A Tom Wallace.

Q And who's the bureau chief for Medicaid policy?

A Ann Dalton.

Q And I know you just said this, and I apologize, but the final decision maker then in the GAPMS process is the Medicaid director. Is that correct?

A Yes. I mean, it typically requires his or her signature.

Q Is that different from being a decision maker?

A A decision point? Yes.

Q No, a decision maker. Sorry.

A That's linguistics, sort of. I mean, it -- I can't reach out to the requester and say yay or nay until Tom has signed or, you know, whoever -- Beth has signed off on the report.

Q Does the Medicaid director review the report and reach an independent conclusion?

MR. PERKO: Object to form. You can answer.

THE WITNESS: I don't know.

BY MS. DeBRIERE::

Q In the GAPMS process you just described from you to your supervisor, to the bureau chief, to the Medicaid director, does AHCA ever rely on individuals outside the agency in the process?

A Not in my experience, no.

Q How many GAPMS reports are issued per year?

A That's kind of a loaded question.

Q I don't mean it to be.

A Okay. In my -- you know, if I can round up three years of doing GAPMS reports, there were a couple of expedited GAPMS that kind of made it all the way

medical necessity?

A I've read it before.

Q I have a copy of it. Do you want to see it?

A Sure.

MS. DeBRIERE: Sorry. It's on page seven, Gary. And what the witness is reviewing -- I think I needed more coffee at lunch -- what the witness is reviewing is 59G-1.010, and it's the definition of medically necessary medical necessity at 2.83 in the policy.

THE WITNESS: Yes.

(Whereupon, Exhibit No. 6 was marked for identification.)

BY MS. DeBRIERE::

Q Do you know what AHCA uses this definition for?

A I mean, I've had -- it's been in literature or in, you know, in reference to the GAPMS process. Beyond that, I don't know how its utilized.

Q How does it relate to the GAPMS process?

A As I understand it, if a GAPMS is approved, as you know, something that Medicaid is going to cover, then it's considered under the blanket definition of that term or phrasing. It's been deemed medically necessary, I guess.

Q If what?
A If it's passed GAPMS.
Q If AHCA determines the service is experimental and will not be covered by Medicaid, would there be any reason to determine whether the service is medically necessary under any other portion of the medical necessity definition?
A That question might come up around the EPSDT consideration, but otherwise, I don't know.
Q You don't know or --
A I can't -- I don't believe so, you know.
Q When the agency decides to exclude a Medicaid service as experimental, does AHCA communicate that information to the public?
A Not in my experience. I've only ever communicated to -- well, I mean, there have been -- there have been requests that have come in that didn't reach the level of a GAPMS, because they didn't even get to that point. It was like, no, we don't cover that, because it's so obvious that we don't cover that. So we would explain to them, you know, these are the things when -- we explain the process to them, and these are things -- but, you know, that's kind of the gist of it.
Q So, in your experience, after determining that a service would be excluded as experimental, does AHCA

notify the general public?

A No, we would notify the requester and then move on to the next project.

Q Would AHCA typically publish that decision on a website?

A Not that I'm aware of, no.

Q Would they provide the general public with the expert reports they relied on during the GAPMS process?

A Not that I'm aware of, no.

Q Does AHCA typically draft a press release about the conclusion that's reached in GAPMS?

A Not in my experience, no.

Q Is the Governor of Florida typically involved in the dissemination of a GAPMS conclusion?

A Not that I'm aware of, no.

Q Any other political figures, are they typically involved?

A Not that I'm aware of, no.

Q Other state agency heads?

A No.

Q Does AHCA publish the exclusion of a service being experimental in a coverage policy or coverage and limitation handbook?

A If they do, I'm not aware of it.

Q If through the GAPMS process a service is

were with her. We shelved it until we got the results. So that -- it's this big study about pregnant women and asthma because the preliminary results were very favorable, and it would have been sort of the -- it would have been a very narrow coverage determination, a very narrow call, but if I remember correctly, the results of that study did not pan out.

Q Okay. Looking at this particular GAPMS --

A No. It was managing asthma in pregnancy. Sorry. Not FMAP.

Q Yeah, especially when you're on state plan, right.

A Yeah.

Q Let's move to one I know you're familiar with, specially-modified low-protein foods. We'll mark as Exhibit 8 -- 9.

(Whereupon, Exhibit No. 9 was marked for identification.)

THE WITNESS: See, this one predates me.

BY MS. DeBRIERE::

Q So what happened there?

A Things didn't move forward. So it was basically starting over and starting from scratch. And so the report that I wrote for -- especially I wrote multiple versions of that report -- looks very different

from that one.

Q Do you remember what organizations on which you relied to write this report?

MR. PERKO: He said he didn't write this report, counsel.

MS. DeBRIERE: I'm sorry. You're right. I strike the question.

BY MS. DeBRIERE::

Q Do you remember on what organizations you relied to write your report on specially-modified low-protein foods?

A I know I consulted organizations concerned with inborn errors of metabolism. And the two, we were directing it specifically to one called phenylketonuria, but there's another one called -- something to the effect of maple syrup disease, so it was organizations that were focused on those two conditions primarily.

Q Do you remember what organizations those were?

A Off the top of my head, I do not.

Q Were you looking -- were you assessing it as to children or as to adults?

A The way, after discussion with my supervisors, the way we were going about it was the argument sort of dictated that we -- that condition requires children to stay on a very strict low-protein diet. It's a lifelong

diet. It's a diet for life. And so what we were able to determine in the research was that, which makes sense, children, you know, when you're a kid, your parent controls your diet, and so you eat what they gave you and parents could keep the children on the diet, but when they started to reach their teenage years, they wanted more autonomy. Nobody wanted to go with their friends to Burger King, while they just sat and had a shake, you know, low-protein, a special shake. And that the research indicated that when children -- in the time of life when people either continue to adhere to the diet or drop off was in their teenage years. So we were targeting under age 21, and with the goal of trying to keep them diet-adherent so that they could progress on to adulthood with good habits and protect their health.

Q Do you remember if one of the organizations you looked at was the American Academy of Pediatrics, or relied on?

A Almost certainly.

Q Why are you -- why are you almost certainly?

A They're kind of a name brand organization.

Q Is it one that you find trustworthy in terms of their opinion?

A I have.

Q Can you look at this document and tell me if

this is -- the reason I ask is that -- skip to the front page, to page three. Do you know if it's complete? If you see there's a page number at the corner there.

A Yeah. Yeah, there's -- there should be a page. Yeah, there's a page there.

Q You don't think it's a typo?

A No, it's -- because on the second page, it picks up with, like, mid-paragraph.

Q Okay. Thank you for that. Were you involved in anything related to the GAPMS for scleral contact lenses?

A I was not.

Q So just going over the GAPMS process generally, in summary, to determine whether a service is experimental under GAPMS, you look at professional literature. And then the most persuasive professional literature is going to be, that's peer review?

A Ideally, sure.

Q You look at whether other state Medicaid programs cover?

A Yes.

Q And you look whether health insurance in the private market covers?

A Yes.

Q And if the majority of states cover, that's

going to be in the favor of finding it not experimental?
A It's hard -- it would be -- make it harder for us to justify that it's experimental.
Q And you look at whether Medicare covers?
A Yes.
Q And, again, whether Medicaid covers favors a finding of not being experimental?
A Yes.
MR. PERKO: Object to form.
BY MS. DeBRIERE::
Q And you look at whether evidence-based clinical practice guidelines exist?
A Yes.
Q And you look at whether the service is accepted by relevant professional medical organizations?
A Yes.
Q How do you -- would the American Medical Association be considered an organization on which AHCA would rely for GAPMS?
MR. PERKO: Object to form.
THE WITNESS: Yes.
BY MS. DeBRIERE::
Q How about the American Psychological Association?
MR. PERKO: Same objection.

THE WITNESS: Yes.
BY MS. DeBRIERE::
Q The American Academy of Child and Adolescent Psychiatry?
MR. PERKO: Same objection.
THE WITNESS: I am not familiar with that organization.
BY MS. DeBRIERE::
Q The American College of Obstetricians and Gynecologists?
MR. PERKO: Same objection.
THE WITNESS: Yes.
BY MS. DeBRIERE::
Q In the past GAPMS, organizations on which you've relied include the American Academy of Pediatrics?
A Yes.
Q You undertake a cost analysis for potential cost-saving to Florida Medicaid when you're doing GAPMS?
A Yeah. I mean, if it's not budget-neutral, it's almost certainly not going to be covered.
Q You do not typically enlist outside medical experts during the GAPMS process?
A I have not.
Q You do not pay outside individuals?

A I don't.
Q You don't ask outside individuals to write a report?
A No.
MR. PERKO: Asked and answered, counsel.
BY MS. DeBRIERE::
Q You do not typically codify your conclusions reached during the GAPMS process into rule?
A I don't believe so.
Q You do not typically develop a website and slogan to advertise a GAPMS conclusion?
A I have not.
Q Generally, other agency heads or political figures not involved in the initiation -- are not involved in the initiation of the GAPMS process?
A Not in my experience.
Q In disseminating its conclusion?
A No.
(Whereupon, Exhibit No. 10 was marked for identification.)
BY MS. DeBRIERE::
Q Let's go to Exhibit 10, is the 2016 GAPMS memo, and this is going to be DEF_000288776 to DEF_00028 8785. Are you familiar with this document, Mr. English?
A I am not.

imagine this is a very large agency. Have you been involved in any conversation around AHCA's coverage of cross-sex hormone therapy?

A I am not.

Q Okay. Do you have any idea as to why, even though you were the GAPMS guy during these dates, that you would not be involved in these decisions?

MR. PERKO: Object to form.

THE WITNESS: I do. What I was explained by Jesse, my supervisor, his version of how -- and I don't know if the same person that wrote the gender dysphoria GAPMS wrote this -- Jesse's explanation for how that author was chosen, he said that it was a meeting between he and Jason and Ann, and Jason had come and asked who they might recommend to write the report, and when my name was brought up, Jesse said no, that he -- I guess he didn't want me working on that. And Ann offered up the actual author, eventual author, and Jesse concurred.

BY MS. DeBRIERE::

Q How do you know that this meeting happened?

A He told me.

Q Jesse told you?

A Uh-huh.

Q Why did Jesse say no? Did he say to you?

A Yes. He -- I believe his perception of it was that it was -- he said that he didn't want me involved with it. He didn't want to be supervising the person who was, and he didn't think that it was something that I would have been willing to do.

Q Was he right?

A Yes.

Q Why?

A Because my perception was that that particular GAPMS was a conclusion in search of an argument.

Q Did Jesse agree with you?

A You'd have to ask him.

Q Why don't you think Jesse wanted to supervise the project?

A We're all sitting here right now.

Q Fair.

A And on top of that, I mean, he was pretty new in his position, too. He had been promoted after Christina left.

Q How long had he been in that position?

A Not super, super long. I mean, God, I think Christina was -- actually, I don't know. She left -- one of the December's during the pandemic, but I don't remember. She went out on maternity leave and never came back, and then he ended up filling her position.

Could have been 2021, or it could have been 2022. I don't honestly recall.

Q Who was the author of the report you're referring to?

A Matt Brackett.

Q Do you know why Mr. Brackett was chosen?

MR. PERKO: Object to form.

THE WITNESS: Jesse told me that he -- he told Jason that Matt would do any assignment that he was given.

BY MS. DeBRIERE::

Q Had Mr. Brackett ever done a GAPMS memo before?

A He had. He was -- he wrote GAPMS prior to my arrival.

Q Why didn't they keep Mr. Brackett in that position? Why did they hire someone new?

MR. PERKO: Object to form.

THE WITNESS: When I arrived, Matt was over the -- I believe he was over durable medical equipment. And I think, just based on conversations he and I had had, there's a kind of a bit of frustration built into the GAPMS position because it's not a priority, you know, outside of a pandemic, even it's just not a priority. And so he

was -- you know, he would tell me, you know, look, I didn't get a lot, you know, through either -- it's kind of a thankless job, but it's important, you know, that kind of thing. So it -- I think he wanted to go do -- he's been here -- you know, I don't know how much longer though, at least a little bit, or maybe more than that longer than me, and I think he just wanted to go do something else.

BY MS. DeBRIERE::

Q Okay. Why do you think it mattered to Mr. Boucher that you not be a part of the gender dysphoria GAPMS?

MR. PERKO: Object to form.

THE WITNESS: My belief is that he didn't see -- he didn't believe that it would be something that I would -- I would be willing to do and he, I believe, was possibly trying to save himself, a hassle as well.

BY MS. DeBRIERE::

Q Let's turn back to the email between you and Mr. Cogle, which is Exhibit 5. On the second page, you have a paragraph that starts, if you will, excuse me, I feel obligated to include this information.

A Yes.

Q Are you familiar with what you wrote there?

A I am.

Q Would you say that's a reason why you didn't want to be involved in the gender dysphoria GAPMS process?

A Yes and no, indifferent all at the same time. I mean, part of why this paragraph was written was out of frustration. Again, I was -- you know, my co-worker's, it was the -- you know, we joked I was the GAPMS guy. That report came out. I read the report. It was not something I felt like I would have produced and because there were a lot of people around inside the agency and my personal life that thought that I wrote the report, because it said, GAPMS, you know. So I had grown tired of -- you know, and at the same time, it's like, you know, my friends are seeing reports about it on television and things like that, or in the newspaper or whatever, it was a news story, a prominent news story with, you know, debate and politics and all these things, and I was a bit frustrated that that was occurring. And combined with the fact that Dr. Cogle was someone I respect, and I kind of in response to the emotion I'd received in his initial email, I wanted to assure him that that wasn't me.

Q I just want to make the record clear by entering in Exhibit 14. And this exhibit is entitled

Florida Medicaid generally accepted professional medical standards determination on the treatment of gender dysphoria. It's dated June 2022.

(Whereupon, Exhibit No. 14 was marked for identification.)

BY MS. DeBRIERE::

Q Is the report we've been talking about that Mr. Brackett authored?

A Yes.

Q And this is the report that Jesse said you would not author, is that correct?

A Correct.

Q And it's the report that you did not want to author?

A Correct. I mean, keep in mind, I found out about it after the project already started. And then I went and asked Jesse about it. I was like, you know, and I wasn't like, you know, who's doing the GAPMS. I was just like, hey, what's going on, you know. And he explained, you know, how Matt was chosen and why I was not, and I was thankful for that and went from there.

Q And you said in your response to my questions about your email to Dr. Cogle that this report did not reflect the level of work that you would do, is that correct?

A Well, that's a -- that's a loaded question. I mean, it's a 45-page report, which is very different from the -- what I was dealing with, which was the push for the trend for tighter cleaner, smaller reports that took less time to read. What was the --

Q Yeah. Why isn't this GAPMS report on gender dysphoria reflective of your work?

A It veers a bit from process.

Q In what ways?

A Well, in terms of the quality of the studies included, the dismissal, the professional organizations and experts that we had frequently cited before, the length of the report, where it originated from.

Q Where did it originate from?

A I would say the executive. Came from they said, you know, Secretary Marstiller, she's part of the executive.

Q Anybody else in the executive?

A Oh, sure. Governor. Yeah.

Q I cut you off.

MR. PERKO: I meant to object to form on that last question.

BY MS. DeBRIERE::

Q You said it dismissed the opinions of professional organizations, where it was initiated was

off, the length of the report was off. Anything else?

A Keep in mind that the people who prepared the report, or Matt and a guy Ni -- I don't remember Ni's last name -- they were not discreet about what they were working on or why, and it seemed to be impacting morale a little bit among some co-workers, and it was kind of an immature sort of approach or attitude or something to it that was off-putting a bit, I suppose, for folks.

Q Are folks in the agency generally aware of things that GAPMS is working on?

A Frankly, most people don't really care or pay attention. You know, everyone has -- just the way everything's set up here, you, you know, everyone has their own little corner of the piece of the puzzle of Medicaid, and it's a big learning curve for everything, and so you want to focus on your little piece of the puzzle and try and grow your puzzle into, you know, understanding how it fits into the main thing. Certain topics sometimes, I had to do one on transanal irrigation, and I caught a lot of grief from some of my co-workers on that one, you know, silly stuff, you know, office banter, that kind of thing, but that one was -- it was just kind of altogether a different thing.

Q You described it as immature.

A Well, certain behavior was.

Q What?

A There was a -- I don't remember the person's name. I was told that they were a trans person. I knew him as this guy who had an office nearby Matt and I, and it was after the report had come out, I believe, and they were, like, kind of whooping it up, yelling back and forth across the hallway, because about -- like the number of views it was getting on Twitter and things like that. And so that employee had to get up and go over and tell them, you know, look, it's -- you know, congratulations on your report, but I feel like you're being somewhat insensitive. And, you know, that was awkward.

Q Yeah. You mentioned that Mr. Brackett was not in -- Mr. Chen -- Dr. Chen?

A He's -- I think he's pharmacist, yeah.

Q Mr. Brackett and Mr. Chen were not discreet about it, what they were working on. How did they characterize what they were working on?

A Just what the topic was. It was actually -- Ni's the one that told me that -- he's who told me that it was -- I was wholly unaware of the assignment, and Ni's the one that told me about the assignment.

Q Is this the first time you've ever been -- since being the GAPMS guy, was the first time you'd ever

been excluded from the GAPMS process?

A Well, I mean, this other one here predates the publication of that one, but --

Q And that --

A -- in April, and this one probably began in April or March or something like that. So, yeah, whichever. The chicken or the egg, whichever one came first. I was unaware of both of those.

Q The title that you were just referencing that is Exhibit 13, I think? Is that right?

A Yes.

Q And do you think that report was a precursor to the Exhibit 14?

MR. PERKO: Object to form.

THE WITNESS: I wouldn't know.

BY MS. DeBRIERE::

Q How many Medicaid services does this GAPMS memo Exhibit 14 analyze, do you know?

A Maybe three.

Q Is that typical?

A No. Well -- I mean, no, I've looked at GAPMS where it was two devices, two different devices at the same time, but never like two different treatments, same time.

Q Do you know why AHCA used that approach here?

A I do not.
Q Would you recommend that approach in a GAPMS process?
A I can't outright say I would or would not. It would depend on the circumstance and how closely related I perceive the procedures or services to be.
Q Do you know if this is supposed to apply to children or adults or both?
A My understanding is both, or to children and -- most of the discussion has been around children. Children.
Q So you don't -- having reviewed this, you can't say?
A I don't recall. I mean, I read it back in, like, June.
Q Okay?
MR. PERKO: About ready for a break, counsel?
MS. DeBRIERE: Mr. English, do you think you can do like 10 more minutes?
THE WITNESS: I can do whatever's good for the order.
MS. DeBRIERE: Is that okay, Gary?
MR. PERKO: Yeah.
BY MS. DeBRIERE::
Q Do you know if AHCA enlisted outside medical

experts to do a literature review for this report?

A That's my understanding.

Q Is that typical for GAPMS?

A Not in my experience.

Q Do you know if they paid these professionals to do the report?

A My understanding is they did.

Q Is that typical?

A Not in my experience.

Q Do you know why AHCA used that approach here?

A I do not.

Q Have you ever -- I'm sorry. Did they attach the expert reports to the final GAPMS report? Did AHCA attach the expert reports to the final GAPMS report?

A I don't know if I saw, like, a copy with attachments or if it's -- I don't recall if it was referenced or included in their report like -- but I remember seeing those when I was looking at it, you know?

Q Is that typical?

A Well, no, I mean, I've never had outside reports to attach to it, were included with the GAPMS.

Q When you mentioned that -- one issue you took with the report is they dismissed professional organizations' opinions. Would those professional

organizations include the Endocrine Society's position?

MR. PERKO: Object to form.

BY MS. DeBRIERE::

Q If you don't remember, that's okay.

A I know who the Endocrine -- who they are. I would be hard-pressed to envision a scenario where I would second-guess them -- and without, you know, really, really good cause.

Q What about the American Academy of Pediatrics?

MR. PERKO: Object to form.

THE WITNESS: No.

BY MS. DeBRIERE::

Q No, you --

A I would be deferential to their recommendations.

Q Are you aware of the coverage of the treatment for gender dysphoria under other Medicaid programs?

A I want to say that things could have changed because I haven't really looked at some of that stuff since last year.

Q Why were you looking at it last year?

A When I --

Q Go ahead.

A If I recall, it's somewhere between maybe 30 and 40 states or something that provide coverage for it.

Q When you undertake GAPMS, how would that factor into your ultimate conclusion?

A If it were 30 states, that would -- it could be a factor. If it were 40 states or more, it would be -- it'd be harder to dismiss. It's something that my supervisor would have been making an inquiry about if I were recommending against coverage.

Q Because that many states covering indicates that it's not experimental?

MR. PERKO: Form.

THE WITNESS: It indicates that there is existing widespread coverage for it.

BY MS. DeBRIERE::

Q How does that factor into whether the service is experimental?

MR. PERKO: Form.

THE WITNESS: It makes an argument for coverage for something easier to make, assuming that they meet the threshold on all the other categories, you know, then that's, you know --

BY MS. DeBRIERE::

Q Do you know if they did a decision tree checklist for the services listed in the June 2022 memo?

A I do not.

Q Do you know if AHCA undertook an Analysis

of -- to determine how excluding coverage of treatment for gender dysphoria would affect the Florida Medicaid budget?

A I do not.

Q Does anything else stand out to you about this memo that we haven't discussed?

MR. PERKO: Object to form.

THE WITNESS: It's frankly unlike anything I've experienced in the process, but I mean, just the sort of -- you know, we're all sitting here, the publicity about it, everything that sort of comes with it. It's unusual, in my limited time here.

BY MS. DeBRIERE::

Q Do you agree with the conclusion?

MR. PERKO: Object to form.

THE WITNESS: I think it's two different issues.

BY MS. DeBRIERE::

Q Yeah.

A I'm not sure that it matters what I believe about the question of whether or not Florida Medicaid should pay for transgender services. I view it as a process issue, and I believe that everyone should have the same -- the same opportunity for review and a consistent process.

Q Was this consistent with the other opportunities people have had for review of a Medicaid service?

A I do not -- I do not believe it was.

Q Do you know how AHCA implemented the conclusions found in this memo?

A I do not. I know they had to write a rule, and I know they had a hearing. That's all I know.

Q Have they talked to you about implementation regarding state amendment at all?

A They have not.

Q Throughout this deposition, I got the sense that you were really good at your job, as the GAPMS guy.

A It's not for me to say. I feel like I put forth some effort.

Q Yeah, and you got a certificate for doing one in eight hours.

A Just a couple of friends, but I think my performance is reflected in my performance reviews.

Q Yeah. And why do you think they moved you from GAPMS to the state plan?

A I asked to be moved.

Q Okay. Why did you ask to be moved?

A Because I felt like the GAPMS process had lost some integrity and I didn't want to be associated with

it. I didn't want the blowback from the requesters out there who were going to wonder why their report wasn't -- I mean, every month it got harder and harder and harder to justify those reports not moving. And I was just, you know, kind of burned out. If you're in a position where you're working on something and they tell you, you know, slow down and stop, you know, then let's go learn something else. And, honestly, I thought leaving would protect me from some of this.

Q You had mentioned that they had to adopt a rule to implement this decision. Is that typical of a conclusion reached through the GAPMS process?

A Not that I'm aware of.

Q The same question with having a hearing. Is that something typically related to a conclusion in the GAPMS process?

A Not that I'm aware of.

Q Has it ever been done, that you're aware of, for any GAPMS conclusions?

A I was never asked to attend a rule hearing or anything related to any of the GAPMS I worked on. So, not that I'm aware of.

MS. DeBRIERE: Are you okay with taking like a 10 minute break?

THE WITNESS: Sure.

TAB 199-3

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.)
)
Plaintiffs,)
)
vs.) NO. 4:22-CV-00325-RH-MAF
)
)
JASON WEIDA, et al.,)
)
Defendants.)

VIDEOCONFERENCE DEPOSITION OF
G. KEVIN DONOVAN, M.D., M.A.
LOCATED IN SAND SPRINGS, OKLAHOMA
TAKEN ON BEHALF OF THE PLAINTIFFS
ON MARCH 22, 2023

REPORTED BY: JANA C. HAZELBAKER, CSR

web page of the Catholic Medical Association?

A I don't think so.

Q So the website states that, "The following are resolutions accepted as positions at the Catholic Medical Association."

And we're going to jump to the resolutions that are listed in the topic of "Family and Sexual Education." Specifically I'm going to look at Resolution 8-12, which is a resolution on transgender treatments.

Resolution 8-12 reads that, "The Catholic Medical Association does not support the use of any hormones, hormone-blocking agents, or surgery in all human persons for the treatment of gender dysphoria."

Were you aware of this resolution of the Catholic Medical Association?

A No. As I've mentioned, I'm not a member of the Catholic Medical Association.

Q And if you --

A I wasn't aware of this.

Q You weren't aware of this?

A No.

Q If you had been aware of this, would it have changed your decision to publish in the Catholic Medical Association's official journal?

A Well, I -- I imagine that I would probably be pleased if anybody agrees with me.

Q So are your beliefs aligned with this resolution?

A I don't know because I haven't seen the full text of it. I just see a title there.

Q So this is the full text of the resolution. The title is "8-12: Resolution on Transgender Treatments." And then it says "Be it resolved."

A Well, then, that does sound reasonable.

Q Okay. And then if we move down to Resolution 8-13, which is the "Resolution on Gender Dysphoria," it reads, "Be it resolved that the Catholic Medical Association and its members reject all policies that condition all persons with gender dysphoria to accept as normal a life of chemical and surgical impersonation of the opposite sex. Further, that the use of puberty-blocking hormones and cross-sex hormones and surgical reassignment surgery be rejected."

Were you aware of this resolution of the Catholic Medical Association?

A No. Like I said, I've never seen this page before and I don't know if any of these were ever adopted.

Q These are on the website of the Catholic Medical Association as adopted resolutions.

A Okay.

Q I'll represent that to you. And so if you had been aware of this resolution, would it have impacted your decision to publish in The Linacre Quarterly, the Catholic Medical Association's official publication?

A No.

Q And are your beliefs around the treatment of gender dysphoria aligned with this Resolution 8-13?

A I would not have used this language, but I don't have severe disagreements with it.

Q Okay. At this point we're going to turn back to what has been marked as Plaintiffs' Exhibit 1. And that is your report, which is not on my screen anymore, so I'm going to have to stop that share again.

(Document is displayed).

This, we already identified, as the expert declaration that was provided, written by you and provided to plaintiffs by the defendants in the lawsuit that brings us here today, Dekker versus Weida.

by your terminology. So you say that you "have studied issues surrounding transgender patients." Specifically, what issues related to transgender patients have you studied?

A Well, I think that the things that I have read about and been concerned about exactly parallel those that you see in the younger patients, as well, in terms of the concept, the diagnosis and the treatment and the results.

Q So can you estimate how many times you've been consulted on issues specific to transgender patients?

A No. I mean, these are not formal consultations, these are discussions.

Q I'm sorry. So going back to your role providing ethical consultations, either -- I guess at Georgetown would have been primarily the period of time we're talking about. Can you estimate how many of those ethical consults would have related to transgender patients?

A None of the hospital consults related to transgender patients as transgender patients.

Q So you've not given an ethical consult with regard to patient care for a patient that was transgender?

A Not for an individual patient, no.
Q And that extends to both children and adults?
A Correct.
Q Moving on to Paragraph 11 where you say, "For ethical as well as medical reasons, I have never prescribed medications nor referred for surgery any patients that consider themselves transgender."
These medical reasons you reference -- going back to your specialty, you're a pediatric gastroenterologist. We've established that. That's right, right? Is that right?
A Yes.
Q Did any of your pediatric gastroenterology patients identify as transgender, to your knowledge?
A No --
Q To your knowledge --
A -- not to my knowledge.
Q Oh, I'm sorry, I cut you off again. I apologize.
What were you saying?
A I just said "not to my knowledge."
Q To your knowledge, have any of your pediatric gastroenterology patients been diagnosed with gender dysphoria?

A Not to my knowledge.

Q Have you ever prescribed a medication to a patient in your role as a bioethicist?

A That's not the role of a bioethicist.

Q Okay. I just wanted to confirm that.

Do bioethicists treat medical conditions with surgical referrals?

A That's not the role of the bioethicist.

Q Okay. When you -- so turning back to Paragraph 11, when you refer to ethical reasons that you don't prescribe medications, is that because your activities as a bioethicist are informed by your Catholic faith?

A No, it's because I think that it's unethical.

Q Do you think that it's unethical because it's not consistent with the ERDs that we talked about as Plaintiffs' Exhibit 4?

A No, I think it's unethical on the face of it. I don't think you have to be Catholic, Muslim, Jewish, or none of the above to come to the same conclusions.

Q In Paragraph 12 you say that, "None of your opinions are biased by professional income."

The entirety of your career in medicine

TAB 200

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, *et al.*, *Plaintiffs*, v. JASON WEIDA, *et al.*, *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

While Defendants correctly acknowledge that a primary question in this case is whether, "based on current medical opinion," Florida's Exclusion and "determination" that medical treatments for gender dysphoria are "experimental is reasonable," *Rush v. Parham*, 625 F.2d 1150, 1157 n.13 (5th Cir. 1980), Defendants' Motion is otherwise a masterclass in misinformation and disinformation.

In addition to misstating facts, Defendants ignore that single most material fact in this case—whether medical treatment for gender dysphoria is experimental—is genuinely disputed, particularly given the overwhelming record evidence that such medical treatment is *not* experimental or investigational, but rather *necessary*, *safe*, and *effective*. This alone warrants denying Defendants' Motion, as "[t]he party

seeking summary judgment bears the exacting burden of demonstrating that there is no dispute as to any material fact in the case." *Warrior Tombigbee Transp. Co. v. M/V Nan Fung*, 695 F.2d 1294, 1296 (11th Cir. 1983).

Take Defendants' opening paragraph. Defendants reference a handful of countries that have purportedly restricted the provision of gender-affirming care in a manner that is both misleading and false.[1] Defendants "ignore European countries where access to trans care has recently expanded (Spain, Portugal, and France)." (Opp. Ex. A.)[2] Indeed, "in France, the use of hormone blockers or hormones of the opposite sex is possible with parental authorization at any age," and surgical treatment for gender dysphoria is likewise available, including "mastectomy, which is authorized … from the age of 14."[3] New Zealand also has not restricted the provision of gender-affirming medical care. (Opp. Ex. B; Opp. Ex. C.)

Defendants argue that because some outlier doctors go against the grain, the Exclusion and their determination is "reasonable" under *Rush*. Not so. Under *Rush*, "whether the state's determination 'is' reasonable, [is] controlled … by 'current

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[1] How countries with nationalized health care systems provide medical care has little bearing here.

[2] Exhibits referred to as "Ex.#" refer to Plaintiffs' trial exhibits filed at ECF 175-184. Exhibits referred to as "Opp. Ex. [letter]" are exhibits attached to this memorandum.

[3] https://www.academie-medecine.fr/wp-content/uploads/2022/03/22.2.25-Communique-PCRA-19-Gender-identity-ENG.pdf.

medical opinion.'" Doc.64 (quoting *Rush*, 625 F.2d at 1157 n.13). "Defendants attempt to create scientific controversy in [an otherwise] uniform agreement through experts who mix their scientific analysis with hypothetical speculation and political hyperbole." *Kadel v. Folwell*, 2022 WL 3226731, at *32 (M.D.N.C. 2022). But "Defendants' belief that gender affirming care is ineffective and unnecessary is simply not supported by the record." *Id.*

Here, Plaintiffs have presented copious evidence demonstrating that gender-affirming care is *not* experimental or investigational, but *necessary*, *safe*, and *effective* medical care that has been provided and studied *for decades*. Each of Plaintiffs' experts completely undermine the State's position, and at minimum, create a genuine issue of material fact. And unlike Defendants' experts (with one exception), Plaintiffs' experts *all* have experience treating or studying gender dysphoria, and its medical treatment. Their testimony shows that gender-affirming care is safe, effective, and widely accepted. Defendants ignore this evidence.[4]

Defendants also fail to contend with the plethora of case law showing that exclusions of medical treatments for gender dysphoria from coverage are unlawful

[4] Defendants reference an expert report from Dr. Brignardello-Petersen, one of AHCA's consultants on the GAPMS Report. Defendants never disclosed Dr. Brignardello-Petersen as an expert in this case and refused to accept service of Plaintiffs' subpoena for her as she is based in Canada. To the extent Defendants seek to introduce Dr. Brignardello-Petersen's report in support of the GAPMS Report or to reference it as expert opinion, Plaintiffs move to strike such references.

and violate the Medicaid Act's comparability and EPDST requirements, Section 1557 of the ACA, and the Fourteenth Amendment's Equal Protection Clause.

Because there are material facts genuinely in dispute and a barrage of case law supports Plaintiffs' claims, the Court should deny Defendants' Motion.

II. STATEMENT OF THE CASE AND FACTS

Correcting every misstatement in Defendants' statement of the case and facts would exceed permitted word limits, so Plaintiffs refer the Court to their Trial Brief and present the following facts.

A. Gender Dysphoria

Gender dysphoria is a serious medical condition, experienced only by transgender people, characterized by the significant distress caused by the incongruence between their sex assigned at birth and their gender identity. (Ex.8, at 10 ¶7; Ex.10, ¶20; Ex.7, ¶24.) Without appropriate treatment, gender dysphoria can cause debilitating anxiety, severe depression, self-harm, and even suicidality. (Ex.7, ¶¶26, 36, 68; Ex.9, ¶41; Ex.10, ¶21.)

B. Treatment for Gender Dysphoria

Gender dysphoria is treatable, and interventions are supported by well-established evidence-based guidelines, for which decades of research and clinical practice provide support. (Ex.9, ¶ 41; Ex.5, ¶ 17; Ex.8, at 12-13 ¶¶ 10-12; Ex.10, ¶¶24-26; Ex.7, ¶¶27-28, 33, 56-59; Ex.142.)

Treatment seeks to eliminate the distress of gender dysphoria by aligning an individual's body and presentation with their internal sense of self. (Ex.7, ¶36; Ex.10, ¶22.) The medical community does not consider these treatments to be experimental or investigational. (Ex.5, ¶¶32-33; Ex.14, ¶¶21-36; Ex.17, ¶23; Ex.8, ¶73; Ex.10, ¶¶ 44-46; Ex.9, ¶89.).

1) The treatment protocols for gender dysphoria

Gender-affirming medical care dates back almost a century. (Ex.5, ¶32, Ex.10, ¶46.) The first gender-confirming surgeries were performed in the 1920s. (Ex.143, at 48-49.) Hormone treatment for gender dysphoria began after estrogen and testosterone became commercially available in the 1930s. (Ex.5, ¶32; Ex.11, ¶32; Ex.2, ¶ 27; Ex.143, at 49.) Puberty-delaying medications have been used to treat gender dysphoria since the late 1990s. (Ex.5, ¶32; Ex.8, ¶24; Ex.142, at 364.)

WPATH first established standards of care for the treatment of gender dysphoria in 1979, which have been continuously maintained and are now in their eighth version ("WPATH SOC8") (Ex.7, ¶27; Ex.8, at 12 ¶10; Ex.9, ¶48; Ex.10, ¶ 24; Ex.17, ¶55; Ex.142, at 361; *see also* Ex.34.) The WPATH SOC8 are based on the best available evidence and professional consensus. (Ex.5, ¶29; Ex.7, ¶28; Ex.8, at 12 ¶10; Ex.9, ¶48; Ex.10, ¶¶ 8, 24; Ex.17, ¶56; Ex.142, at 361; *see also* Ex.34, at S8, S247-S251.)

The Endocrine Society's Clinical Practice Guidelines are largely consistent with the WPATH SOC8 and were developed using rigorous scientific methods. (Ex.5, ¶¶17-18; Ex.7, ¶¶31-33; Ex.8, at 13 ¶12; Ex.9, ¶53; Ex.10, ¶26; Ex.17, ¶¶57-58; Ex.142, at 361; *see also* Ex.123; Doc.193-24.)

The WPATH SOC8 and the Endocrine Society Guidelines provide for medical interventions that are individualized based on patient needs and may include puberty-delaying medications, hormone therapy, or surgeries. (Ex.8, at 12 ¶10; Ex.7, ¶40; Ex.9, ¶57; Ex.10, ¶ 25; *see generally* Ex.34; Ex.123; Doc.193-24.) Treatment protocols differ for adolescents (minors who have started puberty) and adults. (Ex.17, ¶59; *see also* Ex.34, at S32, S48, S111, S129; Ex.123, at 3878, Table 5.) No medical or surgical treatments are provided to any patient until *after the onset of puberty*. (Ex.8, at 17 ¶18; Ex.7, ¶41; Ex.9, ¶44; Ex.17, ¶¶25, 59; *see also* Ex.34, at S69; Ex.123, at 3870.)

America's major medical organizations agree gender-affirming medical care is necessary for people with gender dysphoria. (Ex.5, ¶30; Ex.7, ¶34; Ex.8, at 12 ¶¶10-11, ¶48; Ex.9, ¶¶54-55; Ex.10, ¶27; Ex.17, ¶60; Ex.142, at 361.)

a) Puberty-delaying medications

For adolescents with gender dysphoria who experience severe distress with the onset of puberty, puberty-delaying medications may be indicated. (Ex.7, ¶42; Ex.8, ¶¶22-23; Ex.9, ¶46; Ex.17, ¶89.) Such interventions afford the adolescent time

to better understand their gender identity while delaying the development of secondary sex characteristics, which can cause severe distress when incompatible with an adolescent's gender identity. (Ex.8, ¶¶23-24; Ex.12, ¶81; Ex.9, ¶66; Ex.17, ¶92.) The treatment is reversible if an adolescent discontinues the treatment, puberty will resume. (Ex.7, ¶42; Ex.8, ¶¶24; Ex.9, ¶65.)

Puberty-delaying medications do not have any long-term implications on fertility or sexual function, and there is no evidence that they impact brain development, emotional regulation, or cognition. (Ex.15, ¶¶21-33; Ex.12, ¶¶17-23; Ex.9, ¶73.) The medical and scientific literature has established that puberty-delaying medications are safe and effective to treat gender dysphoria in adolescents. (Ex.5, ¶32; Ex.9, ¶¶63, 78-82; Ex.8, ¶¶25-29, 99-101; Ex.16, ¶¶51-54; Ex.12, ¶¶73-74; *see also*, *e.g.*, Exs. 141, 163, 165, 167, and 168.)

b) Hormone therapy

For some adolescents and adults with gender dysphoria, hormone therapy may be medically necessary. (Ex.17, ¶96; Ex.8, ¶32; Ex.7, ¶43, Ex.9, ¶¶46, 72.) Gender-affirming hormone therapy is a partially reversible treatment, meaning some of the hormones' effects are reversible, while others are not. (Ex.7, ¶43; Ex.8, ¶32.) Hormone therapy allows for a physical development more closely aligning with a person's gender identity, helping alleviate gender dysphoria. (Ex.9, ¶¶60, 71.)

The scientific literature shows that hormone treatment is safe and effective to treat gender dysphoria in adolescents and adults. (Ex.9, ¶¶86-88; Ex.8, ¶¶ 34-40; Ex.17, ¶¶101-102; *see also*, *e.g.*, Ex.166; Ex.180; Ex.221; Ex.156; Ex.197; Ex.176; Ex.195; Ex.164; Ex.212.)

c) Surgery

Gender-confirming surgery may be indicated for some transgender adults and older adolescents to align their primary and secondary sex characteristics with their gender identity. (Ex.8, ¶42; Ex.10, ¶22.) Surgeons regularly perform these procedures to treat conditions other than gender dysphoria. (Ex.10, ¶38.) The scientific literature shows that surgery is a safe and effective treatment for gender dysphoria. (Ex.10, ¶¶40-42, 46; Ex.8, ¶¶44-45; Ex.5, ¶32; *see also*, *e.g.*, Ex.202, Ex.208; Ex.178; Ex.192; Ex.198; Ex.193.)

2) The quality of the evidence

The quality of the evidence supporting these gender-affirming medical interventions is comparable to studies supporting other, well-established treatments and procedures. (Ex.8, ¶¶70-90; Ex.5, ¶¶18-28; Ex.11 ¶¶55, 83; Ex.10, ¶52-54; Ex.17, ¶106.) Scientific ratings of evidence generally employ stringent standards that are not satisfied for many commonly prescribed treatments. As one recent scientific article concluded, "only a minority of outcomes for health care interventions are supported by high-quality evidence." (Ex.182.) The fact that a

treatment is not supported by "high-quality" evidence does not mean that the treatment is unsupported in the literature and clinical practice, that it is experimental or investigational, or that it is not medically necessary. (Ex.14, ¶75.) That is because "[t]o determine whether a treatment is safe and effective, and whether it is experimental or investigational, we look at the whole body of research and clinical experience." (Ex.12, ¶73.) "By this measure, gender-affirming medical care as treatment for gender dysphoria has been shown to be safe, effective, and is not experimental or investigational." (*Id.*)

3) Psychotherapy alone is not an effective treatment for gender dysphoria.

There is no established safe and effective alternative to gender-affirming medical care for treating gender dysphoria. (Ex.10, ¶58; Ex.7, ¶37; Ex.11, ¶¶23-24, 47.) Defendants present psychotherapy alone as an alternative but have offered no evidence to support that claim. (Opp. Ex. D (Weida), 88:18-22.) None exists. While behavioral health interventions are an important component of gender-affirming care for many, the literature has established for decades that mental health interventions alone are insufficient to treat gender dysphoria. (Ex.7, ¶37; Ex.11, ¶48; Ex.17, ¶91; Ex.8, ¶112; Ex.10, ¶58; Ex.158, at 13.)

III. ARGUMENT

A. Defendants' determination that gender-affirming medical treatments are experimental is unreasonable, or at least, genuinely disputed.

This Court, relying on *Rush*, 625 F.2d 1150, articulated as a controlling question in this case "whether, based on current medical knowledge, the state's determination that these treatments are experimental is reasonable."[5] Here, AHCA's determination was not reasonable, or at minimum, there is a genuine issue of material fact on that point.

Defendants' own Medicaid regulations set forth six specific criteria that govern whether a service is consistent with generally accepted professional medical standards, as opposed to experimental or investigational. Fla. Admin. Code ("FAC") 59G-1.035(4); *see also K.G.*, 864 F.Supp.2d at 1321. These GAPMS factors show that the excluded services are not experimental. AHCA's skewed and incomplete

[5] Of note, *Rush* turns on the "reasonable standards" provision of the Medicaid Act, 42 U.S.C. §1396a(a)(17), whereas Plaintiffs claim that the Exclusion violates the EPSDT and comparability provisions. (Doc.1, at ¶¶275-80). Nevertheless, Plaintiffs agree that if the treatments are experimental, the Exclusion does not violate EPSDT requirements. Ex.62; *K.G. ex rel. Garrido v. Dudek*, 864 F.Supp.2d 1314, 1321 (S.D. Fla. 2012), *aff'd in part, rev'd in part sub nom. Garrido v. Dudek*, 731 F.3d 1152 (11th Cir. 2013). Regardless, Plaintiffs contend the Exclusion could violate the Medicaid Act's comparability requirement, Section 1557, and the Equal Protection Clause even if Defendants' conclusion was reasonable. The Court has acknowledged that possibility. (Doc.64, at 4.)

consideration thereof underscores that its determination was not reasonable.[6] *See K.G.*, 864 F.Supp.3d at 1322.

1) Evidence-based clinical practice guidelines

Two professional medical associations – WPATH and the Endocrine Society – have published clinical practice guidelines recommending gender-affirming care for the treatment of gender dysphoria in persons meeting specific criteria. (Ex. 34; Ex.123; Doc.193-24.) These guidelines establish the authoritative protocols for health care providers working with transgender patients. (Ex.7, ¶39; Ex.9, ¶¶48-49, 56; Ex.10, ¶24; Ex.324, at 4.) And no published clinical practice guidelines recommend the use of psychotherapy alone to treat gender dysphoria. (Ex.9, ¶14.)

Defendants' argument that the WPATH and Endocrine Society guidelines are biased and not evidence-based is without merit. First, it is *de rigeur* for professional medical associations to advocate on behalf of health care providers and patients. (Ex.14, ¶¶54-56.) That does not undermine—let alone, invalidate—their published clinical practice guidelines. Second, the fact that WPATH members drafted the Standards of Care reflects not bias or a conflict of interest, but that clinicians and researchers with the requisite expertise in transgender medicine drafted them. (Ex.12, ¶42; Ex.5, ¶¶9-11.) Third, the WPATH and Endocrine Society guidelines

[6] That AHCA even initiated the GAPMS process for these services reveals that the process was a sham, as it is not used for already-covered services. (Ex.30; Doc.120-6, 93:13-93:21.)

are based on rigorous reviews of the peer-reviewed scientific literature, as well as extensive clinical experience. (Ex.34, at App'x A; Ex.123, at 3872-73; Ex.17, ¶¶55-58; Ex.5, ¶¶18-24, 29; Ex.7, ¶¶28, 33.)

Moreover, the guidelines themselves were peer-reviewed and published in medical journals. "That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995).

Defendants' attempt to discredit these clinical practice guidelines is even more remarkable considering AHCA's prior reliance on these very guidelines during GAPMS processes. For example, the 2016 GAPMS report on puberty suppression therapy included the Endocrine Society guidelines without any suggestion that they were somehow invalid. (Ex. 240.)

2) Published reports and articles in the authoritative medical and scientific literature

Abundant "peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations" examines the use of puberty delaying medications, hormone therapy, and surgery to treat gender dysphoria. FAC 59G-1.035(4)(b).

In drafting the GAPMS Report, AHCA ignored most of the body of peer-reviewed literature on gender-affirming care. (Doc.120-6, at 147:12-147:25; Doc.84-1, ¶4.) The "assessment" by Dr. Brignardello-Peterson and Dr. Wiercioch included just 27 studies published between 2020 and 2022 (Ex.324, at 10-11.)—hardly a comprehensive review. (Ex.324, at 10-11; Ex.7, ¶¶80-81.)

The GAPMS Report and Defendants' experts attempt to discount the supportive literature they did consider as "low quality." That claim is highly misleading and at minimum surfaces a factual dispute. (Ex.324, at 11-12; Ex.5, ¶¶19-22.) While randomized trials are rated as high-quality evidence and observational studies as low-quality evidence (Ex. 5, ¶20), for ethical and practical reasons, it is not possible to conduct randomized trials involving medical treatments for gender dysphoria. (Ex.8, ¶¶74-85; Ex.10, ¶¶52-53; Ex.5, ¶¶27-28; Ex.9, ¶17; Ex.7, ¶83.) The lack of randomized trials does not render the existing research insufficient to inform clinical decision making. (Ex.324, at 13; Ex.14, ¶30; Ex.10, ¶56; Ex.13, ¶8; Ex.8, ¶¶73, 88-90.)

3) Effectiveness in improving prognosis or health outcomes

The peer-reviewed literature shows that puberty-delaying medications, hormone therapy, and surgery are: 1) safe and effective for the treatment of gender dysphoria; and 2) when used for that purpose, correlated with additional positive

health outcomes, including improved quality of life, mental health, and psychosocial functioning. (Section II.B, *supra*.)

4) Utilization trends

The GAPMS Report makes no mention of this factor. There has been a notable increase in the utilization of gender-affirming medical care over the last three decades, and AHCA's own data reflects this increase. (Ex.5, ¶¶39-40; Ex. 317; *see also* Ex.6, at ¶59.) Paradoxically, AHCA appears to view that rise in utilization as a reason to implement the Exclusion. (Ex.335.) But what it shows is that the services are commonly used and not experimental. *See Rush*, 625 F.2d at 1156, n.11 (contrasting service that is "generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used" with a one that "is rarely used, novel, or relatively unknown").

5) Other coverage policies

AHCA's coverage exclusion is an outlier among health insurance plans. Most health plans, in Florida and elsewhere, do not have categorical transgender-specific exclusions. (Ex.6, ¶¶40-46; *id.* ¶35 (highlighting that 25 states and D.C. prohibit such exclusions in state-regulated individual and group plans); Ex.5, ¶42.) In drafting the GAPMS report, AHCA did not even review private insurance policies. (Doc.120-6, at 149:2-152:6.)

Only 9 of the 56 states and territories operating a Medicaid program exclude coverage of gender-affirming medical care. (Ex.6, ¶¶54, 57.) Even among those jurisdictions, Florida's exclusion stands apart for its breadth and scope. (Ex.6, ¶¶ 55-57.) And Florida Medicaid itself covered this care until the Exclusion was adopted. (Doc.120-6, at 66:25-68:17, 74:18-75:9, 84:2-18, 243:7-15; Ex.257; Ex.317.)

While other nations' coverage policies have never factored into the GAPMS process, Defendants argue that their determination regarding puberty-delaying medications, hormone therapy, and surgery reflects an "international consensus" on the issue. (Mot. at 24-25.) That is wrong and misleading. Defendants have not conducted a comprehensive review of other countries' policies regarding gender-affirming care. And Defendants have misrepresented those nations' policies. (Ex.14, ¶¶73-82; Doc.142-11.)

6) Recommendations or assessments by clinical or technical experts on the subject or field

Recognized clinical and technical experts in the field of transgender medicine agree that puberty-delaying medications, hormone therapy, and surgery are safe and effective treatments for gender dysphoria. (Ex.8, ¶121; Ex.9, ¶89; Ex.11, ¶¶53-54, 100; Ex.17, ¶¶23, 133; Ex.10, ¶¶23, 43, 81; Ex.324, at 4-5.) But AHCA did not seek recommendations or assessments from recognized experts; it consulted a handful of vocal opponents of gender-affirming care.

B. Plaintiffs' Medicaid Act Claims Are Viable.

1) The EPSDT and Comparability Provisions of the Medicaid Act Are Enforceable Pursuant to 42 U.S.C. § 1983.

The Court should reject Defendants' argument that Plaintiffs have no private cause of action to enforce their Medicaid Act claims. For more than 20 years, the Supreme Court has required lower courts to apply a three-prong test to determine whether a statutory provision gives rise to a federal right under 42 U.S.C. § 1983. *See Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002); *Blessing v. Freestone*, 520 U.S. 329 (1997). Under *Blessing*, courts must evaluate three elements: first, Congress must intend the provision in question to benefit the plaintiff; second, the right contained in the provision must not be so "vague and amorphous" that its enforcement would strain judicial competence; third, the statute must unambiguously impose a binding obligation on the state. 520 U.S. at 340-41 (citations omitted). *Gonzaga* clarified the first prong of the test, instructing that the provision in question must contain unambiguous "right- or duty-creating language," as opposed to language with an aggregate, rather than individual, focus. 536 U.S. at 284 n.3; *see also* 42 U.S.C. §§ 1320a(2), (10) (congressional intent that provisions of the Social Security Act, of which Medicaid is a part, are privately enforceable).[7]

[7] Citing *Collins v. City of Harker Heights*, 503 U.S. 115, 119 (1992), Defendants argue that the EPSDT and comparability provisions do not create enforceable rights because § 1983 "does not provide a remedy for abuses that do not violate federal law." (Mot. at 28.) *Collins*, which did not involve a federal law, is inapposite. There,

Blessing also instructs plaintiffs to plead their complaints in "manageable analytic bites" and courts to determine whether "each separate claim" satisfies the test. *Blessing*, 520 U.S. at 342; *id*. at 340. Here, Count III of Plaintiffs' complaint alleges that the Exclusion violates the EPSDT provisions, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r)(5), and 1396a(a)(43)(C), and Count IV alleges that the Exclusion violates the comparability requirements, 42 U.S.C. § 1396a(a)(10)(B). (Doc.1, at ¶¶275-80.)

Every federal appellate court to have considered whether the EPSDT provisions are enforceable by Medicaid beneficiaries through section 1983 has concluded that they are. *See S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 602-07 (5th Cir. 2004); *Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs.*, 293 F.3d 472, 477-79 (8th Cir. 2002); *Miller v. Whitburn*, 10 F.3d 1315, 1319-20 (7th Cir. 1993); *see also Waskul v. Washtenaw Co. Cmty. Mental Health,* 979 F.3d 426, 445-48 (6th Cir. 2020) (finding § 1396a(a)(10)(A) enforceable in non-EPSDT case); *Bontrager v. Ind. Fam. & Soc. Servs. Admin,* 697 F.3d 604, 606-07 (7th Cir. 2012) (same); *Watson v. Weeks*, 436 F.3d 1152, 1159-62 (9th Cir. 2006) (same).

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the Supreme Court held that even if the allegations in the complaint were true, there was no constitutional violation. *Id*. at 125-30. Defendants make no such argument, and this Court has found that if Defendants' determination that the excluded treatments are experimental was unreasonable, Defendants have violated the Medicaid Act. (Doc.64, at 3-6.)

Defendants' argument that these courts failed to grasp the nature of a federal right under *Gonzaga* is unfounded. Take, for example, *S.D. ex rel. Dickson v. Hood*, in which a Medicaid beneficiary sought to enforce the EPSDT provisions. Assessing the first *Blessing*/*Gonzaga* prong, the Fifth Circuit concluded that section 1396a(a)(10)(A)—which requires that the State "must provide for making medical assistance available, including at least the care and services listed in paragraph (1) through (5), (17) and (21) of section 1396d(a) of this title, to all individuals" who meet the eligibility criteria—contains "precisely the sort of 'rights-creating' language identified in *Gonzaga* as critical to demonstrating a congressional intent to establish a new right." *S.D.*, 391 F.3d at 603. The Court also found that the EPSDT provisions do not have an aggregate focus but rather are "'concerned with whether the needs of [particular individuals] have been satisfied.'" *Id*. at 604 (quoting *Gonzaga*, 536 U.S. at 275). Turning to the second prong, the Court found that enforcement of the EPSDT provisions does not "strain judicial competence; it is the sort of work in which courts engage every day." *S.D.*, 391 F.3d at 605 (quotations omitted).[8] And third, the Court concluded that the provisions impose binding requirements on participating states. *Id*. at 605-06.

[8] While Defendants claim otherwise, district courts are clearly capable of determining whether health care services are "necessary" under section 1396d(r)(5). *See, e.g.*, *K.G.*, 981 F.Supp.2d at 1291-92; *C.R. ex rel. Reed v. Noggle*, 559 F.Supp.3d 1323, 1337 (N.D. Ga. 2021).

Similarly, two circuits have concluded that the comparability provision is enforceable through section 1983.[9] *See Waskul*, 979 F.3d at 446-48; *Davis v. Shah*, 821 F.3d 231, 255 n.12 (2d Cir. 2016).[10] In *Waskul*, the Sixth Circuit found that the comparability provision – which requires that "the medical assistance made available to any individual described" must "not be less in amount, duration, or scope than the medical assistance made available to any other such individual," 42 U.S.C. § 1396a(a)(10)(B) – contains "the kind of individually focused terminology that unambiguously confers an individual entitlement under the law." *Id*. at 447 (cleaned up). The Court further determined that the provision is "amenable to judicial remedy," as it "sets forth criteria for determining whether . . . services are equitably provided," and that the provision is "couched in mandatory rather than precatory language." *Id*. at 448 (cleaned up).

These cases establish that the EPSDT and comparability provisions create individual federal rights for Medicaid beneficiaries and are thus "presumptively

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[9] In *Harris v. James*, 127 F.3d 993 (11th Cir. 1997), the Eleventh Circuit held that a federal regulation itself cannot create an enforceable right under section 1983. *Id.* at 1008. The Court made clear that it was not deciding whether the statutory comparability provision could give rise to a federal right. *Id*. at 1011. Thus, *Harris* has no bearing on the issue before this Court. *See Doe v. Chiles*, 136 F.3d 709, 714-15 (11th Cir. 1998).

[10] Multiple district courts have reached the same conclusion. *See, e.g.*, *Cruz v. Zucker*, 116 F.Supp.3d 332, 345-46 (S.D.N.Y. 2015); *Women's Hosp. Found. v. Townsend*, 2008 WL 2743284 (M.D. La. July 10, 2008); *Michelle P. v. Holsinger*, 356 F.Supp.2d 763, 767-68 (E.D. Ky. 2005).

enforceable by § 1983." *Gonzaga*, 536 U.S. at 284. Defendants cannot make the "difficult showing" that Congress expressly prohibited reliance on section 1983 or that it provided a comprehensive remedial scheme intended to preclude individual suits to rebut this presumption. *Blessing*, 520 U.S. at 346. Congress has not done so. *See Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 521-22; *see also City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113, 121-22 (2005).

Finally, *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320 (2015), does not implicate the enforceability of Medicaid's EPSDT and comparability provisions pursuant to section 1983. *Armstrong* concerned a Medicaid payment provision (not EPSDT or comparability) that health care providers (not Medicaid enrollees) were seeking to enforce under the Supremacy Clause (not section 1983). 575 U.S. at 323-34. Unlike the provisions at issue here, the provision at issue in *Armstrong*, 42 U.S.C. § 1396a(a)(30)(A), had been found unenforceable pursuant to section 1983 by most courts, including this one. *See Fl. Pharmacy Ass'n v. Cook*, 17 F.Supp.2d 1293 (N.D. Fla. 1998). The plurality's reasoning in *Armstrong* did not involve and certainly did not overrule the section 1983 enforcement test. *See*, *e.g.*, *BT Bourbonnais Care, LLC v. Norwood*, 866 F.3d 815, 820 (7th Cir. 2017); *Legacy Cmty. Health Servs., Inc. v. Smith*, 881 F.3d 358, 373 (5th Cir. 2018).

2) The Exclusion Violates the Medicaid Act's EPSDT Requirements.

The EPSDT requirements' fundamental purpose is to ensure that Medicaid recipients under age 21 receive the "health care they need when they need it." *M.H. v. Berry*, 2021 WL 1192938, *6 (N.D. Ga. 2021) (cleaned up). Specifically, they require each state Medicaid program to cover any service allowable under § 1396d(a) if "necessary . . . to correct or ameliorate" health conditions regardless of whether the state covers the service for adults. 42 U.S.C. §§ 1396d(r)(5), 1396a(a)(10)(A), 1396d(a)(4)(B); *see, e.g., Moore ex rel. Moore v.* Reese, 637 F.3d 1220, 1233-34 (11th Cir. 2011); *S.D*, 391 F.3d at 589-93. "The EPSDT obligation is thus extremely broad." *Katie A., ex rel. Ludin v. L.A. County*, 481 F. 3d 1150, 1154 (9th Cir. 2007); *see also Smith v. Benson*, 703 F.Supp.2d 1262, 1269-70 (S.D. Fla. 2018). And "there is a very strong inference to be inclusive rather than exclusive" when determining the meaning of "correct or ameliorate." *Ekloff v. Rodgers*, 443 F.Supp.2d 1173, 1180 (D. Ariz. 2006). Further, states must take the proactive step of ensuring that services determined to be medically necessary for a particular beneficiary are actually arranged for. 42 U.S.C. § 1396a(a)(43)(C); *Katie A.*, 481 F. 3d at 1158-59.

Here, the EPSDT provisions require Defendants to cover the gender-affirming services barred by the Exclusion. Puberty-delaying medications, hormone therapy, and surgery fall within the scope of benefits listed in § 1396d(a). *See* 42 U.S.C. §

1396d(a)(1) (inpatient hospital services), (2)(A) (outpatient hospital services), (5)(A) (physicians' services), (12) (prescribed drugs). And, for many transgender young people, the services are "necessary . . . to correct or ameliorate" their gender dysphoria. *Id*. § 1396d(r)(5).

Broad consensus within the medical community recognizes that these treatments can be medically necessary for transgender adolescents and young adults, based on their individual needs. Prior to implementing the Exclusion, AHCA reached the same conclusion, covering each of these services for a significant number of transgender Medicaid beneficiaries under age 21. (Ex.317.) Indeed, AHCA covered puberty-delaying medications for K.F. and S.D. (Doc.120-6, at 247:9-247:20), and hormone therapy for Mr. Rothstein (*id*. at 246:15-247:6).

3) The Exclusion Violates the Medicaid Act's Comparability Requirement.

The Medicaid Act requires AHCA to ensure that the "medical assistance made available to any [categorically needy] individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240. Federal regulations make clear that states "may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c).

Courts regularly hold that the comparability requirement "prohibits discrimination among individuals with the same medical needs stemming from different medical conditions." *Davis*, 821 F.3d at 258; *see also White v. Beal*, 555 F.2d 1146, 1148 (3d Cir. 1977); *Cota v. Maxwell-Jolly*, 688 F.Supp.2d 980, 993 (N.D. Cal. 2010).

While AHCA refuses to cover various surgical procedures necessary to treat gender dysphoria, the agency covers the same surgeries when necessary to treat other conditions. (Ex.4 at Definitions ¶ 13; Ex.1, at ¶¶ 8-12.) Multiple federal courts have held that such a policy violates the comparability requirement by discriminating based on diagnosis.[11] *See*, *e.g.*, *Flack v. Wis. Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1019 (W.D. Wis. 2019); *Fain v. Crouch*, 2022 WL 3051015, *13 (S.D. W. Va. 2022).

The same reasoning applies to the categorical exclusion of hormone therapy. AHCA does not cover testosterone or estrogen when necessary to treat gender dysphoria but covers the same prescription drugs when necessary to treat other conditions. (Ex.4, ¶13; Ex.1, ¶8.) While Defendants argue that these uses are not

[11] Defendants argue that there is no "equivalence between" a mastectomy performed to treat gender dysphoria and a mastectomy performed to treat breast cancer because in the breast cancer context, "diseased breast tissue is removed from the body." (Mot. at 28.) Defendants do not explain why that distinction is meaningful and ignore that a mastectomy is routinely performed (and covered by AHCA) in patients whose breast tissue is not "diseased." (Ex.10, ¶¶14, 24.)

equivalent for purposes of Medicaid coverage, the prescription drug provision of the Medicaid Act indicates otherwise. The statute requires states to cover all FDA-approved drugs when they are prescribed for a "medically accepted indication," subject to certain limited inapplicable exceptions.[12] 42 U.S.C. §§ 1396r-8(k)(2), 1396r-8(d)(1)(B); Ex.63, at 2; *see also Edmonds v. Levine,* 417 F.Supp.2d 1323, 1338 (S.D. Fla. 2006). A "medically accepted indication" is a use that is FDA-approved or "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the Medicaid Act. 42 U.S.C. § 1396r-8(k)(6); *see also id.* § 1396r-8(g)(1)(B)(i) (listing three compendia, including DRUGDEX). Thus, under the Medicaid Act, a use that is FDA-approved stands on equal footing with a use that is supported by citation in a compendium. *See Edmonds*, 417 F.Supp.2d at 1337 (holding that AHCA cannot "substitute its own judgment for that of Congress" and deny coverage for uses of a prescription drug that are supported by citation in a compendium).

Here, citations in DRUGDEX support the use of various forms of testosterone and estrogen to treat gender dysphoria. Ex.25, at 18-21, 23-26, 29-36; Ex.26at 23-25, 27-28, 34-35. *See Dobson v. Sec'y of Health & Hum. Servs.*, 2022 WL 424813 at *7 (11th Cir. 2022) (interpreting the phrase "supported by one or more citations"

[12] Conversely, nothing in the Medicaid Act prohibits states from covering FDA-approved drugs when they are prescribed for a use that is not FDA-approved or supported by citation in a compendium.

in § 1396r-8(k)(6) to mean a citation "tend[s] to show or help[s] prove the efficacy and safety of the prescribed off-label use"). But while that use is on par with any FDA-approved use for purposes of Medicaid coverage, Florida only covers testosterone for FDA-approved indications. (Ex.27; Ex.25, at 10-11.) Moreover, as a matter of practice, AHCA covers testosterone cypionate, testosterone enanthate, and estrogen for ***absolutely any use*** – whether the use is FDA-approved, supported by citation in a compendium, or not – other than to treat gender dysphoria. (Ex.28.)[13] Thus, AHCA is excluding coverage for only one "medically accepted indication" (gender dysphoria) and providing coverage for every other indication, even those that are not medically accepted.

C. The Exclusion Violates Section 1557 of the ACA.

Section 1557 creates "an affirmative obligation not to discriminate in the provision of health care." *Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 955 (9th Cir. 2020). Section 1557 requires, in relevant part, that "[a]n individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), … be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42

[13] https://ahca.myflorida.com/content/download/8681/file/PDL.pdf.

U.S.C. § 18116(a). Title IX prohibits discrimination "on the basis of sex." 20 U.S.C. § 1681.

"To state a claim under [Section 1557], a plaintiff is required to show that he or she (1) was a member of a protected class, (2) qualified for the benefit or program at issue, (3) suffered an adverse action, and (4) the adverse action gave rise to an inference of discrimination." *Griffin v. Gen. Elec. Co.*, 752 F.App'x 947, 949 (11th Cir. 2019). Plaintiffs address each element in turn.

1) The Exclusion discriminates against Plaintiffs based on sex.

The Exclusion discriminates based on sex in three distinct ways. First, the Exclusion speaks in explicit gendered terms and *facially discriminates* based on sex. Second, the Exclusion discriminates based on sex stereotypes relating to a person's sex assigned at birth. And third, the Exclusion discriminates based on sex because it discriminates based on transgender status.

a) The Exclusion facially discriminates based on sex.

On its face, the Exclusion discriminates based on sex. The Exclusion explicitly precludes Medicaid coverage for "services for the treatment of *gender* dysphoria," including "*[s]ex* reassignment surgeries" and any "procedures that alter primary or secondary *sexual* characteristics." FAC 59G-1.050(7). "A facial inquiry is what it sounds like: a review of the language of the policy to see whether it is facially neutral or deals in explicitly racial or gendered terms.'" *Kadel*, 2022 WL

3226731, at *18 (cleaned up).

Here, one cannot "'try writing out instructions' for which treatments are excluded 'without using the word[] … sex (or some synonym).'" *Kadel*, 2022 WL 3226731, at *19 (quoting *Bostock*, 140 S. Ct. at 1746). "It can't be done." *Bostock*, 140 S. Ct. at 1746. It is impossible to determine whether a particular treatment is for "*gender* dysphoria,"[14] leads to ""*[s]ex* reassignment," or "alter[s] primary or secondary *sexual* characteristics"—and thus, whether the Exclusion applies—without comparing the member's sex assigned at birth to how it might be impacted by the treatment. *Kadel*, 2022 WL 3226731, at *19.

A barrage of case law examining similar exclusions supports this conclusion. *See*, *e.g.*, *Fain*, 2022 WL 3051015, at *8; *Fletcher v. Alaska*, 443 F.Supp.3d 1024, 1027, 1030 (D. Alaska 2020); *Flack v. Wisconsin Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1019-22 (W.D. Wis. 2019); *Boyden v. Conlin*, 341 F.Supp.3d 979, 1002-03 (W.D. Wis. 2018).

The Eleventh Circuit's decision in *Adams by & through Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791 (11th Cir. 2022) (en banc), does not affect this straightforward analysis. In *Adams*, the Eleventh Circuit was concerned not with whether the policy at issue discriminated based on sex but "whether discrimination based on biological sex necessarily entails discrimination based on transgender

[14] Gender dysphoria necessarily considers an individual's sex assigned at birth.

status." *Id.* at 809. Indeed, the court found that a "bathroom policy requir[ing] 'biological boys' and 'biological girls'—in reference to their sex determined at birth—to use either bathrooms that correspond to their biological sex or sex-neutral bathrooms," *id.* at 801, facially "classifie[d] on the basis of biological sex." *Id.* at 803.[15]

Because a beneficiary's sex (however, one defines it) plays "an unmistakable and impermissible role in the" decision to deny Medicaid coverage under the Exclusion, the Exclusion facially discriminates based on sex. *Kadel*, 2022 WL 3226731, at *28.[16]

b) The Exclusion discriminates based on sex because it discriminates based on sex stereotypes.

Excluding coverage for gender-affirming medical care because it "*alter[s]* primary or secondary *sexual* characteristics," FAC 59G-1.050(7), "entrenches" the sex-stereotyped "belief that transgender individuals must preserve the genitalia and other physical attributes of their [sex assigned at birth] sex over not just personal preference, but specific medical and psychological recommendations to the

[15] Section 1557 only incorporated the grounds and enforcement mechanisms of Title IX, not any of its exemptions or carve-outs. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F.Supp.3d 1, 43 (D.D.C. 2020).

[16] The holding in *Lange v. Houston County, Georgia*, 499 F.Supp.3d 1258, 1275 (M.D. Ga. 2020) ("*Lange I*"), is unavailing. (Doc.137 at 2-3.) *Lange I* is particularly unpersuasive for Plaintiffs' statutory claims, where Congress has directly renounced *Geduldig*'s reasoning.

contrary." *Boyden v. Conlin*, 341 F.Supp.3d 979, 997 (W.D. Wis. 2018). This is a "form of sex stereotyping where an individual is required effectively to maintain his or her natal sex characteristics." *Id.*; *see also Flack*, 328 F.Supp.3d at 951. It "is textbook sex discrimination." *Kadel*, 2022 WL 3226731, at *19.

Accordingly, courts throughout the country have found similar discrimination against transgender people to be rooted in impermissible sex stereotyping. *See*, *e.g.*, *Kadel v. Folwell*, 446 F.Supp.3d 1, 14 (M.D.N.C. 2020); *Toomey v. Arizona*, 2019 WL 7172144, at *6 (D. Ariz. Dec. 23, 2019).

This principle accords with longstanding Eleventh Circuit precedent that "[a]ll persons, whether transgender or not, are protected from discrimination on the basis of [a sex stereotype]." *Adams,* 57 F.4th at 813 (quoting *Glenn v. Brumby,* 663 F.3d 1312, 1318-19 (11th Cir. 2011)). *Adams* does not change this result. Unlike in *Adams*, the Exclusion hinges on prohibiting coverage for procedures that "*alter* primary or secondary *sexual* characteristics," FAC 59G-1.050(7), and "services for the treatment of *gender* dysphoria," FAC 59G-1.050(7), which by definition refers to the psychological distress that results from an *incongruence between one's sex assigned at birth and one's gender identity*. (Ex.33).

c) The Exclusion discriminates based on sex because it discriminates based on transgender status.

In *Bostock*, the Supreme Court explained that "it is impossible to discriminate against a person for being … transgender without discriminating against that

individual based on sex." 140 S.Ct. at 1741. And it is settled law that a policy that discriminates based on conduct or characteristics that either define or are closely correlated with a particular group facially discriminates against that group. *See*, *e.g.*, *Christian Legal Soc'y v. Martinez*, 561 U.S. 661, 689 (2010); *Lawrence v. Texas*, 539 U.S. 558, 583 (2003) (O'Connor, J., concurring).

Here, only transgender people have gender dysphoria. *See Fain*, 2022 WL 3051015, at *6; *see also C.P.*, 2022 WL 17788148, at *6; *Kadel*, 2022 WL 11166311, at *4; Section II(A), *supra*. Thus, the medical care singled out by the Exclusion is medical care that only transgender people need or seek. *See Fain*, 2022 WL 3051015, at *8; *Toomey*, 2019 WL 7172144, at *6; *Flack*, 328 F.Supp.3d at 950.

2) Plaintiffs have suffered an adverse action giving rise to an inference of discrimination.

Plaintiffs suffered an "adverse action" due to the Exclusion. Because of the Exclusion, Plaintiffs have lost Medicaid coverage for necessary medical treatment recommended by their doctors that would otherwise be covered. Defendants promulgated the Exclusion with discriminatory intent to achieve a discriminatory effect. The Exclusion bans coverage of medically necessary care for the treatment of gender dysphoria, which only transgender persons need. *See also Kadel*, 2022 WL 3226731, at *20.

Moreover, where the state "intentionally penalizes a person identified as male

at birth for . . . actions that it tolerates in [someone] identified as female at birth"—here, pursuing medical intervention to affirm a female identity—"sex plays an unmistakable and impermissible role." *Bostock*, 140 S.Ct. at 1741-42. Put another way, whether coverage is prohibited turns explicitly on a person's sex assigned at birth.

D. The Exclusion Triggers Heightened Scrutiny Under the Equal Protection Clause and Defendants Have Not Met Their Burden.

None of Defendants' arguments undermine the triable issue that Defendants' Exclusion violates Equal Protection because it discriminates based on sex and transgender status. And because the Exclusion discriminates based on sex and transgender status, Defendants must show that an "exceedingly persuasive justification" supports the Exclusion. *United States v. Virginia*, 518 U.S. 515, 531 (1996).

1) <u>The Exclusion discriminates based on sex, triggering heightened scrutiny.</u>

As outlined above, the Exclusion (1) *facially discriminates* based on sex; (2) discriminates based on sex stereotypes relating to a person's sex assigned at birth; and (3) discriminates based on sex because it discriminates based on transgender status.

Defendants argue that *Adams* held that "sex-based discrimination is discrimination based on biological sex" and that the Exclusion "does not make a

distinction based on biological sex." (Mot. at 32.) Not so, *see supra*. But even viewed in that (incorrect) framing, the Exclusion discriminates based on sex because the Exclusion prohibits coverage of procedures that ""*alter* primary or secondary *sexual characteristics*." FAC 59G-1.050(7). Such characteristics are biological.

Defendants further argue that rational basis applies because the Exclusion purportedly discriminates not based on sex, but on "medical diagnosis." (Mot. at 32.) But this does not save the Exclusion, either. Federal courts have rejected identical arguments. *Kadel*, 446 F.Supp.3d at 18. Only transgender people need coverage for "services and treatment for *gender dysphoria*" because only transgender people are diagnosed with gender dysphoria.

Defendants also argue that because the Exclusion is applied to both transgender people who were assigned female at birth and those who were assigned male at birth, it does not discriminate "based on sex." (Mot. at 32.) But that one group of transgender people are not treated worse than another does not change the fact that the Exclusion discriminates based on sex. "[T]he Equal Protection Clause, extending its guarantee to any person, reveals its concern with rights of individuals, not groups." *J.E.B. v. Alabama ex rel. T.B.*, 511 U.S. 127, 152 (1994) (Kennedy, J., concurring) (cleaned up); *see also Loving v. Virginia*, 388 U.S. 1, 8 (1967).

Finally, Defendants' reliance on *Geduldig v. Aiello*, 417 U.S. 484 (1974), is unavailing.

First, the Exclusion explicitly and facially classifies based on sex. *See Fletcher*, 443 F.Supp.3d at 1027, 1030; *see also Whitaker v. Kenosha Unified Sch. Dist. No.1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017). Every person to whom the Challenged Exclusion applies is therefore discriminated against because of sex.

Second, *Geduldig* only held that an exclusion of pregnancy from a disability benefits program with no showing of "pretext" is not *per se* "discrimination against the members of one sex." 417 U.S. at 496 n.20. But "[s]ome activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). Here, the Exclusion categorically excludes gender-affirming care from coverage, "which is only sought by transgender individuals." *Brandt v. Rutledge*, 2021 WL 3292057, at *2 (E.D. Ark. Aug. 2, 2021). That is precisely what *Geduldig* and *Bray* prohibit.

Third, the centrality of gender transition to transgender identity distinguishes this case from *Geduldig*. Unlike the pregnancy exclusion in *Geduldig*, the Exclusion here is based on a characteristic that defines membership in the excluded group. Pregnancy is not the defining characteristic of a woman. Living in accord with one's gender identity rather than birth-assigned sex is the defining characteristic of a transgender person. *See*, *e.g.*, *Glenn*, 663 F.3d at 1316.

2) The Exclusion discriminates based on transgender status and therefore independently triggers heightened scrutiny.

Defendants misconstrue the reach of the *Adams* case again in their assertion that the court "explained what constitutes unconstitutional discrimination based on transgender status." (Mot. at 32.) But the *Adams* court did no such thing. True, the *Adams* court expressed in *dicta* "doubt that transgender persons constitute a quasi-suspect class" because "the Supreme Court has rarely deemed a group a quasi-suspect class." 57 F.4th at 803 n.5. But that does not mean that "[t]ransgender individuals [] aren't entitled to heightened constitutional review per se." (Mot. at 33.)

Discrimination based on transgender status is separately entitled to, at least, heightened scrutiny because transgender people meet all of the indicia required. *See Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 607 (4th Cir. 2020); *see also Karnoski v. Trump*, 926 F.3d 1180, 1200 (9th Cir. 2019). "[T]ransgender people as a class have historically been subject to discrimination or differentiation; … they have a defining characteristic that frequently bears no relation to an ability to perform or contribute to society; … as a class they exhibit immutable or distinguishing characteristics that define them as a discrete group; and … as a class, they are a minority with relatively little political power." *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 288 (W.D. Pa. 2017).

3) There is a genuine dispute of material fact as to whether Defendants engaged in purposeful discrimination.

Defendants must "treat all persons similarly situated alike" or "avoid all classifications that … that reflect a bare desire to harm a politically unpopular group." *Glenn*, 663 F.3d at 1315 (cleaned up). That said, because the Exclusion is facially discriminatory, a showing of intentional discrimination is unnecessary. *See Cmty. Servs., Inc. v. Wind Gap Mun. Auth.*, 421 F.3d 170, 177 (3rd Cir. 2005).

Determining discriminatory intent is guided by an eight-factor test. *See League of Women Voters of Fla., Inc. v. Fla. Sec'y of State*, 32 F.4th 1363, 1373 (11th Cir. 2022) (cleaned up). Here, these factors are met.

- *The impact of the challenged law*: "[T]he Exclusion impacts only transgender individuals—that provides some circumstantial evidence of intentional discrimination." *Lange v. Houston Cnty., Georgia*, 608 F.Supp.3d 1340, 1355 (M.D. Ga. 2022) ("*Lange II*"). *See also supra*.
- *The historical background:* Here, Florida Medicaid covered medical treatment for gender dysphoria, until 2022, when Florida's government adopted a blizzard of anti-LGBTQ laws. This includes restrictions on the coverage and provision of gender-affirming care, "Don't Say or Trans" laws, banning of books discussing LGBTQ identities, bans on drag performances, and more. (Opp. Ex. E; Doc.1, ¶¶126(a)-(f).)

- *The specific sequence of events leading up to its passage:* Plaintiffs have laid out circumstantial evidence concerning this factor, including the coordination with the Governor's Office, FDOH, and anti-transgender activists.
- *Procedural and substantive departures:* Plaintiffs have documented a litany of procedural and substantive departures, including AHCA's: (1) hiring of outside consultants, which AHCA had never done for a GAPMS (Doc.120-6, at 137:10-12, 139:17-138:3), all of whom opposed gender-affirming care (Ex.324, at 7-9); (2) not enlisting or even considering any consultant supporting the provision of gender-affirming care (Doc.120-6, 135:10-15; Doc.120-9, 112:5-23); (3) employing an unprecedented GAPMS process for a treatment already covered (Doc.120-6, 93:13-21); (4) bypassing the employees typically tasked with conducting GAPMS processes (Doc.120-9, 85:16-19); and (5) closely coordinating with and having the process originate from other agencies like FDOH and the Governor's Office, (Doc.120-6, at 89:18-19, 90:25-91:1, 92:2-4; Opp. Ex. D (Weida), 15:2-18:3; Ex.302).
- *The contemporary statements and actions of key legislators:* Plaintiffs have pointed to some of these demeaning and offensive statements. (Doc.1, ¶126(g).)

- *The foreseeability of the disparate impact and knowledge of that impact:* The impact on transgender Medicaid beneficiaries was both foreseeable and communicated to Defendants during the notice-and-comment process. (Ex. 323, at 6; Ex. 324, at 2; Ex. 325, at 3-4).
- *The availability of less discriminatory alternatives*: "There is no evidence [Defendants] considered less discriminatory alternatives." *Lange II*, 608 F.Supp.3d at 1356.

When it comes to whether Defendants engaged in purposeful discrimination, "the facts are hotly disputed," at least. *Lange II*, 608 F.Supp.3d at 1356.

IV. CONCLUSION

For the foregoing reasons, the Court should deny Defendants' Motion.

Respectfully submitted this 28th day of April 2023.

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CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F), I certify that this Motion contains 7,999 words.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of April 2023, a true copy of the foregoing has been filed with the Court utilizing its CM/ECF system, which will transmit a notice of electronic filing to counsel of record for all parties in this matter registered with the Court for this purpose.

/s/ Omar Gonzalez-Pagan
Counsel for Plaintiffs

TAB 200-1

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, *et al.*, *Plaintiffs*, v. JASON WEIDA, *et al.*, *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

DECLARATION OF OMAR GONZALEZ-PAGAN

Pursuant to 28 U.S.C.§ 1746, I, Omar Gonzalez-Pagan, do hereby declare as follows:

1. I am over 18 years of age.

2. I am Counsel at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.

3. I have personal knowledge of the stated herein, except those stated on information and belief, and if called upon, could and would testify competently to them.

4. I submit this declaration in support of Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment.

5. Attached as **Exhibit A** is a true and accurate copy of an email with the subject line "A Message from your WPATH President, Dr. Marci Bowers" sent to WPATH members on April 21, 2023, as publicly posted on https://listloop.com/wpath/mail.cgi/archive/adhoc/20230421130649/.

6. Attached as **Exhibit B** is a true and correct copy of article "Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand," published in the peer-reviewed academic Journal of New Zealand Medical Journal in December 2018.

7. Attached as **Exhibit C** is a true and correct copy of the publication "Primary Care Gender Affirming Hormone Therapy Initiation Guidelines: Aotearoa New Zealand guidelines for commencing GAHT for adults in primary care," published in March 2023.

8. Attached as **Exhibit D** is a true and correct copy of excerpts of the transcript of the deposition of Jason Weida on April 24, 2023 taken in relation to the above-captioned matter.

9. Enclosed as **Exhibit E** is a true and correct copy of the press release issued by Equality Florida on April 11, 2023 announcing their "TRAVEL ADVISORY: FLORIDA MAY NOT BE A SAFE PLACE TO MOVE OR VISIT."

I declare under the penalty of perjury that the foregoing is true and correct.

Dated this 28th day of April 2023.

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan

TAB 200-2

ListLoop (https://listloop.com/wpath/mail.cgi)

A Message from your WPATH President, Dr. Marci Bowers

From: "WPATH" <wpath@PROTECTED>
Subject: A Message from your WPATH President, Dr. Marci Bowers
Date: April 21st 2023

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

April 21, 2023

Dear Colleagues,

In the United States, 2023 has been a difficult year thus far for trans rights, to say the least. Although anti-trans sentiment has simmered for years, the exponential rise in TGD identification among adolescents has triggered unprecedented attacks against all things trans. More than 400 anti-transgender bills, particularly in conservative states, see anti-transmessaging as a winning political posture for some. Eleven (11) states alone have already banned or restricted gender affirming care for gender diverse adolescents. Last week, Missouri became the first state to attempt gender enforcement on *adult* populations when attorney general, Andrew Bailey, issued an 'emergency declaration' that added draconian new hurdles for adult trans care to its adolescent ban. It is already probable that gender affirming care will be a wedge issue in the 2024 US election cycle.

Globally, many of the arguments used here in the US to ban transgender care have been cherry-picked or use narrowly excerpted language for restrictions that have been implemented in gender

services policies in Sweden and the UK---'lack of evidence', 'experimental' and 'focus on mental health'. They also ignore European countries where access to trans care has recently expanded (Spain, Portugal, and France). And unlike Swedish and British restrictions---which do not end treatment but rather, make research participation compulsory in order to answer remaining questions---conservative US policy makers have no interest in research on TGD medical therapy; they only care about shutting it down. Rather than safeguard young people by outlawing automatic weapons and high-capacity munitions, conservatives feel that banning trans care and removing LGBTQ-themed books will better protect society.

Caught in the middle are TGD individuals, providers, and families, who are now in anguish here in US-affected states. WPATH membership continues to receive stories of growing despair, clinics closing, families moving or seeking healthcare out of state [see link]. (https://www.vice.com/en/article/wxj5pw/florida-lgbtq-clinics-anti-trans-laws) Suicidality and desperation are again, needlessly in play.

Telemedicine and the emergence of sanctuary US states (California, Minnesota, and Colorado) that have chosen to defend access to trans care, provide some hope. But real progress on the road back will be difficult until the flow of anti-trans legislation slows and then stops. If there is one reductionist word that WPATH does not deserve, it is advocacy--all scientific organizations participate in some form of advocacy.

That said, the scientific and biological arguments can all be won and should continue to be argued. In a recent interview, Dr. Eli Coleman responded "*WPATH followed a rigorous, multi-year process and was based on the best available scientific evidence and weighing all risks and benefits to arrive at the recommendations in our Standards of Care 8 guidelines. Our multi-step methodology is clearly set forth in the guidelines themselves. When you compare the process we followed, the SOC8 has by far the more robust methodology than any other trans health related guidelines. We had 119 experts from around the world involved, developed PICO questions which formed the basis of systematic reviews, used a consensus-based approach (Delphi) involving all committee members to arrive at our conclusions and then graded the strength of our recommendations. We had an extensive period of public comment on a draft of the SOC8 and this input was checked against the available evidence resulting in the final version of the SOC8. The rationale for our recommendations is clearly explicated in the SOC8 referencing the extant research. WPATH stands behind our process and conclusions.*"

The recent New York Times opinion piece, "*What Decades of Providing Trans Care Have Taught Me*", was my take on the situation and can be read here (https://wpath.org/media/cms/Documents/NYT%20OpEd%20M%20Bowers%20Apr%201%202023.pdf).

The **first step** on the road back, in my opinion, will be to allow the public to hear the anguish and the stories of those in pain as a direct result of anti-trans legislation, difficult as this will be to watch---and to pin this pain upon those legislators and policy makers who have inflicted the agony. In my interview

with CBS Evening News to be aired any day, I called it 'legislative cruelty'. The moment we are in reminds me of San Francisco's Harvey Milk and his plea to gay persons to come out. We need to be heard—trans persons, allies, parents, families, politicians, clergy---those who have been hurt and those who know us.

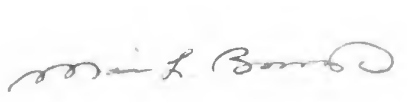
The **second step** on the road back will be to unite disparate causes in our fight against a common foe. An attack on trans care is an attack on women. It is an attack on black people, brown people, and Asian people. It is an attack on Jewish, Muslim, Hindi, Sikh, and true Christian communities. It is an attack on diversity and all of the ideals that diversity holds. It is an attack on us all. A majority of Americans favor access to adolescent trans care see link to NPR-Marist poll (https://maristpoll.marist.edu/polls/npr-pbs-newshour-marist-poll-transgender-rights-april-2021/) but the support is regional and it is thin. We need to better explain what adolescent TGD care looks like, why it is effective and indicated and who these patients really are. Anti-trans legislation needs to be fought with every voice, every thought, every inclination by all who know it. We need to make anti-trans legislation a *losing political issue*.

Already lost in this debate is the deplorable state of health and sex education throughout the Southern US. Furthering this ignorance, books are now banned, especially and specifically those with LGBTQI themes. It is of little surprise to many that persistent rates of new HIV infection, incest, and STDs remain highest where sex education is lowest, most in states where anti-trans legislation has been proposed.

And finally, '*What is a Woman?*', the title to a trite and condescending 2022 American movie produced by conservative Matt Walsh, whose edits left out any answer to the question, as though the answer was obvious. What was cut from the piece was reality; that nature lacks a definitive answer to the question. Because there is no biological measure----not chromosomes, not hormones, not anatomy nor any of the six other biological markers of sex---a woman is what society sees based upon the gender identity the individual projects. No measure in biology gets it right every time. For every rule, there is an exception. Sex and gender are complicated and diverse---but let us explain the phenomena, not allow the issues to be put back in the societal closet. Ultimately, what terrifies conservatives most is that gender diversity is a force of nature that can no longer be contained by religious conscription or enforcement of a gender binary.

Killarney, Ireland and EPATH will again surely exceed expectations as we meet April 26-28, 2023.

Until we all dance once more….



Marci L Bowers, MD

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TAB 200-3

Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand

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ABSTRACT

Internationally and within Aotearoa, New Zealand, there has been a substantial increase in the demand for gender affirming healthcare over the past decade. It is likely that this level of referrals to health services will continue in the foreseeable future. The Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand were developed following the recognition that the previous good practice guide required updating to be in step with current practice and international standards. This article presents a summary of the guideline focusing on puberty blockers, hormonal therapies, access to surgery and other gender affirming healthcare. We hope these guidelines will support the development and provision of services providing gender affirming healthcare around the country and provide helpful guidance to all health professionals involved in the care of trans people.

Internationally and within Aotearoa, New Zealand, there has been a substantial increase in the demand for gender affirming healthcare over the past decade. The Youth'12 survey estimated that approximately 1.2% of adolescents in Aotearoa, New Zealand identify as transgender.[1] As societal acceptance for trans people grows, it is likely that this level of referrals to health services will continue in the foreseeable future.[1,2]

Transgender healthcare is rapidly evolving. Table 1 includes some of the terminology healthcare professionals may encounter. The World Professional Association of Transgender Health (WPATH) is the international body responsible for producing standards of care (SOC) for transgender health based on international clinical consensus.[3] These are currently being revised and version 8 will inform practice internationally and in Aotearoa, New Zealand.

The Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand[4] were developed following the recognition that the previous good practice guide required updating to be in step with current practice and international standards. This guideline is not intended to replace the WPATH SOC but to present additional guidance for the provision of gender affirming healthcare in Aotearoa, New Zealand. This article presents a summary of gender affirming healthcare discussed in the larger document.

Methods

This guideline was produced in collaboration with trans community members and after consultation with many services and health professionals throughout Aotearoa, New Zealand, who work professionally

Table 1: Terminology.

Gender identity
A person's concept of their self as male, female, a blend of both or neither. Gender identity can be the same as, or different to, the sex assigned at birth.
Gender expression
The external presentation of one's gender. This can be expressed through one's name, clothing, behaviour, hairstyle, voice or any other way. A person's gender expression may or may not conform to socially defined behaviours and characteristics typically associated with being either solely masculine or feminine.
Gender diverse
A term to describe people who do not conform to their society or culture's expectations for males and females. Being transgender can be one way of being gender diverse, but not all gender diverse people identify as being transgender and vice versa. Gender creative or gender expansive are other similar terms that are used when referring to children.
Assigned male at birth
A person who was thought to be male when born and initially raised as a boy.
Assigned female at birth
A person who was thought to be female when born and initially raised as a girl.
Trans or transgender
A term for someone whose gender identity does not align with their sex assigned at birth. This term is often used as an umbrella term, recognising that people may describe themselves in many ways including the use of indigenous terms such as; whakawāhine, tangata ira tāne, tāhine (Māori), mahu (Hawai'i and Tahiti), vakasalewalewa (Fiji), palo- pa (Papua New Guinea), fa'afafine (Samoa), akava'ine (Rarotonga), fakaleiti or leiti (Tonga), fakafifine (Niue).
Cis or cisgender
A term for someone whose gender identity aligns with their sex assigned at birth.
Trans boy/male/man
A term to describe someone, assigned female at birth, who identifies as a boy/male/man.
Trans girl/female/woman
A term to describe someone, assigned male at birth, who identifies as a girl/female/woman.
Non-binary
A term to describe someone who doesn't identify exclusively as a man or a woman. There are many different ways that people may be non-binary male or female.
Gender dysphoria
A term that describes the distress experienced by a person due to the incongruence between their gender identity and their sex assigned at birth.
Social transition
The process by which a person changes their gender expression in social situations to better align with their gender identity.
Gender affirming healthcare
Healthcare that is respectful and affirming of a person's unique sense of gender and provides support to identify and facilitate gender healthcare goals. These goals may include supporting exploration of gender expression, support around social transition, hormone and/or surgical interventions. This may also involve providing support to whānau, caregivers or other significant supporting people.
Pronoun
A word used in place of a noun (or name). Pronouns include: he/him, she/her or they/them. Other gender neutral pronouns in use include ze and hir.

to advance healthcare for trans people. While regional differences in practice exist, the document describes principles and approaches that encompass this diversity. The gender affirming hormonal therapy guidelines in this document draw significantly on those published by the Endocrine Society.[5]

Principles of gender affirming healthcare

These guidelines are based on the principle of Te Mana Whakahaere; trans people's autonomy of their own bodies, represented by healthcare provision based on informed consent.[6] The informed consent process involves several conversations between the trans person and clinician(s) before starting treatments that have an irreversible component to increase certainty that they are adequately prepared and are making a fully informed decision.[7]

The use of Sir Mason Durie's Te Whare Tapa Whā as a framework highlights the equal importance of spiritual, family, mental and physical health.[8] Health providers have a duty to approach care holistically and in partnership.[4] Involving practitioners with expertise in mental health is important for two reasons. Firstly, mental health professionals with the appropriate skills can assist with the informed consent process. Secondly, it is increasingly recognised that discrimination and marginalisation experienced by trans people contributes to high rates of anxiety and depression.[9–11] The Youth'12 survey highlighted the mental health disparities experienced by trans young people compared to their cisgender peers with 41% vs 12% experiencing significant depressive symptoms and 20% vs 4% reporting an attempted suicide, respectively, in the past 12 months.[1] While there is no New Zealand data for older trans people it is likely that they also experience elevated rates of anxiety and depression as overseas studies have found.[9] Because of this, health services that have good links with peer support groups and mental health professionals will be more responsive to the needs of trans people accessing gender affirming healthcare.

Each person presenting to a health service has their own unique clinical presentation and needs. While many trans people will benefit from hormone therapies and surgical interventions, some may require only one or neither of these options.[12] Clinicians should not assume that everyone wants to conform to binary (male or female) gender norms and be open to gender affirming healthcare that aligns with non-binary identities.[3] When outer gender expression is congruent with an inner sense of self, most trans people will find increased comfort, confidence and improved function in everyday life.[13] Avoiding harm is a fundamental ethical consideration for health professionals when considering healthcare. Withholding or delaying gender affirming treatment is not considered a neutral option, as this may cause harm by exacerbating any gender dysphoria or mental health problems. This is no different from harm that can be caused by withholding or delaying other medically necessary care.

Gender affirming healthcare

Gender affirming healthcare may include provision of puberty blockers in children and adolescents, and hormone therapy in older adolescents and adults. The criteria for access to gender affirming hormones are persistent well-documented gender dysphoria, the capacity to make a fully informed decision and to consent for treatment, 16 years of age or older, and significant medical or mental health concerns must be reasonably well controlled. However, it is increasingly recognised that there may be compelling reasons, such as final predicted height, to initiate hormones prior to the age of 16 years for some individuals, although there is as yet little published evidence to support this.[5] There is no upper age limit to starting gender affirming hormone therapy. These criteria reflect the WPATH SOC which emphasise that having medical or mental health concerns does not mean gender affirming care cannot be commenced, rather that these need to be managed as part of an informed consent process.[3] This readiness can be assessed by a prescribing provider or mental health professional who is experienced and competent at working with trans people.

The informed consent process for readiness for puberty blockers, gender affirming hormones or surgery are detailed in the WPATH SOC.[3] The main components include assessing gender dysphoria, discussing social transition, gender expression and physical transition options, and providing a space to consider the implications of these options, with regard to safety, expectations

and impact on social, emotional, academic/occupational functioning. For all trans, particularly children and young people, consideration of psychosocial supports, especially family/whānau support is essential. Provide support to families and additional guidance if this support is absent. If this aspect of the assessment is not completed by a medical professional, then communication between the mental health professional and the prescriber/surgeon should occur to ensure a holistic approach to assessment.

Fertility preservation should be discussed prior to starting puberty blockers, gender affirming hormone therapy or gonadectomy.[5] Refer to local fertility services for access to funded cryopreservation of gametes. For those starting feminising hormones, who have reached at least Tanner stage 3, it is recommended that cyropreservation of sperm be considered.[5] For those in early adolescence (Tanner stage 2–3), collection of mature sperm will not usually be possible as mature sperm are produced from mid puberty (Tanner stage 3–4).[7] For those starting masculinising hormones, the option of egg or ovarian tissue storage should be discussed, recognising however, that this involves invasive procedures that are not currently funded where reproductive organs remain. There is no current evidence to suggest that testosterone exposure affects the likelihood of future healthy egg harvesting, and there are many reports of trans men who have ceased testosterone, for the purposes of achieving conception, having successful pregnancy outcomes.[14] However, it is unknown what effect the duration of testosterone therapy has on ovarian function.

Testosterone therapy does not provide a guarantee of adequate contraception and is contraindicated in pregnancy because of potential harm to the fetus from the androgenising effects of treatment.[15] Provide contraceptive advice prior to starting testosterone. Progesterone based Long Acting Reversible Contraception (LARCs) such as (Depo provera®, Jadelle®) or Intrauterine Devices (IUDs) such as Mirena®/ IUCDs are suitable options. Note that IUD insertion may be technically more challenging in those with a degree of cervical atrophy from testosterone therapy.

Puberty suppression using gonadotropin releasing hormone (GnRH) agonists

Puberty blockers can be prescribed from Tanner stage 2 to suppress the development of secondary sex characteristics and may be still beneficial when prescribed later in puberty to prevent ongoing masculinisation/feminisation.[5] Puberty blockers are considered to be fully reversible and allow the adolescent time prior to making a decision on starting hormonal therapies. Monitoring of height is recommended as adult height may potentially be increased if prolonged puberty suppression delays epiphyseal fusing.[5] A bone age may be helpful to assess whether epiphyseal closure has occurred when considering what rate of hormonal induction to use. Concern has been raised regarding the long-term impact of puberty suppression on bone mineral density.[5] It is therefore advisable to encourage young people on puberty blockers to have an adequate calcium intake, provide vitamin D supplementation where needed and encourage weight bearing exercise.[7] Bone density measurements (DEXA) can be considered in those requiring a prolonged period on puberty blockers or have significant additional risks for reduced bone density.

Puberty blockers halt the continuing development of secondary sexual characteristics, such as breast growth or voice deepening, and relieve distress associated with these bodily changes for trans young people.[16,17] For trans men and others assigned female at birth, the puberty blockers will induce amenorrhoea, reducing distress associated with menstruation.

Currently goserelin (Zoladex®) implants have sole subsidy status, although leuprorelin (Lucrin®) injections are fully funded for children and adolescents who are unable to tolerate administration of goserelin.[18] Table 2 presents clinical recommendations for puberty blockers, and standard dosing schedules. Puberty blockers should be continued until further treatments such as initiating other anti-androgens, accessing orchiectomy or other surgical interventions are decided on.

Table 2: Clinical recommendations and dosing schedules for puberty blockade.

Medical examination and investigations during suppression of puberty	
Examination	Every 3–6 months: height, weight, consider sitting height, BP, Tanner stage to ensure complete suppression
Blood tests	Every 6–12 months: LH, oestradiol or testosterone. LH should be suppressed <2.0 units/L along with clinical features of puberty arrest.
X-rays	Bone age on left hand if clinically indicated
If major risk factors for osteoporotic # or prolonged time on puberty blockers	Consider DEXA imaging and Vitamin D treatment.
Leuprorelin (Lucrin®)	11.25mg IM every 12 weeks*
Goserelin (Zoladex®)	10.8mg SC implant insertion into lower abdomen every 12 weeks*

*Frequency can be reduced to 10 weeks if incomplete LH suppression, puberty progression, or ongoing menses.

Gender affirming hormonal therapy

Adults should undergo a medical examination and investigations prior to starting hormones (Table 3). It is important to evaluate and address any medical conditions that could be exacerbated by treatment.[5] As with the use of oestrogen or testosterone in any context, clinicians should consider whether patients are; smokers, have a history of heart failure, cerebrovascular disease, coronary artery disease, atrial fibrillation, or personal risk factors for cardiovascular disease, history or family history of venous thromboembolism (VTE), migraine, history of sleep apnoea or hormone-sensitive cancers (eg, breast, prostate, uterine or testicular). Prescribers are advised to not consider any of the above conditions as absolute contraindications, but to consider and discuss any risks presented as part of the informed consent process.

Feminising hormonal therapy (Table 4)

Oestradiol valerate can be started in conjunction with an anti-androgen agent or added to a GnRH agonist (leuprorelin/goserelin). Goserelin (Zoladex®) is an option where oral anti-androgen agents are not tolerated. Anti-androgens are no longer required following orchiectomy or genital gender reassignment surgery. Start a low dose of oestradiol valerate (Progynova®/Estradot®) and increase the dose every 6–12 months depending on the clinical effect.

Table 3: Medical examination and investigations prior to commencing gender affirming hormonal therapy.

Physical examination	**Investigations**
Blood pressure	Electrolytes if starting spironolactone
Height	HbA1c if risk factors suggest indicated
Weight	Lipids if risk factors suggest indicated
BMI	Prolactin if starting oestrogen
Tanner stage (in adolescents)	LH
	Testosterone level
	Oestradiol level
	Urine/serum HCG if commencing testosterone

Table 4: Feminising gender affirming hormonal therapy dosing regimen and expected effects.[5]

Medication	**Dose (adults and older adolescents)**		
Anti-androgen agent options (not required post gonadectomy)			
Cyproterone	Starting dose: 25–50mg po daily Usual maintenance dose: 25–50mg po daily, although smaller doses (12.5mg) may be effective		
Spironolactone	Starting dose: 50–100mg po daily Usual maintenance dose: 100–200mg po daily		
Oestrogen options			
Oestradiol valerate (Progynova®)	Starting dose: 1mg po daily* Usual maintenance dose: 2–4mg, maximum 6mg po daily		
Oestradiol patch (Estradot®)	Starting dose: 25mcg patch twice weekly Usual maintenance dose: 100–200mcg patch twice weekly		
Effect of oestrogen	**Expected onset**	**Expected maximum effect**	**Reversibility**
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair[a]	6–12 months	>3 years	Possible
Male pattern baldness	Variable	b	
Voice changes	None	c	

a - Complete removal of hair requires laser treatment;
b - Familial scalp hair loss may occur if estrogens are stopped;
c - Treatment by speech-language therapists for voice training is most effective.

Potential complications for feminising oestrogen therapy include VTE particularly if aged >40 years and within the first two years of treatment.[5] Transdermal oestrogen has lower risks for thromboembolism than oral oestrogen and should be considered particularly if increased risks are present. It is unclear whether oestrogen therapy may adversely affect the lipid profile and blood pressure, but any effect is likely to be modest.[19,20] Liver dysfunction and gallstones are occasionally seen, although a clinically significant rise in the prolactin level is an uncommon occurrence.[21] There may be alterations in mood and libido.

Table 5: Masculinising gender affirming hormonal therapy dosing regimen and expected effects.[5]

Medication	**Dose (adults and older adolescents)**		
Androderm® patches	7.5mg daily (local irritation common)		
Sustanon® (testosterone esters)	250mg/ml IM every 3 weeks[a]		
Depo T (testosterone cypionate)	100–200mg IM every two weeks or, 100mg SC weekly–200 mg SC every 2 weeks		
Reandron® (testosterone undecylate)	1,000mg IM every 10–12 weeks (second dose at six weeks to achieve steady state)		
Effect of testosterone	**Expected onset**	**Expected maximum effect**	**Reversibility**
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[b]	variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of voice	6–12 months	1–2 years	Not possible
Increased sexual desire	variable	variable	Likely

a - Sustanon contains peanut oil (arachis oil) and should be potentially avoided in those with peanut allergies.
b - Highly dependent on age and inheritance; may be minimal.

Masculinising hormonal therapy (Table 5)

Testosterone can be added to a GnRH agonist or started on its own. Start a low dose of testosterone and increase gradually. Potential complications include polycythemia, which if severe, increases the risk of a thrombotic event. Periods will usually cease within the first 3–6 months of therapy. For those moving from GnRH agonists to testosterone, continue the blocker until the person is on the full testosterone dose and well virilised to avoid any undesired bleeding. For those not started on a GnRH agonist and not ready to start testosterone other interventions to achieve bleeding cessation include:

- Primolut® (norethisterone) po 5mg bd to 10mg tds. Note: Norethisterone is partially metabolised to ethinylestradiol, which at these high doses is equivalent to levels in the combined oral contraceptive.
- Provera® (medroxyprogesterone) po 10mg tds or 20mg nocte
- Combined Oral Contraception—continuous active pill taking to avoid menstruation
- Depo-provera® (medroxyprogesterone acetate) 150mg IM every 12 weeks
- Mirena® (levonorgestrel)—intrauterine device

The additional consideration of need for adequate contraception may affect the choice made.

Trans people receiving maintenance hormonal therapy should have ongoing medical assessments and investigations as illustrated in Table 6.

Table 6: Maintenance surveillance for gender affirming hormone therapy.[5]

	Investigation	Frequency
All persons	HbA1c—if risk factors suggest indicated	Annual
	Lipids—if risk factors suggest indicated	Annual
	Consider DEXA imaging if major risk factors for osteoporosis	
Feminising gender affirming hormone therapy	Electrolytes if on spironolactone and after a change in dose	Annual
	Liver function tests	Annual
	Testosterone—aim for <2nmol/L	3 monthly during first year, then annually
	Oestradiol – avoid supraphysiological levels (target <500pmol/L)	3 monthly during first year, then annually
	Prolactin	2 yearly
Masculinising gender affirming hormonal therapy	Testosterone – aim for male reference range[a]	3 monthly during first year, then annually
	Full blood count[b]	Every 3 months for first year, then 1–2 yearly
	Liver function tests	3 monthly during first year, then annually

a – testosterone should be measured midway between Depo T and Sustanon injections, immediately prior to a Reandron injection, and at least two hours after application of a testosterone patch.
b-consider testosterone dose reduction if Hct >0.54.

Gender affirming surgery

While many trans people are comfortable without, for others surgery is essential to alleviate their body dysphoria and live fully and authentically in their gender. Availability and funding are significant issues within Aotearoa, New Zealand. District health boards (DHBs) have expertise around provision of chest surgery (chest reconstruction to masculinise/breast augmentation to feminise where there has been no response to oestrogen), hysterectomy, oophorectomy and orchiectomy. Some DHBs have expertise in plastic surgical techniques such as laryngeal shaves and facial feminisation. Clinicians should be aware of local services and referral pathways. Currently access to genital reconstruction surgery (metoidioplasty or phalloplasty (masculinising) and vaginoplasty (feminising)) is via the Ministry of Health high-cost treatment pool (see website[23]).

Table 7 presents the surgical criteria recommended in the Aotearoa, New Zealand guidelines. These are the same as the current WPATH SOC.[3]

Other gender affirming care

Laser hair removal is important, particularly as feminising therapies will not completely halt facial hair growth that is already established. Be aware of local providers and support access where possible. Wearing a chest binder to achieve a more masculine chest appearance may be important; discuss safe use to prevent health risks associated with prolonged use.[24] Speech and communication are fundamental to people's genders. The goal of speech-language therapy is to help trans people develop voice and communication that reflects their gender.

General healthcare

All New Zealanders have the right to healthcare that is respectful and non-discriminatory. Ensuring healthcare services

Table 7: Aotearoa, New Zealand Guidelines and WPATH SOC v7 criteria for access to gender affirming surgery.[3]

- Criteria for access to chest reconstruction surgery:
  - Persistent, well-documented gender dysphoria.
  - Capacity to make a fully informed decision and to consent for treatment.
  - Age of majority.
  - If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormonal therapy is not a prerequisite for masculinising chest surgery but is recommended for a minimum of 12 months prior to consideration of feminising chest surgery.

- Criteria for access to hysterectomy, salpingo-oophorectomy and orchidectomy:
  - Persistent, well documented gender dysphoria.
  - Capacity to make a fully informed decision and to consent for treatment;
  - Age of majority.
  - If significant medical or mental health concerns are present, they must be well controlled.
  - 12 continuous months of hormone therapy as appropriate to the patient's transition goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones).
- Criteria for access to metoidioplasty or phalloplasty (masculinising) and for vaginoplasty (feminising):
  - Persistent, well documented gender dysphoria.
  - Capacity to make a fully informed decision and to consent for treatment.
  - Age of majority.
  - If significant medical or mental health concerns are present, they must be well controlled.
  - 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones).
  - 12 continuous months of living in a gender role that is congruent with their gender identity (note that this can include gender identities other than male and female).

In New Zealand, current practice is that the person must be 18 years or older to access publicly funded surgeries as above and in addition to the referral letter from the prescribing clinician, a letter of support from a mental health professional should be provided. The role of the mental health professional is to ensure that the person is psychologically prepared for the surgery (for example, has made a fully informed decision with clear and realistic expectations and is practically prepared for the event).

are inclusive of gender diversity is fundamental to good health care for trans people. Apart from gender affirming healthcare, trans people experience the same health needs as others. Those who have not undergone surgical removal of their breasts, cervix, uterus, ovaries, prostate or testicles remain at risk of cancer in these organs and should undergo screening as recommended. Manage sensitively, as many trans people find cancer screening extremely challenging, both physically and emotionally. Refer trans women for mammograms as per the National Breast Screening programme. Use of internal oestrogen cream prior to cervical smears in trans men may reduce discomfort and reduce the risk of inadequate smear tests.

General recommendations

Based on the guidelines outlined above, to best support the needs of transgender people in Aotearoa, New Zealand, we recommend that:

1. All health services provide equitable and accessible gender affirming healthcare services that align with international standards, evidence-based literature and community feedback.

2. DHBs enable flexible and responsive pathways on the basis of informed consent and self-determination.
3. Health services enable the involvement of trans people, including Māori trans people, in decisions that affect them regarding the development and provision of services.
4. Health services must support the development of culturally appropriate practice within clinical settings that acknowledges kaupapa Māori health frameworks.
5. DHBs provide clear information about pathways to access gender affirming healthcare services. This is inclusive of health services delivered by DHBs and primary healthcare.

Conclusion

The Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand have been developed in acknowledgement of the substantial increase in demand and significant evolution that has occurred in the period since the publication of currently used documents. The above summary provides an overview of gender affirming healthcare, while the full guideline details the role of the healthcare workforce in the provision of holistic healthcare for transgender people. We hope these guidelines will support the development of health services around the country, and provide helpful guidance to all health professionals involved in the care of transgender people.

Competing interests:
Nil.

Acknowledgements:
This guideline would not have been possible without the contributions and support of many people from around Aoteaora, New Zealand. We would like to thank Abbi Pritchard-Jones, Ahi Wi-Hongi, Alex Kerr, Dr Andrew Marshall, Dr Aram Kim, Dr Bridget Farrant, Dr Debbie Hughes, Duncan Matthews, Evolve Youth Service, Dr Fionna Bell, Frances Arns, Gender minorities Aotearoa, Jacky Byrne, Dr Jane Kennedy, Dr Jane Morgan, Jay Kuhtze, Jeanette Mackenzie, Dr Louise Albertella, Lyndon Moore, Mani Mitchell, Prof. Mark Henrickson, Dr Massimo Giola, Dr Michael Roberts, Dr Nicole McGrath, Dr Paul Hoffman, Phylesha Brown-Acton, Piripi Wills, Raj Sing, Rebecca Zonneveld, Dr Rick Cutfield, Roxanne Henare, Dr Simon Denny, Dr Susie Mollar, Taine Polkinghorne. We would also like to thank the Northern Region Clinical and Consumer Advisory Group for their guidance in developing this document.

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URL:
https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2018/vol-131-no-148714-december-2018/7771

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TAB 200-4

Primary Care Gender Affirming Hormone Therapy Initiation Guidelines

Aotearoa New Zealand guidelines for commencing GAHT for adults in primary care.

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Acknowledgements

The authors would like to thank everyone who provided feedback on earlier versions of this document, especially members of the Professional Association for Transgender Health Aotearoa (PATHA) and the Royal New Zealand College of General Practitioners (RNZCGP).

Contents

Glossary of terms

In the field of transgender health, language continues to change and evolve. When in doubt about what language to use with patients, clarify the patient's preferred terminology and use their preferred language.

Transgender (or trans)

People whose genders differ from societal expectations based on their sex assigned at birth; in this document we use this term to include transgender men, transgender women, non-binary people (who do not solely identify as a man or a woman), tangata ira tāne, whakawāhine, irawhiti, and some takatāpui and MVPFAFF+[a] people.[1]

Cisgender (or cis)

A term for someone whose gender identity aligns with their sex assigned at birth.

Gender dysphoria

The distress or discomfort some trans people experience when their gender and body do not feel connected or congruent. Not all trans people experience gender dysphoria.

Gender euphoria

Feeling comfortable in your body. Some people experience this as joy and happiness.

Gender incongruence

A marked and persistent incongruence between an individual's presumed and experienced gender. Often referred to as a diagnostic code from the ICD-11 as outlined in Appendix A.

Gender affirming hormone therapy (GAHT)

The hormone therapy taken by some transgender people to embody and affirm their gender, often leading to improved psychological wellbeing and quality of life.

E-GAHT is used to abbreviate oestrogen-based gender affirming hormone therapy, and T-GAHT to mean testosterone-based gender affirming hormone therapy.

[a] MVPFAFF+ is an acronym to describe Pasifika gender identities: Mahu (Hawai'i and Tahiti), Vaka sa lewa lewa (Fiji), Palopa (Papua New Guinea), Fa'afafine (Samoa), Akava'ine (Rarotonga), Fakaleiti (Tonga) and Fakafifine (Niue).

Purpose and scope

This guideline aims to facilitate a primary care-based approach and to give general practitioners (GPs) and nurse practitioners (NPs) tools and information to safely initiate gender affirming hormone therapy (GAHT) in collaboration with their patients. They remove a standard requirement for a mandatory mental health assessment, instead encouraging an individualised approach which utilises psychological support and input only when needed.

Referral to secondary care is only initiated when needed and the primary care prescriber remains the primary or sole treating clinician for the majority of people. This aims to reduce unnecessary barriers and improve access to GAHT, in turn improving health outcomes for transgender adults in Aotearoa New Zealand (NZ).

All transgender people have a right to self-determination, autonomy and dignity when accessing healthcare, including gender affirming healthcare. This guideline aims to outline an open and transparent, person-centred approach to commencing GAHT which views the patient as a competent adult who has the capacity to make their own decisions about their body and health.

By working in partnership with the patient, this approach aims to empower patients by helping them to understand the benefits and risks of GAHT, enabling them to make an informed decision about starting GAHT.

Many transgender people will be well informed about their healthcare and patients will arrive with a wide range of levels of knowledge about GAHT. The prescriber's role is to ensure safety by following prescribing and dosing guidelines, assessing medical risk, providing education about expected outcomes, and monitoring treatment, in collaboration with their patient.

This document describes an approach to care for adults. Whilst the principles of self-determination, autonomy and informed consent remain the same in adolescents, there are added considerations and complexities in working with a younger population which were felt to be beyond the scope of this guideline. These considerations include the importance of youth development, family support, safety and the potential differences in both medications used and dosing. We recommend healthcare providers refer to the latest Standards of Care version 8 (SOC-8), released by the World Professional Association for Transgender Health (WPATH), for guidance for working with transgender children and adolescents.[2]

It is intended that these guidelines are used in conjunction with the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa New Zealand* [3] and local health pathways. They sit within the context of these national guidelines, which have a broader scope of all types of gender affirming care for people of all ages. These national guidelines were informed by Tā Mason Durie's models of health: Te Pae Māhutonga, using guiding principles of te mana whakahaere (autonomy) and ngā manukura (community leadership),[4] and Te Whare Tapa Whā, considering physical health, spiritual health, whānau health, and mental health.[5]

Importantly, GAHT is only one aspect of the wider process of gender affirmation, which may include medical, legal and social steps. Every transgender person is unique, and so may want to undertake some, none, or all of these steps to affirm their gender. Similarly, they may place different weight upon each of these and so pursue these in different orders. How to affirm one's own gender is a very individual decision, and there is no right or wrong way to do so.

Introduction

GAHT refers to the hormone therapy taken by some transgender people to embody and affirm their gender, often leading to improved psychological wellbeing and quality of life.[6] As outlined in the national guidelines,[3] gender affirming care, including GAHT, is a key part of transgender people's lives, and should be considered holistically in the context of their social and whānau relationships and spiritual wellbeing.[5]

Historically, the provision of GAHT has been limited to specialised secondary care services, which has contributed to restricted access to gender affirming care. Transgender people continue to face many barriers to accessing appropriate care in a timely manner, including cost, travel (particularly for patients in rural areas) and waiting times, partly due to increasing numbers of people accessing this type of care.[7] The increase in numbers of people seeking GAHT is thought to be due to greater awareness and reduced societal stigma when compared with previous decades. In the 2018 Counting Ourselves transgender health survey, 19% of participants reported an unmet need for GAHT.[8] The most commonly reported barriers were not knowing where to go (40%), cost (28%) and fear (26%). An informed consent model of care (further explained below), distributed among primary care providers, is the best model of care to reduce the current unmet need for GAHT.

In NZ, GAHT is currently initiated by a variety of health professionals in different clinical settings. This can include GPs, NPs, endocrinologists, sexual health physicians, adolescent health physicians and paediatricians. At the time of writing, pathways to access GAHT vary depending on locality. However, initiation of GAHT is increasingly being provided in primary care settings due to increasing demand and greater recognition of the barriers that transgender people, particularly those living outside of main cities, face when accessing secondary care services. Patients have a right to access GAHT in a timely manner within their local communities. To work towards this, these guidelines have been developed to assist all primary care providers by providing the information they need to initiate and provide repeat prescriptions of GAHT, with the aim of supporting their patients' gender affirmation and removing barriers for transgender adults accessing hormones. These guidelines are informed by the *Aotearoa Guidelines for Gender Affirming Health Care*[3] and overseas guidelines which have been adapted for local use.[9-13]

This document is a partnership between transgender and cisgender professionals; its authors include general practitioners, a primary care nurse, endocrinologists, a sexual health physician, an adolescent health physician, psychologists, academics and peer supporters. Whilst we appreciate that not all GPs and NPs will choose to initiate GAHT, this guideline has been written for those who do want this guidance.[b]

Many of the current pathways to access GAHT in NZ include the requirement of a psychosocial assessment by a mental health professional. These are often performed by psychologists and psychiatrists, resulting in long wait times for clients or a high cost barrier if more timely care is sought in the private system (which is not available or affordable to many people). Many transgender people experience this approach as pathologising, and may worry they have to prove they are 'transgender enough' or say the right thing in order to access the treatment they know they need to affirm their gender.[14] It is not the role of a health professional to make a judgement on whether a patient's gender (e.g. a non-binary gender) is valid or whether a patient is male or female enough. In some parts of NZ, it can be challenging to find a mental health professional to conduct this assessment at all.

[b] We recognise that not all primary care prescribers will want to initiate GAHT, and that challenges such as funding, appointment length and availability, increasing workloads and burnout all exist in NZ at this time. However, we feel it is important that those who wish to provide this care have access to practical guidance as provided in this document and are supported to prescribe GAHT for their patients. Supporting transgender patients to access GAHT in a timely manner which recognises their autonomy is very rewarding work, and we encourage primary care to get involved.

These guidelines outline an approach where the primary care team works in collaboration with patients to meet their gender goals, provides education about GAHT and general health, and helps to support patients' understanding of the risks and benefits of GAHT to make well-informed decisions about their health. This is often referred to as an 'informed consent model' and is the approach used in this document (see 'Informed consent' below for more detail).

Being transgender is not a mental illness.[15] Societal stigma and prejudice can lead to transgender people experiencing disproportionately high levels of discrimination, harassment, homelessness, unemployment, abuse and violence. The resulting gender minority stress can lead to the inequitable rates of poor mental health experienced by transgender people as a population.[16-18]

As a result, some transgender people will present with mental health conditions which require input from secondary care. As with any patient seen in primary care, psychologists, psychiatrists or secondary mental health services only need to be involved for those who are experiencing moderate to severe mental illness. Everyone else can, in theory, be managed in the community with their regular primary care team, which could include support from counsellors, health improvement practitioners or other mental health providers as needed.

For those who request it, counselling or psychotherapy can be of benefit, not as an assessment tool or mandatory part of accessing GAHT, but instead to provide psychological support during a time of change which can be stressful due to both personal and societal factors. For example, people may find it helpful to have support with exploring their gender or sexuality (particularly adolescents), the 'coming out' (or disclosure) process (especially to family or their workplace), and navigating experiences and concerns around transphobia, social stigma and other aspects of adjusting to this time of change. Ideally this support would be provided by mental health professionals such as counsellors or psychologists (or peer supporters where appropriate) who have high levels of transgender cultural safety.

Primary care is the ideal place for meeting most of the healthcare needs of transgender people, including hormone initiation, as primary care teams are part of patients' local communities, and are experts in whole life experience, including normal life events which may require their input. GPs and NPs take a holistic approach which considers a patient's physical health, mental health, culture, social supports, environment and lifestyle factors, which is well suited to providing gender affirming healthcare.

Primary care practitioners are able to work together with each transgender person to understand their gender embodiment goals, discussing options and together finding the most appropriate care for the individual. A patient with more complex mental health issues can still be referred to a psychologist or mental health team as needed, but there is no good reason for this to be the default approach. Likewise, a patient with more complex physical health issues can still be referred to an endocrinologist or sexual health physician. The Counting Ourselves survey[8] found that 48% of respondents felt that their doctor did not know enough about transgender healthcare, so health provider education is an important aspect of ensuring health needs can be adequately met.

The authors recognise that this is a rapidly evolving field of medicine. The guidelines were written in February 2023 and will require review in three years' time. We welcome and encourage research to evaluate the impact and outcomes of these guidelines, as well as the experiences of patients and providers.

Informed consent

The informed consent model of care views treatment as collaborative between the patient and healthcare provider. It is a term commonly used in medical practice to describe the interactive process of a health practitioner providing a patient with information and the patient using this to make an informed decision about their healthcare. In gender affirming healthcare, the term acknowledges that transgender people are the experts on their own gender, and the experiences, goals and needs that are related to their gender, while also acknowledging that healthcare providers have the expertise to provide this care in a way that maximises safety and efficacy.[19]

Informed consent is a process that respects patient autonomy and dignity and assumes capacity. As such it does not require a routine referral to secondary services or the private equivalent for a psychosocial assessment prior to initiating GAHT. We acknowledge the varied interpretations of the term 'informed consent' within transgender healthcare, and so have described here what is meant by informed consent in this guideline.

The use of 'informed consent' in this guideline reflects that used by the Medical Council of New Zealand (MCNZ)[20] to describe the process of providing information, including risks and benefits about a treatment, in a way that the patient can understand, as part of a trusting clinician–patient relationship, so that the patient can make a fully informed decision about care. In the case of a patient-centred approach to GAHT, the patients bring their own individualised gender embodiment goals and are active participants in the process.

Informed consent is an important component of the biomedical ethics principle of respect for patients' autonomy; this respect for autonomy should be balanced against the principles of beneficence and nonmaleficence.[21] This is reflected in *Cole's Medical Practice in New Zealand*, which states that the principle of informed consent serves to protect patient autonomy and a patient's right to determine what they want to do with their body, but that patients do not have a right to be provided treatment that is not clinically indicated.[22]

Primary care is the ideal place to create a safe and affirming space for gender affirming care. Primary care clinicians work as collaborative partners to establish lifelong relationships with the patient as the primary decision-maker. This partnership supports patient understanding of the risks and benefits of GAHT, including the impact on other areas of life such as work or education, relationships, sexual function and fertility, and works to promote general health and wellbeing. These guidelines serve as a starting point for patients and clinicians to develop a care plan appropriate to each individual's needs. Peer supporters, primary care nurses, primary mental health services, counsellors, psychologists and social workers may be involved in the delivery of hormones and GAHT health education. A multi-disciplinary approach is useful, although we recognise this is not always possible.

Like other medical interventions with similar risks, an external mental health assessment is not mandatory before accessing GAHT for adult patients. Providers should be aware that GAHT is often associated with improvements in a patient's mental health.[23] A patient who has severe mental health difficulties will likely still be able to provide informed consent, but may require support and treatment from a mental health professional alongside starting GAHT. For adults with a complex presentation or those who are requesting less common treatments or treatments with limited research evidence, further advice or assessment from different health professionals is likely to be required.[2] Remember that gender affirming healthcare may reduce mental distress, and that withholding or delaying care unnecessarily is unethical and could worsen a person's mental health. See FAQ 2 for more details.

The starting point when assessing capacity is always to presume that an adult has capacity to make the decision.[22] A patient has capacity to make a decision if they understand the nature and effects of the treatment; can weigh up options; balance risks and benefits; foresee consequences of consenting (or not consenting); demonstrate consistency in their decision-making; have no undue influence from a third party and can communicate their decision. In most cases for patients with diminished capacity to consent, external support may be required to assess capacity.

Examples of situations where capacity to consent may be diminished include cognitive impairment, intellectual disability, dementia, psychosis, or mania of a degree that it may be impacting on their ability to adequately understand and balance necessary information. In these cases only, a formal capacity assessment is an essential part of the informed consent process, ideally conducted by a health professional who knows the patient well.[24] A mental health professional may be able to assist with a capacity assessment. Providers should be aware that patients with diminished capacity still have a right to timely access to care, and this may involve the use of a supported decision-making process; see the section on diminished capacity in the Frequently Asked Questions section (FAQ 4) for more details.

We encourage prescribers to take a harm reduction approach to the initiation of GAHT, particularly when a patient is self-sourcing GAHT. If a patient is taking GAHT formulations which are unavailable in NZ or outside of recommended dose ranges, a plan to transfer onto NZ medications and doses in line with these guidelines should be negotiated in partnership with your patient.

WPATH Standards of Care Version 8

These guidelines align with the GAHT recommendations from the WPATH Standards of Care version 8.[2] Full details of the SOC-8 criteria for GAHT can be found in Appendix A, and these have been incorporated throughout this guideline. The SOC-8 recommendations refer to the International Classification of Diseases and Related Health Problems (ICD-11)[25] coding for Gender Incongruence, the details of which can also be found in Appendix A.

Stages of gender affirming hormone therapy initiation

These guidelines are based on providing individualised care in a staged format with a new patient. There is no set number of appointments that a patient must be seen for prior to starting GAHT, and this will vary depending on complexity, practitioner experience and appointment length. In some situations, several stages could be completed in one longer appointment, whilst in other situations it might take multiple appointments to work through one stage. Similarly, each person's body and gender embodiment goals are different, and it may take more appointments, working with your patient, for you both to understand what works best for them. This may require trialling different dosages and types of hormones and making changes where needed.

When patients consent to treatment it is good practice to allow reasonable time for the patient to make their decision. The MCNZ states that a key principle of informed consent is that it is an interactive process and not a one-off event.[20] For this reason, prescribers may wish to separate stages 3 and 4 into separate appointments, to allow patients time to consider the information provided, and to provide an opportunity to ask further questions.

The stages outlined below help to ensure that GAHT is prescribed as safely as possible, and help to ensure the best outcome for the patient's overall wellbeing. Stages 1 to 3 should be completed prior to prescribing hormones. These can be undertaken by a GP, NP, primary care nurse, or a combination of these colleagues working together in one practice.

Terminology used in this guideline

E-GAHT is used to abbreviate o*estrogen-based GAHT* (previously known as feminising GAHT).

T-GAHT is used to abbreviate *testosterone-based GAHT* (previously known as masculinising GAHT).

Stages in starting GAHT	
Stage 1	Introduction, relationship building, information gathering
Stage 2	Medical review (including fertility discussion)
Stage 3	Hormone information and education
Stage 4	Hormone initiation (first prescription)
Stage 5	Maintenance prescribing and long-term follow-up

Stage 1:

Introduction, relationship building, information gathering

Stage 1

Introduction, relationship building, information gathering

- General introduction to the service and how the process of getting started on GAHT will work.
- Check patient's name, gender and pronouns and ensure they are recorded accurately on the Practice Management System (PMS). Check which name your patient would like you to use when calling them from the waiting room. Adding this information as an alert or a 'post-it note' on the PMS may be helpful.
- Explore gender embodiment goals for gender affirming care.
  - You could ask: Think about your body as it is now, what would you like to stay the same? What would you like to change?
  - See Tables 1 and 2 for physical effects of GAHT. Sometimes people's goals may not require or be achievable with GAHT, so it is important to explore this with your patient.
  - People's goals are individual and may change over time. Work together with your patient over time, adjusting medication as needed in response to their needs and goals.
- Current and recent past gender experiences (see example questions in Appendix B).
- Give information about other supports. These may be available on your health pathways. Some examples can be found here:

  Gender diversity support services – Health Navigator

  Rainbow organisations – Te Ngākau Kahukura
- Give hormone information sheet (Appendix E) if appropriate at this stage (this will be explained to patient fully at Stage 3, but this gives the patient an opportunity to take it home and read it).
- HEeADSSS[26] or similar psychosocial assessment, including asking about patient supports.

Stage 2:

Medical review (includes fertility discussion)

Stage 2

Medical review (includes fertility discussion)

- Past medical and surgical history – for E-GAHT ask specifically about breast cancer, venous thromboembolism (VTE), cardiovascular disease (CVD), migraines, liver disease.
- Review mental health including current supports and strengths (consider PHQ-9 and GAD-7 if relevant) – arrange any extra support or referrals if indicated.
- Social history – including alcohol, drugs, and smoking/vaping. Discuss risk reduction, e.g. smoking cessation.
- Family history – ask specifically about VTE, CVD, breast cancer and liver disease.
- Medications and allergies – you may wish to check if the patient is 'self-medicating' with hormones (e.g. self-sourcing hormones online).
- Sexual health review (including discussion about the need for any STI testing, contraception and/or HIV PrEP where relevant).
- Any increased risks from hormonal therapy to manage – there are very few, if any, medical contraindications.
  - For E-GAHT consider discussion with secondary care if there is migraine with aura, CVD, VTE history or significant liver disease. (See E-GAHT section and FAQ 5 for more detail.)
  - Pregnancy is an absolute contraindication for T-GAHT (consider checking a Beta hCG level). Relative contraindications include severe hypertension, sleep apnoea and polycythaemia since these conditions can be exacerbated by testosterone.[2]
- Recommend cervical screening for patients who are over 25 years old and have a cervix.
- Update or establish baseline observations – blood pressure and weight.
- Offer trans culturally safe counselling or peer support – this can be very useful alongside GAHT.
- For those starting E-GAHT offer speech and language therapy referral for voice therapy (in some regions this may be available for those starting T-GAHT, but as T-GAHT lowers the voice this is less often required).

Note: There is no need for a routine genital or breast examination.

Stage 2

Medical review (includes fertility discussion)

Baseline bloods

- E-GAHT – LFT, lipids, FSH, LH, oestrogen, testosterone. Electrolytes if starting spironolactone. HbA1c if indicated by risk factors.
  - If referring for fertility preservation include HIV, syphilis, hepatitis B&C.
- T-GAHT – LFT, lipids, FSH, LH, oestrogen, testosterone FBC and Beta hCG. HbA1c if indicated by risk factors.
- Prolactin measurement is not usually required, see FAQ 6.

Fertility (reproductive options)

You will need to assess your patient's capacity to understand the effect of GAHT on reproduction and explore reproductive options with the individual prior to the initiation of gender affirming treatment. This is discussed in more detail at Stage 3 (hormone information) but is also included here so that relevant blood tests can be included in the baseline bloods if required for those starting E-GAHT.

A pamphlet about fertility preservation for transgender people can be found here:
Transgender fertility: Preservation and treatment (PDF, 813KB)

- E-GAHT (assigned male at birth): E-GAHT may result in permanent loss of fertility.[27] There is funding available for fertility preservation (check with your local service for current eligibility criteria).

  Fertility preservation is not a requirement for GAHT, but it is essential to discuss this with your patient. If referral for fertility preservation is desired, include HIV, Syphilis and Hepatitis B & C on baseline bloods.
- T-GAHT (assigned female at birth): T-GAHT usually causes ovarian suppression. This may be reversible on stopping testosterone (which may result in a return of spontaneous fertility) but may also be irreversible.[28-30] Patients should be aware that if they wish to become pregnant in the future, they will need to stop testosterone (as it is a teratogen) and that they may require fertility assistance in the form of egg harvesting. Egg harvesting can usually be undertaken at the time of desired pregnancy (and egg quality is unaffected by testosterone), so is not necessarily required prior to starting GAHT.[30] For this reason, egg harvesting is currently only funded for those having a surgical removal of reproductive organs. A funded assessment with a fertility specialist to discuss options prior to starting T-GAHT may be available if your patient wishes to discuss this in more detail.

Menstrual cessation

Many transgender and non-binary people assigned female at birth experience dysphoria with menstruation. This can be significant, and for some may contribute to poor mental health or even suicidality. It is important to discuss this and to offer menstrual cessation options if this is desired. Although testosterone usually results in amenorrhoea, starting menstrual cessation sooner is often welcomed and desired by patients.

When considering which option to use it is important to take into account whether contraception is required. Table 1 outlines options for menstrual cessation. Medication used for menstrual cessation can usually be stopped (if not needed for contraception) once the patient is established on testosterone and menstruation has ceased. Menstruation may persist despite adequate testosterone levels in 5–10% of people,[31] in which case progesterone therapy could be continued.

Table 1: **Menstrual cessation options**

Contraceptive	Depo-provera Mirena Combined contraceptive pill	Usual contraception dose	Oestrogen containing medication may not be desired by trans masculine people.
Not contraceptive	Norethisterone (Primolut)	5mg BD	Can increase to 10mg BD for 1 week if breakthrough bleeding then reduce slowly. Occasionally need to stay at higher doses.
	Medroxyprogesterone (Provera)	10–20mg once daily – up to 10mg TDS	
	Utrogestan	100–200mg daily	

Note: Testosterone is NOT a contraceptive.

Stage 3:

Hormone information and education

Stage 3

Hormone information and education

Check blood results and discuss these with the patient as necessary.

Address any remaining concerns or questions.

Ensure referrals are completed and that the patient is linked to appropriate supports.

Prior to starting E-GAHT: check that fertility preservation has been organised (if desired).

Go through hormone information and education (detailed in the following pages), including gender embodiment goals, side effects, risks, permanent effects, and time frame for changes. Some people may decide not to continue with GAHT in the future, so it is important to discuss the permanent and non-permanent changes. (See also FAQ 1.)

Highlight that changes will be gradual, occurring over years. Explain the need for regular review and monitoring in the first year and ongoing need for bloods and clinical review thereafter.

Provide written information and a copy of the consent form.[c] These forms can be found in Appendices E and F.

Document whether the patient has capacity to provide informed consent to commence GAHT, whether they meet the SOC-8 criteria for hormone treatment (see Appendix A) and that you have discussed fertility (see PMS shortcuts in Appendix C).

The checklist in Appendix D can be used to ensure all steps have been completed prior to prescribing.

[c] A consent form can be a useful addition and may act as a guide to the clinician to check all of the relevant points have been discussed, but is not a requirement. We have included it here as an option. By far the most important aspect of informed consent is the conversations between the patient and clinician outlined here. If these are well documented and the patient has had time to consider the information and ask questions, this is more important than a written consent form. See the MCNZ statement on informed consent for more detail.

Stage 3

Hormone information and education

T-GAHT — Information to cover in the consent process

We recommend using the patient information sheet in Appendix E to make it easier to cover this information with the patient. This will provide a handy reminder and prompt of what you need to cover when providing information about GAHT.

- Explain which preparations of testosterone are available (and check patient preferences for which to use), frequency of administration and the option of self-injecting (full medication details can be found below in 'GAHT initiation protocol').
- Recommended monitoring for T-GAHT:
  - Bloods and blood pressure (BP) 3–6-monthly in the first year, thereafter annually or as clinically indicated. Note the timing of the blood test when measuring testosterone levels (see below).

Discuss the changes expected with T-GAHT

Changes occur gradually over months to years (see Table 2). Physical examinations are not necessary. Often reassurance is required, especially in the first 6 months.

The following infographic can be helpful: Effects and expected time course of a regimen consisting of testosterone

Note – your patient may prefer the use of non-gendered language when describing their genitals, so we recommend asking them what words they prefer and then using those. Commonly used terms (at the time of writing) include 'front hole' or 'internal genitals'.

- Permanent effects:
  - Deepening of the voice,
  - Increased body hair growth including facial hair,
  - Androgenetic alopecia,
  - Genital changes: clitoral enlargement (may be up to 1–3cm) and this can feel uncomfortable and even painful initially. Vaginal dryness can be relieved with oestrogen cream or an over-the-counter product for vaginal dryness and ensuring use of extra lubrication for vaginal sex.
- Sex – vaginal dryness increases the risk of STIs including HIV, so it is advisable to use condoms if having sex using this part of the body. Lubrication can help with any associated discomfort. Testosterone is not a contraceptive.
- Effects which are likely reversible: acne/oily skin, increased muscle mass/ strength, redistribution of body fat, increased libido. Irritability and frustration may be variably present.
- Menstruation stops in most people (around 90%) after 1–6 months.[31] *(Many patients prefer the term 'monthly bleeding'.)*
- Fertility – You may have already discussed this in Stage 2, but it is repeated here to ensure it isn't missed. T-GAHT usually causes ovarian suppression. This may be reversible on stopping testosterone (which may result in a return of spontaneous fertility) but may also be irreversible.[28-30] Patients need to understand that if a future pregnancy is desired it will mean stopping testosterone (as it is a teratogen) and may require fertility assistance in the form of egg

harvesting. Egg harvesting is more effective at the time of desired pregnancy (and egg quality is unaffected by testosterone), so is not required prior to starting GAHT.[28]

It is possible to become pregnant while taking testosterone even if menstruation has stopped, so **contraception is essential if there is any sexual contact that would put someone at risk of pregnancy**. Testosterone is likely to be harmful to a developing fetus and should not be used during pregnancy.

- Risks – Polycythaemia, liver dysfunction, pelvic pain, raised cholesterol and raised blood pressure.[32-34] Studies in cisgender men indicate a slight increased VTE risk in the first 6 months on testosterone therapy.[35]
- Cancer screening
  - Discuss the importance of cervical screening for anyone with a cervix.
  - Breast screening is recommended from age 45 years for anyone who has breasts. Those who have had 'top surgery' (this commonly used term refers to chest reconstruction surgery or bilateral mastectomy) should follow the advice of their surgeon, as this may depend on the extent of the surgery performed. Some people may be advised to have clinical examinations and possibly ultrasound screening.
  - Ensure recalls are not removed if gender is changed on the PMS.
- Gender affirming surgery – provide information on local pathways for surgery. Your patient may be especially interested in accessing top surgery. Availability varies between localities; check your local health pathways. A stocktake of availability as of 2021 can be found here: An update for the provision of gender affirming healthcare across the district health boards of Aotearoa New Zealand – PATHA. Gender affirming genital surgery referral forms can be found here: The Gender Affirming (Genital) Surgery Service – Ministry of Health.

Table 2: **Effects of testosterone-based hormones (T-GAHT)**

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[a]	Variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of the voice	6–12 months	1–2 years	Not possible
Increased sexual desire	Variable	Variable	Likely

[a] Highly dependent on age and inheritance; may be minimal.

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Stage 3

Hormone information and education

E-GAHT — Information to cover in the consent process

We recommend using the patient information sheet in Appendix E to make it easier to cover this information with the patient. This will provide a handy reminder and prompt of what you need to cover when providing information about GAHT.

- Explain that E-GAHT involves using two medications – an oestrogen and a testosterone blocker:
  - — Oestrogen:

    Explain which preparations of oestrogen are available (tablets or patches). Explain that there is no good evidence yet that one form of oestrogen is better than another in terms of effects, but that oestrogen patches are likely to carry a lower risk of VTE and LFT dysfunction than tablets.[36, 37]
  - — Testosterone blocker:

    Discuss options for androgen blockade (spironolactone or cyproterone). There are no studies yet that compare efficacy in E-GAHT, therefore patients can select their preferred approach, in discussion with their prescriber and taking into account potential side effects and risks, and any relevant health conditions or medications.
    - o Spironolactone is a blood pressure tablet at low doses but works as a weak anti-androgen at higher doses. It will not suppress testosterone levels but will block the effects of testosterone in the body, promoting breast growth and slowing down body hair. Common side effects include dizziness and urinary frequency.
    - o Cyproterone in very small doses (12.5mg daily or less) will suppress testosterone to < 2 nmol/L but does not suit everyone. Side effects can include fatigue and low mood. Shortness of breath is an uncommon side effect but should be counselled for. Larger doses have been associated with liver function abnormalities and there is a dose-dependent and cumulative risk of meningioma thought to be related to doses of 25mg daily or greater.[38-40] Evidence in other areas of healthcare shows the risk of VTE is increased with cyproterone use.[41]
- Recommended monitoring for E-GAHT
  - — Bloods and blood pressure 3–6-monthly in first year, thereafter annually or as clinically indicated.

Discuss the changes expected with E-GAHT

- Changes occur gradually over months to years (see Table 3). Physical examinations are not necessary. Often reassurance is required, especially in the first 6 months. The following infographic can be helpful: Effects and expected time course of a regimen consisting of an anti-androgen and estrogen.
- Permanent effects:
  - — Fertility is thought to be permanently affected by E-GAHT.[27, 42] Fertility preservation is recommended in young people and is usually funded. It is essential to have and document this discussion prior to prescribing E-GAHT.

  - Breast development is gradual over 2–years.[32] It can be helpful to manage expectations as many people develop an A cup or smaller after 1 year on E-GAHT.[43] This can be a common source of dissatisfaction.[44]
- Effects which are likely reversible: softer skin, decreased muscle mass, thinning of body hair, fat redistribution to buttocks, hips and thighs.
- Libido usually reduces when taking androgen blockers. Erections usually reduce in frequency and may be less firm and shorter lasting (Sildenafil can be helpful for some people). Testicles can shrink to less than half their original size.
- E-GAHT does NOT change:
  - Voice pitch (voice therapy may be available via a speech and language therapist depending on local pathways)
  - Facial bone structure
  - Prominence of the tracheal cartilage (Adam's apple)
  - Growth of facial and body hair, which slows but does not stop completely (laser hair removal if desired can be funded by a WINZ disability allowance if the patient has a community service card or is on a low income.
- Side effects – breast tenderness and weight gain. In the first few days to weeks there may be nausea and headaches which usually settle.
- Risks – VTE (risk can be lowered, see FAQ 5), raised cholesterol, gallstones, raised BP, possible increase in breast cancer risk.[32] We recommend explaining the symptoms of deep vein thrombosis and pulmonary embolism and advising patients to seek urgent medical help if these occur.
- Cancer screening – Breast screening is recommended from age 45 years for anyone who has breasts.
- Gender affirming surgery – provide information on local pathways for surgery. Availability varies between localities; check your local health pathways. A stocktake of availability as of 2021 can be found here: An update for the provision of gender affirming healthcare across the district health boards of Aotearoa New Zealand – PATHA. Gender affirming genital surgery referral forms can be found here: The Gender Affirming (Genital) Surgery Service – Ministry of Health.

Table 3: **Effects of oestrogen-based hormones (E-GAHT)**

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	Unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	Unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair	6–12 months	>3 years[a]	Possible
Male pattern baldness	Variable	[b]	
Voice changes	None	[c]	

[a] Complete removal of hair requires laser treatment. [b] Familial scalp hair loss may occur if oestrogens are stopped.
[c] Treatment by speech-language therapists for voice training is most effective.

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Stage 4:

Hormone Initiation

Stage 4

Hormone Initiation

- Ensure Stages 1–3 are complete and that patient is happy to start GAHT (see checklist in Appendix D). If using the consent form, ensure this has been signed by the patient.
- Document patient's capacity to provide informed consent, whether they meet the SOC-8 criteria for GAHT (see Appendix A) and that you have discussed fertility (see Appendix C for PMS shortcut suggestions).
- Inform the patient that using these medications for gender affirmation is an unapproved use of an approved medication.[45] These medications are widely used around the world for this purpose and there is a recognised clinical justification for their use. This is also known as 'off-label' use.

  As a prescriber you must explain what is being prescribed, and why, and obtain informed consent from your patient. It is acknowledged, however, that when off-label use of a medicine is so common that it is regarded as usual practice, obtaining separate consent (for off-label use) may not be considered necessary, and this is at the clinician's discretion.[46]
- Give GAHT prescription as per GAHT initiation protocol below. Arrange to follow up in 3 months.
- T-GAHT: arrange a nurse appointment for ongoing injections.

Stage 5:

Maintenance prescribing and long term follow up

Stage 5

Maintenance prescribing and long term follow up

In the first year, follow up every 3 months, or more often if needed; thereafter as needed depending on individual needs. Generally, an annual review is recommended, but for patients who have been stable on GAHT for a significant time it may be appropriate to extend this.

- Review effects of medications and check the patient is happy to continue taking GAHT.
- Adjust doses as per hormone protocol.
- Monitor BP and bloods 3–6-monthly in the first year (or more often if necessary) then annually or as clinically indicated. Monitoring is primarily with dose changes, which is likely to be every 3 months, but flexibility may be needed. Monitor weight as appropriate.
- Monitor mental and physical health. Encourage lifestyle/health behaviours which reduce the risks associated with GAHT, e.g. smoking cessation, cholesterol reduction, moderate alcohol use.
- If needed, connect to mental health and peer support.
- Make referrals for other gender affirming care as desired by your patient.
  - Gender affirming genital surgery referrals are via the Ministry of Health. For further detail see 'Gender affirming (genital) surgery service forms' here: The Gender Affirming (Genital) Surgery Service – Ministry of Health
  - For other gender affirming surgeries refer to your locality health pathways.

GAHT Initiation Protocol

GAHT Initiation Protocol

This protocol relates only to the initiation of gender affirming hormone therapy in adults and is to be used by prescribers after following GAHT Stages 1–3 described above.

The starting protocols below are for adults who have NOT been on gonadotropin releasing hormone (GnRH) agonists (also known as puberty blockers) from a young age (Tanner stage 2–3). For those who have been on puberty blockers from Tanner stage 2–3, GAHT initiation should progress more gradually.[32]

This section outlines the medications used in GAHT, dosage guidance, recommended monitoring, and a protocol for initiating GAHT.

Oestrogen-based Gender Affirming Hormones (E-GAHT)

Table 4: **Overview of E-GAHT**

Oestrogen formulation	Starting dose	Maximum (usual maintenance dose)	Notes
Oestradiol valerate (Progynova)	1–2mg daily	4–6mg daily	Increasing by 1–2mg every 3–6 months is generally recommended.
Oestradiol patch (Estradot)	25–50mcg patch twice weekly	100-200mcg patch twice weekly	Increasing by 25–50mcg every 3–6 months is generally recommended. Lower VTE risk than oral oestrogen. Recommended if liver or lipid dysfunction or >45 years old.
Androgen blocker*	**Starting dose**	**Maximum (usual maintenance dose)**	**Notes**
Spironolactone	50–100mg daily	200mg daily	Unable to use serum testosterone for clinical guidance as spironolactone blocks the effect of testosterone on the tissues rather than its production. Monitor potassium level.
Cyproterone	12.5mg daily (or 12.5-25mg on alternate days)	12.5mg once daily (or 12.5-25mg on alternate days)	Use lowest effective dose. Use of higher doses long-term has been linked to meningioma. Consider review and discussion every 5 years if remaining on this long term. Contra-indicated in history of thromboembolic disorders as increases VTE risk. Monitor liver function.
Goserelin	10.8mg SC implant insertion into lower abdomen every 12 weeks		Not first line in adults due to high cost and good availability of alternative options.

***The androgen blocker is no longer required if the patient has had an orchiectomy.**

For guidance on E-GAHT in individuals with increased cardiovascular or VTE risk, see FAQ 5. For a comment on Progesterone use See FAQ 8.

Table 5: **E-GAHT recommended monitoring**

Investigation	Comment
Electrolytes	If patient is on spironolactone.
Liver function tests	If abnormal, use transdermal oestrogen as first choice. Monitor if on cyproterone.
Lipids	
Oestrogen	Only checked to ensure levels are not supraphysiological. Some guidelines would recommend an upper limit of 700–750 pmol/L[32] but there is insufficient evidence to definitively recommend any target range. Experience suggests that oestrogen levels or dose do not correlate well with physical effects or self-reported satisfaction with E-GAHT, and exogenous oestrogen is not well measured in the serum.
Testosterone	On cyproterone – levels would typically be <2nmol/L (or higher if wanting to maintain erectile function). On spironolactone – no need to measure as it doesn't usually suppress (see above); instead, be guided by clinical response.

E-GAHT
Starting Protocol

Prior to first prescription	Complete Stages 1–3 in the primary care protocol for starting GAHT. This includes a psychosocial assessment, medical review, baseline blood tests, blood pressure, weight, fertility preservation (if desired), and informed consent outlining effects (including permanent changes) and risks of GAHT by a knowledgeable healthcare provider. Provide the patient with information sheet and document consent.
Commence GAHT – first prescription	**Oestrogen** – *one of*: Estradiol (Progynova) 1–2mg OD *or* Estradot patches 25–50mcg twice weekly ***AND*** **Testosterone blocker** – *one of*: Spironolactone 50–100mg OD *or* Cyproterone 12.5mg OD (or 12.5–25mg on alternate days)
3 months after commencing hormones	If no concerns, adjust androgen blocker to maintenance dose and commence gradual increase in oestrogen dose: • Oestrogen can be increased: — Progynova by 1–2mg every 3–6 months up to maximum of 6mg — Estradot by 25–50mcg every 3–6 months up to maximum of 100–200mcg twice weekly. • Spironolactone – consider increasing to 200mg OD (if potassium level is normal). • Cyproterone – continue 12.5mg OD (or 12.5–25mg on alternate days). • Bloods for potassium (if taking spironolactone), liver function, lipids. • Check blood pressure.
3-monthly appointments in first year, can be 12-monthly thereafter if stable	At each follow-up visit: • Review progress and discuss any issues or questions. • Check on physical and mental health and social supports. • If your patient has an orchiectomy the androgen blocker can be stopped. • Ensure monitoring is up to date: — Check blood pressure 3–6-monthly in the first year, thereafter 12-monthly. — Monitor blood tests 3–6-monthly in the first year, thereafter 12-monthly or as clinically indicated (see Table 5 for details).

Testosterone-based Gender Affirming Hormones (T-GAHT)

Table 6: **Overview of T-GAHT**

Testosterone formulation	Standard starting dose	Maximum (usual maintenance) dose	Notes
Depo-testosterone (testosterone cypionate)	100mg IM/SC* every 2 weeks or 50mg SC weekly	200mg IM/SC* every 2 weeks or 100mg SC weekly	Testosterone level should be measured mid-way between injections. Patient can be taught to self-inject.
Sustanon (testosterone esters)	125mg (0.5ml) IM* every 3 weeks	250mg (1ml) IM* every 3 weeks	Testosterone level should be measured mid-way between injections. Patient can be taught to self-inject.
Reandron (testosterone undecylate)	Less commonly used as a starting testosterone, but can be started at 500mg IM The second dose can be given after 6 weeks to achieve steady state and thereafter continue 12-weekly	750–1000mg IM every 10–14 weeks	Testosterone level should be checked immediately prior to injection. Injection must be given by a health professional (due to risk of oil embolism).
Androderm patches	5mg daily	5–10mg daily	Testosterone level should be measured in the morning. Skin irritation is common.

* Depo-testosterone is licensed for IM use. It is not licensed for subcutaneous administration in NZ but can be administered this way if preferred, with weekly dosing appearing to be most commonly used.[47]

Low dose testosterone is discussed in FAQ 7.

Table 7: **T-GAHT recommended monitoring**

Investigation	Comment
Full blood count	If the haematocrit > 0.52 reduce the dose of testosterone and/or discuss with an endocrinologist or haematologist.
Liver function tests	
Lipids	
Testosterone	• Aim for usual male reference range for standard doses. • Check 6–12-monthly once patient has been on testosterone for around 6–9 months (it takes time for levels to stabilise initially). • Timing of blood test is dependent on testosterone formulation – see Table 6 above. • If raised, reduce testosterone dose and repeat level in 3 months.

T-GAHT
Starting Protocol

Prior to first prescription	Complete Stages 1–3 in the primary care protocol for starting GAHT. This includes a psychosocial assessment, medical review, baseline blood tests, blood pressure, weight, and informed consent, outlining effects (including permanent changes) and risks of hormones by a knowledgeable healthcare provider. Provide the patient with an information sheet and document consent.
Commence GAHT – first prescription	Depo-testosterone 100mg IM/SC fortnightly (or 50mg SC weekly) *or* Sustanon 125mg (0.5ml) IM every 3 weeks *or* Reandron 500mg IM with 750–1000mg IM at 6 weeks (thereafter 3-monthly) *or* Testosterone patch 5mg daily
3 months after commencing hormones	• Review progress and discuss any issues. • Bloods for complete blood count (monitor haematocrit), liver function, lipids. • Blood pressure. • If no concerns, increase hormones to maintenance therapy. If patient wishes to switch testosterone preparation, the preferred testosterone can be administered at the time the next dose of the previously used testosterone is due. • Plan for testosterone level measurement at the appropriate time (after at least 6 months on GAHT. See Table 6 for timing of blood test).
3-monthly appointments in first year, can be 12-monthly thereafter if stable	At each follow-up visit: • Review progress and discuss any issues or questions. • Check on physical and mental health and social support. • Ensure monitoring is up to date: — Blood pressure 3–6-monthly in first year, thereafter 12-monthly. — Bloods 3–6-monthly in first year, thereafter 12-monthly or as clinically indicated (see Table 7 for details, including timing of testosterone measurements). • Provide education about self-injection if appropriate.

Frequently Asked Questions

(FAQs)

1. What if my patient stops taking hormones?

Affirming one's gender is not necessarily a linear process and may take place over a lifetime. Some people experience their gender more fluidly than others and it is common for someone's understanding of, and comfort with, their gender identity and gender expression to evolve throughout their lives. Someone's decision to start GAHT and a later decision to stop GAHT can both be the right decision for them at that stage of their lives. This is not – and should not – be viewed as a mistake or a failure. Similarly, some patients may shift from identifying with a binary gender to non-binary gender (or vice versa), and their goals from their transition may change accordingly. Stories of this nature are common, and often referred to as 'non-linear transitions'. They are simply reflective of the variety of human experience.

Some providers may feel anxious about 'getting it wrong' or worry that their patient may later regret their decision. The informed consent process outlined in this document respects the autonomy of the patient as a competent adult who has the capacity to make their own decisions about their body and health once they have been given the necessary information. Patients accessing GAHT have an equal right to receive support from health professionals and from family/friends/whānau where needed. By working in partnership, this approach seeks to enhance a given patient's understanding of the potential benefits and risks of GAHT. The provider's role is to provide support and information, and to ensure safety by following prescribing and dosing guidelines, monitoring treatment and monitoring for potential risk. As part of a patient-centred approach, the patient should be an active partner in decisions about GAHT based on their own gender embodiment goals, and information provided to them about likely changes to them (both reversible and irreversible) and risks.

We are beginning to understand more about non-linear transitions (sometimes discussed in the context of 'retransition' or 'detransition') and the reasons people's goals, gender identities, gender expressions, or engagement with treatment change. Frequently, people who have stopped affirming their gender (whether temporarily or permanently) do so due to external factors, including pressure from family, discrimination and social stigma.[48] Detransition is not the same as regret. Social connections and support can be a preventative factor by allowing people to be themselves despite external pressures. Trying to ensure that patients have relational support for their decision-making –for example, from family, friends, whānau and health professionals – where this is requested or needed is important. It is essential that healthcare providers are available to support patients with non-linear transitions, and it can be useful to make this support clear when initiating GAHT. If hormones are stopped, it is important to ensure restoration of physiological sex hormone levels to remove risks of longer-term hypogonadism.

2. Can I still prescribe GAHT where there are significant mental health concerns?

Many (but not all) transgender people experience mental health conditions, often due to gender minority stress.[49] This is caused by negative social attitudes, discrimination, prejudice and violence. Discomfort between a person's intrinsic sense of identity, their body and how they are perceived by others also contribute to distress, as can difficulty in accessing gender affirming services (including GAHT) in a timely manner.[50] Symptoms of anxiety, low confidence, depression, anxiety, disordered eating and trauma are common.

Where a patient has severe mental health concerns that meet the criteria for secondary mental health services, then refer them to these services. However, if a patient's mental health concerns *do not* affect their capacity to provide informed consent for GAHT, then you can concurrently commence GAHT. If you are concerned about your patient's capacity to give consent to GAHT due to their mental health, then this may need to be addressed first and onward referral may be recommended (refer to FAQ 4 on diminished capacity below for more detail). If you are unsure, you can seek consultation from secondary services to see if an onward referral would be recommended. If secondary mental health input is not required,

give your patient advice, support, and treatment for mental health as with any other patients.

Gender affirming healthcare may reduce mental distress, so withholding or delaying care unnecessarily is unethical and could worsen a person's mental health. It is important to weigh up the risks and benefits of these decisions, noting that onward referral may at times come with barriers for patients such as long wait times, transport issues or cost. Doing nothing is not a neutral option and can result in harm to your patient. There should always be the option to refer more complex situations to secondary care for input if a GP or NP feels it is outside of their scope or experience.

3. My patient is autistic. Does this impact on their capacity to give informed consent to start GAHT?

It has been consistently shown that transgender or non-binary people are more likely to be autistic than cisgender people, although there is no consensus as to why.[51] Autism is a neurodevelopmental phenomenon that manifests in a wide variety of ways dependent on the individual. Autistic people may have different cognitive, sensory or social processing, and as a result they may see the world and interact with others differently.

Being neurodivergent does not routinely impact on an individual's capacity to give informed consent. However, some autistic people may need more time to provide information about themselves or may need questions to be asked in a different way, so they are able to communicate their gender identity, embodiment goals for GAHT, and/or demonstrate their understanding of the risks and benefits. It is important to recognise these differences and to create an environment where autistic patients are supported to communicate and engage in a way which feels more comfortable to them, to share the cognitive load, increase their overall comfort, and reduce their feelings of stress. Where a patient is not able to provide you with the information you need, or demonstrate understanding, then it is hard for them to show capacity. It is the job of providers to reduce barriers in any way we can to maximise their ability to demonstrate this.

For patients whose social communication difficulties impair their ability to demonstrate their understanding, in a way required to give informed consent, additional support may be required. This could include referral to communication, mental health or Autism support services (if timely access to these services is available locally).

4. When does a patient have diminished capacity to provide consent?

In Aotearoa New Zealand, adult patients have the right to be presumed to have capacity to give informed consent, unless there are reasonable grounds to believe otherwise.[52] Reasons for diminished capacity might include intellectual disability, brain injury or cognitive impairment, e.g. dementia, psychosis and mania. Some people may have capacity but have difficulty in communication and may need support to aid this process.

If a patient can retain information that they need about GAHT (i.e. risks and benefits), demonstrate understanding of how this will affect their lives (e.g. changes to their body, including permanent changes), weigh the information to come to a decision and clearly communicate a decision based on this understanding and reasoning, then they have capacity to give informed consent to GAHT.

Patients without full capacity still have a right to access care in a timely manner and to have a supported role in decision-making for their care, as indicated under Right 7(4) HDC Code of Rights:[52] The usual procedure for this is for the GAHT prescriber to come to a decision that is in the patient's best interest based on:

(1) the patient's views, level of capacity, wishes and assent.

(2) the views of a suitable person suitable person who is interested in the welfare of the patient, such as a caregiver or family member who knows the person well, or a wider circle of people that includes friends and whānau. This may include an enduring power of attorney or a welfare guardian if one is appointed.

(3) the prescriber's and other

health professionals' expertise of the risks and benefits to the patient.[53]

Prescribers should take care to ensure to provide information to patients in a way that is accessible and appropriate to their level of understanding. Referral to a colleague or appropriate secondary service may aid the decision-making process for patients with diminished capacity.

5. What if my patient starting E-GAHT has a heightened risk of thrombosis or cardiovascular disease?

Patients need to be informed that oestrogen increases the risk of thrombosis and cardiovascular disease. Smoking cessation should be strongly supported. However, it would be unethical to withhold E-GAHT on these grounds. Instead, clinicians should discuss both benefits and risks of E-GAHT with their patients and mitigate any increased risk as much as possible.

In someone with risk factors for thrombosis and/or increased cardiovascular risk (e.g. smoking, ischaemic heart disease, migraine with aura, older age) it is recommended:

- To use transdermal rather than oral oestrogen, as evidence suggests the risk of VTE with transdermal use is similar to population risk.[36, 37] It is sensible to use the lowest effective dose.
- Cyproterone at higher or contraceptive doses (Ginet) increases the risk of VTE[41] and is contraindicated in those with a history of thromboembolic disorders.[54] There are insufficient data to be certain as to whether these risks are removed through the use of lower doses (12.5mg daily). Clinicians should consider alternative androgen blockade options (spironolactone or Gosarelin) in those with an increased VTE risk.

6. Do I need to measure prolactin?

Several guidelines recommend measuring prolactin at baseline and during follow-up in those on E-GAHT, but at present there is no compelling evidence to suggest that E-GAHT increases the risk of pathological hyperprolactinaemia outside of cyproterone use at higher than contemporary recommended doses.[55] There is no such recommendation for cisgender women using contraceptive doses of oestrogen, oestrogen for menopausal therapy, or during pregnancy when oestrogen levels would be expected to be similar or higher to those achieved with E-GAHT. Indeed, oestrogen therapy is frequently used in women with known prolactinomas who are intolerant of dopamine agonist therapy. Furthermore, mildly elevated prolactin measurements that are unlikely to be significant are very common, and the routine measurement of prolactin therefore raises the risk of unnecessary further investigations. We suggest clinicians use clinical judgement when determining if prolactin measurements are required.

7. My patient is requesting low-dose testosterone.

Some people, often those who are non-binary, choose to start on lower doses of testosterone (sometimes referred to by patients as 'micro-dosing'). There is a lack of any evidence to guide low-dose hormone regimens. Patients may choose to remain on a low dose long term, or more slowly increase up to standard maintenance doses over time. A more gradual increase may give some control over the speed of onset of the experienced effects, although this is not guaranteed. When obtaining consent, it is essential to inform the patient about all the same effects, including the permanent changes, as standard testosterone dosing, as all of these occur at lower doses.

There is a lack of evidence to support an optimum testosterone level in this context. Testosterone supplementation is indicated in hypogonadal cisgender men to reduce an increased cardiovascular and bone health risk that is otherwise seen. However, there is currently no literature to indicate an absolute testosterone level below established local reference ranges at which this increased risk becomes apparent. Acknowledging this, and the lack of data in the context of T-GAHT, it is not yet possible to define a minimum testosterone

level when using T-GAHT and patients should be aware of this. In practice, many clinicians would recommend a minimum testosterone level of 6–8 nmol/L.

8. My patient is requesting a medication that is either not in these guidelines or not licensed in New Zealand.

In these guidelines, we recommend the use of medications that either have an established evidence base in the use of GAHT, have a long history of use in GAHT, or are widely used in other populations and risk profiles are therefore well understood. These guidelines align with and support many other guidelines in this area. However, overseas practice may differ, and patients may ask about the use of medications not included in these guidelines. The following are frequently encountered enquiries:

T-GAHT

Oral testosterone

Andriol capsules are not licensed in Aotearoa New Zealand for GAHT, and at the time of writing are not funded. Oral testosterone is not used as a first-line option in T-GAHT due to the fluctuation in testosterone levels throughout the day and the need for frequent dosing, as well as being less effective at stopping menstruation.[12] They can be used on a case-by-case basis, particularly in someone who is needle-phobic and is unable to tolerate transdermal testosterone. They should be avoided if liver disease is present[54] and LFTs should be monitored as with other testosterone regimes. If this option is used, Andriol can be started at 40mg daily and be increased up to 120mg daily in 2 divided doses. When measured, testosterone levels should be checked prior to the morning dose.

E-GAHT

Progesterone

Progesterone is occasionally prescribed as part of gender affirming care. Anecdotally, some people who take E-GAHT have reported benefits of using progesterone on breast development, sleep, mood, and other physical changes. Micronised progesterone (utrogestan) is prescribed for menopausal hormone therapy in many cisgender women and is now funded in Aotearoa New Zealand.

However, there are no current high-quality data to indicate any effect of progesterone for gender affirmation,[56, 57] and no data on safety. It is therefore not included in the majority of international guidelines for gender affirming hormone therapy.[2, 3, 10, 32] Authors of the WPATH SOC-8 attempted to complete a systematic review on this issue but failed to identify enough data to make any recommendations for or against the use of any progesterone in this context, and noted 'existing data suggest harm is associated with extended progestin exposure'.[2] Progesterone treatment in other contexts is associated with weight gain, mood disturbance, fatigue, an increased risk of breast cancer, and venous thromboembolism (VTE).[2, 58] It is not clear how generalisable the data from cisgender women is to transgender populations, who tend to be younger and less likely to use equine oestrogen.[2, 59] Utrogestan is likely to have a lower risk of side effects than older progesterones,[60, 61] and emerging evidence suggests a lower associated risk of breast cancer. Further studies in cisgender and transgender people are required however to confirm this.

This guideline is therefore unable to make a recommendation for or against progesterone use in GAHT at this stage, and we await the outcome of research trials designed to address these questions with interest.

Clinicians may be asked to prescribe progesterone as part of E-GAHT. This should prompt a discussion about expectations and outcomes, potential risk, and current evidence. This discussion may reveal other ways in which doses of existing medications can be adjusted to support your patient's gender embodiment goals. Prescribing decisions ultimately rest with the clinician, but patient autonomy, gender embodiment goals and self-determination for patient choice should be considered and respected.

Anti-androgens

There are no high-quality data to indicate that the use of any particular anti-androgen is superior to any other. We support the use

of spironolactone or cyproterone as both have been used widely in E-GAHT for several decades, and experience with both medications is now extensive in both transgender and other populations. Both are funded for use in GAHT. Cyproterone is associated with an increased risk of liver dysfunction, VTE[41] and meningioma,[38, 39] however, and the lowest effective dose (12.5mg daily or on alternate days) should be used if this is chosen. GnRH agonists (Goserelin) are licensed for use in GAHT and are an option if oral options are not tolerated, with the available evidence suggesting a comparable effect.[62]

Flutamide is recommended by some overseas guidelines on E-GAHT, but is associated with hepatotoxicity, and its use is recommended against by many guidelines on the management of hirsutism in cisgender women for this reason.[63] 5α-inhibitors (often termed dihydrotestosterone blockers) are less effective than other anti-androgens but are occasionally used to reduce androgenic hair loss. Bicalutamide is a potent anti-androgen but is associated with hepatotoxicity and reported cases of fulminant hepatitis.[64] While there remains a lack of any evidence to indicate superiority of Flutamide, 5α-inhibitors or Bicalutamide as anti-androgens in E-GAHT, we recommend against their use because of likely increased treatment risks.[62]

Oestrogen

The goal of GAHT is to provide physiological hormone levels. To achieve this with E-GAHT, oestrogen must be administered, and testosterone must be blocked or lowered, and neither approach is effective in isolation. Unfortunately, many of the physical effects of having progressed through a testosterone-based puberty are not reversed through hormonal therapy alone, and the effect of E-GAHT commenced beyond this age may therefore be less than optimal.

— Higher doses of oestrogen

There is currently no evidence to suggest that a dose of oestrogen higher than 200mcg/24 hours via patch or 6mg daily orally is helpful, and, indeed, poor evidence to suggest any strong correlation between oestrogen doses at recommended levels and outcomes at all.[65] The recommended upper limits of oestrogen dosing in these guidelines align with SOC-8 and the Endocrine Society.[2, 32] While some guidelines recommend a target oestrogen level, there are few available data to definitively specify any target range, and those guidelines that do incorporate such a target generally acknowledge this.

— Oestrogen use without anti-androgen therapy

Some patients advocate for the use of oestrogen therapy alone at higher doses to suppress testosterone production in lieu of additional anti-androgen therapy. By definition, however, this requires the use of oestrogen at supraphysiological levels, with high circulating levels of oestrogen required to suppress pituitary gonadotrophin output and therefore lower testosterone levels to the desired target. There is no evidence to suggest this approach results in improved physical outcomes, and, while there is little evidence specifically on this approach, the use of oestrogen at higher than physiological levels is likely to increase the risks associated with oestrogen use.[65] Aligning with most guidelines on this subject,[32] we therefore recommend against this approach.

— Intramuscular oestrogen

Some international guidelines include IM oestrogen alongside oral and transdermal options,[10, 32] but it is neither licensed nor funded in Aotearoa New Zealand. There is no evidence to suggest that IM oestrogen is any more effective than transdermal oestrogen, and both are likely to be associated with a lower risk of liver dysfunction than oral oestrogen. It is unclear whether the VTE risk may also be lower than seen with oral oestrogen. However, in contrast to transdermal oestrogen, significant variation in oestrogen levels is noted with IM oestrogen, with levels far in excess of those recommended by most guidelines often seen shortly after administration in particular.[32] There are no high-quality data to advise on whether this may increase oestrogen-related risks. There is little guidance on monitoring levels in patients on intramuscular oestrogen as part of GAHT but dosing guidance can be found in the Endocrine Society guidelines.[32]

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Appendix A:

WPATH SOC-8 hormone criteria and ICD-11 gender incongruence

The statements below outline a summary of the SOC-8 criteria for GAHT. However, there are a lot of nuances around each point, which are discussed in more depth in the full SOC-8 document, which can be found here: Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

SOC-8 Summary Criteria for hormonal treatment for adults and adolescents[2]

- Gender incongruence is marked and sustained;
- Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
- Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
- Other possible causes of apparent gender incongruence have been identified and excluded;
- Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
- Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

ICD-11 description of Gender Incongruence[25]

Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior to the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Appendix B:

Sample questions for gender history and embodiment goals

- How would you describe your gender?
- How did you come to learn your gender as it is now?
- What steps have you taken to feel more comfortable in your gender? For example, changed your name or pronouns, dressing differently? How does that feel for you?
- Are you hoping to take any other steps in your transition? What are your current goals? How would you like to embody your gender?
  - *Thank you for sharing that with me. I'm going to make a note of your goals – please let me know if these goals ever change so I can continue to recommend the best care for you.*
- Have you thought about how you will manage a change in appearance at school/work/study/home?
- Who is/are your support/s with this process?
- Have you talked to anyone about your gender identity and your plans to affirm your gender through medical treatment?

  (Of course, there is no requirement for a person to discuss this with others, but this question can help to identify support – or lack of it – and thereby facilitate conversations around this. For example, if a younger person hasn't got parental support, it might be worth having a conversation about how they plan to approach this when there are noticeable physical changes. Family support is important and if not available then other supports should be identified.)
- When did you start thinking about taking hormone therapy?
- What do you think will be the main benefits of hormone therapy? What are you looking forward to?
- Think about your body as it is right now:
  - What would you like to stay the same?
  - What would you like to change?
- How do you imagine your life will change if you start hormone treatment?
- Are there any changes that you are not sure about?
- Do you foresee any concerns or challenges?
- Are you aware of the impacts of hormones on your fertility/ability to have children in the future? Would you consider a referral to a fertility service to store gametes?
  - *Lots of people find it quite difficult to think about how our fertility might affect us in the future, so I'd really encourage you to take your time when you're thinking about this. You don't have to answer now but we should talk about this again before you start hormones.*
- Some people find it useful to have the support of a peer support worker or talk therapist to help with decisions or support. Would you like a referral to a talk therapist with experience around this?
- Some people change their minds about taking hormones, often because of family or society pressures. Have you thought about this at all? (You can emphasise that this does not worry you and encourage them to talk to you, let them know that you are available for support whatever decisions they make in the future.)

Appendix C:

Examples of Practice Management System shortcuts

These can be added to your practice management system (PMS) to use as personal shortcuts to save time when writing your notes.

Capacity

Patient has the capacity to provide informed consent to start gender affirming hormone therapy.

WPATHSOC-8

Patient meets the criteria for hormonal treatment from the WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC-8).

T-GAHT

We have discussed the information on the consent form and patient information sheet, and I have provided copies of both. Discussed effects of hormones, time taken to see changes, which changes are permanent, risks, side effects, medication options and monitoring, cervical screening, and importance of not getting pregnant on testosterone and need for contraception even if periods have stopped. Discussed potential impact on future fertility including that testosterone needs to be stopped if wishing to conceive and that egg harvesting may be required to achieve a pregnancy.

E-GAHT

We have discussed the information on the consent form and patient information sheet, and I have provided copies of both. Discussed effects of hormones, time taken to see changes, which changes are permanent, risks, side effects, medication options and monitoring. I have explained that GAHT does not change voice, bone structure or Adam's apple. Discussed permanent effect on loss of fertility and fertility preservation has been offered.

Appendix D:

Checklists which can be used prior to first GAHT prescription

T-GAHT Checklist

- ☐ Discussed gender embodiment goals and expectations of GAHT
- ☐ PMH, DH, FH, SH, HEeADSSS
- ☐ MH review – offer support options as needed
- ☐ Check on family/community support
- ☐ Fertility/reproductive options discussed
- ☐ Information on consent form and info sheet explained and copy provided to patient
- ☐ Offered menstrual cessation options
- ☐ Discussed contraception
- ☐ Discussed cervical screening and set recall
- ☐ Baseline bloods (FBC, LFT, LH, FSH, oestrogen, testosterone, lipids and consider HbA1c & Beta hCG)
- ☐ Baseline BP & Wt
- ☐ Document capacity to provide informed consent and whether they meet the SOC-8 criteria for hormone treatment
- ☐ Consent form signed (if using)
- ☐ Arrange for nurse appointment for injection, GP appointment for follow-up in 3 months and set recall for 3–6-monthly bloods and plan to measure testosterone after 6–9 months

E-GAHT Checklist

- ☐ Discussed gender embodiment goals and expectations of GAHT
- ☐ PMH, DH, FH, SH, HEeADSSS
- ☐ MH review – offer support options as needed
- ☐ Check on family/community support
- ☐ Discuss likely infertility and offer fertility preservation
- ☐ Information on consent form and info sheet explained and copy provided to patient
- ☐ Discussed – voice therapy, other supports
- ☐ Baseline bloods (LFT, lipids, electrolytes, LH, FSH, testosterone, oestrogen, consider HbA1c & HIV, syphilis, hep B & C if preserving fertility)
- ☐ Baseline BP & Wt
- ☐ Document capacity to provide informed consent and whether they meet the SOC-8 criteria for hormone treatment
- ☐ Consent form signed (if using)
- ☐ Arrange for follow-up in 3 months and set recall for 3–6-monthly bloods

Appendix E:

Patient information sheets

Oestrogen-based gender affirming hormone therapy

The person prescribing your hormones should go through and discuss all of this information with you. If you have any questions or anything is unclear, please discuss this with your health provider.

Which medications are used?

Two medications are used as part of oestrogen-based hormone therapy:

- Oestrogen to provide the hormone oestrogen.
- Testosterone blockers (or anti-androgens) are given alongside this to block the hormone testosterone. If you have an orchiectomy (removal of external gonads or testicles) this medication is no longer needed.

Oestrogen comes in tablets or patches. There is no evidence of a difference in feminising outcomes or effects between these, so you can choose which you prefer, in discussion with your prescriber and taking into account your medical history. Patches are likely to carry a lower risk of blood clots. Taking high doses does not cause changes to happen more quickly and can put your health at risk. There is no evidence to support higher doses or regimes outside of standard guidelines.

Oestrogen tablets are taken every day. Oestrogen patches are applied to the lower abdomen and changed twice a week.

Testosterone blocker options are spironolactone or cyproterone. Both are a tablet taken every day or every other day. There is no evidence of a difference in feminising effects between these.

Spironolactone is a blood pressure tablet at low doses but works as an anti-androgen at higher doses. It will not suppress testosterone levels but will block the effects of testosterone in the body, promoting breast growth and slowing down body hair. Side effects can be low blood pressure, dizziness and passing urine more often.

Cyproterone in very small doses (12.5mg daily or less) will suppress testosterone but it does not suit everyone. Side effects can include fatigue/tiredness and low mood. Shortness of breath is an uncommon side effect but is possible. Larger does have been associated with liver function abnormalities and with a benign brain tumour called a meningioma, but this is thought to be related to long-term use of doses greater than 25mg daily. Evidence in other areas of healthcare shows the risk of blood clots is increased with cyproterone use.

These hormones are fully funded by PHARMAC, which means they cost the same as other routine prescriptions.

What blood tests do I need?

A baseline blood test is often performed before starting hormone therapy, then ongoing monitoring blood tests are usually 3–6-monthly for the first year and 6–12-monthly thereafter (or as agreed with your healthcare provider). You will usually also need to have your blood pressure and weight checked every year.

The blood test will check your liver function and cholesterol levels, as well as monitoring hormone levels. If you are taking spironolactone your potassium level will be monitored.

When taking spironolactone, the testosterone level measured in your blood test may remain raised, as spironolactone mostly acts to blocks testosterone's effect on the tissues in the body, rather than reducing the release of testosterone. For this reason, there is no need to check testosterone levels on a blood test if you are taking spironolactone.

Oestrogen levels are only checked to ensure levels are not too high as this can lead to health risks. Oestrogen levels do not correlate well with physical effects or reported satisfaction, and there isn't enough evidence to suggest a target range. Instead your oestrogen dose will be adjusted in line with standard dose ranges and your experiences of the effects.

Expected effects

Effects are gradual and timing varies, but it can take years for the full effects to be seen. The effects are largely dependent on genetics and the age you start hormones, rather than the dose or type of medication you take. It is important to have realistic expectations about the effects of hormones. The table below outlines the expected timing of the effects, and this link shows the expected effects in a picture: Effects and expected time course of hormone therapy consisting of an anti-androgen and oestrogen

The following changes are permanent (these will not reverse if you stop taking hormones):

- Breast growth – breast growth is gradual over 2–3 years. Most people starting oestrogen-based hormone therapy after puberty can expect to develop an A cup or smaller. As with all people who develop breasts, these vary in size and shape.
- Loss of fertility – your external gonads (testicles) may shrink and eventually stop producing sperm. This may lead to a permanent loss of fertility. Fertility preservation is usually available free of charge. Your GP or nurse practitioner can refer you for this before you start hormones.

The following changes are not permanent (these may reverse if you stop hormones):

- Softer skin
- Decreased muscle mass and strength
- Less body hair – decreases in thickness and grows more slowly but it doesn't go away completely. Some people choose electrolysis or laser treatment for a more permanent solution.
- Redistribution of fat (more on hips, bum, thighs)

Things that don't change:

- Facial hair growth slows down but doesn't stop completely.
- Voice stays the same (voice therapy may be available in your region).
- Bone structure of your face and Adam's apple doesn't change.

Effect of oestrogen	Expected onset	Expected maximum effect	Reversibility
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	Unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	Unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair	6–12 months	>3 years[a]	Possible
Male pattern baldness	Variable	[b]	
Voice changes	None	[c]	

[a] Complete removal of hair requires laser treatment.
[b] Depending on your family history, balding may occur if oestrogens are stopped.
[c] Treatment by speech-language therapists for voice training is most effective.

(Reproduced with permission from the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand*)

Sex

A baseline blood test is often performed Your sex drive is likely to be lower. You will soon notice that you get hardening or stiffening of your erectile tissue (erections) less often and when this does occur, it may be more difficult to sustain. If this is causing issues with sex, you can ask your GP for medication to help this. Lowering the dose of your testosterone blocker may also help. Your external gonads (testicles) will usually shrink to less than half of their original size. Although your sperm count is likely to be lowered (see below), it isn't always, and so if you have sex with someone who is able to become pregnant, you should use contraception.

Fertility

The impact on fertility is unclear but it is safest to assume that within a few months of starting oestrogen-based hormone therapy you could permanently and irreversibly lose the ability to create sperm. Fertility preservation is usually fully funded and your GP or nurse practitioner can refer you for this.

Side effects and risks

- Common side effects include breast tenderness and weight gain. Nausea and headaches can occur when starting oestrogen and usually settle in the first few days or weeks.
- Please tell your healthcare provider if you develop migraine headaches.
- Full medical effects and long-term safety are not known. For most people, benefits outweigh risks, but it depends on other risk factors you may have (such as family history, body size, smoking and blood pressure level).
- There is a small increased risk of liver problems and raised cholesterol (these are both monitored on the blood tests).
- There is an increased risk of blood clots. Using oestrogen patches instead of tablets reduces this risk.
- Risk of health problems are higher if you smoke or are overweight or are over the age of 45 years.
- There may be a slight increased risk of breast cancer compared with cisgender men.

Emotional health

You may feel more emotional. It is not known exactly how hormones will impact your mental health and this varies between individuals. It is a bit like going through a second puberty, so you may experience a rollercoaster of emotions, or you may notice no change. Some people experience mood swings or a worsening of anxiety or depression. You may prefer to start the hormones when you have an upcoming period without big life stressors. We know that gender affirmation can also be a stressful time and many people benefit from extra support through this. Please discuss this with your health provider who can give you options for counselling or peer support. Many people find it very helpful to talk to someone who understands gender affirmation, and it can be helpful to explore concerns around coming out (disclosure), stress with family, social and internalised transphobia, anxiety, uncertainty, acceptance etc. You can find details about support options here:

Gender diversity support services – Health Navigator

Rainbow organisations – Te Ngākau Kahukura

Cancer screening

Breasts – breast screening (mammograms) from the age of 45 years as per national screening guidelines is recommended for anyone with breasts. This is a free service. You can find out more about breast screening and mammograms here: Breast screening – Time to Screen

Prostate – the prostate is a small gland which surrounds the opening of the bladder. If you have a prostate gland it is possible to develop cancer in this. Prostate cancer is most common over the age of 50 years. If you develop trouble with peeing, such as poor flow, dribbling, trouble starting or stopping peeing, peeing more often or blood in your pee, you should speak to your health provider.

Appendix E:

Patient information sheets

Testosterone-based gender affirming hormone therapy

The person prescribing your hormones should go through and discuss all of this information with you. If you have any questions or anything is unclear, please discuss this with your health provider.

Testosterone

Testosterone comes in injections and patches. The most common form is injectable testosterone, as patches commonly cause skin irritation. These hormones are fully funded by PHARMAC, which means they cost the same as other routine prescriptions. There is no evidence of any difference in outcomes or effects between the different forms of testosterone.

There are three forms of injectable testosterone:

- Depo-testosterone is given every 2 weeks.
- Sustanon is given every 3 weeks.
- Reandron is given approximately every 3 months.

Depo-testosterone and Sustanon can be self-injected at home if you wish to do so (but can also be given in clinic by a nurse). The nurse can teach you how to safely self-inject if this is your preferred option. You can also find useful information about this here: Transgender health injection guide

Reandron must be given by a health professional, and you will be seen in clinic for these injections.

Monitoring

Monitoring blood tests are usually needed before starting hormone therapy, then usually 3–6-monthly for the first year and 6–12-monthly thereafter (or as agreed with your healthcare provider). You will usually need to have your blood pressure and weight checked every year. The blood test will check your liver function and cholesterol levels, as well as monitoring hormone levels.

While most monitoring is started at baseline and then 3-monthly, the exception to this is your testosterone level. It takes time for this to stabilise, so it is not usually measured until 9–12 months after starting testosterone. When having a blood test for testosterone, the timing of your blood test is important and depends on which formulation of testosterone you are on:

- Depo-testosterone and Sustanon – check testosterone level mid-way between injections.
- Reandron – check testosterone level just before next injection.

Expected effects

Everyone is different in how quickly they respond to testosterone, but you will start to notice changes in your body gradually over the first few months (see table below). It takes years for the full effects to be seen. This link shows this in a picture: Effects and expected time course of testosterone hormone therapy

The following changes are permanent (these will not reverse if you decide to stop taking testosterone):

- Deeper voice (this can start with a scratchy feeling in the throat)
- Increased hair growth on your body (chest, back, arms)
- Facial hair (the amount varies from person to person)
- Hair loss at temples, possibly becoming bald with time depending on your age and family history.
- Genital changes: Erectile tissue (clitoris) growth around 1–3cm. This can feel uncomfortable or even painful initially.

The following changes are not permanent (these may reverse if you stop testosterone):

- Skin oiliness and acne (acne is usually worst in the first year then gradually improves. You can discuss acne medications with your health provider if needed.)
- Redistribution of body fat (less fat on hips, bum and thighs)
- Increased muscle mass and upper body strength
- Increased sex drive
- Monthly bleeding (periods) usually stops after 1–6 months (for most people but not all. Your prescriber can give you medication to stop monthly bleeding in the meantime if you need this.) Please let us know if you experience any bleeding after your monthly bleeding has stopped.

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[a]	Variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of the voice	6–12 months	Variable	Not possible
Increased sexual desire	Variable	Variable	Likely

[a] Highly dependent on age and inheritance; may be minimal.

(Reproduced with permission from the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand*)

Fertility and contraception

Long-term effects on fertility are not clear. Testosterone stops the ovaries from working and it is not known whether this is reversible or not. If you wish to carry a pregnancy in the future, you will need to stop testosterone as it is harmful to a developing fetus (the exact length of time it needs to be stopped before getting pregnant is not known, so make sure you discuss this with your doctor).

After stopping testosterone your fertility could return allowing you to become pregnant without assistance. However, it may not return, and you may not be able to become pregnant without fertility assistance. This assistance usually involves egg harvesting which is an invasive procedure where eggs are removed using a needle. Testosterone does not usually affect the quality of the eggs, so if it is desired this procedure can be carried out at the time it is needed and is not usually recommended before starting hormone therapy.

If you have surgery which involves removing your reproductive organs, you may be able to access funded egg storage and can discuss this with your health provider. If you would like to discuss fertility options in more detail you can request a referral to a fertility specialist.

Testosterone is NOT a form of contraception. If you are having sex which could result in pregnancy (front hole (vaginal) sex with someone whose body produces sperm), you should use contraception even if your periods have stopped.

Sex

Your libido (sex drive) may increase and your genitals, especially your erectile tissue (clitoris), will grow. This can lead to sex and orgasms feeling different. Testosterone can cause the internal genitals (vagina) to become dry, which can cause sex to feel uncomfortable. This can be eased by using additional lubrication (lube). If you have ongoing problems with discomfort in this area, an oestrogen cream can make the internal genital area feel much more comfortable. Your GP or nurse practitioner can prescribe oestrogen cream, or you can try an over-the-counter cream for dryness such as the Vagisil range.

Side effects and risks

- Increased red blood cells (this can thicken the blood increasing risk of stroke or heart attacks. Red blood cells are monitored on your blood tests.)
- Possible risk of liver problems or raised cholesterol (these are monitored on your blood tests).
- There may be an increased risk of blood clots.
- Risk of health problems are higher if you smoke or are overweight.
- Full medical effects and risks are not known.
- Potential risk of testosterone injections include pain at the site and infection. Steps are taken to reduce this risk. Reandron can rarely cause an oil embolism which is when a tiny amount of oil gets into the blood stream. This is why Reandron should be given by a health professional.

Emotional health

It is not known exactly how it will impact on your mental health and this varies between individuals. It is a bit like going through a second puberty, so you may experience a rollercoaster of emotions, or you may notice no change. You may prefer to start the hormones when you have an upcoming period without big life stressors. You may find your mental health improves, but we know that gender affirmation can also be a stressful time and many people benefit from extra support through this. Please discuss this with your health provider who can give you options for counselling or peer support. Many people find it very helpful to talk to someone who understands gender affirmation, and it can be helpful to explore concerns around coming out, stress with family, social and internalised transphobia, anxiety, uncertainty, acceptance, etc. You can find details about support options here:

Gender diversity support services – Health Navigator

Rainbow organisations – Te Ngākau Kahukura

Cancer screening

Cervical screening – this is recommended for anyone aged 25–69 years old who has a cervix. From July 2023 this can be done using a simple swab (which you can choose to do yourself in private). More details here: Cervical screening – Time to Screen

It is possible that changing your gender marker on your primary care practice computer system could result in you not getting a reminder when you are due for this test, so please discuss with your GP or nurse if you think this could be the case. The HPV vaccine greatly reduces your risk of cervical cancer. If you have not had this vaccine, please discuss this with a nurse or GP.

Breast screening – if you have breasts, screening mammograms are recommended from age 45 years. If you've had top surgery, you will need to follow the advice of your surgeon, which may be to perform regular self-exams and ask your GP about annual chest wall examinations with possible ultrasound scans. More information here: Breast screening – Time to Screen

Appendix F:
Consent forms

Consent form for starting oestrogen-based hormone therapy

This consent form outlines important information you might want to talk to your health team about before starting hormones to feminise the body.

Progynova (oestradiol valerate) tablets or **Estradot** (oestradiol hemihydrate) patches provide the feminising hormone oestrogen. Testosterone blockers are needed as well unless orchiectomy surgery has occurred.

Oestrogen tablets/patches will gradually feminise the body.

Permanent body changes (even if you stop taking the tablets):

- Gradual increase in breast size over 2–3 years.
- Your oestrogen dose is increased slowly for best breast development.
- It is not known if taking oestrogen increases the risk of breast cancer. Take care of your breasts – it is recommended to follow the normal breast screening guidelines for women.

Non-permanent body changes (that may reverse if you stop the oestrogen):

- Softer skin
- Decreased muscle mass
- Less body hair
- More fat on buttocks, hips and thighs

Things that don't change much:

- Facial hair slows down but doesn't stop completely
- Voice stays the same
- Bone structure of your face and Adam's apple doesn't change

If you stop taking your hormones some body changes stay but you may find that your body will slowly masculinise.

Fertility

Taking the hormones stops your testicles producing testosterone. Your testicles may shrink by up to 50% and may eventually stop sperm production. If it is important for you to preserve your fertility you might want to freeze your sperm before you start treatment. Your health team will talk to you about this.

Sex

Taking the blocker tablets may lower your sex drive so that you are not as interested in having sex any more. You may find that you get erections less often and that your penis doesn't get as hard any more. If you want to be able to use your penis for sexual pleasure talk to your health team and they will review your medications.

Mental health

Some people may feel more emotional taking oestrogen. Some people find their mental health improves – the effects of hormones on the brain are not fully understood. Transitioning can be a stressful time and many people need some help adjusting to the physical and emotional changes. It is really important that you let your health team know if you are having problems so that they can help you access the support you need.

Common side effects

- Nausea
- Headaches
- Tender breasts
- Weight gain

Most side effects should settle within a few days to weeks of starting the medications. Please tell your health team if you have any side effects, especially headaches or migraines.

Potential risks of oestrogen

The full medical effects and safety of taking hormones are not fully known. The potential risks of taking oestrogen must be weighed against the benefits that hormones can have on your health and quality of life.

Likely increased risk

- Blood clots – deep vein thrombosis (DVT), pulmonary embolism (blood clot in the lung), stroke, heart attack
- Changes to cholesterol (may increase risk of pancreatitis and heart disease)
- Gallstones

Possible increased risk

- Increased blood pressure
- Liver problems
- Increased prolactin and possibility of benign pituitary tumours

Possible increased risk if you have extra risk factors

- Heart disease
- Diabetes

No increased risk or unknown

- Breast cancer

Some of these risks are reduced by using oestrogen patches instead of tablets.

Go to the emergency department or seek medical help urgently if you have:

- A swollen painful leg
- Chest pain or difficulty breathing
- Vision or speech problems.

These symptoms might mean you have a serious problem like a blood clot.

The risk of having a blood clot is much higher if you smoke or are overweight.

Blood clots are more common as you get older. Stopping oestrogen before and after surgery can help reduce the risks of blood clots around this time.

Keeping in touch with your health team for regular check-ups and blood tests is an important part of your care and will reduce the risks of taking hormonal therapy.

Are there any other questions you want to ask?

It is your health team's responsibility to best support you to make the decisions that are right for you and to keep ourselves up to date so that we can best inform you.

For many different reasons people question whether or not they want to continue to take hormones. This can be a normal part of your journey. Please feel free to discuss this with your prescriber before you stop your medication. Come and talk – your health team is always ready to listen.

I wish to start feminising hormone therapy:

Name .....

Date .....

Prescribed by:

Name .....

Date .....

Appendix F:
Consent forms

Consent form for starting testosterone-based hormone therapy

This consent form outlines important information you might want to talk to your health team about before starting hormones to masculinise the body.

There are different types of testosterone that are taken to masculinise the body. Everyone is different in how quickly they respond to testosterone but you will start to notice changes in your body gradually over the first few months. It may take several years before the full effect is felt. While there are different ways of getting testosterone into the body most people are on injections.

Permanent body changes (even if you stop taking testosterone):

- Deeper voice
- Increased growth of hair – with thicker hairs on arms, legs, chest, back and abdomen
- Gradual growth of moustache/beard hair
- Hair loss at the temples – possibly becoming bald with time
- Genital changes – clitoral growth (typically 1–3 cm) and vaginal dryness.

Non-permanent body changes (that may reverse if you stop the testosterone):

- Skin changes – increased oil and acne
- Change in body shape – less fat on buttocks, hips and thighs
- Increased muscle mass and upper body strength
- Increased sex drive
- Periods usually stop after 1–6 months

Things that don't change much:

- Breast tissue looks a bit smaller due to fat loss
- Possible weight gain or loss

Fertility

While it is not known what the long-term effects are of taking testosterone some trans men find that if they stop their testosterone they will become fertile again and can get pregnant. There are no guarantees for anyone and it is probably harder to get pregnant the older you are and the longer you have been on testosterone.

Testosterone is dangerous for the developing fetus – you must not get pregnant while you are on testosterone. Even after your periods stop you might still be at risk of getting pregnant. If you are having any sexual contact that puts you at risk of pregnancy you must talk to your health team about contraception options.

Sex

Taking testosterone causes your vagina to become dryer and more fragile. This increases the risk of sexually transmitted infections (STIs), including HIV if you are having any sexual contact with this part of the body. Condoms provide good protection against STIs and lubricant helps to prevent any discomfort.

Mental health

Some people find that testosterone can cause emotional changes such as increased irritation, frustration and anger. Some people find their mental health improves – the effects of hormones on the brain are not fully understood.

Transitioning can be a stressful time and many people need some help adjusting to the physical and emotional changes. It is really important that you let your health team know if you are having problems so that they can help you access the support you need.

Potential risks of testosterone

The full medical effects and safety of taking hormones are not fully known. The potential risks of taking testosterone must be weighed against the benefits that hormones can have on your health and quality of life.

Likely increased risk

- Increased red blood cells (polycythemia) – might thicken the blood and increase the risk of a stroke or heart attack
- Sleep apnoea (sleep disorder)

Possible increased risk

- Increased blood pressure
- Liver problems
- Increased prolactin and possibility of benign pituitary tumours

Possible increased risk if you have extra risk factors

- Diabetes
- Increased blood pressure

No increased risk or unknown

- Breast cancer
- Cervical, ovarian, uterine cancer
- Blood clots – deep vein thrombosis (DVT)

The risk of health problems is higher if you are a smoker or overweight.

Keeping in touch with your health team for regular check-ups and blood tests is an important part of your care and will reduce the risks of taking hormonal therapy.

Are there any other questions you want to ask?

It is your health team's responsibility to best support you to make the decisions that are right for you and to keep ourselves up to date so that we can best inform you.

For many different reasons people question whether or not they want to continue to take hormones. This can be a normal part of your journey. Please feel free to discuss this with your prescriber before you stop your medication. Come and talk – your health team is always ready to listen.

I wish to start masculinising hormone therapy:

Name .....

Date .....

Prescribed by:

Name .....

Date .....

Appendix G:

Testosterone administration

Practical tips for health professionals

Visual overview of available formulations of injectable testosterone

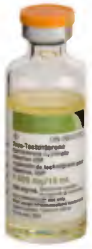
NB: this is not patient information. Useful resources for patients wishing to self-administer Sustanon or Depo-testosterone can be found here: Transgender health injection guide

Reandron
(testosterone undecanoate)

Comes in a vial. Usually given 12-weekly. Single use vial, dose up to 4ml.

Sustanon
(testosterone esters)

Comes in a glass ampoule. Single use, usually given 3-weekly. Can be self-administered.



Depo-testosterone
(testosterone cypionate)

Comes in a vial, each vial contains 5-10 doses. Usually given fortnightly. Can be self-administered.

General advice for all formulations:

- The first injection can be very significant for people – they may have waited a long time to start. Important not to rush; ensure privacy.
- Obtain and document consent, ensure person is aware of potential side effects.
- All formulations should be administered slowly.
- 20-minute wait after the first injection is recommended in case of allergy.

Storage

- All formulations need to be stored below 30°C (e.g. in a cool cupboard away from direct sunlight). Do not refrigerate or freeze.
- Sustanon should be used immediately once the ampoule is open as it cannot be resealed.

Preparation

- As with all medicines, check expiry date first, and '5 rights of medication administration' (the right person, drug, dose, route, time).
- Slightly warming the formulation beforehand in one's hands it easier to prepare and administer.
- Injecting the same volume of air as the dose required into the vial for Reandron and Depo-T can break the vacuum and make it easier to draw up the liquid, but this is not essential. This will not be possible with Sustanon.
- Always check for air bubbles in the syringe and remove prior to administration.

Administration

- As with any deep intramuscular injection the ***ventrogluteal*** site is the best administration site for all formulations: reported to be less painful, less risk of injury to underlying nerve structures, less risk of oil embolism as no major blood vessels, and usually less adipose tissue and more muscle. However, it can be given in the ***dorsogluteal*** site. The same site should not be used every time, so rotate between left and right side each injection.
- Can be given standing or supine per personal preference (supine recommended for Reandron). People self-administering their testosterone usually use the vastus lateralis or rectus femoris sites as better access.
- All formulations are given as a deep intramuscular injection so best use a 38mm (1.5") 22 G needle to administer. Important to inject into deep muscle as testosterone can cause necrosis or abscess formation if given too superficially/into adipose tissue.
- Depo T can also be given subcutaneously but there is not yet enough evidence around the safety and efficacy of giving Sustanon via this route. Note that the dose and regime for subcutaneous administration of Depo T is not the same as for the intramuscular route.
- As with all intramuscular injections, Z-track technique is recommended to prevent tracking of the medication into the subcutaneous tissue.
- Always aspirate first before injecting solution to ensure the needle is not in a blood vessel.
- All formulations should be administered ***slowly*** and at a steady, controlled pace.

Disposal

- Some people like to keep their ampoules/ vials so check first before disposal.
- Dispose of all syringes per usual protocol, e.g. via a sharps bin.
- Local needle exchanges often have facilities for safe sharp disposal for self-administration.

Reandron

- Ideally given over 4 minutes, very thick solution so takes time, be patient!
- Doses should not be split (i.e. needs to be given as 4ml dose not 2 x 2ml).
- Use an 18G needle to draw up medication then change to 38mm 22G or 21G needle to administer.
- For dose of 3ml or less, use a 3ml syringe as resistance will be less. For a dose of 4ml use a 5ml syringe.

Sustanon

- Contains arachis oil – check no peanut allergies first.
- When breaking the top, have the 'small blue dot' facing away from you. This indicates the weakest point of the vial. You can then break the vial by snapping the top off towards you. Use a gauze or tissue to do this to protect your fingers from the glass – can be sharp.
- Use a blunt filter needle in case of glass fragments to withdraw solution into the syringe.
- Change to 38mm 22G needle when ready to administer.
- Use a 1ml tuberculin syringe or 3ml syringe, depending on dosage. For a dose of 1ml, a 3ml syringe is usually easier to prepare.

Depo-testosterone

- Use within 28 days.
- Use alcohol swab to clean the rubber bung each time before drawing up (allow time to dry).
- Replace lid and secure until next visit.
- Can use 18G needle to draw up medication then change to 38mm 22G needle to administer.
- Can use 1ml tuberculin syringe or 3ml syringe, depending on dose.

RULE FOUNDATION
rulefoundation.nz

TAB 200-5

United States District Court
Northern District of Florida

Case Number: 4:22-cv-00325-RH-MAF

August Dekker, et al.
Plaintiffs,
vs.
Jason Weida, et al.
Defendants:
_____/

VIDEOCONFERENCE DEPOSITION OF
JASON WEIDA

DATE: April 24, 2023
TIME: 3:00 p.m. - 6:31 p.m.
LOCATION: 119 South Monroe Street, Suite 500
Tallahassee, Florida 32301
REPORTED BY: John Bilich, Notary Public
JOB NO.: 5884626

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Also Present:
Thomas Thomas, Videographer
Anna Gonzalez, Paralegal (By Video Conference)
Pillsubry Winthrop Shaw Pittman, LLP

A No.
Q Do you recall being in attendance at a meeting with officials from the governor's office and people from the Florida Department of Health, as well as people from AHCA prior to April 20th of 2022?
A Not -- may I ask you a clarifying question?
Q Yes, of course.
A Okay. Regarding gender-related issues?
Q Correct. Well, gender dysphoria and transgender issues in particular, not gender issues generally.
A Right, I just want to make sure, because we have a lot of meetings and I have met with the Department of Health in the past on a range of topics. But with respect to the topics at issue in this lawsuit, I do not recall being at a meeting with all of those individuals.
Q Do you recall being in a meeting with some subset of those individuals?
A Yes, I do.
Q Okay. When was that?
A I don't have an exact date, but I believe it would have been early April.

Q Who was present in the meeting?
A So in addition to myself -- well, I want to be -- I just want to be clear here. So I remember two such meetings, and I don't remember exactly who was at one meeting versus the other, but I can tell you who I remember being at both of those meetings cuz I know that there was at least one person and possibly more who was at one, but not both, and I just don't remember which ones those were. But I can just tick through the whole list if that's okay with you?
Q Fair enough. Before you do that, was the other meeting -- you mentioned that one meeting was early April. Was the other meeting in March, or was the other meeting after the meeting in early April?
A I believe it was after the meeting in early April.
Q So, as you recall today, you had a meeting in early April and then a meeting after that meeting, correct?
A That's correct.
Q All right. So let's start with, tell me everyone that you can remember that was in those meetings collectively, since you can't remember who was in which one.

A Right. So, collectively, obviously without representing that they were all there for both, the people that I remember being at one or the other, or possibly both of those meetings, were secretary Marstiller, who was the secretary of the Agency for Healthcare Administration at the time. Cody Farrill, who was the chief of staff at the Agency for Healthcare Administration at the time, Josie Tamayo, who was the General Counsel for the Agency for Healthcare Administration at the time. Andrew Sheeran, who at the time was the chief litigation counsel. He worked for Josie Tamayo. He's our current General Counsel, but at the time he was the chief litigation counsel. I recall Ryan Newman being present. Ryan is and was at the time the governor's General Counsel. And at one or both of those meetings, Katie Strickland, who is the deputy chief of staff for the governor, one of the deputy chiefs of staff. And I also recall Maureen Furino, although I don't remember if she was present or just called in. I think she might have called into the meeting. So I don't think she was technically present.

Q And who is she?

A She is a deputy General Counsel. She

worked for Mr. Newman.

Q Okay. Anyone else you recall being there?

A Not that I can recall.

Q Who called the meeting?

A I don't know who --

Q -- organized -- (Talking simultaneously.) [Inaudible].

A I don't know.

Q How did you find out you were going to be there, or needed in the meeting?

A I believe I was invited by somebody from the agency management team at the Agency for Healthcare Administration. I just don't remember who that would've been.

Q What were you told the meeting was going to be about?

A I was told the meeting was going to be about recent guidance that had been issued by the United States Department of Health and Human Services regarding treatments for gender dysphoria.

Q And do you recall who told you that?

A No, I don't.

Q Do you recall, did you get a calendar invitation for the meeting?

A I don't recall. It was about a year ago,

Q Yes.

A So, I don't have the full list in front of me, but my understanding is that there are, I don't know exactly how many, but several coverage policies in the Bureau of Medicaid policy that provide for various mental health and behavioral health services for the treatment of gender dysphoria.

Q What analysis was done to determine whether or not there's any evidence that psychotherapy or behavioral health therapy on its own is an appropriate treatment for gender dysphoria?

A Well, the GAPMS report focused on the procedures that are described in the current rule. The GAPMS report did not focus on, directly at least behavioral health services. So that was not part of the GAPMS process or the review.

Q Has any analysis been done to determine whether or not psychotherapy or behavioral health therapy alone is an appropriate treatment for gender dysphoria?

A I don't know the answer to that question.

Q Shouldn't you know the answer to that question? Is if that's the only thing that's covered for gender dysphoria, shouldn't you know, as

TAB 200-6

Posted on 04/11/2023 by **brandon (/user/730)**

Equality Florida Issues Advisory Warning For Travel

ST. PETERSBURG, FL -- Today, Equality Florida took the extraordinary step of issuing a travel advisory, warning of the risks posed to the health, safety, and freedom of those considering short or long term travel, or relocation to the state. The move comes in response to a wave of safety inquiries Equality Florida has received following the passage of laws that are hostile to the LGBTQ community, restrict access to reproductive health care, repeal gun safety laws, foment racial prejudice, and attack public education by banning books and censoring curriculum.

“As an organization that has spent decades working to improve Florida’s reputation as a welcoming and inclusive place to live work and visit, it is with great sadness that we must respond to those asking if it is safe to travel to Florida or remain in the state as the laws strip away basic rights and freedoms,” said **Nadine Smith, Equality Florida Executive Director**. “While losing conferences, and top students who have written off Florida threatens lasting damage to our state, it is most heartbreaking to hear from parents who are selling their homes and moving because school censorship, book bans and health care restrictions have made their home state less safe for their children. We understand everyone must weigh the risks and decide what is best for their safety, but whether you stay away, leave or remain we ask that you join us in countering these relentless attacks. Help reimagine and build a Florida that is truly safe for and open to all, and where freedom is a reality, not a hollow campaign slogan.”

Governor Ron DeSantis, who has made the extremist policies the centerpiece of his presidential campaign strategy, has weaponized state agencies to silence critics and impose sanctions on large and small companies that dissent with his culture war agenda or disagree with his attacks on diversity, equity, and inclusion.

Already, the adopted and proposed policies detailed in the travel advisory have led Florida parents to consider relocating (https://19thnews.org/2023/02/queer-florida-parents-leaving-state-dont-say-gay/), prospective students to cross Florida colleges and universities off their lists (https://www.forbes.com/sites/petergreene/2023/03/31/survey-1-in-8-florida-incoming-freshmen-plan-to-flee-desantiss-education-policies/?sh=c2cc6f42dfda), events and conferences to cancel future gatherings (https://www.lgbtqnation.com/2022/09/large-gaming-event-set-florida-canceled-dont-say-gay-law/), and the United States military to offer redeployment for service members whose families are now unsafe in the state. Businesses have spoken out against the governor’s abuse of state power to punish dissent, with Disney CEO Bob Iger calling DeSantis “anti-business and anti-Florida (https://www.theguardian.com/us-news/2023/apr/04/disney-bob-iger-ron-desantis-florida).” The worsening attacks, especially those targeting transgender youth, have also led to the proposal of policies around the country (https://thehill.com/homenews/3861492-amid-tidal-wave-of-anti-trans-legislation-democratic-states-race-to-become-refuges-for-gender-affirming-care/) to provide refuge for those fleeing states like Florida.

The Florida Immigrant Coalition, a statewide immigrant rights coalition of 65 member organizations and over 100 allies, also issued a travel advisory today (https://floridatraveladvisory.com/), urging reconsideration of travel to Florida and providing critical information about where immigrant travelers can learn more about their constitutional rights. And just weeks ago, Florida chapters of the NAACP voted unanimously (https://naacp.org/articles/naacp-florida-state-conference-recommends-travel-advisory-state-response-african-american) to request similar warnings to the Black community about the risk of traveling or relocating to the state.

Equality Florida's full travel advisory follows.

MEMORANDUM

To: Interested Parties

From: Equality Florida

Subj.: TRAVEL ADVISORY: FLORIDA MAY NOT BE A SAFE PLACE TO MOVE OR VISIT

Date: April 12, 2023

Today, Equality Florida took the unprecedented step of issuing a travel advisory to individuals, families, entrepreneurs, and students warning that Florida may not be a safe place to visit or take up residence. The advisory comes after passage of laws that are hostile to the LGBTQ+ community, restrict access to reproductive health care, repeal gun safety laws and allow untrained, unpermitted carry, and foment racial prejudice. The Governor has also weaponized state agencies to impose sanctions against businesses large and small that disagree with his attacks on diversity, equity, and inclusion.

Florida has recently adopted a slate of hateful laws, and is fast-tracking additional measures that directly target the rights of LGBTQ+ individuals and basic freedoms broadly. Already, those policies have led Florida parents to consider relocating (https://19thnews.org/2023/02/queer-florida-parents-leaving-state-dont-say-gay/), prospective students to cross Florida colleges and universities off their lists (https://www.forbes.com/sites/petergreene/2023/03/31/survey-1-in-8-florida-incoming-freshmen-plan-to-flee-desantiss-education-policies/?sh=c2cc6f42dfdahttps://www.forbes.com/sites/petergreene/2023/03/31/survey-1-in-8-florida-incoming-freshmen-plan-to-flee-desantiss-education-policies/?sh=c2cc6f42dfda), events and conferences to cancel future gatherings (https://www.lgbtqnation.com/2022/09/large-gaming-event-set-florida-canceled-dont-say-gay-law/), and the United States military to offer redeployment for service members whose families are now unsafe in the state. These laws and policies are detailed below.

Assaults on Medical Freedom

- Florida's Boards of Medicine and Osteopathy have adopted policies banning access to lifesaving medical care for transgender youth and the Agency For Health Care Administration has eliminated Medicaid coverage for transgender adults accessing that care
- Florida is poised to pass laws creating criminal penalties for medical providers who provide medically necessary care for transgender youth, weaponizing the courts to shred existing child custody agreements and reassign transgender youth to an unsupportive parent, and severely restricting access to prescribed medical care for transgender adults
- Florida has passed or is poised to pass bills that restrict access to reproductive health care, including a near-total abortion ban, which threatens to force people to travel out of state or seek unsafe, illegal abortions.

These policies disproportionately harm marginalized communities, including the direct impacts on the transgender community and communities of color, and could lead to serious health consequences. Transgender people in Florida are facing the immediate threat of loss of lifesaving, medically necessary care and families risk interference in child custody arrangements at the hands of an unsupportive parent and a weaponized state court system. These attacks pose an imminent threat to the health and safety of all in Florida and potential travelers should be aware of the risks.

Assaults on Academic Freedom

- The Florida legislature has sought to strip Diversity, Equity, and Inclusion (DEI) programs from colleges and universities, that help LGBTQ and minority students thrive
- The Governor has initiated a hostile, right-wing takeover of higher education, and installed partisan allies to implement a conservative overhaul of public universities
- His administration has taken aim at AP African American studies, threatening to sever ties with the College Board over the inclusion of queer history and intersectionality in the course, and college majors, including gender studies

These actions by the Governor pose a serious threat to academic freedom, free speech, and the pursuit of knowledge. DEI departments play a crucial role in promoting diversity and inclusion on campus, and their removal undermines the ability of students and faculty to engage in critical discussions about issues of race, gender, and identity.

Furthermore, the replacement of university presidents with political appointees threatens the independence of higher education institutions, and undermines the ability of these institutions to make decisions that are in the best interest of their students, faculty, and staff. These attacks on public education are deeply concerning, and further reinforce the message that Florida is not a welcoming state for people from all backgrounds. We urge individuals, families, entrepreneurs, and students to consider the implications of traveling to or residing in Florida, and to support efforts to defend public education and academic freedom in the state.

Censorship and Erasure of the LGBTQ Community

- Florida has passed a prohibition on classroom instruction on sexual orientation and gender identity in public schools
- This law has already precipitated a raft of damaging impacts in school districts across the state, including
    - Hundreds of book challenges and bans targeting titles written by LGBTQ authors and/or including LGBTQ characters
    - The refusal of districts like Miami-Dade to recognize LGBTQ History Month
    - The removal of rainbow Safe Space stickers
    - The censorship of graduation speech content to remove references to LGBTQ identities
    - Warnings to educators and administrators to hide family photos
- Lawmakers are currently considering a bill to extend that prohibition through 8th grade, while the Department of Education is set to decide on a policy proposal that would expand it to all grades and revoke teacher licenses over violations
- Florida is poised to pass a bill that would ban transgender people from updating their birth certificates to reflect their gender identity

The infamous Don't Say LGBTQ law has made Florida synonymous with the anti-LGBTQ movement to empower government censorship and book banning across the nation. That law, along with additional proposals being considered, has turned the state's classrooms into political battlefields and is telegraphing to LGBTQ families and students that they are not welcome in Florida.

Assaults on Arts, Entertainment, and Sports Participation

- Florida has passed a ban on transgender women and girls from participating in school sports consistent with their gender identity
- Lawmakers are poised to pass restrictions on certain live drag performances, stage shows, and local pride celebrations, limiting parents' ability to determine what content may be suitable for their families

The far-right's obsession with drag queens has put LGBTQ people in physical danger across the country, but especially in Florida. In 2022 alone, the LGBTQ media organization GLAAD found 141 incidents of anti-LGBTQ protests and threats targeting drag events. Right-wing media like Fox News and Libs Of TikTok have misrepresented what occurs at drag events and taken examples out of context to create fear and misunderstanding. This has had real world consequences, with protests and threats of violence against venues hosting drag shows.

In Florida, Orlando organizers were forced to cancel Drag Queen story hour due to threats from Neo-Nazis (https://www.orlandoweekly.com/news/orlando-area-drag-queen-story-hour-canceled-due-to-neo-nazi-threats-32762594). This last December in Lakeland (https://www.fox13news.com/news/demonstrators-wearing-nazi-gear-show-up-outside-lakeland-charity-event-that-included-drag-performers), masked individuals in Nazi gear, waving Nazi flags ambushed a charity event hosted by drag queens while projecting hateful messages onto local buildings.

Assaults on Business

- DeSantis has recently signed a bill that restricts businesses from providing diversity and inclusion training to their employees, a blatant attempt to dictate to businesses what they can and cannot do, and to prevent them from training their employees to be better prepared for a diverse workforce and customer base
- The Florida legislature is expected to pass SB 1438, which weaponizes state agencies with more power to politically target LGBTQ-friendly businesses who open their doors to live drag performances, with threats of fines, license revocation, and jail time. Individuals that admit minors with an accompanying parent would be charged with first degree misdemeanor crimes.
- The governor has weaponized the state legislature against businesses that stand with their LGBTQ employees and clients and against his agenda, most notably wielding two special sessions of the legislature to punish Disney, the state's largest single-site employer

The Miami Herald recently reported (https://www.miamiherald.com/news/politics-government/state-politics/article273247175.html) that DeSantis-controlled agencies sought to punish and revoke the liquor license of an Orlando establishment that hosted a live drag performance even after the state's own investigators reported that they saw nothing "lewd". The discriminatory targeting of LGBTQ-friendly businesses by the state will have a broader chilling effect over drag performances, an intended consequence of this type of censorship.

Disney has also recently denounced the governor's actions against them, with CEO Bob Iger calling the state's policies "anti-business and anti-Florida (https://www.theguardian.com/us-news/2023/apr/04/disney-bob-iger-ron-desantis-florida)."

These laws and actions are harmful to businesses and their employees, as they undermine efforts to create inclusive workplaces and hinder the ability to effectively engage with diverse customers and clients. It also sends a message that Florida is not a welcoming state for people from all backgrounds and that discrimination is acceptable.

Efforts to Foment Racial Prejudice

- Florida has passed a bill that would limit the honest teaching of history and systemic racism in schools
- The state passed another that restricts voting access for people of color and is currently considering additional voting restrictions
- DeSantis' new elections police have abused their power to aggressively target and prosecute returning citizens, mostly Black Floridians, for voting after official government entities told them they were eligible to vote (https://www.politico.com/news/2022/08/26/desantis-voter-fraud-defendants-florida-00053788)

These laws create an unsafe and unwelcoming environment for LGBTQ+ individuals, women, people of color, and other marginalized communities. They send a message that discrimination and prejudice are acceptable in Florida, and we cannot in good conscience encourage people to visit or move to a state that is openly hostile to their basic human rights.

As a result of these dangerous and discriminatory laws, we urge individuals, families, entrepreneurs, and students to reconsider travel plans to Florida and to consider the impact that their travel and economic choices can have on promoting equality and justice for all.

Repealing of Gun Safety Laws

The passage of deadly permitless carry makes Floridians less safe (https://everytownresearch.org/solution/strong-standards-for-carrying-concealed-guns-in-public) and signals the reversal of the progress made after Pulse and Parkland. Coupled with the state's infamous Stand Your Ground law, Permitless Carry threatens to exacerbate Florida's violent crime rate at a time when the state's homicide rate ranks 20th in the nation, exceeding both California and New York.

LGBTQ Floridians know all too well that the gun lobby's obsession with easy access to deadly weapons can make hatred and bigotry lethal (https://www.hsph.harvard.edu/news/hsph-in-the-news/do-guns-make-us-safer-science-suggests-no/). Gun violence is not abstract or hypothetical -- it is stealing our loved ones. Those considering travel to Florida should weigh the potentially deadly consequences of the DeSantis Administration's decision to eliminate basic training and permitting requirements in order to concealed carry a firearm.

Attacks on Immigrant Communities

Florida has passed and is poised to pass legislation targeting immigrant communities, with consequences that could include arrest for operating a vehicle, no matter the state you are from, reduced access to health care services, and compromised safety. A bill currently being considered by the Florida legislature could impose criminal penalties on any who shelter, support, or provide transportation to undocumented immigrants. And these moves come just months after Governor DeSantis trafficked migrants from Texas to Massachusetts in a cruel scheme to use their suffering as campaign marketing material.

The threats posed to immigrants in Florida led the Florida Immigrant Coalition to issue its own advisory urging reconsideration of any travel to the state. That advisory can be found here (https://floridatraveladvisory.com/).

Conclusion

Taken in their totality, Florida's slate of laws and policies targeting basic freedoms and rights pose a serious risk to the health and safety of those traveling to the state. We regret that these attacks have already led many to flee the state and are driving others to consider relocation. And, in a state whose economy is fueled by visitors from around the world, it is with great sadness that Equality Florida has had to take the extraordinary step of responding to inquiries by issuing an official advisory warning about the risks of travel to the state.

Equality Florida will continue providing information and resources to those impacted by these laws and policies. Visit our Open Doors Florida directory (https://opendoorsflorida.com/) to find businesses with nondiscrimination policies and procedures. And if you experience discrimination, report it to our team here (https://eqfl.org/lgbtq-protections) or call our Main Office at 813-870-3735.

It is our hope that those Floridians who can, will stay and engage more deeply in the fight against the state's all-out assaults on democracy and freedom. This moment calls for a grassroots movement in defense of justice and equality for all -- so that we can turn back the tide of right wing authoritarianism, recommit to building a state that is safe and open to all, and once again celebrate Florida as a free state.

Blog

April 2023

March 2023

February 2023

January 2023

December 2022

November 2022

October 2022

September 2022

August 2022

July 2022

June 2022

May 2022

April 2022

March 2022

February 2022

January 2022

December 2021

November 2021

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January 2008

December 2007

November 2007

October 2007

July 2007

March 2007

November 2006

August 2006

July 2006

June 2006

May 2006

April 2006

March 2006

February 2006

Privacy Policy (/privacy)

TAB 210

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, *et al.*, *Plaintiffs*, v. JASON WEIDA, *et al.*, *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

PLAINTIFFS' MOTION REQUESTING JUDICIAL NOTICE AND INCORPORATED MEMORANDUM OF LAW AS TO GOVERNMENTAL ACTIONS, POLICIES, AND REPORTS

Pursuant to Federal Rule of Evidence 201, Plaintiffs respectfully request that this Court take judicial notice of the governmental actions, policies, reports, statements, and proposed legislation detailed below, which document the history of discrimination against transgender people and governmental positions relating to gender-affirming care and the treatment of gender dysphoria:

(1) Florida Agency for Healthcare Administration, *Prior Authorization Criteria, Testosterone (non-injectable formulations)* (revised March 13, 2023), filed as **Pl. Trial Ex. 27** (ECF 175-27).

(2) U.S. Department of Health and Human Services, *EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* (2014), filed as **Pl. Trial Ex. 62** (176-22).

(3) Centers for Medicare & Medicaid Services, *CMCS Informational Bulletin 2* (July 21, 2022), filed as **Pl. Trial Ex. 63** (ECF 176-23).

(4) Centers for Medicare & Medicaid Services, *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (Aug. 30, 2016), filed as **Pl. Trial Ex. 64** (ECF 176-24).

(5) U.S. Commission on Civil Rights, *The U.S. Commission on Civil Rights Statement Condemning Recent State Laws and Pending Proposals Targeting the Lesbian, Gay, Bisexual, and Transgender Community* (April 18, 2016), (statement by the U.S. Commission on Civil Rights "strongly condemn[ing] recent state laws passed, and proposals being considered, under the guise of so-called 'religious liberty' which target members of the lesbian, gay, bisexual, and transgender ('LGBT') community for discrimination"), filed as **Pl. Trial Ex. 69** (ECF 176-29).

(6) U.S. Commission on Civil Rights, *The U.S. Commission on Civil Rights Condemns the Announced Military Ban on Transgender Individuals* (August 18, 2017) (statement by the U.S. Commission on Civil Rights

condemning the announced policy to "not accept or allow transgender individuals to serve in any capacity in the U.S. Military" and "strongly urg[ing]" its reconsideration), filed as **Pl. Trial. Ex. 70** (ECF 176-30).

(7) U.S. Department of Health and Human Services, Departmental Appeals Bd., Appellate Div., Decision No. 2576 (May 30, 2014), filed as **Pl. Trial Ex. 71** (ECF 176-31).

(8) U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, *Gender Affirming Care and Young People*, filed as **Pl. Trial Ex. 72** (ECF 176-33).

(9) Substance Abuse and Mental Health Services Administration, *Ending Conversion Therapy* (Oct. 2015), filed as **Pl. Trial Ex. 73** (ECF 176-33).

(10) Substance Abuse and Mental Health Services Administration, *Moving Beyond Change Efforts* (2023), filed as **Pl. Trial. Ex. 74** (ECF 176-34).

(11) National Child Traumatic Stress Network, *Gender-Affirming Care is Trauma-Informed Care*, filed as **Pl. Trial Ex. 75** (ECF 176-35).

(12) U.S. Presidential Proclamation, Transgender Day of Visibility, 2022, filed as **Pl. Trial Ex. 76** (ECF 176-36).

(13) U.S. Presidential Proclamation, Transgender Day of Visibility, 2023, filed as **Pl. Trial Ex. 77** (ECF 176-37).

(14) Executive Order, Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation (Jan. 20, 2021), filed as **Pl. Trial Ex. 78** (ECF 176-38).

(15) U.S. Commission on Civil Rights, *Working for Inclusion: Time for Congress to Enact Federal Legislation to Address Workplace Discrimination against Lesbian, Gay, Bisexual, and Transgender Americans* (Nov. 29, 2017), filed as **Pl. Trial Ex. 131** (ECF 178-11).

(16) National Academies of Sciences, Engineering, and Medicine, *Understanding the Well-Being of LGBTQI+ Populations* (2020), filed as **Pl. Trial Ex. 142** (ECF 178-22).

(17) National Academies of Sciences, Engineering, and Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), filed as **Pl. Trial Ex. 143** (ECF 178-23).

(18) U.S. Department of Justice, Dear State Attorneys General Letter re Transgender Youth (March 31, 2022), filed as **Pl. Trial Ex. 356** (ECF 184-21).

(19) Office of the Press Secretary, *Presidential Memorandum for the Secretary of Defense and the Secretary of Homeland Security* (August 25, 2017), 82 Fed. Reg. 167, https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-secretary-defense-secretary-homeland-security/ (Presidential directive excluding transgender people from open service or accession in the United States armed forces) (last visited May 2, 2023).

(20) Fla. SB 254/H.B. 1421 (2023) (criminalizing doctors for providing gender-affirming care to minors and prohibiting gender marker amendments on Florida birth certificates), https://www.flsenate.gov/Session/Bill/2023/254 (last visited May 2, 2023).

(21) Fla. H.B. 1223/S.B. 1320 (2023) (redefining "sex" to exclude the existence of transgender people, mandating the use of pronouns corresponding to sex assigned at birth, and banning classroom instruction relating to sexual orientation and gender identity in schools through the 8th grade),

https://www.flsenate.gov/Session/Bill/2023/1223 (last visited May 2, 2023).

(22) Fla. S.B. 1674/H.B. 1521 (2023) (prohibiting gender-inclusive restrooms and changing facilities in schools, private businesses, public shelters, and healthcare facilities), https://www.flsenate.gov/Session/Bill/2023/1674 (last visited May 2, 2023).

(23) Fla. S.B. 952/H.B.1265 (officially titled the "Reverse Woke Act," if passed the law would punish companies for providing affirming health insurance policies by holding employers liable in perpetuity for any future "detransition" treatment an employee may ever seek if they provide health insurance coverage for gender-affirming healthcare), https://www.flsenate.gov/Session/Bill/2023/952 (last visited May 2, 2023).

MEMORANDUM OF LAW

Federal Rule of Evidence 201 allows this Court to take judicial notice of adjudicative facts that cannot reasonably be disputed and are subject to ready proof. Specifically, "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose

accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). The Court is required to take judicial notice upon Plaintiffs' request where, as here, the Court "is supplied with the necessary information." Fed. R. Evid. 201(c). All of these requirements are met here.

The facts proposed for judicial notice are relevant to this proceeding. Plaintiffs have asserted that Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion") discriminates against them based upon their transgender status and sex, which includes, but is not limited to, their gender identities. The adjudicative facts contained within the governmental actions, policies, reports, statements, and proposed legislation referenced above are relevant to show and summarize the unfortunate history of discrimination, harassment, and violence transgender people have faced because of their gender identity, and to detail policies regarding Medicaid coverage for gender-affirming healthcare and treatments both at the federal level and in Florida. That the above-listed actions, policies, reports, statements, and proposed legislation document the history of discrimination against transgender people, or describe federal and state policies pertaining to coverage for gender-affirming care, are admissible facts and, as publicly available records, can be readily authenticated by this Court. *See* Fed. R. Evid. 902(6).

A court may take judicial notice of various governmental actions, including matters of political history, the enactment of statutes, agency reports, and public

records. *See*, *e.g.*, *Mincey v. Head*, 206 F.3d 1106, 1130 n.58 (11th Cir. 2000) (taking judicial notice of the enactment of federal legislation); *Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1278 (11th Cir. 1999) (holding that a court "may take judicial notice (for the purpose of determining what statements the documents contain and not to prove the truth of the documents' contents) of relevant public documents"); *Shahar v. Bowers*, 120 F.3d 211, 214 (11th Cir.1997) (en banc) (stating by way of explanation that judicial notice may be taken of "matters of political history: for instance, who was president in 1958"); *Terrebonne v. Blackburn*, 646 F.2d 997, 1000 n. 4 (5th Cir. 1981) ("Absent some reason for mistrust, courts have not hesitated to take judicial notice of agency records and reports"); *Wilder v. Aramark Svcs., Inc.*, No. 3:17cv239/RV/EMT, 2018 WL 5274257 (N.D. Fla. 2018) (taking judicial notice of a contract that was a matter of public record, noting that court may take judicial notice of "public records[.]"); *Capece v. The Depository Tr. & Clearing Corp.*, No. 05-80498 CIV RYSKAMP, 2005 WL 4050118, at *5 (S.D. Fla. Oct. 11, 2005) ("The excerpts from the Federal Register, as well as the SEC release and website information are records or reports of a governmental agency, which satisfy the second prong of Rule 201(b)."); *Brooks v. United States*, 273 F. Supp. 619, 624 (D.S.C. 1967) (taking judicial notice of adjudicative facts "taken from official governmental reports").

Facts and documents found on government websites are also proper subjects for judicial notice. *See Sec. of Labor v. American Bronze Foundry, Inc.*, 2013 WL 5720146, *3, fn. 4 (M.D. Fla. Oct. 21, 2013); *Setai, Hotel Acquisition, LLC v. Miami Beach Luxury Rentals, Inc.*, 2017 WL 3503371, *7 (S.D. Fla. Aug. 15, 2017); *Turbyfill v. Scottsdale Indemnity Co.*, 2016 WL 741657, *2 (N.D. Fla. Feb. 24, 2016); *Paralyzed Veterans of America v. McPherson*, 2008 WL 4183981, *5 (N.D. Cal. Sept. 9, 2008).

CONCLUSION

Wherefore, based on the foregoing, Plaintiffs respectfully request that this Court take judicial notice of the above adjudicative facts pursuant to Federal Rule of Evidence 201(b), as they are not subject to reasonable dispute.

Dated: May 3, 2023

Respectfully Submitted,

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CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F), I certify that this Motion and Incorporated Memorandum of Law contains 1,461 words.

/s/ William C. Miller
Attorney for Plaintiffs

CERTIFICATE OF SATISFACTION OF ATTORNEY-CONFERENCE REQUIREMENT

Pursuant to Local Rule 7.1(B), counsel for Plaintiffs and counsel for Defendants conferred via email regarding the instant motion on May 3, 2023. Defendants indicated they oppose the relief requested herein.

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of May, 2023, a true copy of the foregoing has been filed with the Court utilizing its CM/ECF system, which will transmit a notice of electronic filing to counsel of record for all parties in this matter registered with the Court for this purpose.

/s/ William C. Miller
Attorney for Plaintiffs

TAB 230-4

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

TALLAHASSEE DIVISION

CASE NO.: 4:22-cv-00325-RH-MAF

AUGUST DEKKER, et al.,

Plaintiffs,

vs.

JASON WEIDA,

Defendant.

_____/

DEPOSITION OF: ANN DALTON

DATE: TUESDAY, JANUARY 24, 2023

TIME: 10:04 A.M. - 6:05 P.M.

PLACE: AGENCY FOR HEALTH CARE ADMINISTRATION
2727 MAHAN DRIVE
TALLAHASSEE, FLORIDA 32308

STENOGRAPHICALLY REPORTED BY: GREG T. SMITH

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I N D E X

INDEX OF EXHIBITS

PLAINTIFF'S EXHIBITS

S T I P U L A T I O N S

It is hereby stipulated and agreed by and between the counsel for the respective parties and the deponent that the reading and signing of the deposition transcript be reserved.

P R O C E E D I N G S

THE COURT REPORTER: Do you swear or affirm that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: Yes.

ANN DALTON,

having first been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. DEBRIERE:

Q. Ms. Dalton, have you ever had your deposition taken before?

A. Yes.

Q. Okay. So I'm just going to walk through some preliminary issues and go over some basic instructions that you've probably heard a million times, and then I'll get started with the questioning.

A. Okay.

MS. DUNN: Sorry. Before we start, can we introduce everybody who is on the phone.

MS. DEBRIERE: Absolutely. Thank you, Chelsea. Before we start, we want to introduces folks on the phone.

MS. DUNN: I think there's one person who is currently muted. Someone just joined.

Shani, are you there?

MS. RIVAUX: Good morning. This is Shani Rivaux.

MS. DEBRIERE: Anyone else, Chelsea?

MS. DUNN: There is one person. I just don't know who it is.

MS. DEBRIERE: Is anybody else there?

MS. DUNN: It's a 305 number. So it's Miami.

MS. CHRISS: That's Jennifer.

MS. DEBRIERE: Okay. Jennifer Altman is the other person.

MS. DUNN: If folks on the line could mute their phones just so we don't have any background noise, that would be helpful. Thanks.

MS. DEBRIERE: So we're just going to mark exhibits as they're discussed. I'll be showing you papers to read off, and we'll just mark them as we move through. As I mark those exhibits, I'm going to read something called a Bates number; that just helps us track what pages we're on when we discuss things. If there's a Bates number, it's probably going to start with "DEF," then underscore, then the Bates number.

I'd like to go ahead and mark the notice of deposition as Exhibit 1. There's no Bates number on

that one.

MS. DUNN: And Catherine McKee just joined the line as well.

MS. DEBRIERE: It's just the notice that brings you here today.

(Plaintiff's Exhibit No. 1 was marked for identification.)

BY MS. DEBRIERE:

Q. So I'm going to be using the acronym GAPMS quite a bit. Do you know what that stands for?

A. Yes.

MS. DEBRIERE: And, Court Reporter, it's G-A-P-M-S.

BY MS. DEBRIERE:

Q. And it stands for generally accepted professional medical standards; which is set forth in 59G-1.035. You probably don't have that memorized. That's okay.

I will use the term "gender dysphoria," which is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth and the associated gender role and/or primary and secondary sex characteristics. When I use that term, can we just agree that's the definition I'm using?

A. Okay.

Q. I'm also going to be using the phrase "categorical exclusion of gender affirming care." And that's just the exclusion set out in 59G-1.050, Subpart 7. That's why we're here for today, for that exclusion of gender affirming care. Do you understand what I mean when I say that?

MR. PERKO: I'm going to object to the form. You can answer.

THE WITNESS: Yes.

BY MS. DEBRIERE:

Q. Well, I do want to make sure you understand what I'm talking about. Would you like to see a copy of the rule before we can agree on use of that phrase? Because as I use it, I do want to make sure we're talking the same thing.

A. Yeah.

MS. DEBRIERE: So we'll mark this as Exhibit 2. It's a copy of 59G-1.050.

(Plaintiff's Exhibit No. 2 was marked for identification.)

BY MS. DEBRIERE:

Q. If you scroll down to Subpart 7 -- scroll down; you're not a computer. If you follow down to Subpart 7 --

MR. PERKO: It's on the back of the page.
BY MS. DEBRIERE:
Q. So when I'm using the phrase "categorical exclusion of gender affirming care," I'm referring to that Subpart 7. Can we agree that that's the phrase that encompasses that portion of the rule?
MR. PERKO: I'm going to object to form.
But you can answer.
MS. DEBRIERE: Well, I think we do need -- Gary, I understand where you're coming from. But I think we just need to figure out a way to shorthand --
MR. PERKO: That's fine.
MS. DEBRIERE: -- that reference.
MR. PERKO: I'm just objecting to the use of "gender affirming care."
MS. DEBRIERE: Okay. How about "treatment for just gender dysphoria"? Would you --
MR. PERKO: That's fine.
BY MS. DEBRIERE:
Q. So we're going to use "categorical exclusion of treatment for gender dysphoria." And when I use that phrase -- categorical exclusion of treatment for gender dysphoria -- I'm referring to that Subpart 7. Can we agree to that?

A. Okay.

Q. I'm also going to use the term "EPSDT services"; which is an acronym for early and periodic screening, diagnostic, and treatment services. When I say "EPSDT," do you know what I mean when I say that?

A. Yes.

Q. So my name is Katy DeBriere. And I represent the plaintiffs August Dekker, Brit Rothstein, and Susan Doe and K.F.

I know you've been deposed before. I'm just going to go over some very brief instructions, just as a refresher.

If I ask a question ask and you don't understand it, don't try to, you know, understand what I'm saying and try to answer the question. Instead, just stop me and tell me to rephrase so that you understand the question. That's no problem at all.

A. Yes.

Q. And speaking one at a time -- I have a horrible habit of speaking over people. But we need to try and do our best to speak one at a time, so the court reporter can get down everything we say. I don't think you're going to have that problem, but I will. So please just let me finish my question before you answer. And I will do my best to do the same when you're

providing an answer back to me; okay?

A. Yes.

Q. Verbal answers -- again, it's clear that you understand. But as we move through, the court reporter can't record things like "uh-huh," or "huh-uh." So if you could just use "yes," or "no," or words whenever you are responding to a question; okay?

A. Yes.

Q. If you need to take a break for any reason, please feel free to ask me. Stop me; tell me you need to take a break. That's not going to be a problem at all. The only thing I ask is that you finish answering your question before we do.

A. Yes.

Q. Okay. Are you on any medications or other substances that can impact your memory today?

A. No.

Q. Can you state your name.

A. Ann Dalton.

Q. And, Ms. Dalton, what did you do to prepare for today?

A. I met with my attorneys.

Q. Okay. And how long did you meet with them for?

A. 45 minutes.

Q. Okay. Did you review any documents?

A. No.

Q. Okay. Can you describe your educational background for me.

A. I have master's degree in music from Florida State University and a bachelor's degree in music from Northern Kentucky University.

Q. What's your current position at the Agency for Health Care Administration?

MS. DEBRIERE: And, Court Reporter, probably throughout the deposition we'll be using "AHCA"; which is the acronym -- AHCA. Or I might reference "the agency" at times. And when I reference "the agency," I mean the Agency for Health Care Administration.

BY MS. DEBRIERE:

Q. So what is your current position at AHCA?

A. I'm the bureau chief of the Bureau of Medicaid Policy.

Q. How long have you worked in that role?

A. Since -- officially, since August 2021.

Q. Okay. What did you do prior to that role?

A. I was an AHCA administrator in the Bureau of Medicaid Policy.

Q. What does that mean to be an AHCA administrator?

A. I was a manager of a team -- the Program Authority Section in the Bureau of Medicaid Policy.

Q. What kind of responsibilities does that entail?

A. The Program Authorities Section was responsible for submitting and maintaining the Medicaid waivers, the Medicaid state plan with the federal partners at CMS; the promulgation of administrative rules; and the PACE program.

Q. And how long were you in that role for?

A. Since August 2018.

Q. What did you do prior to that?

A. I was a program administrator over a section in the Bureau of Medicaid Policy.

Q. And what responsibilities does that entail?

A. That section was titled Program Policy. And it was responsible for the Children's Health Insurance Program or CHIP Program; the provider enrollment policy; the eligibility rule; and a few other rule areas that I can't remember.

Q. What do you mean by eligibility rule? What's that?

A. The -- I don't remember the exact rule number. But it is the rule that outlines the eligibility criteria for recipients in the Medicaid program.

Q. Okay. Is that related to what category of

Medicaid someone would fall under in order to be eligible for Medicaid?

A. I believe so.

Q. Okay. And how long were you in that position for?

A. From January 2018 to August of 2018.

Q. And what did you do prior to that?

A. I worked at the Department of Elder Affairs as a senior management analyst in the Long Term Services and Supports Bureau.

Q. And how long were you in that role for?

A. From August 2017 to January 2018.

Q. Did that role require any knowledge about Medicaid?

A. Yes.

Q. And did that role require any knowledge about rulemaking?

A. Not the promulgation process itself, per Chapter 120; but the development of rule language, yes.

Q. Okay. And when did you start at DOEA?

A. June 2012.

Q. Okay. And so what other positions did you hold there between June 2012 and when you became the senior program management analyst?

A. I held various analyst positions within the

same unit.

Q. Okay. And did those other positions require knowledge of Medicaid?

A. Yes.

Q. And did those other positions require knowledge about rule promulgation?

A. The same as the senior management analyst would have.

Q. In your current role at AHCA, who is your direct supervisor?

A. Currently Brian Meyer is my direct supervisor.

Q. And who is that person's supervisor?

A. Jason Weida.

Q. And what is Brian Meyer's position at the agency?

A. These changes are recent. And I'm not sure of the exact title of his position.

Q. How is his position in relation to Tom Wallace? Or I should ask: What is Tom Wallace's position at the agency?

A. He's a deputy secretary at the agency.

Q. Does Brian Meyer supervise him?

A. No, I believe they're the same position.

Q. Okay.

A. But, again, these are recent changes, and I'm

not quite sure of the exact title.

Q. What was Brian Meyer's role before he changed into the role he currently is in?

A. He was assistant deputy secretary of operations.

Q. Okay. Is Brian within the Bureau of Medicaid Policy?

A. No.

Q. Okay. Is he within any specific bureau at the agency?

A. No.

Q. Describe your current role at the agency for me. What are the responsibilities?

A. I oversee the Bureau of Medicaid Policy. The Bureau of Medicaid Policy is responsible for the federal authorities; which are the contracts between us and the federal government that manage the Medicaid program in Florida. Promulgates -- we oversee the promulgation of all the rules and rule class 59G; which are the Medicaid rules. Oversee the coverage policy development; those coverage policies are promulgated in administrative rule, but outline the specific services and the criteria for reimbursement.

The administration of the CHIP program is also part of the bureau's responsibility. And the managed

care plan contracts -- the drafting of those contracts and policy actions related to the managed care program.

Q. What are coverage policies?

A. Coverage policies are documents that contain the information needed by providers and recipients that describes the service and also provides the information that they would need to be reimbursed -- providers would need to be reimbursed for a service. It describes who can provide the service, who can receive the service, and then any service criteria or details around that service.

Q. What do you mean "service criteria"? Can you explain that further.

A. A description of the service and then any exclusions, if there are any, pertaining to that service. It's different for each coverage policy.

Q. Okay. And what are coverage handbooks?

A. "Handbooks" is a term that we used to use at the agency. A lot of the coverage polices were -- they are now separate coverage policies, but they were contained in bigger handbooks that have since been kind of broken down to be more service specific. And so the term that we use now to describe the information that was previously contained in the handbooks is "coverage policy."

Q. Are the handbooks promulgated into rule?
A. Yes.
Q. And does the agency still rely on those handbooks in determining service eligibility?
A. If the information from a handbook was moved to a coverage policy, the coverage policy would be promulgated in the rule and the handbook would no longer be part of that rule.
Q. Can you give a recent example of the handbook information moving into a coverage policy rule.
A. It's not that recent, but it's the first one that comes to my mind -- is the Home Health Handbook was broken down into three coverage policies, I believe, around 2016. And those three policies are the Home Health Services Coverage Policy, Personal Care Services Coverage Policy, and the Private Duty Nursing Services Coverage Policy.
Q. Okay. And this will seem like a simple question. But where do those coverage policies -- can the public access those coverage policies?
A. Yes.
Q. And where would they access those coverage policies?
A. The agency has an external web page specific to all the coverage policies, fee schedules, reimbursement

policies.

Q. And the policies that are on that public facing website, are they all inclusive of the policies on which the agency relies for determining coverage? Strike that question.

Is it an exhaustive -- is what is contained on the agency's website, is it an exhaustive list of Medicaid coverage policies?

A. All the policies promulgated in class 59G. And the rules or links to the FAR notice are on our website, yes.

Q. Are there any coverage policies not on the website on which AHCA relies to determine coverage of Medicaid services?

A. Not that I'm aware of.

Q. What is a fee schedule?

A. A fee schedule is the document that provides information on billing codes, the description associated with a code, and the amount that Medicaid will reimburse for fee for service.

Q. What is fee for service?

A. Fee for service is a delivery system where the State pays providers directly -- reimburses them directly for the service provided.

Q. Is that in contrast to managed care?

A. It's a different delivery model.

Q. If a Medicaid service is listed on the fee schedule, does that mean Medicaid covers it?

I'll strike that. I think I can ask a question that well help here.

If a Medicaid service is on the fee schedule, does that mean Medicaid does not categorically exclude it?

MR. PERKO: Object to form.

MS. DEBRIERE: You can go ahead and answer if you understand. If you don't understand, please feel free to ask me to rephase.

THE WITNESS: I don't think I understand.

BY MS. DEBRIERE:

Q. If a Medicaid service is listed on a fee schedule, does that mean that Medicaid is willing to pay for it if the recipient meets all eligibility criteria for that service?

A. So the fee schedules have to be used in conjunction with the coverage policy. So, like I said, the fee schedule contains the coding that the provider needs to use in order to get reimbursed, and, in most cases, the amount and description. But the parameters of who can receive the service -- what kind of providers can get reimbursed for the service -- that's in the

coverage policy.

Q. Okay. What would it mean if a Medicaid service was not on the fee schedule?

A. So the fee schedule document and the term as we would use "fee schedule" does not include all of the services. Some of those are going to be found in the reimbursement methodology rules, if there's not a specific fee equated to a specific code. So there's also reimbursement methodology rules and documents as well.

Q. Are there services -- Medicaid services on the fee schedule that AHCA will not cover?

A. I don't know if there's any. But it would be -- any information about how the services covered would be included -- either on the fee schedule or in the coverage policy.

Q. Okay. Do your responsibilities currently include developing coverage policies for the Florida Medicaid program?

A. I oversee the teams that are responsible for that, yes.

Q. And who are those individuals? Or let's start with: Who are the teams?

A. The team primarily responsible for the majority of the coverage policies is the team managed by Jesse

Bottcher; he's the AHCA administrator. And he has three program administrators who report directly to him.

Q. And who are those people?

A. Christine Polacheck [phonetic], and she oversees the specialized services section. John Matson, he's the manager over at the primary and preventative services section. And then Tim Beaner is the manager over the behavioral health and behavioral analysis section.

Q. Are those the only teams over which you manage? Or are there other teams?

A. I have five AHCA administrator direct reports.

Q. Okay.

A. And then one program administrator direct report. So I have six direct management team reports.

Q. So who are the other ones?

A. Catherine Mcgrath is the AHCA administrator over the program authority section. Ashley Peterson is the AHCA administrator over at the pharmacy policy section. One of them is vacant -- the managed care contract AHCA administrator position. Devona Pickle, she is the AHCA administrator over the Canadian Prescription Drug Importation team. And Jesse Bottcher. And then Lakeva Campbell [phonetic] is a program administrator over the administrative unit who does the

administrative functions of the bureau.
Q. Who works under Jesse Bottcher?
A. That was Christine Polacheck, John Matson, and Tim Beaner.
Q. And do you know who Mr. Jeff English is?
A. Yes.
Q. And who is his supervisor?
A. His current supervisor is Cole Giering.
Q. Who is Mr. Giering's supervisor?
A. Catherine Mcgrath.
Q. And Mr. Bottcher -- does he supervise the person who undertakes GAPMS analysis?
A. The position that is designated to do the GAPMS is under Jesse Bottcher.
Q. Okay. And who does Ms. Peterson supervise?
A. The pharmacy policy team, which consists mostly of pharmacists within the bureau.
Q. How many pharmacists are there?
A. In Ashley's section, there are currently three.
Q. Do you know the names of any of those people?
A. Yes. Jessica Forbes, Kelly Rubin, Susan Williams.
Q. Are you familiar with a person named Nai Chen?
A. Yes.
Q. And who is his supervisor?

A. D.D. Pickle.
Q. And was Mr. Chen ever involved in the pharmacy policy? Did Mr. Chen ever work for the pharmacy policy unit?
A. No.
Q. How long has Mr. Chen been in that position?
A. I don't remember.
Q. More than a year?
A. Yes.
Q. More than two years?
A. I'm not sure.
Q. Okay. Does Mr. Chen in his position have any responsibilities over pharmacy coverage policies?
A. None that are currently promulgated.
Q. What about policies that are not promulgated?
A. I don't know if there's going to be the need for a coverage policy or what types of administrative rule we're going to need to implement the Canadian Prescription Drug Importation Program once that's federally approved -- which is why I answered how I did.
Q. Are there any other pharmacy related activities that Mr. Chen engaged in the past year?
A. Yes.
Q. What are those?
A. His -- he's part of the Canadian Prescription

Drug Importation Program team. And there has been pharmacy related activity regarding the SIP approval.

Q. What does SIP stand for? Or you can just describe it if that's easier.

A. It's the proposal or the importation program plan that the federal government authorized states to submit or request approval of in order to develop an importation program. And this was submitted to the FDA.

Q. What does the Canadian Prescription Drug Importation unit do?

A. Their primary responsibility is to implement the Canadian Prescription Drug Importation Program that was statutorily authorized -- and I think it was in 2019 -- which includes seeking that federal approval from the FDA and any implementation activities in managing the contract with LifeScience Logistics -- the agency's vendor who assists with that program.

Q. And did Mr. Chen over the past year have any responsibilities related to pharmacy activities that did not involve the Canadian Prescription Drug Importation Program?

A. Yes.

Q. And what were those?

A. I can't recall all the specific assignments. But he has helped with several research projects. I

No. 23-12155

In the United States Court of Appeals for the Eleventh Circuit

AUGUST DEKKER, BRIT ROTHSTEIN, SUSAN DOE, by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., by and through his parent and next friend, JADE LADUE,

Plaintiffs-Appellees,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, *et al.*,

Defendants-Appellants.

On Appeal from the U.S. District Court for the Northern District of Florida, No. 4:22-cv-00325, Honorable Robert L. Hinkle, District Judge

APPELLEES' APPENDIX
VOLUME 10 OF 10 (Tabs 230-4 – A)

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TABLE OF CONTENTS

Tab/Docket No.

VOLUME 1 OF 10

VOLUME 2 OF 10

VOLUME 3 OF 10

VOLUME 4 OF 10

VOLUME 5 OF 10

VOLUME 6 OF 10

VOLUME 7 OF 10

VOLUME 8 OF 10

VOLUME 9 OF 10

TAB 230-4 (continued)

think he has assisted Ashley's team with some questions or answering questions. And he's been available to assist with just different research projects.

Q. Was he involved at all with the categorical exclusion of treatment for gender dysphoria in developing the pharmacy coverage decisions related to that?

A. So when you ask that, you're specifically talking about the rule?

Q. I'm talking about the rule and the ways in which AHCA is implementing the rule.

A. I don't know to the extent -- I know that he assisted with research for the GAPMS report.

Q. Okay. And by GAPMS report, is that the report that is related to the categorical exclusion for treatment of gender dysphoria?

A. Yes.

Q. Why did Mr. Chen assist the pharmacy unit with the GAPMS report instead of the other pharmacists in the pharmacy policy unit? I'll strike that.

Why did Mr. Chen -- does the Canadian Prescription Drug Importation unit focus on pharmacy policies unrelated to the Canadian Prescription Drug Importation Program typically?

A. Since there's been such a long delay with the

federal approval of the Canadian Prescription Drug Importation Program, that team has assisted with various other projects within the bureau.

Q. Okay. Is that why Mr. Chen assisted with the GAPMS report for the exclusion of the treatment for gender dysphoria?

A. Yes.

Q. What types of services does AHCA develop coverage policies for? Actually -- I'm sorry; strike that. I apologize.

What does the Pharmacy Policy unit do?

A. Their job entails a lot of duties. Primarily they host and oversee the PNT and DUR meetings -- public meetings and the boards associated with that. They oversee the coverage policies specific to pharmacy. They assist with any contract language for the managed care contacts for pharmacy. They oversee the contract for our PBM contractor Magellan. Those are the primary duties.

Q. What does PBM stand for?

A. Pharmacy benefits manager.

Q. And what is that?

A. PBMs can have various duties. But the contract that I'm referring to is our rebate negotiation contract.

Q. Okay. And you said that PBM contract is with Magellan; is that correct?
A. Yes.
Q. Okay. What's DUR?
A. Drug Utilization Review Board.
Q. And I think you used one other acronym when you were discussing the public facing pharmacy meetings.
A. PNT.
Q. And what does that stand for?
A. I believe it's pharmaceuticals and therapeutics.
Q. Okay. And what is that?
A. All the responsibilities of that board are outlined in statute.
Q. Okay.
A. I can't think off the top of my head. But they meet quarterly. And we host those meetings and schedule them.
Q. Okay. A few more questions about Mr. Chen.
Is Mr. Chen a pharmacist?
A. I believe so.
Q. And is he the only pharmacist in the Canadian Prescription Drug Importation Program unit?
A. None of the other members of that team are pharmacists.

Q. So Mr. Chen is the only one?
A. Yes.
Q. Okay. Did any other pharmacist assist with the 2022 GAPMS relating to exclusion of treatment for gender dysphoria?
A. I don't know.
Q. What types of services does AHCA develop coverage policies for?
A. The coverage policies are -- outline the services that the State covers through the state plan -- Medicaid state plan or Medicaid waivers. So those are just any Medicaid related service.
Q. Does AHCA develop coverage policies for surgeries?
A. Yes.
Q. How about for prescription drugs?
A. Yes.
Q. Does AHCA develop coverage policies for every Medicaid service?
A. I don't know.
Q. Have you ever had a situation where a Medicaid recipient requests coverage for a service and there is no policy?
A. I personally have not, no.
Q. Okay. And what process does AHCA use to decide

whether to provide coverage of a Medicaid service?

A. That really depends on the specifics of what that service is.

Q. Does every service have a different process?

A. The process could vary based on what the service is that we are determining coverage for.

Q. Do you use the same process for developing pharmacy policy coverage?

A. I can't speak to the process or approach of the analysts. The process of promulgating the coverage policies into rule is always going to be in accordance with Chapter 120.

Q. During your time at AHCA, have you developed -- have you been involved in developing or has your team -- those you supervise -- been involved in developing new coverage policies to cover services?

A. Yes.

Q. Can you remember a specific service that you did that for?

A. Yes. We are currently in the process with promulgating the iBudget Waiver handbook. And as part of the updates to the handbook, one of those is to develop a new life skills development for Level 4 service. As part of that process, we also worked with our federal partners at CMS to get a waiver amendment

approved. That's a very recent example of a new service being developed.

Q. Do you have an example of a state plan service that you developed coverage for that's under current development?

A. Yes. We recently added some Puro Meno products to the DME fee schedule.

Q. And so in that instance, did you establish a coverage policy for those specific items of DME?

A. We did a coverage determination to determine if and how they could be included as a covered service as part of the DME service.

Q. And what is DME?

A. Durable medical equipment.

Q. And that includes medical supplies?

A. Yes.

Q. And Puro Meno would be a medical supply?

A. Yes.

Q. And you, to cover that service, incorporated it onto the fee schedule?

A. Yes.

Q. Did you do --

Okay. How did you assess whether to decide to incorporate Puro Meno into the fee schedule?

A. So I can't speak to all the steps that the

analyst -- the specific steps that they took. But just speaking overall, determined if we had the legislative and state plan authority to cover it; determined if it was -- if there would be a fiscal impact.

And we approach coverage like that example to, you know, try and make sure it's budget neutral since we are -- our coverage is driven by our general appropriations and our state general appropriations act. And then determined if and what types of updates would be needed to any of the Medicaid rules. That's the general process for determining that kind of coverage.

Q. So to make a coverage determination you look at your legislative authority -- authority under the state plan -- and you do a fiscal analysis and hope for budget neutrality. You check to see if there's any updates to Medicaid rules. Anything else?

A. Making sure that it's an allowable service under Medicaid, as well; which would entail that it meets all federal, state rules and regulations for coverage. But, like I said, all the details of the research that the team does -- I can't speak to exactly everything that they read or looked at.

Q. And if in that coverage determination you decide to cover that service, do you then incorporate it into the fee schedule?

A. In the example I gave, that's what we did, yes.
Q. Are there any situations where you would not incorporate it into the fee schedule?
A. Yes.
Q. What are those circumstances?
A. That would vary depending on what the actual request or coverage benefit is that we're looking.
Q. Can you think of an example?
A. Yes. Last legislative session, I believe it was, there was a specific language regarding the coverage of human donor milk and milk derivatives for inpatient use. Because it was under inpatient, that is a -- the reimbursement for that is different and isn't included in a fee schedule.
Q. Okay. That makes sense.
Once this coverage determination is made, do your responsibilities include reviewing that to determine whether to approve the decision?
A. Yes.
Q. And how do you go about doing that?
A. We usually meet with the team. We do a walkthrough, have discussions around the proposal and the recommendation. And then we put together -- depending on what the change is, put together a document to get approval from management -- upper management.

Q. Does that document have a specific title -- the same title every time?

A. No.

Q. How would you identify that document?

A. So if a fee schedule change was needed, there is a formal routing process for the rule promulgation process that would be routed through management and signed off on.

Q. Okay. Are there other documents that would be routed through management to be signed off on?

A. Yes.

Q. And what are the titles of those documents?

A. It depends on the situation. For example, we also have a steering committee at the agency for the division of Medicaid. And we call that a decision point that would be to the steering committee.

Q. Okay.

A. And the Medicaid director or agency leadership is part of that committee. And so that is also a way for us to get approval.

Q. For those coverage determinations that you reviewed and put together in a document for administrative review, who in the administration reviews that document?

A. Depends on what that is. So for administrative

rule -- that needs to be signed off by several agency leadership; including the general counsel, the agency secretary for a proposed rule. So it would depend on what the final document is who the final signatory would be.

Q. Distinct from implementation of the coverage determination, is there a review by the administration of just whether to cover the Medicaid service?

A. It depends on what the specific circumstances are.

Q. Okay. Can you think of an example of the administration reviewing a determination of whether to cover a service?

A. Can you be more specific? So the waiver example I used a while back would be signed to submit the waiver -- the iBudget waiver -- with the changes. That would have been signed by the Medicaid director prior to submission to federal CMS.

Q. How long have you been involved in the process of doing coverage determination?

A. Since my time at AHCA.

Q. Okay. So since -- I'm trying to take notes here. So since August of 2018?

A. January of 2018.

Q. January of 2018. Thank you.

And when you're making coverage determinations, you coordinate with AHCA rules unit if a rule change is needed; is that right?

A. Yes.

Q. Okay. Under what bureau does the AHCA rules unit fall?

A. Under the Bureau of Medicaid Policy.

Q. Okay. So under your unit?

A. In the bureau.

Q. I'm sorry. Under you're bureau?

A. Yes.

Q. And you coordinate with AHCA's pharmacy policy unit; which falls under your -- the pharmacy policy unit falls under your bureau as well; is that right?

A. Yes.

Q. Okay. Do you coordinate with other bureaus in developing coverage determinations?

A. Yes.

Q. Which ones?

A. All the bureaus in the division work closely together. And there have been some recent changes with that structure. But speaking prior to those changes, the Bureau of Medicaid Program Finance would be probably be the primary bureau; because they assist with determining or setting our fee schedules and our rates

and the methodologies and doing fiscal impact analyses -- data analytics -- Medicaid data analytics.

As part of the whole development package, we talk to all the bureaus because plan management operations can be affected if there is an update to the contracts. The Bureau of Medicaid Quality who monitors and oversees the provision of services through those contracts -- and they have various other duties. But depending on what the change is, we would communicate with most of the bureaus within the division.

Q. Okay. You just mentioned some recent changes in terms of that structure. What are those recent changes?

A. The Bureau of Medicaid Finance and Medicaid Data Analytics are reporting directly to Tom. And Plan Management Operations, Quality, and Policy are reporting directly to Brian Meyer.

Q. And why is that a change?

A. Previously I had been reporting directly to Tom Wallace.

Q. Is Brian Meyer's position a new one?

A. I don't know all the details of those changes.

Q. Okay. Who made the decision to make those changes?

A. I don't know.

Q. Okay. Who oversees the rules unit?
A. Cole Giering is program administrator of the rules unit.
Q. How long has he been in that position?
A. I'm not sure exactly. But it was since I've been bureau chief.
Q. Okay. So --
A. August of 2021.
Q. Thank you.
Do you coordinate -- in making coverage determinations, do you coordinate with the chief medical officer for AHCA?
A. Yes.
Q. Who is that?
A. Dr. Christopher Cogal.
Q. Can you describe how you coordinate with him, what that process looks like.
A. Again, it really depends on the specific question or policy we're reviewing. But it would consist of meetings or discussions.
Q. What types of things would you discuss?
A. So, for example -- I'm going to go back to the two examples of recent activity. So he wasn't involved in the iBudget Waiver changes at all. But for the human donor milk, he assisted when we had originally done the

legislative bill analysis when the legislation was first proposed. And so for the development of how to implement the changes, he was consulted. I don't know the specific conversation, but I do know that he was involved in that process.

Q. On what kind of expertise do you rely on him for? What kind of input does he provide in the process? Is it medical in nature?

A. I don't know.

Q. Okay.

A. To the extent -- I know he's an available resource for the team. But I don't know to the extent that -- of his involvement.

Q. When he gets involved, is it through a formal process? Or is it just a decision to reach out and ask him for advice? How would you characterize it?

A. From my experience at the bureau level, it's been more informal. I know that there have been -- he's been formally asked to review bill analysis or -- but how that process works, I don't know.

Q. Okay. Are there people under you who are more likely to communicate with Dr. Cogal?

A. I believe there's staff that communicate with him more than others, yes.

Q. What staff are those?

A. Ashley Peterson has been meeting with him on some projects lately. Again, it really depends on the project. But we are working with him on continuous glucose monitoring -- questions around coverage there. And Jesse Bottcher and his team.

Q. When you say Jesse Bottcher and his team, would that include the GAPMS process?

A. His team is responsible for it.

Q. In coordinating with Dr. Cogal -- in the coordination between Mr. Bottcher's team and Dr. Cogal, would that include the GAPMS process?

A. I don't know the extent to which he is involved in that.

Q. Okay. To your knowledge, has he ever been involved in that?

A. I don't know specifically.

Q. Have you and Dr. Cogal and anyone from Mr. Bottcher's team ever met to discuss the GAPMS process?

A. The process, yes. When I first took the role, we had met to talk through the process. But I can't remember the specific conversation.

Q. Okay. Switching gears a bit. When I use the term "Florida Medicaid managed care plan," do you know what it means?

A. Yes.
Q. What does that term mean?
A. Those are the managed care plans that the agency contracts with to provide the services through the managed care delivery model.
Q. Do Medicaid managed care plans have their own coverage policies?
A. The agency's coverage policies are incorporated into the managed care plan contracts by reference. And there are requirements outlined in the contract with how the managed care plans have to provide services.
Q. Are you aware of managed care plans having their own policies that incorporate Florida Medicaid's policies?
A. I don't know.
Q. Have you ever seen a copy of a Florida Medicare managed care plan document that discusses the coverage of a Florida Medicaid service?
A. I reviewed the plans' member handbooks or enrollee handbooks. And I've seen their resources available on their websites that weigh out what they cover. I can't remember if I've ever seen an official document titled "Coverage Policy."
Q. So my question is: Have you ever seen a document from a Medicaid managed care plan -- formal or

informal, it doesn't matter -- with information that contains the criteria used to determine if Florida Medicaid will cover a service?

A. I believe that information is in the handbooks. But I can't recall any specific documents drafted by the plans.

Q. What unit would be responsible for communicating with managed care plans about their coverage of Florida Medicaid services?

A. That would depend if they had a question for the agency on the agency's coverage of a covered service or a contractually required service. Those most likely would be sent to Medicaid policy.

Q. Okay.

A. To review.

MS. DEBRIERE: Okay. Yes. Definitely. Just a couple more questions, if that's okay.

BY MS. DEBRIERE:

Q. Are you okay Ms. Dalton?

A. Yes.

Q. Who would review those questions? Who specific -- like, what specific individuals?

A. It would depend on what the question was.

Q. Okay. If the managed care plan doesn't have a question, is there any process that exists that just

involves overseeing whether a Medicaid managed care plan is covering a Florida Medicaid service?

A. The Bureau of Plan Management Operations is the bureau that oversees the adherence to the contract. All the contract managers for the individual plans are housed there. So if it was a compliance question on if the managed care plan was following the requirements in the contract, that would be Plan Management Operations most likely who would be the first point of contact for the plans.

Q. Okay. Can MCOs create their own guidelines for implementing AHCA coverage policies?

A. I don't know.

Q. Who would know that?

A. It would be in the contracts.

Q. Okay.

A. The parameters around what their materials are allowed to contain and if the materials have to be reviewed and approved by the agency.

Q. Okay. And that would be the Bureau of Planned Management Operations who does that -- takes on that role? And if not, then who?

A. I believe it would depend on what the materials being reviewed are. Just like with reporting -- there are different report owners in different bureaus within

the division of Medicaid that review compliance with the -- the plan's compliance with the contracts. But the first point of contact for submitting those materials and making sure that they're submitted would be through Plan Management Operations.

Q. And who is that bureau chief? Remind me.

A. Pam Hall.

Q. Okay. One last question. Are you aware that MCOs have their own guidelines for specific types of Medicaid services?

A. I can't speak to that. I don't know.

Q. Do you know who would know?

A. Are you asking if it's a required -- or if they're allowed to --

Q. No. I'm just asking if you're aware. So are you aware that they have their own --

MR. PERKO: Asked and answered.

MS. DEBRIERE: -- criteria guidelines?

THE WITNESS: I would have to review the contract.

BY MS. DEBRIERE:

Q. Okay. So is that a no, you are not aware as we sit here today without having anything in front of you?

A. Correct. I don't know without seeing a specific example or reviewing the contract.

Q. Okay. Do you want to take a break?
A. Yes.
(Brief recess.)
BY MS. DEBRIERE:
Q. Ms. Dalton, just briefly -- when we took a break, did you discuss this deposition with anyone?
A. No.
Q. Did you discuss it with your attorneys?
A. Just briefly.
Q. Okay. When I use the term "quality improvement organizations" or QIOs, do you know what I mean?
A. Yes.
Q. What does that term mean?
A. Quality improvement organization.
Q. Yeah. Is eQHealth a QIO?
A. Yes.
Q. And what do they do?
A. I don't know the whole scope. But their main function in their contract with the agency is the -- to do prior authorization for fee for service services.
Q. Okay. What does prior authorization mean?
A. It's a utilization management tool to ensure that the services are in their scope, authorized, and appropriate.
Q. By "appropriate," what do you mean?

A. That the service that's being requested is allowable and delivered within the parameters of the Medicaid program.

Q. Who makes the request for prior authorization?

A. I don't know the details of how the process works.

Q. Okay. By parameters, do you mean the parameters set by AHCA's coverage policies?

A. Yes. And administrative rule.

Q. Okay. Is administrative rule distinct from a coverage policy?

A. Yes. Not all of the administrative rules incorporate a coverage policy by reference.

Q. Okay. So an example of that would be the definition of medical necessity -- would be an administrative rule that sets out the parameters for coverage but does not include a specific coverage policy?

A. The definition of medical necessity is actually in the definitions policy -- which is a document incorporated by reference into the text of the administrative rule.

Q. Okay. Do QIOs like eQHealth -- do they have their own coverage criteria they rely on?

A. Yes.

Q. Do you coordinate with QIOs regarding those coverage criteria?

A. I personally do not.

Q. Does anybody on your team?

A. The eQHealth contract is housed in the Bureau of Medicaid Quality.

Q. Okay.

A. So they would be a lead in managing of that contract and communicating with the vendor. But I do know that we have communicated with them in the past -- the Bureau of Medicaid Policy has.

Q. What types of things have you communicated about in the past?

A. The first example that comes to mind is recently the agency opened the definitions rule policy and did communicate that that rule was being opened with eQHealth.

Q. Okay. Are MCOs and QIOs bound by AHCA's coverage policies?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: As I stated before, the contract for the managed care plans incorporates the coverage policies by reference. And the plans are not allowed to be more restrictive than the coverage

policies. I don't know the specific language off the top of my head with the requirements of how they adhere to the policies. But that is in the contract.

BY MS. DEBRIERE:

Q. Okay. So the MCO's obligation to adhere to AHCA's coverage policies is set forth in the contract?

A. Yes.

Q. Okay. What about QIOs?

A. I don't know the specific language off the top of my head. But that information is also in the contracts on how the managed care plans' contracted QIO vendors are expected to operate.

Q. Okay. Is there a formal approval process for the QIO's coverage criteria?

A. I don't know.

Q. Is Magellan a QIO?

A. I don't know.

Q. Okay. Does Magellan conduct prior authorization of Florida Medicaid services?

A. I don't know.

Q. Does Magellan review the request of a Medicaid recipient to authorize prescription drug services in the Fee for Service program?

A. I don't know.

Q. Do you know what -- do you know if Magellan plays any role in determining coverage of pharmacy services under Florida Medicaid?

A. I believe the agency has a contract with them to adjudicate the claims. But I don't know the scope of that contract.

Q. What do you mean by adjudicate the claims?

A. I don't know the whole scope of that process or the contract.

Q. When you just use that phrase, what did you mean by that?

A. That they're involved in the reimbursement process.

Q. Okay. And would the reimbursement process involve determining the eligibility for the service itself?

A. I don't know the extent of that process.

Q. Would anybody at AHCA know or be able to answer that question?

A. I don't know.

Q. Moving back to coverage determinations undertaken by your bureau, who is the final decisionmaker as to whether AHCA will adopt that coverage determination?

A. Can you repeat the question.

Q. So earlier we were talking about your bureau undertaking coverage determinations of Florida Medicaid services; correct?

A. Yes.

Q. Who is -- before AHCA or anyone at AHCA can act on that determination, who is the final decisionmaker?

A. Again, it depends on the circumstances. And I can only speak to the signatory of who needs to be -- to officially sign off. But the example I used before for a federal authority submission, that would be whoever was designated from the agency as the Medicaid director or the Medicaid state plan approver.

Q. Okay.

A. And then administrative rule to actually complete the promulgation process. That's actually signed off by the head of the agency, which here would be our secretary.

Q. Okay. When coverage policies are promulgated, are there multiple drafts of those policies? Are there ever multiple drafts of those policies?

A. Can you repeat the question.

Q. When you're developing a coverage policy, are there multiple drafts?

A. It would it depend on what the change was.

Q. So there are times when coverage policies have

multiple drafts?

A. Yes.

Q. And how do you track any changes to those policies during the drafting process?

A. So specific to the coverage policy, we typically use a document called a revisions template; which tracks the changes being proposed.

Q. Okay. Is there a limit to the people who can make changes to the revisions document?

I'm sorry; the revision just tracks who has made the changes; is that right?

A. So it tracks what the old policy said, what the new changes are, if there's a reason for the change. I'm not sure if it includes who the requester of the change is.

Q. Okay. Does it record who is making the change?

A. I can't recall if that's on the template.

Q. Is anybody at AHCA allowed to make a change?

A. So for most of the coverage policies, there's a subject matter expert assigned to that program area who any changes would filter through. And then they have to work with the rules unit who is actually making the changes to the coverage policy and promulgating that through the rulemaking process.

Q. Okay. Just switching quickly to some specific

Medicaid services. Are coverage policies regarding surgery adopted into rule?

A. Yes.

Q. And are they in handbooks or a handbook?

A. I don't believe it's one specific handbook.

Q. Do you remember the names of any of the handbooks they are contained in?

A. We have a transplant services coverage policy.

Q. Okay.

A. Which I would consider inclusive of surgical. We have an inpatient services coverage policy. Without seeing the list of policies, I can't recall off the top of my head.

Q. Give me one second.

Would coverage policies about surgeries be in the Ambulatory and Surgical Center Services Policy?

A. I don't know the content of that policy off the top of my head.

Q. Okay. You said inpatient hospital services would contain surgery policies?

A. I don't know all the content in the policy without looking at it. But it...

Q. If it mentions surgery in the handbook, is it going to have a coverage policy related to it?

How would you know if a handbook covered

surgery or contained a surgery coverage policy in it?

A. I would have to read the handbook. Depending on what the specific question was, what type of surgery.

Q. Okay. What about prescription drug coverage policies? Are those adopted into rule?

A. I believe there is a rule specific to pharmacy policies and prescription drugs, yes.

Q. Okay. And then I'm just going to flip my computer around here and go to this page. We're looking at what's titled Agency for Health Care Administration Drug Criteria. AHCA.myFlorida.com/Medicaid/prescribed_drug_criteria.shtml.

And I assume, Ms. Dalton, I'm seeing here -- are you just seeing a list of drug criteria?

A. Yes.

Q. Is this an exhaustive list of the drug criteria that AHCA relies on?

A. I don't know.

Q. Who would know that?

A. Ashley Peterson and her team may be able to confirm.

Q. Okay. And why wouldn't this be an exhaustive list?

MR. PERKO: Object to form.

THE WITNESS: I'm not personally very familiar with this page.

MR. PERKO: Counsel, for the record, can we read the URL.

MS. DEBRIERE: Absolutely. Well, I think I -- Gary, do I not know what a URL is?

MR. PERKO: The website address.

MS. DEBRIERE: So I think we read most of it. But I can start with https://AHCA.myFlorida.com/Medicaid/prescribed_drug/drug_criteria.shtml.

MR. PERKO: Thank you.

MS. DEBRIERE: Absolutely.

BY MS. DEBRIERE:

Q. Do you know what categorical exclusion means?

MR. PERKO: I'm going to object to form. I guess I'm a bit confused, Counsel. You already defined what categorical exclusion means at the beginning of this deposition.

MS. DEBRIERE: Well, that's categorical exclusion -- you're right, Counsel. It contained the statement "categorical exclusion"; just categorical exclusion of a very specific set of services. The treatment for --

MR. PERKO: That wasn't the definition at the

beginning. But go ahead.

BY MS. DEBRIERE:

Q. How about this, Ms. Dalton: Can you provide an example of a categorical exclusion under Medicaid?

A. I can't think of an example. I'm familiar with the term. I cannot think of an example.

Q. Okay. I'm trying to think of one too.

Does AHCA -- does Florida Medicaid cover private duty nursing service for individuals over the age of 21?

A. Not through the state plan.

Q. Okay. Do they cover it through home and community based services with a Medicaid waiver?

A. Yes.

Q. Okay. And if Florida Medicaid does not cover private duty nursing services for individuals over 21 under the Medicaid state plan, is that a categorical exclusion?

A. Yes.

Q. And does the agency categorically exclude any Medicaid service for beneficiaries under the age of 21?

A. Can you repeat the question.

Q. I'm sorry. Bear with me one second, Ms. Dalton. I'll come back to that.

Do your responsibilities include ensuring that

coverage policies meet the standards under EPSDT?

A. The Bureau of Medicaid Policy doesn't oversee the monitoring of the adherence to the policies or the provision of services. In terms of ensuring that the policy language complies with the federal EPSDT requirements, yes.

Q. And how do you ensure that compliance when developing coverage policies?

A. It depends on the specific coverage policy. But the majority of the service specific coverage policies include language incorporating EPSDT by reference and language from the federal regulation.

Q. Generally speaking, what is that EPSDT requirement?

A. That the State must provide all medically necessary services to children ages under 21.

Q. Does the State have to provide a service under EPSDT to a Medicaid recipient under 21 if that service is experimental?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Do you know what I mean when I say experimental?

A. Yes.

Q. So same question. Does the State have to

provide coverage to children under age 21 if that health service is considered experimental?

MR. PERKO: Object to form.

THE WITNESS: The State is allowed to develop its own definition of medically necessary or medical necessity; which Florida has done and promulgated in administrative rule. And part of that definition does include the parameters by which a service would not be determined medically necessary; and, therefore, not required under the EPSDT.

BY MS. DEBRIERE:

Q. Okay. And that definition of medical necessity includes the requirement that the service not be experimental; correct?

A. I cannot recall the exact definition off the top of my head. But that is in -- promulgated in the definition coverage policy.

Q. When you say that is --

A. The definition of medical necessity.

MS. DEBRIERE: Okay. We can mark -- I have a copy of the rule so you can reference it. We can mark that as Exhibit 3. And that's 59G-1.010.

We might have forgotten to put a copy in. If we did, it's my fault.

MS. DUNN: I have a copy right here.

(Plaintiff's Exhibit No. 3 was marked for identification.)

MS. DUNN: Yeah. It's right there. Last definition on that page.

THE WITNESS: It doesn't seem to be the whole --

MS. DUNN: It's not.

MS. DEBRIERE: It's not. We ended it at "N," because it's a very large coverage policy and we are trying to save some trees.

BY MS. DEBRIERE:

Q. So if you look at the definition of "medically necessary" or "medical necessity," does that contain a requirement that the service not be experimental?

A. Yes.

Q. And so under EPSDT, can the agency deny a medical service to a child under 21 if they deem it to be experimental?

A. Yes.

Q. Okay. Who is responsible for compliance with EPSDT? Is it a specific person?

A. I don't know who is responsible.

Q. Is it someone within your bureau regarding EPSDT as it relates to the development of coverage policies?

A. There isn't a specific person in my bureau, no.
Q. Are there any written guidelines about ensuring compliance with EPSDT with developing coverage policies?
A. Can you repeat.
Q. Are there any written guidelines relied on to determine whether a coverage policy complies with EPSDT, other than that contained in the Federal Medicaid Act?
A. I don't know specific -- all the specific documents that the analysts rely on when developing the coverage policy. But as part of that process, the expectation is to review the federal guidelines and statute and other rules and regulations of governing the Medicaid program to ensure that the coverage policy adheres to the Medicaid program federally and state.
Q. And that's an expectation of the staff within your bureau?
A. Yes. It's the common practice when approaching research regarding changes to the policy -- a policy.
Q. Okay. When I use the term "comparability," do you know what I mean as it's laid out in regulations implemented in the Federal Medicaid Act?
A. You may have to give me some more context.
Q. So under the Federal Medicaid Act, there is a requirement that state agencies who administer Medicaid do so in a way that all Medicaid recipients receive

comparable services. Are you familiar with that requirement?

A. Vaguely sounds familiar.

Q. Is your bureau required to be familiar with that requirement in developing coverage policies?

A. I can't speak to that without more information.

Q. Okay. Is there anyone who can speak to the requirement -- is there anyone who can speak to ensuring that the policy comply with comparability under the Federal Medicaid Act?

A. So, again, I think it really would depend on what the specific question is regarding or which specific coverage policy. As I said before, a lot of the coverage policies have a specific subject matter expert with knowledge of that service area. So it just really would depend.

Q. Okay. I'm just going to make myself a note.

What is the purpose -- turning back to Exhibit 3 and the definition of medical necessity -- what's the purpose of AHCA's medical necessity standard?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Does AHCA's medical necessity standard have a purpose?

MR. PERKO: Object to form.

THE WITNESS: I don't know what you mean.
BY MS. DEBRIERE:
Q. What is the purpose of the definition of medical necessity?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. What do you use it for?
A. The definition is relied on a lot. Most of the service specific coverage policies refer and incorporate by reference the definitions policy and make a statement that the service must be medically necessary as part of the requirement for reimbursement.
Q. If a Medicaid recipient makes a request for a Medicaid service, in order for that service to be authorized, does it have to be medically necessary?
A. Yes.
Q. Do managed care plans rely on AHCA's medical necessity standard in their prior authorization process?
A. I can't recall the exact contract language. But, yes.
Q. And what about QIOs?
A. I don't know.
Q. Regardless of the method in which Medicaid is delivering the service -- fee for service or managed care -- in order for that surface to be authorized, does

it have to be medically necessary?

A. I don't know the details of the actual authorization process. I do know that the expectation from policy prospective is that the services have to be provided in accordance with the agency's coverage policies and administrative rules.

Q. And that includes the definition of medical necessity?

A. Yes.

Q. If AHCA finds that a Medicaid service is experimental, would AHCA or a contractor or managed care plan still review whether service meets other portions of AHCA's medical necessity definition?

A. I don't know the extent of their review.

Q. What about your review at AHCA for fee service?

A. Again, I don't know eQHealth or QIO vendors' process.

Q. Do all Florida Medicaid services require prior authorization?

A. I don't know. I don't believe so.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 4, which is the GAPMS Report on Cross-Sex Hormone Therapy, dated May -- I believe we did the May version.

So what I'm showing you is Bates stamped

beginning at Defendant 00126105. I should pull out my own copy.

And that continues through, Court Reporter -- this one is not Bates stamped. It's weird. This one doesn't have a copy. This copy is not Bates stamped. But it is entitled Cross-Sex Hormone Therapy GAPMS Determination Report With Recommendation.

That's very odd. Very odd. I don't think it's a huge deal.

(Plaintiff's Exhibit No. 4 was marked for identification.)

BY MS. DEBRIERE:

Q. So on the last two pages, Ms. Dalton, starting at "Coverage policy" -- and it starts, "Federal regulations."

"Federal regulations for Medicaid..." and continues on through the definition of medical necessity --

MR. PERKO: Can you give a page number.

MS. DEBRIERE: Oh, yes. Thank you, Gary.

So page 8, 9, and a tiny bit of the top of 10.

THE WITNESS: I'm there.

BY MS. DEBRIERE:

Q. Take all the time you need to read it. And

afterwards, if you can tell me if this is an accurate portrayal of the standard used to determine Florida Medicaid coverage for prescription drugs.

MR. PERKO: Do you have another copy?

Thank you.

BY MS. DEBRIERE:

Q. I think it starts at the top of page 8 -- middle of page 8. So reviewing that standard, is that what's used to determine whether Florida Medicaid will cover a prescription drug?

A. Can you direct me more to where you're referring. I read both pages 8 and 9, and I don't think I can speak to the specifics of all this information.

Q. Okay. When reviewing whether to cover a prescription drug, does AHCA look at -- here on page 8 it says AHCA is -- "The program is required to asses data on drug use against predetermined standards consistent with the following compendia." And then it lists three types of compendia and the peer reviewed medical literature. Is that an accurate statement of AHCA policy?

A. I don't know.

Q. Who would know that?

A. I don't know if I can speak for them. But I would ask one of the pharmacists.

Q. Would you ask Ashley Peterson? Or would you ask one of the pharmacists that works under her?

A. I specifically would go to Ashley, as she's my direct report. And then she would research the question for me.

Q. Okay. Would research involve asking one of her pharmacists?

A. I don't know. I can't speak for her process.

Q. So going to page 9, top of the page says, "In order to be reimbursed by Medicaid, a drug must be medically necessary."

Is that the same as the definition contained in the 59G-1.010 that we just reviewed -- Exhibit 3?

A. I don't understand what you mean by the same.

Q. Does medically necessary mean the same as the definition in the definitions policy?

A. I would think so.

Q. Okay. And it is, "Either prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in the Medicaid Act or prior authorized by a qualified clinical specialist approved by that agency."

Is this an accurate recitation of the standard AHCA uses to authorize prescription drug coverage?

A. I don't know.

Q. Would Ashley Peterson know that information -- her or her team?

A. I would think so, yes.

Q. Okay. The next thing it says, "The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows." And then it lists three criteria.

Reading over that statement, are these currently the criteria AHCA uses in authorizing drugs for off label purposes?

A. Again, I don't know.

Q. Would Ashley Peterson know the answer to that question?

A. I would think her team would, yes.

Q. Is this the type of information -- looking at this, is this the type of information that would be contained in a coverage policy adopted in rule?

A. I'm not sure.

Q. Why aren't you sure? What's throwing you about it?

A. I don't know the content of the rules off the top of my head.

Q. But I think my question is a little different. So does this appear to be the type of information that would be contained in a coverage policy adopted into

rule?

A. I can't speak to that. I don't know because of the reason I stated. I will say the coverage policies traditionally do not repeat regulation or requirements or information that are found elsewhere; for example, in Florida statute or in federal regulation. And each coverage policy is structured somewhat similarly, but does contain very different information. So I don't know if this is information that's found off the top of my head in one of our policies.

Q. Okay. I think you -- do all prescription drugs require prior authorization to be reimbursed by Medicaid?

A. I don't know.

Q. Who would know that?

A. I would think Ashley Peterson and her team. Or it might be available on the information on our website regarding pharmacy policy and authorization criteria.

Q. Okay. So Ms. Peterson would be familiar with authorization criteria for prescription drugs?

A. Yes. Or she would know where to look.

Q. Okay. Specifically related to pharmacy coverage policies, how are they developed?

A. The coverage of the pharmacy services is a little different than the other coverage policies. I

don't know all the details that go from the analysts into the developments. But because there is different statutory requirements -- Florida statutory requirements around pharmacy services, including the PNT and DUR board -- the process for overseeing the coverage of pharmacy services is a little different.

Q. In reviewing whether a prescription drug requires a coverage policy -- strike that.

Do you use the GAPMS process to determine pharmacy coverage -- to determine whether coverage of a prescription drug is experimental?

A. I don't know specifically for determining if a prescription drug is experimental. I don't know.

Q. When you develop coverage policies in your bureau, does that include a determination as to whether a service is experimental?

A. So the coverage policies are drafted specific to the covered services that we've been approved to provide.

Q. Okay.

A. By the federal government. So that is the driving factor on how we would initially approach the coverage and organize or draft a coverage policy asserting a service that we are authorized to provide.

Q. So separate and apart from developing coverage

policies, the responsibilities of your bureau also include determining whether a service is experimental; is that correct?

A. So that would be part of the GAPMS process that is outlined in administrative rule.

Q. Okay. Do you use the GAPMS process for prescription drugs?

A. Without researching or consulting others on the team for a specific example, I don't know the interplay between the different authorities and how that works.

Q. Which team is responsible for the GAPMS process?

A. That position is within the Medicaid -- Bureau of Medicaid Policy.

Q. Earlier speaking about teams under the bureau, which teams is responsible for the GAPMS process?

A. Jesse Bottcher is the manager over the position that is primarily responsible for the GAPMS process.

Q. Are there any other teams that are primarily responsible for the GAPMS process? Or is it only Jesse's team?

A. So in terms of listing that as a primary responsibility on a job description, that would be Jesse's team.

Q. Should the people on Jesse's team be aware of

every GAPMS process that's undertaken?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: So as the bureau chief of Policy, I do try to keep staff within the bureau aware of everything that's happening within the bureau -- especially when a determination has been made. Jesse's team would definitely need to be aware, because there could be potential impacts with a specific service coverage policy. But I do think every circumstance is different. So I can't say just in a general statement to your question.

BY MS. DEBRIERE:

Q. Would it be typical for Jesse's team to not be aware of a GAPMS report being developed?

A. I can't say if it would be typical. I have not overseen very many GAPMS in my time as bureau chief.

Q. So as the bureau chief with Jesse's team being primarily responsible for GAPMS, would you as that chief endeavor to ensure that Jesse's team was aware of all GAPMS reports being written?

A. Yes. We meet the managers on -- my direct reports and I meet regularly at least twice a week for an hour and discuss projects that are going on with each team and provide updates. So the ongoing bureau

activities are regularly discussed with the management team.

Q. Okay. Do you know what a drug compendium is?

A. I recognize the term, but don't think I can define it.

Q. Do you know which compendia are listed in the Federal Medicaid Act?

A. No.

Q. I'm just going to screen share again. I'm showing right now on my screen -- the URL is https://AHCA.myFlorida.com/Medicaid/prescribed_drug/pharm_thera/pdf/PDL.pdf. The title of this document is Preferred Drug List, Effective January 21st, 2023.

Do you know what the preferred drug list is?

A. Yes.

Q. What is it?

A. It's list of drugs developed that the managed care plans must adhere to. And it has to do with rebate negotiations and is recommended by the PMT committee.

Q. Perhaps you just answered this. But who develops the PDL?

A. The agency.

Q. What is the PMT committee's role in it?

A. Per statute, they make recommendations to the agency.

Q. Okay. Does the DUR have any role in developing the PDL?

A. I don't know. I don't believe so.

Q. And this PDL applies to managed care plans; is that correct?

A. And fee for service.

Q. Okay. So on here -- I'm going to have to do Control+F. Pardon; one second.

It's very small. So tell me if you need to make it any bigger.

Okay. On here you will see the drug estradiol -- e-s-t-r-a-d-i-o-l -- listed. And there is many versions here starting at it looks like this line continuing all the way down until we hit norethindrone AC. So the fact that estradiol is lied on the PDL, does that mean Florida Medicaid will cover it if the eligibility criteria are met? Excuse me. Scratch that.

Since estradiol is listed on this PDL, does it mean that Florida Medicare will cover it?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. If any drug is listed on the PDL, does that mean Florida Medicaid will cover it?

A. I don't know the interplay between the PDL and

the other rules and regulations covering pharmacy services.

Q. Okay. Over in this column at the top of page, it reads "Clinical PA required." And it also has a column for a minimum and a maximum age. What does clinical PA required mean?

A. Operationally, I don't know.

Q. Do you know it in any other version?

A. I understand the words. But I don't know in the context of the program or the PA process what that means.

Q. What does "PA" stand for?

A. Prior authorization.

Q. Okay. Is it possible that clinical PA -- so if we scroll down to estradiol -- this version with a minimum of an age of zero, maximum age of 999 -- and it says "no" under the column of clinical PA required, do you know what that means?

A. No.

Q. Who would know that?

A. Ashley Peterson and her team are lead on this.

Q. Do you know what it means to have a minimum age column? Why that's significant or why it's on there?

A. Specific to this document, no.

Q. Same with maximum age?

A. No, I don't know the reason why it's on there.
Q. Since you've been at the agency -- January 2018?
A. Yes.
Q. How many GAPMS processes have you been involved in?
A. Two completed. And maybe one or two discussions.
Q. How many pending?
A. I don't know.
Q. Do you know currently how many GAPMS are pending?
A. Clarify "pending."
Q. Why don't you tell me what you meant by completed.
A. Two that have been signed by agency leadership.
Q. Okay. And how many reports are in the stage of being written and not yet signed?
A. I don't know.
Q. To be clear, though, as bureau chief you meet weekly with Jesse Bottcher and his team who are primarily responsible for GAPMS.
A. I meet weekly with Jesse Bottcher and my team.
Q. Okay.
A. I don't regularly meet with the individual

teams, but with the managers.

Q. When you meet with Jesse, do you discuss GAPMS?

A. Not routinely. We have before.

Q. What are the other responsibilities of Jesse's team?

A. The three managers under Jesse each have units that are responsible for the developments of the service specific coverage policies. His team also oversees the eligibility policy and the provider enrollment policy, updates all the fee schedules -- so works closely with fiscal agent operations to ensure updates are made to the MMIS system and with Medicaid program financing the development of fee schedules. And that's the bulk of their responsibilities.

Q. So when you're meeting with Jesse weekly, what are you discussing about his team?

A. It depends on what -- the highest priority assignments are usually up first; things that are due that week.

Q. Okay. So you do not routinely discuss GAPMS -- that was your testimony just a second ago?

A. Yes. I wouldn't say that it's a subject that we discuss at every meeting or routinely at our individual meetings, no.

Q. And you organize what you discuss based on what

has the highest priority?

A. Yes, typically.

Q. Okay. How familiar with you with the GAPMS process?

A. In terms of all the research and everything that goes into developing, I'm not as familiar. But I am familiar with the routing process, the rule, the authority for that process.

Q. Okay. So just generally, what does AHCA use the GAPMS process for?

A. So if the agency receives a request for coverage -- typically that's how the process would be initiated. If the coverage was determined to not be something that the agency could proceed with -- possibly adding to the fee schedule or incorporating into a service definition -- then the GAPMS process would be used.

Q. Okay. How is the GAPMS process initiated?

A. I believe it's a rule how to.

Q. Would it be helpful if you had the rule in front of you?

A. Yes.

MS. DEBRIERE: Okay. Let's mark that as Exhibit 5. That's Rule 59G-1.035.

(Plaintiff's Exhibit No. 5 was marked for

identification.)
BY MS. DEBRIERE:
Q. So how is GAPMS initiated?
A. A request is submitted to the health services research inbox in the Medicaid Policy Bureau.
Q. Who can submit a request to that inbox?
MR. PERKO: Object to form.
THE WITNESS: I believe anyone can.
BY MS. DEBRIERE:
Q. Okay. Is that the only way that a request is submitted for AHCA to undertake a GAPMS?
A. No.
Q. What are other ways?
A. So in the contracts with the plans, there's also language on how a managed care plan can submit a request to the agency for review -- not necessarily through the health services inbox. I can't recall the exact direction. But there's also the opportunity for the clients to request a review.
Q. When that review is requested, is it -- is the standard process used? Is the standard GAPMS process used?
A. I'm not sure. I believe it may be expedited. But I'm not sure to the specifics of the process.
Q. Who would be most familiar with that process?

A. Either Jesse Bottcher or Jeffrey English.
Q. Okay. So you mentioned managed care plans can submit a request -- or anyone can submit a request through the health services inbox. Are there any other ways that a request can be submitted to the agency to undertake a GAPMS?
A. Yes.
Q. And what are those ways?
A. I don't know all the ways. But I can't think of us not approaching the process if we received a request outside of getting it specifically through the health services research inbox.
Q. How often --
A. Which is -- I'm hesitating because I couldn't see us not -- like, refusing to complete the process if it was received another way.
Q. How often does that happen?
A. So, like I said before, in my time as bureau chief, there haven't very many finalized GAPMS. Or that process has not been a part of my day-to-day work. So I'm not sure.
Q. Okay. So you cannot recall another way that a GAPMS request came to the agency, other than through a managed care plan or the health services inbox?
A. So for the most recent GAPMS report, that was a

request from -- I believe it was the secretary. But I don't know if it went through the inbox specifically or not.

Q. Okay. So that's another way that the GAPMS process can be requested -- is through the secretary?

A. That's the way that it has been.

Q. Okay. How many times?

A. I don't know.

Q. And when you say the most recent GAPMS report, do you mean the GAPMS report related to gender dysphoria?

A. Yes.

Q. When that request came in through the secretary, did the secretary identify why she was making that request?

And, I'm sorry, do you mean Secretary Marstiller?

A. Yes.

Q. Okay. Did she identify why she was making that request?

A. I can't recall the contents of the specific request.

Q. Did the request come -- who did the request from Marstiller go to?

A. I don't know.

Q. How did you find out about it?
A. I just can't remember if I was sent the letter in an email. But it was then discussed by my manager.
Q. And that manager was? Is?
A. At the time was Jason Weida, who is the assistant deputy secretary.
Q. And did you receive the letter from Secretary Marstiller before that discussion occurred?
A. Yes.
Q. And how long between receiving the letter and having -- how long past between receiving that letter and having that conversation with Mr. Weida?
A. I don't remember.
Q. Was it, like, hours? A day? Several days? Within the same week?
A. I don't remember.
Q. Okay. Was that discussion just between you and Mr. Weida? Or were there other people?
A. I don't remember in the initial conversation if there was anybody with me.
Q. Okay. Was it -- where did it take place?
A. I believe it was in Jason's office.
Q. Okay. Did Jason ask you to come to his office to have the conversation? How were you notified of the meeting?

A. I don't remember. We had standing meetings in his office; he was my -- or I was his direct report. So I don't remember if it was part of that when we were talking about assignments and priorities or separate. I can't remember.

Q. What was Mr. Weida's position at the time at the agency?

A. He was the assistant deputy secretary for Medicaid policy and quality.

Q. And then who is in that position prior to him?

A. I think Shevaun Harris.

Q. Okay.

A. There was a gap in between. But I think she was the last person.

Q. Okay. And who took that position after Mr. Weida?

A. That position is currently vacant.

Q. Okay. And has Brian Meyer ever held that position?

A. No.

Q. Okay. Prior to your meeting with Mr. Weida but after your received the request from Secretary Marstiller, did you communicate with anybody else about the request?

A. Can you repeat the question.

Q. Between the time that you received the request from Secretary Marstiller -- the letter -- and meeting with Mr. Weida, did you have a conversation with anyone else about the request?

A. I don't believe so.

Q. Okay. Were you surprised to see the request?

A. No.

Q. Why not?

A. Medicaid Policy -- I think we're unique in that bureau because no one day is exactly the same. There's always something new coming out from the federal government, from legislative action, from leadership. So I think that's kind of part of the job of being the bureau chief of Medicaid policy.

Q. Okay. What was -- when you met with Mr. Weida, did you develop a plan about how to honor the Secretary's request?

A. Yes.

Q. And what was that plan?

A. The team that was going to work on it was the Canadian Prescription Drug Importation Plan team; following the regular GAPMS process in terms of research and report and development.

Q. Did you identify who was going to be on that team?

A. Yes.
Q. And who did you identify?
A. Matt Brackett, Nai Chen, and D.D. Pickle.
Q. As part of that plan -- and to be clear, the secretary's request was specifically a request to undertake a GAPMS investigation?
A. Yes; to review through that process.
Q. Okay. And the team identified was Brackett, Chen -- and I forgot the --
A. Their manager, D.D. Pickle.
Q. D.D. Pickle. Thank you.
So you previously testified that the team primarily responsible for GAPMS was led by Jesse Bottcher. Why was Jesse Bottcher not part of the team to undertake this GAPMS?
A. So there was several factors considered. Matt Brackett has worked with the bureau a long time and previously had the position responsible for -- primarily responsible for the GAPMS. D.D. Pickle has also been with the bureau and agency a very long time. So I would say that the historical knowledge, the bandwidth -- having bandwidth to focus on completing the GAPMS -- were probably the two biggest factors.
Q. When you say bandwidth, what do you mean?
A. So that team -- their primary responsibility is

the Canadian Prescription Drug Importation Program, which is not approved federally. So our ability to move forward with the day-to-day operations and implementation of that program is stalled. Due to that, that team has been available to assist in other areas within the bureau when needed.

Q. Was the team that's primarily responsible for GAPMS -- were they overwhelmed with doing GAPMS at the time?

A. I don't know.

Q. But you used the fact that Mr. Brackett and D.D.'s team generally would have a lot of time to work on GAPMS as a deciding factor to pick the team for this report; is that right?

A. Yes.

Q. But you didn't first check whether the team that's primarily responsible for GAPMS would have the time to do the report?

A. No.

Q. Okay. How long has Mr. Chen been with the agency?

A. I don't remember.

Q. Would you classify him -- as you did Ms. Pickle and Mr. Brackett -- as being with the agency for a long time?

A. No.
Q. So he did not have that historical knowledge that Mr. Brackett and Ms. Pickle have with the agency?
A. No.
Q. And that was a deciding factor in picking the team?
A. Yes.
Q. When you met with Mr. Weida to pick this team, did Mr. Weida suggest the names or did you?
A. I believe I did.
Q. Okay. Other than the length of time at the agency and bandwidth, what criteria -- did Mr. Weida give you any criteria in terms of picking the team?
A. I don't think so, no.
Q. Did you use any other factors other than the length of time at the agency and bandwidth to select this team?
A. I think it's still the same as historical knowledge. But I have worked very closely with D.D. and Matt in my various positions. I knew Matt had some knowledge of previous similar requests, as well extensive knowledge of the standard GAPMS process. And it was a team of three that was available. So I think that still kind of historical knowledge and bandwidth were really the biggest factors.

Q. You said Mr. Brackett had experience with previous similar requests. What were those previous similar requests?

A. I believe there was a GAPMS request in the past before my time with the agency that had to do with hormone treatment.

Q. Would it be -- and it was hormone treatment. When you say a similar request, was it for GAPMS?

A. Yes.

Q. Would it have been the cross-sex hormone therapy GAPMS that is Exhibit 4?

A. No.

Q. How do you know?

A. The date on this. The one I was thinking of was much earlier before my time.

Q. Before your time -- do you have any sense of when that might be?

A. Maybe 2016 or 2017.

Q. Do you know who the Governor of Florida was in 2016 or 2017? I'm sorry. It's not a test, I promise.

Was it Rick Scott?

A. Yes.

Q. Okay. And was the interim secretary at the time at AHCA, was it Justin Senior?

A. Yes.

Q. And was Beth Kidder there at that time at AHCA?
A. Yes.
Q. And all of those people are listed on this Exhibit 4 --
A. So my document has Beth Kidder crossed out and looks to be a draft document from May 20th, 2022.
Q. Is there a name that replaced Beth Kidder on that?
A. Ashley Peterson.
Q. Okay. Do you know when Ashley Peterson joined AHCA?
A. I believe it was 2021.
Q. Okay. And is it --
MR. PERKO: Counsel, it's 1:30. Are we going to stop for lunch?
MS. DEBRIERE: We can if you want to.
MR. PERKO: Do you want to? It's up to you.
THE WITNESS: At some point.
MS. DEBRIERE: That's fine. Can I just finish up here real quick.
BY MS. DEBRIERE:
Q. So is it possible that this document was created in 2017?
A. I'm looking at a document that has track changes that appear to be since then. But I don't know.

Q. Why do those track changes appear to be since then?

A. Since the date was updated to May 20th, 2022.

Q. Okay. There's some editing in the column. It's very faint. Can you see it?

A. Yes.

Q. And the initials of editor appear to be GS.

A. Yes.

Q. Do you have any idea who that would be?

A. No.

Q. Do you know anybody here with the initials GS?

A. I'm sure somebody here has those initials, but I don't know off the top of my head.

Q. So Mr. Brackett was involved with a GAPMS related to cross-sex hormone therapy, but it wasn't necessarily this one; is that right?

A. I don't know the level of his involvement, but I know that he had some knowledge or knew about it.

Q. Okay. Did he do any other GAPMS related to the treatment of gender dysphoria?

A. I don't know.

Q. Mr. Chen -- did he have any previous experience with GAPMS?

A. I don't know.

Q. Ms. Pickle -- has she had any previous

experience with GAPMS?
A. I don't know.
Q. And you've explained why Mr. Brackett, Ms. Pickle, and Mr. Chen were selected for the team. Why was Mr. Bottcher not selected?
A. I can't recall all the details of the decision. But Jesse Bottcher's team is one of the busiest in the bureau, and has a lot of time sensitive work that they are constantly working on. So I think that had something to do with it, since he is the manager of an entire section.
Q. I think you had previously testified there weren't a lot of GAPMS pending at the time this request come through; is that right?
A. I didn't know the bandwidth or the workload.
Q. Okay. You didn't know the bandwidth. So you didn't know if, for example, Mr. English had the bandwidth to handle the GAPMS report?
A. No.
Q. Do you want to take a break?
A. Yes.
(Brief recess.)
BY MS. DEBRIERE:
Q. Previously before break we were talking about the selection of Mr. Brackett to be on the GAPMS report

team for gender dysphoria. And you mentioned that he had drafted previous similar GAPMS in the past. And I believe you used the example of cross-sex hormones.

Were there any other similar requests that he drafted related to gender dysphoria in the past?

MR. PERKO: Object to form.

THE WITNESS: Just to clarify, I'm not sure if he drafted it.

MS. DEBRIERE: I'm sorry; yes.

THE WITNESS: I know he had some historical knowledge of previous GAPMS.

MS. DEBRIERE: Okay.

THE WITNESS: So can you repeat your question.

BY MS. DEBRIERE:

Q. Did he have hysterical knowledge of previous GAPMS related to gender dysphoria?

A. Outside of the one that I referred to earlier?

Q. No, including that one.

A. Yes, I believe he had some historical knowledge of previous GAPMS.

Q. Other than the one you referenced earlier, are you aware of any other GAPMS that he was involved in related to gender dysphoria?

A. I don't know the extent of all the GAPMS he was involved in.

Q. Also earlier when you were discussing your responsibilities under GAPMS, you mentioned routing.

A. Yes.

Q. Can you describe that a little bit.

A. As the bureau chief of Bureau of Medicaid Policy, any official documents that leave the bureau are usually reviewed by me. And so routing process is the hierarchy of reviewers through wherever the final reviewer or signatory or approver. That's what I was referring to by routing process.

Q. Okay. Does every GAPMS report have a routing process?

A. Yes.

MS. DEBRIERE: Okay. Can I have the 2016 GAPMS routing form. And we'll mark it as Exhibit 6.

MS. DUNN: I can tell from this exhibit that when we printed these the Bates numbering got cut off. So I will look it up and read --

MS. DEBRIERE: That's a bummer.

MS. DUNN: I know.

(Plaintiff's Exhibit No. 6 was marked for identification.)

BY MS. DEBRIERE:

Q. Okay. So do you recognize this document?

A. Not this specific document. But this appears

to be a policy routing and tracking form.

Q. And is that form the same as the form you currently use to track -- to route and track?

A. Sometimes.

Q. What other forms do you use?

A. Prior to the pandemic, we used this form primarily. Since returning to the office there have been different variations of routing and tracking forms developed for different teams or documents -- types of documents.

Q. Do you use the same routing and tracking form for GAPMS?

A. So I've only approved two GAPMS in my time. And I can't remember if this was the -- this format was what was used to route it to me.

Q. Okay. But there was a form used to route it to you when you approved -- when you approved your two GAPMS?

A. I believe so.

Q. Okay. And on this GAPMS form, it says prepared by Monique Johnson. What does it mean to be prepared by? Was the form prepared by Ms. Johnson? Or was the GAPMS report prepared by Ms. Johnson?

A. I don't know.

MS. DEBRIERE: Okay. Could I see the 2022

GAPMS. This will be Exhibit 7.

(Plaintiff's Exhibit No. 7 was marked for identification.)

BY MS. DEBRIERE:

Q. So I'm handing you -- and Gary will want to take a look at it too -- again, the first page of the document is entitled "Medicaid Policy Routing and Tracking Form." If you go through the entire document, it should also include the June 20, 2022, GAPMS report on treatment of gender dysphoria.

MR. PERKO: I believe it was June 2nd.

MS. DEBRIERE: June 2nd. Excuse me.

BY MS. DEBRIERE:

Q. So looking at the document -- the first page, is this the Medicaid Policy Routing and Tracking Form that was associated with the GAPMS report on the treatment of gender dysphoria?

A. Yes.

Q. How do you know?

A. These are my initials.

Q. Okay. So you've seen this before?

A. Yes.

Q. I do want to point out "prepared by" here. What does that mean?

A. That Matt Brackett prepared the routing

package.

Q. Okay. Did he also prepare the GAPMS report itself?

A. Yes.

Q. Do you know if the person who prepares the routing and tracking form -- if they are the person who also prepares the GAPMS report?

A. Can you repeat the question.

Q. The person who prepares the Medicaid Policy Routing and Tracking Form, do they also prepare the GAPMS report itself?

A. I don't know how all the team members are instructed to fill out the report or -- I'm sorry -- fill out the tracking form.

Q. Is there any other way to determine who has prepared a GAPMS report?

A. I don't know. But speaking in general assignments -- these forms are used for other assignments. And there are a lot of assignments that are done collaboratively. So, yeah. I don't know specifically how else you would know just looking at documentation.

Q. Would that information be contained on an AHCA shared drive?

A. It's possible.

Q. Okay. Is there a reason the GAPMS report doesn't identify an author on the report?
A. I don't know.
Q. Okay. A couple other things. On the section line here, it says Canadian Prescription Drug Importation Program. But we have established this was the routing and tracking form for the GAPMS report related to the treatment of gender dysphoria. Are those two things related?
A. So the Canadian Prescription Drug Importation Program is the section of who developed the report. And it lets us know how the hierarchy of the routing should go through the management levels within the bureau and outside.
Q. So it was the Canadian Prescription Drug Importation unit who prepared the GAPMS report on the treatment for gender dysphoria?
A. So that's what I would interpret this section -- why it's listed there next to this section. It's the section responsible for routing and lets us know the hierarchy of the management.
Q. Okay. And then just looking down at the "Reviewed by and Routing Timelines," the start date is June 1st, 2022, for everybody except Mr. Wallace; who has a date of June 2nd, 2022. And the end date is June

1st, 2022, except for Mr. Wallace. Does that indicate that you Mr. Weida and Ms. Pickle all reviewed the report and signed off on it on the same day?

A. That the official routing and the signature occurred on the same day, yes.

Q. What do you mean by official routing?

A. So the date that this form and the final routing package was ready for signature.

Q. And what was continued in the final routing package?

A. I believe it was just the report.

Q. Okay. So the final report -- what was being tracked through this routing and tracking form?

A. Yes.

Q. Were there any attachments to the final report that were also reviewed?

A. The expert witness reports were also reviewed. But I can't remember if they were included in this routing package at the same time.

Q. Who reviewed those final expert reports?

A. I don't remember.

Q. Did you review them?

A. I don't remember if I reviewed them all. But I had seen them -- at least some of them. I can't remember if I reviewed them all formally.

Q. Okay. Turning just back to the general GAPMS process. Is the GAPMS process ever initiated to assess existing coverage of Medicaid services?

A. Can you repeat the question.

Q. Is the GAPMS process ever used to assess existing coverage of Medicaid services?

A. I don't know specifically.

Q. Okay. Who would know that?

A. Are you asking if it ever has or ever would?

Q. Ever would.

Would Ms. Pickle know that?

A. So my personal experience with the GAPMS process is somewhat limited. But it is such a unique process. I feel it's hard to answer that without each situation or each request that we would get would be unique, because that process is dealing with questions that fall outside of something that's easily answered policy question.

MS. DEBRIERE: Have we entered the GAPMS rule into evidence yet? Can we do that now. And that's to be 59G-1.0 -- I thought we had. Oh, it's 5. Okay. Sorry. That's my fault.

MR. PERKO: That's fine.

BY MS. DEBRIERE:

Q. So a couple questions about the language of the

rule. First under (1)(b), "health services" is defined as diagnostic tests, therapeutic procedures, or medical devices or technologies.

Under what category would prescription drugs fall in this definition?

A. I don't know.

Q. You are familiar with the GAPMS rule, though; correct?

A. Yes. I've read the GAPMS rule.

Q. Would prescription drugs fall under any of these categories?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I wasn't part of the original drafting of this rule text. So in order to interpret the policy, I would need to do research.

BY MS. DEBRIERE:

Q. Who would you ask?

A. I would probably start with Ashley Peterson.

Q. Okay. And going down to 3, the second sentence -- "The public may request that a health service be considered for coverage under the Florida Medicaid program by submitting a request."

What does this sentence mean to you?

A. There's much room for interpretation. It says

the public may request a public health service be considered for coverage.

Q. Does this sentence mean that the public may request that Florida Medicaid consider whether to exclude a service previously covered?

MR. PERKO: I'm going to object to form.

THE WITNESS: So I think it could. Not only do we update the coverage policies to include new services, but we do change the scope of a service as part of that process. So if there was a question that was not clear within the scope of the service, I can see how that might apply.

Or the example that you used earlier with a service that's only provided to under 21. If that service was -- if we received a request to make that service available for over 21. So I can think of examples where it wouldn't have to be a new service.

BY MS. DEBRIERE:

Q. Does this rule cover a public's request to take a service away?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know?

A. Public -- that would be a legal interpretation

or policy interpretation that would need consultation with the agency for me to answer.

Q. As the bureau chief of Medicaid Policy, you're responsible for developing coverage policies; correct?

A. I oversee the teams that develop coverage policies, yes.

Q. And you are responsible for overseeing the teams that develop administrative rules to implement those coverage policies; correct?

A. Yes.

Q. So you would be responsible for understanding how rules that implement coverage policies should be interpreted.

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Is it your responsibility to understand the content of this rule?

A. Yes.

Q. Okay. But you can't tell me how to interpret that second sentence in Subpart 3?

A. So if we received a request and I wasn't clear on the authority, there's several steps I would take to confirm that the agency's position is we have authority -- which would be to review any other applicable laws or regulations; would be to consult with

my team and with agency management and perhaps with legal if I was not sure whether a specific question or scenario that was received. We may not have the authority to take an action.

Q. So when reading the second sentence in Subpart 3 -- "The public may request a health service be considered for coverage" -- in order to understand what that sentence means, would you undertake any of the steps you just described?

A. It would depend on the exact question. If I wasn't clear with what the request was and how that authority applied, then I would take further steps to make sure that I understood how the rule applied to the request.

Q. Did you do that for -- okay. Okay. Let me make a note.

In the legal consultation part, it trigged me to remember just a housekeeping question. At lunch did you speak with your attorneys --

A. No.

Q. -- about the deposition?

A. No.

Q. Okay. Does the GAPMS process typically look at an individual service when you're undertaking analysis?

A. I don't know.

MS. DEBRIERE: Okay. Can I have either the Van Mol or Van Meter ATF. It doesn't matter. And we'll mark that as Exhibit 8.

(Plaintiff's Exhibit No. 8 was marked for identification.)

BY MS. DEBRIERE:

Q. So at the top of the page you have a -- did you approve this document?

A. Yes.

Q. Okay. So under "Reason for Occurrence," it says, "On April 20th, 2022, the Bureau of Medicaid Policy received a request for a time-sensitive analysis of service coverage. While such requests are typically for a single service or good --" Is that a correct statement?

A. I don't know.

Q. But you wrote this?

A. No. I signed this.

Q. Okay. Were you the one making the request?

A. No.

Q. Who was making the request?

A. Devona Pickle.

Q. Okay. Before you sign something, do you have to agree with the language contained therein?

A. Yes.

Q. So at the time you signed this, you agreed with the statement that such requests are typically for a single service or good?

A. Yes.

Q. Okay. But now you don't know if GAPMS are typically used for a single service or good?

A. My experience with GAPMS is limited. And I trust the expertise of my staff. And one of the reasons I asked or had recommended that this team be responsible was because of their historic knowledge of the GAPMS process.

Q. And when you say that, that includes D.D. Pickle; correct? You trust her expertise on the GAPMS process?

A. Yes.

Q. Okay. Are you aware of a standard operating procedure used for the GAPMS process?

A. I've heard mention of it. But I don't believe I've ever seen it.

Q. Who did you hear mention of it from?

A. I can't remember. Either Matt or Jesse.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 9, which is the GAPMS Decision Tree Checklist.

(Plaintiff's Exhibit No. 9 was marked for

identification.)
BY MS. DEBRIERE:
Q. Do you recognize this document, Ms. Dalton?
A. I believe I've seen this before.
Q. Do you know what it's used for?
A. I believe this was developed to determine if a request just goes through the coverage determination process or should be handled as a GAPMS.
Q. Okay. And tell me the difference between a coverage determination and something that needs to go through the GAPMS.
A. I don't know everything that goes into how that decision is concluded. But in general, a coverage determination is when it's very clear that the agency has the authority to add a service and that it meets all of the agency's rules and -- for example, an optional state plan service that the agency currently doesn't cover but is clearly allowed through federal CMS would be a coverage determination. Where the GAPMS process is driven by the rule you referenced earlier that describes when it's not clearly meeting all the requirements and laid out in the current coverage policies.
Q. So much earlier in the deposition you gave an example of a coverage determination of a medical supply for -- was it Amino Foods?

A. Puro Meno.
Q. Puro Meno Foods. Why didn't you use the GAPMS process for that? Did you use the GAPMS process for that?
A. No.
Q. Why not?
A. Because the agency already covered similar products.
Q. Okay. Was that the only factor in determining whether to assess it using GAPMS?
A. I don't remember the conversations with the team when I was briefed on the recommendation.
Q. Was a GAPMS Decision Tree Checklist done for Puro Meno Foods?
A. I don't believe so. I never saw one, no.
Q. Okay. Who undertakes the process to fill out the decision tree?
A. I don't know.
MS. DEBRIERE: I apologize. Can we take just a two-minute break.
MR. PERKO: Sure.
(Brief recess.)
BY MS. DEBRIERE:
Q. Do you know how to interpret the answers on a decision tree checklist?

A. No, I don't believe I've ever seen one filled out.

Q. Okay. There's a space here that says "GAPMS Topic." What would go in that space? Do you know?

A. I don't know.

Q. Would a decision tree checklist be generated for every GAPMS request that comes in?

A. I don't know.

Q. Who would know that?

A. I don't know. I don't know if this is still the internal process. I don't know.

Q. Who would know whether it was still the internal process?

A. Jesse Bottcher.

Q. Okay. Would the members of Jesse Bottcher's team also know?

A. No, I don't think anyone currently on his team would know.

Q. How about anybody previously on his team -- I'm sorry; back up.

So no one on Jesse Bottcher's team is in charge of the GAPMS process?

A. The GAPMS position is currently vacant.

Q. Would anybody who was in charge of the GAPMS process at some point know whether the decision tree

checklist is used in the GAPMS process?
A. I don't know.
Q. And there's only one position that would know that, and that is currently vacant; correct?
A. I believe so, yes.
Q. And what is that position called?
A. I believe it's a Government Analyst II.
Q. And so there's just that one position in charge of knowing the GAPMS process?
A. As far as I know, yes.
Q. Okay. We touched on this a bit earlier. Does AHCA use the GAPMS process for prescription drugs?
A. I don't know.
Q. When you were giving an example of similar requests that Mr. Brackett handled for GAPMS, the example you gave was cross hormone therapy; correct?
MR. PERKO: Object to form.
THE WITNESS: I believe that was the example I gave.
BY MS. DEBRIERE:
Q. And what is cross-sex hormone? What is a hormone?
A. I don't think I can recite the clinical definition.
Q. Is the hormone a prescribed drug?

A. I believe so.
Q. So then you're aware of one instance in which GAPMS was used for determining -- for assessing a prescription drug?
A. Yes.
Q. But you don't know generally if GAPMS is used to assess prescription drugs?
A. My knowledge of GAPMS is limited. So to speak in generalities -- but I do see where in 2016 there was the GAPMS on hormone suppression.
Q. Okay. Is GAPMS the only method AHCA relies on to determine whether a Medicaid service is experimental?
A. I don't know. I know we have a clinical trials coverage policy. So there may be circumstances where it's clear that coverage would be -- that coverage policy or the clinical trials rule would apply. And I don't know all the details of how the QIO vendors -- what that process, all that entails.
Q. Whether the QIO venders would determine whether something is experimental?
A. Or if it was clear the clinical trial policy would apply instead. So I don't know to the extent of if there could possibly be.
Q. What is the clinical trials policy?
A. It's a rule that outlines the agency's coverage

for recipients participating in a clinical trial.

Q. And what does that type of authorization entail?

A. I don't know the specifics.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should be excluded?

A. Can you repeat the question.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should not be covered?

A. I don't know the specifics. But if, for example, a pharmaceutical is not FDA approved, there would be perhaps, like, a different process where it wouldn't have to go through the process.

Q. What is the significance of a drug being FDA approved for the purposes of coverage?

A. I don't know the details.

Q. What do you know about it?

A. I believe there's federal requirements on if a drug is not FDA approved -- there is certain coverage requirements.

Q. Do you know if that relates to the compendia we were earlier talking about?

A. I don't know.

Q. Okay. If AHCA is determining whether a production drug is experimental, does AHCA consider whether the drug is FDA approved?

A. I believe so.

Q. If a particular use for a drug has been FDA approved, can AHCA deem the drug experimental for that use?

A. Can you repeat the question.

Q. If a particular use for a drug has been FDA approved, can AHCA deem that drug experimental for that use?

MR. PERKO: I'm going to object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. But FDA approval bears on a determination as to whether AHCA will cover a drug; is that correct?

A. Yes, I think it's considered.

Q. If it's not -- if a drug is not FDA approved, are there circumstances under which AHCA will still cover the drug?

A. I don't know. But I think there is federal regulations around what's allowable.

Q. In the Federal Medicaid Act?

A. I believe.

Q. You mentioned just a second ago, a clinical

trials coverage policy. Where does that policy live?
A. In Rule Class 59G on our website.
Q. If it's not there where would we find it?
A. In the Florida Administrative Code.
Q. It should be in Chapter 59G?
A. But it should be on our website.
Q. Okay. And it is adopted as a rule?
A. Yes.
Q. Okay. Once AHCA reaches a decision through the GAPMS process, describe the implementation of that decision.
A. So, again, in my experience -- I've only been bureau chief for two finalized decisions that were different. And I can't remember all the steps to implementation. But once a determination of any coverage is made, then there's a process of how to notify the public. There's a process for notifying the plans of changes if it affects the plans. There's a process of making sure that the -- any other associated rules that may be impacted are updated.
Q. Anything else?
A. If a training is needed, it depends on what it is. But there could be other.
Q. Who would you train?
A. So, again, just speaking generally -- the

managed care plans; the public; if it's fee for service, the providers; especially if it has to do with submitted claims.

Q. What are the two final reports that you have overseen as bureau chief?

A. So it was the GAPMS that we're discussing today.

Q. And, again, that's the one that relates to treatment of gender dysphoria?

A. Yes. And then the -- I can't remember the exact name of the other GAPMS. But it was through a managed care plan request.

Q. Was it an expedited GAPMS?

A. I don't believe so.

Q. Do you remember what the service was at issue?

A. I do not.

Q. Okay. And the process for an expedited GAPMS, that's different from the traditional GAPMS process?

A. I'm not sure of the differences outside of the timeframe.

Q. Is it different as to how you would inform the public about it?

A. I don't know. I can't recall what steps we took after notifying the plans of the final decision.

Q. Okay. Through the traditional GAPMS process --

do you have any GAPMS right now that are in the final stages?

A. No.

Q. Okay. And you don't know how many requests are currently pending?

A. I don't know.

Q. So the last GAPMS that was finalized was in June of 2022?

A. Yes.

Q. Okay. And now we're in February of 2023. And there's no GAPMS that are ready for finalization at this point?

A. I don't know what stages of development they are.

Q. Okay. Is there anything on your desk to review?

A. I don't know. I don't remember if I have anything pending.

Q. Okay. When you were meeting with Mr. Weida about the June 2022 GAPMS report related to the treatment for gender dysphoria, that report had not been drafted; correct?

A. Sorry. Can you repeat that.

Q. Yeah. Absolutely. So earlier you spoke to meeting with Mr. Weida once you received the request

from the secretary to undertake the GAPMS for treatment of gender dysphoria; do you remember?

A. Yes.

Q. During that meeting had the GAPMS report been drafted yet? I know it seems like a silly question. But I'm asking at face value.

At the time you met with Mr. Weida, had the GAPMS report been drafted yet?

A. The GAPMS report I was discussing with him? No.

Q. Okay. But you have a good memory of that report before it was even drafted; is that right? You were able to recount details to me about discussing that report about before it had been drafted; is that right?

A. Throughout the process there had been discussions. But I don't know if I remember all the details.

Q. What I'm wondering is just why that report sticks out in your mind, but now you can't recount any other GAPMS reports that are pending. Is there a reason for that?

A. I have a lot of documentS in my queue at any one time. And it's really on the onus of the analyst -- part of their job responsibilities -- to make sure assignments are completed and finalized and routed and

closed. So because there was discussion and updates on the status and progress of the report -- and it was not that long ago -- I remember having conversations about the report.

Q. There are GAPMS reports pending right now, though; right?

A. I don't know. I don't know what the GAPMS queue is right now.

Q. Okay. So you don't know if there's anything in the queue right now?

A. Correct.

Q. But you do remember details about the GAPMS report related to treatment of gender dysphoria?

A. Details on the process?

Q. Yeah.

A. Yes.

Q. Okay. When I say "rulemaking process," do you understand what I'm referring to?

A. Yes.

Q. And do your current responsibilities at AHCA include the rulemaking process?

A. Yes.

Q. Can you describe those responsibilities.

A. I review drafts of the coverage policy and the documents that go along with the rule promulgation

process. I sometimes participate in the public meetings and review provider alerts or other notices associated with the process.

Q. Anything else?

A. Not that I can think of.

Q. Okay. Do you ever review public comment associated with the rule?

A. It depends.

Q. So you have before?

A. More in my old role as the AHCA administrator.

Q. Okay. Can you remind me the dates you were in that role.

A. August 2018 to August 2021.

Q. And in your previous roles at AHCA as well as DOEA, you had rulemaking responsibilities; is that right?

A. DOEA was more of the drafting of the policy and not the promulgation process.

Q. Okay.

A. And then AHCA has been more on the promulgation process -- administrative process.

Q. So you'd say you had experience with Florida agency rulemaking?

A. Yes.

Q. When I say "rule workshop," do you understand

what I'm referring to?

A. Yes.

Q. When I say "rule hearing," do you understand what I'm referring to?

A. Yes.

Q. What is the difference?

A. Chapter 120 has different public meetings outlined in different stages of the process. The workshop as we use it here is primarily for the rule development stage of the administrative process. And the hearing occurs at the proposed rule stage.

Q. Okay. When you say the development of the rule, does that mean generally the rule language itself has not yet been drafted or proposed?

A. It depends.

Q. Okay. So is there a difference between workshop and hearing?

A. They're both public meetings meant to garner input from the public and make the public aware of the changes. But per Chapter 120, there are differences because of the different stages of the process.

Q. Okay. Why was there no public workshop held for the rule development of the change to Rule 1.050 excluding the treatment for gender dysphoria?

A. I don't know.

Q. Were you here were when that happened?
You were?
A. Yes.
Q. Okay. While here, have you had public comment on rule workshops for other rules?
A. Can you repeat the question.
Q. Since you've been here at AHCA, have you -- let me ask this question: When the rule was developed to exclude treatment of gender dysphoria per 1.050, were the you bureau chief for Medicaid Policy?
A. When the rule was promulgated?
Q. Well, when you were having the -- when you noticed the proposed rule and had the rule hearing.
A. For this specific rule?
Q. Yes.
A. Yes.
Q. Okay. In your role as bureau chief, have you ever -- in your role as bureau chief, have you been involved in rule workshops for other rules?
A. Yes.
Q. So why weren't you involved in the rule workshop for the exclusion of treatment for gender dysphoria; do you know?
A. I can't remember. I believe I was out of town.
Q. Okay. If you weren't out of town, would you

have been involved in it?

A. I don't remember the discussion around that. But I'm not always involved in the workshops or rules.

Q. How is that determined?

A. It depends on the circumstances and the content of the rule. But I can't remember the specific conversation when that was determined.

Q. Was there a public workshop for the exclusion of the treatment for gender dysphoria? There was only a public hearing; correct?

A. I know there was only one public meeting. I can't remember.

Q. Generally what's the process for planning a rule hearing?

A. We determine a date, a location, and who will be in attendance. And the date and location is included in the notice.

Q. And when you say who will be in attendance, who does that mean?

A. Who the subject matter experts or other agency staff will conduct the public meeting.

Q. Okay. And what do you mean by subject matter expert?

A. So I think I described it a little before how for most of the coverage areas there is a specific

analyst responsible for the development of that policy. So, for example, if there was a change to respiratory services, whoever that suggest matter expert or analyst is would typically be present at the workshop since they have the in-depth knowledge on the changes being proposed.

Q. Is that person always a person employed by the agency?

A. The subject matter expert for all our coverage policies are individuals employed with the agency.

Q. Okay. Are there any written protocols regarding the planning of a rule hearing?

A. I know we've developed process maps and procedures. But I don't know the details of planning a hearing specifically and how detailed those documents are on that process.

Q. What's a process map? What does that entail or detail?

A. There's a graphic that was created before my time that -- it's a real nice layout of the administrative rulemaking process.

Q. Okay.

A. And so it has -- it's a graphic, and it's one page. So it's easy to put on your wall.

Q. And your responsibilities include sometimes

attending rule hearings?

A. Yes.

Q. Since you've been the bureau chief, how many rule hearings have you attended?

A. I don't think I've attended any hearings.

Q. As a State agency employee -- either at DOEA or AHCA -- how many rule hearings have you attended?

A. So at DOEA I attended several AHCA rule hearings in the audience. In my previous position with the agency, I think it was only a handful.

Q. Does that mean five?

A. Yes; I'd say five or less.

Q. Okay. Who else from AHCA attends rule hearings? Let me ask this: Are there AHCA staff who attend rule hearings as part of their job description -- they have to be at every rule hearing?

A. I don't know if that's actually in the job descriptions. But Cole and his team -- since they set up the workshop or hearing or the public meeting -- their responsibilities include making sure they have the speaker list, making sure that everybody is escorted into the building, that the speakers can be heard. So they're in attendance for all of the public meetings.

Q. Okay. And do you know if they have any protocol off which they operate -- written protocol for

conducting the hearing?

A. I believe there's an internal process and process map. But I don't know the details off the top of my head what's included in that document.

Q. Is it the rules unit that is in possession of that document?

A. I would think so, yes.

Q. Okay. In your experience, aside from the agency who attends the hearing?

A. From the public?

Q. I mean, I think that would be the only other option; right?

What types of people from the public?

MR. PERKO: Object to form.

THE WITNESS: That would really depend on what the change is and who is impacted.

BY MS. DEBRIERE:

Q. In your experience attending public hearings -- rule hearings -- are there typically more than 25 people from the public that show up at the rule hearing?

A. I would say yes. Especially since the hearings are now -- have a virtual option. The majority of them are virtual and in person.

Q. Are there typically more than 25 people who show up in person?

A. So I haven't participated in all of them. In the last few that I participated in, there was not 25.

Q. In the last one you participated in how many were there?

A. Less than ten.

Q. Does AHCA ever invite specific persons from the public to attend the rule hearings?

A. Yes.

Q. And how do they do that invite?

A. A provider alert is sent out to the providers. Usually that goes along with the FAR notice that was posted and the public was noticed. If it's a sister agency, it might be by email. So if we believe a rule might impact a sister agency, we might reach out specifically.

Q. So other than posting the public notice and the FAR provider alerts and emails to potentially impacted sister agencies, is there any other way the agency invites specific people to attend the hearing?

A. I believe we sent calendar invites before.

Q. To what people? How did you decide on sending calendar invites?

A. The specific example I'm thinking of is a sister agency for the iBudget handbook. We invited ADP to participate and sent them a meeting invite so they

can block that time.

Q. Okay. Have you ever invited Medicaid recipients other than through the public notice to attend a rule hearing?

A. I don't know, outside of the public notice process.

Q. In your experience?

A. I personally have not.

Q. Okay. Do any State agencies in hosting a rule hearing, do they arrange for transportation for individuals from the public to attend that hearing?

MR. PERKO: Object to form.

THE WITNESS: I can't speak for any other agency. I don't know.

BY MS. DEBRIERE:

Q. What about at DOEA? Did that ever happen?

A. I don't believe I ever participated in an actual public meeting hosted by DOEA.

Q. That's right. You said that.

What about AHCA? Are you aware of AHCA ever arranging transportation for individuals from the public to attend a hearing?

A. Not that I'm aware of.

Q. Are you aware of anyone from the public being paid to attend a hearing?

A. No.
Q. Are you aware of anyone who is a subject matter expert being paid to attend a hearing?
A. I know we've reimbursed the subject matter experts. But I'm not sure if that was specifically -- attending the hearing was specifically included.
Q. And these are subject matter experts that are employed with the agency?
A. I don't know how that process works. But they're not full-time employees with the agency. I believe it's like consultants.
Q. Okay. What's the average length of a hearing?
A. I don't know the average. I know our public meetings typically range between 30 minutes and two hours.
Q. Okay. On average how many comments do agencies receive for a rule hearing? Is there an average?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Do you think 100 comments is a lot of public comments to receive at a hearing?
MR. PERKO: Same objection.
THE WITNESS: I really don't know.
BY MS. DEBRIERE:

Q. In your experience, does a State agency ask outside legal counsel to attend and perhaps in rule hearings?

A. Can you repeat the question.

Q. In your experience, does a State agency normally ask that outside legal counsel attend a rule hearing?

A. I don't know.

Q. When you planned this last rule hearing, did you ask outside legal counsel to attend?

A. Can you specify which hearing.

Q. Yeah. There was a hearing a couple of weeks ago on the change to the medical necessity definition.

A. Yes. The workshop.

Q. Workshop. Did you ask outside legal counsel to attend that workshop?

A. I personally did not.

Q. Did outside legal counsel attend that workshop?

A. I don't believe so.

Q. And have you ever attended a rule hearing where outside legal counsel was asked to participate in?

A. I can't recall if that circumstance has ever happened.

Q. So it's not usually -- it's not the standard course of things for outside legal counsel to attend?

A. Correct.

Q. All right. Turning to the exclusion for treatment of gender dysphoria under Rule 59G-1.050. Prior to the adoption of this exclusion, did any coverage policies regarding any of the services listed there -- sorry. Strike that.

Prior to the adoption of the exclusions set forth -- I'm not sure you're looking at the right rule. 59G-1.050. Exhibit 2. It would help me to tell you the exhibit number. And then it's Subpart 7.

So prior to the adoption of that rule -- that Subpart 7 -- did any coverage policies exist regarding the services that are now subject to that exclusion?

A. Can you repeat that question.

MS. DEBRIERE: Court Reporter, can you read back that last question.

(The preceding question was read back by the reporter.)

THE WITNESS: There was not a specific coverage policy for services for the treatment of gender dysphoria.

BY MS. DEBRIERE:

Q. Does that mean those services were never covered to treat gender dysphoria by Florida Medicaid?

A. I don't believe there was any policy language

that specifically outlined coverage of the services listed in this section.

Q. If there was no specific policy language, does that then mean those services were not covered to treat gender dysphoria by Florida Medicaid?

A. I don't know the extent to what providers were reimbursed for providing the services.

Q. So even if there wasn't a coverage policy specifically related to these services, it's possible that Florida Medicaid was covering the services for the treatment of gender dysphoria?

A. It's possible Florida Medicaid reimbursed for these.

Q. Are there circumstances in which AHCA might not have an explicit or affirmative coverage policy, but would consider a request for a service on a case-by-case basis?

A. Can you repeat the question.

Q. Are there circumstance in which AHCA might not have an explicit coverage policy regarding those services -- or any service -- but would consider a request for a service on a case-by-case basis?

A. I don't know specifically if it's case-by-case basis. But I believe that the plans -- that some of the request from the managed care plans may be specific to a

request for a specific coverage. So when plans request for a GAPMS to be provided, it could be being driven by a specific case.

Q. Okay. So even though a coverage policy does not exist regarding the coverage of a specific service, there are circumstances in which AHCA might still cover that service?

A. Yes.

And I apologize. On your last question I think I heard you specific about GAPMS, which is what I answered. So I apologize.

Q. That's okay. No, that's fine. You're referring to not the last question, but the question before that; is that right?

A. Yes.

Q. Okay. But your response on that last question, you understood the question?

A. Yes.

Q. Okay. Will Florida Medicaid cover an EPSDT service if that service is experimental?

A. So in order for an EPSDT service to be covered, it has to meet the definition of medical necessity.

Q. And that medical necessity definition includes the requirement that the service not be experimental?

A. Yes.

Q. Okay. So you received a request from Secretary Marstiller via email to engage in a GAPMS regarding treatment for gender dysphoria; correct?
A. I can't remember if it was email.
Q. Right. But you received the request somehow?
A. Yes.
Q. And roughly when was that; do you remember?
A. I don't remember.
Q. And then the next step was speaking with Mr. Weida about the letter?
A. Yes.
Q. And developing the plan as to who was going to --
A. Yes. Developing how the process would work.
Q. Were all the decisions reached in that one meeting with Mr. Weida?
MR. PERKO: Object to form.
THE WITNESS: No.
BY MS. DEBRIERE:
Q. Okay. So after that meeting with Mr. Weida, what happened next?
A. I can't remember the exact timeline of events. I know we met at some point with the Canadian Prescription Drug Importation team.
Q. And they were the ones who were put in charge

of doing this GAPMS?
A. Yes.
Q. Okay.
A. And there was several conversations following that.
Q. Were those conversations limited to yourself, Mr. Brackett, Mr. Chen, and Ms. Pickle? Or were there other people involved?
A. I can't remember the chronology. I know after the report and then into the rulemaking Cole Giering was brought into the conversation. Legal counsel -- there was conversations with the experts.
Q. Who were the experts?
A. I can't remember all their names. I don't know if we have that list here.
Q. Did you ever personally speak with any of the experts?
A. No.
Q. Are all the experts listed here on what would be will be your Exhibit 7 on page 45?
A. I believe so, yes.
Q. Was a Dr. Von Mol ever involved as an expert?
A. I believe so.
MS. DEBRIERE: And let me just mark this as Exhibit 10.

(Plaintiff's Exhibit No. 10 was marked for identification.)

BY MS. DEBRIERE:

Q. And this is a document -- an After the Fact Request Form Under 35K. This form is indicating what?

A. Consultant services for vendor name Andre Van Mol.

Q. And what kind of consulting services did Dr. Van Mol provide?

A. I don't know all the details of that -- what the contractor provided. But it was as part of the GAPMS process.

Q. Okay. Why was it time sensitive? It indicates on that form it was time sensitive. Why?

A. I don't know why the request was time sensitive.

Q. Who would know that?

A. I don't know.

Q. Okay. At any time throughout the process did you feel like there was an urgency to the development of the report and rule?

A. Yes. The time sensitive nature was communicated.

Q. By?

A. I don't know remember if it was in the original

request or if it was later in conversations with leadership. I can't remember exactly who. But I think the expectation to follow the process but work as quickly as possible was apparent.

Q. Okay. But you cannot provide me an explanation as to why it was identified as time sensitive?

A. Correct.

Q. I believe we already marked ATF to Dr. Van Meter as Exhibit 8.

Dr. Van Mol -- do you know if he attended the rule hearing for the exclusion of treatment for gender dysphoria?

A. I don't know.

Q. Okay. What does this document, Exhibit 8, indicate to you?

A. An approval for consultant services for vendor named Quintan Van Meter.

Q. Okay. And what kind of services did he provide in exchange for that reimbursement?

A. Consultant services.

Q. Consulting on what?

A. As part of the GAPMS process.

Q. Do you know what specific stages he provided consultation on?

A. I don't.

Q. Do you know whose idea it was to use him?
A. I don't.
Q. Do you know whose idea it was to retain any of the outside experts?
A. No.
Q. Was it internal to AHCA, that decision? Did someone at AHCA decide to retain outside experts?
A. I don't know.
Q. Who would have made that decision?
MR. PERKO: Asked and answered.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Are you aware of AHCA retaining outside experts for any other GAPMS report?
A. I don't know.
Q. Other than Dr. Van Meter and Dr. Van Moll -- I'm sorry.
Was there a Dr. Grossman involved in the process?
A. Yes.
Q. And what was Dr. Grossman's role?
A. I believe it was the same -- consultant services.
Q. For the development of the report?
A. Yes.

Q. Okay. Do you know if they were reimbursed to participate in the hearing?
A. I don't know.
Q. Okay. Were any of the -- other than Dr. Van Mol and Dr. Van Meter -- was Dr. Brignardello-Petersen reimbursed by AHCA for consultant services related to the development of the exclusion of treatment for gender dysphoria?
A. I don't know off the top of my head.
Q. What about Dr. James Cantor?
A. I don't know off the top of my head without consulting if there was an invoice.
Q. Is that true for all the experts?
A. I can't remember how exactly the contracts -- the contracted services were reimbursed.
Q. Were they reimbursed?
A. They were.
Q. Looking at Van Meter's form -- why did you sign that form for a $34,000 reimbursement if you didn't know what Van Meter was doing?
MR. PERKO: I'm going to object to form.
THE WITNESS: So I know that Van Meter was consulting as part of the project. I just don't know throughout the process all the specific details of that consultation.

BY MS. DEBRIERE:

Q. Would you assume each expert listed was similarly compensated for the amount that Dr. Van Meter and Van Mol were compensated?

A. I'm not going to assume. Just looking at the two invoices, they are very different.

Q. In what ways?

A. This one has a not to exceed amount. And then this one has as dollar amount.

Q. Okay. Is that the only way they're different?

A. No.

Q. How else are they different?

A. The one for Quinton Van Meter has specific information regarding his MFMP registration.

Q. What is MFMP?

A. My Florida Market Place.

Q. Okay. Any other ways that they're different?

A. Some of the other language is different. The dates are different. But aside from that, no.

Q. How often do you approve an After the Fact Request Form for reimbursement of outside expertise?

A. Not often.

Q. How many times have you done it for expertise not related to the treatment of gender dysphoria?

A. I can't recall if I actually approved the

invoice; but I believe there was a consultant for the Canadian Prescription Drug Importation Program at one point. And I just can't remember the time.

Q. Is that the only time you can remember?

A. Yes.

Q. Okay. So when you were approving these forms that don't come across your desk often, do they strike you as something that needed careful review?

A. The invoice itself?

Q. The reason for reimbursement.

A. Yes. But the invoice itself seems pretty straightforward that a reimbursement based on services provided -- that had already been provided would be signed.

Q. Did you do a carful review of the reason for reimbursement?

MR. PERKO: Object to form.

THE WITNESS: I guess I'm not sure what you mean by careful review. I personally was not involved in all of the consultation services provided. But I did meet with the team and knew that services were provided.

BY MS. DEBRIERE:

Q. Prior to you receiving this request for reimbursement, did you know these experts were being

relied on for consultation?
A. Yes.
Q. Did you have to approve that request?
A. I don't know if there was a request initiating the services. I don't remember.
Q. Was there a need to approve the decision to rely on outside experts?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. Was there a requirement that consulting with outside experts be approved prior to the consultation?
MR. PERKO: Object to form.
THE WITNESS: Can you repeat that question.
BY MS. DEBRIERE:
Q. Was there -- who consulted with the outside experts?
A. Again, I don't know the extent of what the consultation services were or who all was part of that.
Q. In order for them to -- in order for the team to develop the GAPMS report -- who wrote it -- in order for them to consult with outside experts, did it require your approval?
A. I don't recall ever approving them.
Q. And the team relying on outside experts to write the GAPMS report on gender dysphoria, did it

require the approval of D.D. Pickle?

MR. PERKO: Object to form.

THE WITNESS: I can't recall how the formal process was initiated.

And I do want to say relying on experts -- there was a lot of additional research done as well as part of the GAPMS process. So I wanted to clarify that.

BY MS. DEBRIERE:

Q. But part of writing the report was consulting with these outside experts; correct?

A. Yes.

Q. And you don't know who made the decision to consult with those experts; is that right?

A. Correct.

Q. Whoever made the decision -- we don't know who that is. But whoever made the decision, did they require approval before they could implement that decision?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. As the bureau chief who oversees the team who wrote this GAPMS report, did you have an expectation that they would come to you for approval to

consult with outside experts that would then be paid?
A. Can you repeat that.
Q. As the bureau chief, the person who oversees the team that wrote the GAPMS report on treatment for gender dysphoria, did you have an expectation that they first ask you permission before they consulted with outside experts who charged for their services?
A. No.
Q. Why didn't you have that expectation?
A. I can't really answer that, as I was not part of the decision to consult with the experts.
Q. Who was part of the decision?
A. I don't know.
Q. But you know you were not part of it. Okay.
At the bottom of the After the Request Form, it states -- for Dr. Van Mol, which is Exhibit 10 -- it states supervisor approval is required. What does that mean?
A. In the routing hierarchy for approval.
Q. Approval of what?
A. For invoices for My Florida Marketplace. I'm the direct supervisor of D.D. Pickle.
Q. So your approval is required for D.D. Pickle to pay this bill?
A. Yes.

Q. Okay. But your approval was not required for D.D. Pickle to incur this bill?

MR. PERKO: Object to form.

THE WITNESS: I don't remember if there was a formal approval to initiate the services.

BY MS. DEBRIERE:

Q. Did you have to have approval to authorize this payment to Dr. Van Mol?

A. I can't remember. I don't know where this goes next in the routing.

Q. Okay. Did you ask permission to approve this from anyone?

A. I can't remember a specific conversation. But I knew it was approved by the agency to consult with -- to have the consultant services.

Q. Okay. Related to that, the last sentence is -- how did you know that?

A. How did I know what? Can you repeat that.

Q. I think you had responded that you knew the agency had approved it. And so my question was: How did you know that?

A. I don't remember the specific conversation. But I do know that it was approved by leadership.

Q. And how do you know that?

A. There must have been a conversation. I just

can't remember an exact -- if there was an exact conversation or a document I signed. I can't remember.

Q. Okay. Do you remember who you had the conversation with or had the document signed by?

A. I don't remember.

Q. The last sentence under that first paragraph, it says, "Verification of the availability of funding and approval from executive leadership was obtained prior to any work being conducted for this project."

Who was that executive leadership?

A. The majority of my discussions were with my direct supervisor. But Tom Wallace ultimately signed the report. And I don't know outside of that who all was involved.

Q. Do you need a break?

A. Yeah.

(Brief recess.)

BY MS. DEBRIERE:

Q. Who decided the amount in those forms?

A. I don't know how the amount was negotiated.

Q. Did you follow up on the amount being requested -- ask any questions about it?

A. I can't remember if I asked any questions. But, again, as it states on the form -- the availability of funding approval for leadership.

Q. So you think whoever that leadership was had approved that amount?
A. I don't know how the reimbursement for the services was negotiated.
Q. Okay. So you didn't ask any questions about the amount or what it was being used for?
MR. PERKO: Object to form.
THE WITNESS: I knew what it was being used for. But I can't remember if I asked any questions about the amount.
MS. DEBRIERE: Okay.
THE WITNESS: I can't recall any.
BY MS. DEBRIERE:
Q. Are there any subject matter experts for the services listed in that exclusion that are full-time employees with the agency?
MR. PERKO: Object to form.
THE WITNESS: I don't believe so, since the services outlined in the policy were not clearly outlined in any existing coverage policy that would have had any subject matter expert assigned to the coverage policy.
BY MS. DEBRIERE:
Q. Do you have a subject matter expert in surgery?
A. I don't know if it's one person or more than

one. We have an area that's responsible for the coverage policies we talked about earlier that contain coverage for surgical procedures.

Q. So you have a subject matter expert for outpatient hospital services?

A. Yes.

Q. And do you have a subject matter expert for inpatient hospital services?

A. I don't know if it's the same person.

Q. Okay. But do you have a subject matter expert in inpatient, it just might be the same person?

A. There's a team responsible for oversight of those policies, yes.

Q. Was that team involved in the development of this GAPMS report?

A. Not to my knowledge. But I can't speak to all of the research and activities that were part of the completion of the project.

Q. Who is that team -- that team that are the suggest matter experts in inpatient and outpatient hospital services?

A. That would be John Matson under Jesse Bottcher who is responsible for primary and preventive surgeries, including dental.

Q. Okay. You had mentioned before the break that

you had communications about the development of the GAPMS report with legal counsel; is that correct?

A. I believe so. I can't remember if it was part of the report or part of the rule. I know for sure with the rulemaking process that legal is involved in that process normally. And they were in this instance as well.

Q. Did that legal include outside counsel?

A. I don't know. I don't remember meeting with outside counsel.

Q. Okay. You don't remember with meeting with Holtzman & Vogel, the law firm?

A. No.

Q. Did you communicate with any other State agencies like the Florida Department of Health about the GAPMS report?

A. I personally did not.

Q. Did anybody at the Agency for Health Care Administration?

A. I don't know.

Q. Did you communicate -- were there any communications between AHCA and the Governor about the development of this report?

A. I don't know.

Q. Did you personally communicate with the

Governor's office about the development of this report?

A. No.

Q. Did you personally communicate with the Governor's office about the exclusion of treatment for gender dysphoria?

A. No.

Q. Were there any communications between AHCA and people that provided public comment at the hearing?

A. I'm sorry; can you repeat the question.

Q. Were there any communications between AHCA -- prior to the hearing, were there any communications between AHCA and the people who provided public comment at the hearing?

A. I don't know.

Q. Did you personally communicate with anyone who provided public content at the hearing prior to the hearing?

A. No.

Q. Was anyone at AHCA aware that specific people would provide public content at the hearing prior to the hearing?

A. I don't know.

Q. Were you aware that there were any specific members of the public who would provide public comment at the hearing prior to the hearing?

A. No.
Q. The person who is identified as authoring the GAPMS report on gender dysphoria is Matt Brackett; correct?
A. Yes, he was the primary author.
Q. Do you recall a meeting between you, Mr. Weida, and Mr. Bottcher discussing who the author of the report would be?
A. I don't remember if Jesse was in any of the conversations.
Q. Okay. Did Jesse ever express a concern to you about someone -- anyone on his team drafting the GAPMS report on gender dysphoria treatment?
A. Prior to?
Q. At any time.
A. Can you say that again.
Q. Did Mr. Bottcher ever express to you concerns over someone on his team drafting the GAPMS report on the treatment for gender dysphoria?
A. Not that I can recall.
Q. Was the GAPMS decision tree used before you decided to undertake the GAPMS analysis that is contained in the June 2022 report?
A. I don't know.
Q. Who would have that information?

Did Secretary Marstiller in her letter to Tom Wallace -- did she direct Tom Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.

THE WITNESS: I can't recall the details of the letter.

MS. DEBRIERE: Me neither. Do we have a copy?

MS. CHRISS: It's the last page right there. It's Attachment A.

MS. DEBRIERE: Oh. It's the very back of Exhibit --

MR. PERKO: It's not attached to ours.

MS. DEBRIERE: Okay.

MS. DUNN: Why don't you pull it off and mark it as a separate exhibit.

MS. DEBRIERE: So we'll mark the letter from Simone Marstiller dated April 10th, 2022, as Exhibit 11. And that's Attachment A to the June 2022, GAPMS report related to the treatment for gender dysphoria.

(Plaintiff's Exhibit No. 11 was marked for identification.)

BY MS. DEBRIERE:

Q. So in this letter is Secretary Marstiller directing Mr. Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.
THE WITNESS: Yes.
BY MS. DEBRIERE:
Q. Do you think that Secretary Marstiller undertook a decision tree prior to writing this letter and sending it to Mr. Wallace?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Has the secretary of AHCA ever personally completed a decision tree on the GAPMS process?
A. I don't know.
Q. Would it be unusual if the secretary of AHCA completed a decision tree on the GAPMS process?
A. I don't know.
Q. Looking at the GAPMS report itself, does it contain a fiscal analysis?
A. I don't know off the top of my head.
Q. Yeah. No, take your time.
A. No, I do not see a fiscal analysis.
Q. Do you see anything related to cost effectiveness?
A. No.
Q. Do you know why that was not included?
A. No.

Q. Is budget neutrality in reaching a GAPMS decision important?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I know that that's something when determining a coverage determination that is taken into consideration. But specific to the GAPMS process, I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know that? Would the person responsible for writing GAPMS reports know that?

A. Yes. Or Jesse Bottcher or Matt Brackett.

Q. Or Jeff English?

A. Yes.

Q. Who decided which services would be assessed in the GAPMS report?

A. I don't know.

Q. So typically a request comes in from the public for a specific service. In this instance, the request came from the secretary; correct?

A. Yes.

Q. So would it have been the secretary who decided which services should be assessed?

A. I can't recall how the decision was made. I do know that that was part of conversations we had during this process. But I can't recall exactly how the

decision was finalized.

Q. Was there ever a discussion about narrowing the types of services to be included?

A. I don't recall specifically. I know that the coverage of behavioral health services was something that was always covered. But outside of that specifically, I can't remember.

Q. Was there ever any discussion about undertaking the GAPMS process for a set of services simultaneously as opposed to a single service?

A. Can you clarify.

Q. In the discussions about writing the report or assessing the services, were there ever any concerns raised about undertaking the process for a set of services as opposed to a single one?

A. I don't recall specifically.

Q. Was there any discussion about EPSDT?

A. I can't remember if it was specific to the development of the report or the rulemaking more specifically. But I believe there was.

Q. And what was discussed?

MR. PERKO: I'm going to object for a second. Did that include counsel? Did those discussions include counsel?

THE WITNESS: Yes.

MR. PERKO: And who was that?
THE WITNESS: I don't remember.
MR. PERKO: But it did include counsel?
THE WITNESS: I believe it was a discussion on the rulemaking with counsel.
MR. PERKO: I'm going to instruct the witness not to answer.
BY MS. DEBRIERE:
Q. Were all discussions had in front of counsel about EPSDT?
A. I don't remember.
Q. How about comparability?
MR. PERKO: I'll ask you the same thing.
THE WITNESS: Can you remind me what you're referencing when you say comparability. I think you mentioned that at the very beginning of the day.
MS. DEBRIERE: Comparability is a requirement under the Federal Medicaid Act in the administration of the coverage of the Medicaid services.
THE WITNESS: I don't recall.
BY MS. DEBRIERE:
Q. Were there communications with the Centers for Medicare and Medicaid Services about AHCA's decision to assess whether the services listed in the exclusion were experimental?

A. I don't know. I personally did not have any conversations.

Q. Who communicates with CMS about those kinds of things?

A. Those kinds of things, you mean changes in coverage?

Q. Does CMS ever reach out to AHCA about concerns they have about an action that they're taking related to Medicaid coverage?

A. Yes.

Q. Who would be the point person at AHCA to have those conversations?

A. So if an update to a federal authority were needed, that would be either Catherine Mcgrath or myself.

Q. Okay. You would not have had -- have you had any conversations with CMS about the GAPMS report related to the treatment of gender dysphoria?

A. No.

Q. Has Catherine?

A. Not to my knowledge.

Q. Have you had any conversations with CMS about the exclusion of the treatment for gender dysphoria as contained in Rule 59G-1.050?

A. I have not.

Q. Has Catherine?
A. Not to my knowledge.
Q. Has anybody else at AHCA?
A. I don't know.
Q. Okay. You mentioned a second ago that you weren't sure if you were talking about EPSDTs as it related to the report or the rulemaking. When you make that distinction, are you referring the writing of the report versus the adoption of the rule?
A. Yes.
Q. Okay. How was it decided that the conclusions from the GAPMS report should be adopted into rule?
A. I'm trying to remember the specific conversations. But I do believe those were conversations with counsel as well.
Q. Okay. The expedited GAPMS that you were involved in from start to finish, was that decision adopted into rule?
A. It was just one other GAPMS. And I don't believe any rule update was needed for that one.
Q. Why was a rule update needed for this GAPMS report?
MR. PERKO: If that's discussion with counsel, I will instruct you not to answer.
THE WITNESS: Because there was not any policy

language that clearly explained the coverage, it was determined that developing policy language was the best approach. Anything past that was -- how that process went was conversation with counsel.

BY MS. DEBRIERE:

Q. How often in your day-to-day in making decisions in your job do you have to consult with legal counsel?

A. Often.

Q. Okay. So does that mean -- okay. Like, every day?

A. I would say the majority of days.

Q. Okay.

A. And I'll just specify. I have some sort of contact or interaction with legal counsel.

Q. On most days?

A. Yes. And, again, because the rule promulgation does require review and some other documents we route are managed care contracts also route through legal. Just to give you examples of why it's quite often.

Q. They're all contacts with legal counsel about things related to the doing of your job?

A. The development of policy and -- yes.

Q. Okay. So there was -- you said there was -- the reason that it needed to be adopted into rule is

because there was no clear coverage policy on the services at issue; is that correct?

A. I can't remember all the factors that went into the decision. But I believe that was one of the factors when it was assessed that there was no coverage policy specific to the treatment of gender dysphoria.

Q. Were there existing coverage guidelines?

A. Not to my knowledge.

Q. At the time were you aware of existing pharmacy policies related to the treatment of gender dysphoria?

A. At what time? Can you specify.

Q. It was 2017/2016.

A. I was not with the agency in 2016. So I would not have been part of any development of policy at that time.

Q. But when you were deciding whether to adopt this exclusion into the rule, did you do any review of existing coverage guidelines or past coverage decisions?

A. I believe we did. But I can't recall the specifics.

Q. Did you review past GAPMS reports regarding the treatment of gender dysphoria?

A. I believe we did.

Q. And why weren't they enough to establish the coverage policy?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. 59G-1.050, Subpart 7 -- it bans Medicaid coverage for puberty blockers, hormones and surgery if done so to treat gender dysphoria; correct?

A. It covers that Medicaid does not cover those services for the treatment of gender dysphoria; correct.

Q. Does it distinguish between adults and children?

A. No.

Q. So the exclusion applies equally to both children and adults; is that correct?

A. Yes.

Q. Okay. And it excludes Medicaid coverage for puberty blockers and hormones and surgery to treat gender dysphoria, but it does not exclude Medicaid coverage for those services to treat other diagnoses; is that correct?

A. Correct.

Q. And I just forgot you answer; I apologize. Were you involved in the rule hearing held on July 8th regarding the exclusion set forth in 1.050?

A. No.

Q. Were you aware that outside legal counsel

participated in that hearing?

A. I don't know if I was made aware prior to today. I can't remember.

Q. At rule hearings you've been in in the past, do the State agencies have a panel of subject matter experts who respond to public comment during the hearing?

A. I can't cite the specific language, but it's actually required per Chapter 120 that the agency has subject matter experts who can speak to the contents of whatever is being discussed at a public meeting available.

Q. Other than the July 8th hearing, are you aware of any time that any agency has retained outside subject matter experts to participate on that panel?

A. I'm not aware of any.

Q. To your knowledge is this the only time AHCA has created a slogan to advertise the conclusion in its GAPMS memo?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Are you aware of the slogan "Let kids be kids"?

A. I've seen the website, yes.

Q. In your experience has AHCA ever designed a website page for any other rule adoption?

A. I can't remember if it was specific to rule adoption. But I can think of a couple of examples where we created web pages for policy updates; for example, for home and community based settings rule that was an administrative rule as well as a federal rule. There's a specific external web page for updates regarding that and information on that rule.

When we received the American Rescue Act funding approval, we created a web page with information on that funding and what those funding could be used for. So I feel like it's pretty common for us to update our external website when there's important information to communicate.

Q. In those other examples, did AHCA ever develop a slogan to go along with those web pages?

A. Not in the examples that I used, I don't think.

Q. Did they issue press releases?

A. The American Rescue Act funding may have had one. But I can't remember.

Q. Okay. Just going back quickly. My co-counsel has pointed out to me that in Chapter 120 it says that at the rule hearing agency staff must be available but not an expert. Do you think maybe you were confusing that requirement that an expert needs to be available under 120?

A. I think it says an agency staff with knowledge.

Q. Okay. "Ensure that staff are available to explain the agency's proposal and to respond to questions or comments regarding the rule." Is that the provision you were --

A. Yes.

Q. -- thinking of? Okay.

Typically when AHCA decides not to cover a particular service, where is that information included?

MR. PERKO: Object to form.

THE WITNESS: I think it depends on the policy. Each policy has different exclusions, if there are any, with the service. Or most of the coverage policies include a section specific to exclusions.

MS. DEBRIERE: Most of the policies? Is that what you said? I apologize.

THE WITNESS: Most of the coverage policies.

BY MS. DEBRIERE:

Q. Okay. And those coverage policies are service specific policies?

A. The examples I was thinking of, yes, were service specific coverage policies and include -- I can't remember exactly what section in the example of where to find that in the coverage policy. But, yes, it would include exclusion specific to the coverage that's

being described in the policy.

Q. Okay. The exclusion on the treatment of gender dysphoria, is it in a service specific coverage policy?

A. No. This is a general Medicaid policy. But it does include coverage information including what Florida Medicaid reimburses for and what it does not.

Q. Does it speak to the exclusion of any other services under Florida Medicaid but those services excluded for the treatment of gender dysphoria?

A. Yes.

Q. Which ones?

A. No. 4 is an example. (4)(b), that speaks to that Florida Medicaid does not cover continuous services after the emergency has been alleviated.

Q. Is that a specific service? Or is that the length of time for any service?

A. I apologize. It's emergency service. It's under the section for emergency Medicaid.

Q. But, again, is that speaking to the coverage of any service deemed emergency?

A. It's specific to emergency services provided to aliens who meet all Florida Medicaid eligibility requirements except for citizenship.

Q. It says an exclusion under Subpart 7 speaks specifically to the exclusion of sex reassignment

surgeries; correct?

A. Services for the treatment of gender dysphoria.

Q. But only three services.

A. Four.

Q. What are examples of procedures that alter primary or secondary sexual characteristics that are not related to surgery?

A. I don't know.

Q. Just going back to the surgery, why not include that in service specific policies that discuss surgery?

A. Can you repeat the question.

Q. Looking at the exclusion of sex reassignment surgeries, why was that not included in the coverage policies related to surgeries that we discussed earlier?

A. I don't recall the specific conversation on how it was decided that this was the most appropriate policy. And I do believe that most of that conversation was with counsel.

Q. So same question for puberty blockers. Why wouldn't you include that in a pharmacy coverage policy?

A. I don't know.

Q. And Subpart 7's subject line is "Gender Dysphoria"; correct?

A. Yes.

Q. And that's a diagnosis?

A. I don't know clinically the definition.
Q. We've been talking about the treatment of gender dysphoria; right?
A. Yes.
Q. So in order to exclude treatment of gender dysphoria, it would be the exclusion of a treatment for a diagnosis; correct?
A. Yes. But I can't speak to the specifics of the diagnosis or what that means in clinical terms.
Q. Okay. For the July 8th hearing, do you know how many public comments were submitted?
A. I don't know.
Q. Do you know if it was more than 100?
MR. PERKO: Asked and answered.
THE WITNESS: I know it was a lot.
BY MS. DEBRIERE:
Q. Okay. And do you know how long it took AHCA to review and consider the comments before adopting the final rule?
A. I don't know the length of time. But I know that all the public comments were reviewed.
Q. Who reviewed them?
A. I know Cole Giering did. I don't know if anybody else -- if anybody else did.
Q. Okay. So after the July 8th hearing up until

the final adoption of the rule, other than reviewing and considering public comment, what else did AHCA do before adopting the rule?

A. Can you repeat the question.

Q. So after the July 8th hearing up until the final adoption of the rule, other than reviewing public comment, what other activities did AHCA undertake in deciding to adopt the rule?

A. I don't know. I can't remember specific to this rule. But after it's been determined there's no changes needed to the rule, the filing for adoption would be the next step.

Q. How do you reach that decision that no changes should be made?

MR. PERKO: Object to form.

THE WITNESS: There's various factors involved in that decision. And it really depends on the specific circumstances.

MS. DEBRIERE: Okay. I don't know what it would be labeled, but do you have an exhibit -- it's an email from Ms. McGriff to Magellan.

MS. CHRISS: Yes. The email exchange between Magellan and AHCA.

MS. DEBRIERE: Thank you.

Court Reporter, just for your reference what we

just marked as Exhibit 12 is Bates stamped DEF_00288753 to 000288756.

(Plaintiff's Exhibit No. 12 was marked for identification.)

BY MS. DEBRIERE:

Q. So Magellan is emailing several people at AHCA. And she says, "Attached are the internal criteria not publicly posted."

What are the internal criteria?

A. I don't know.

Q. Does Magellan rely on internal criteria for the coverage of Medicaid services?

A. I don't know.

Q. What does "CCM" mean? It's right after that sentence. "Attached are the internal criteria 'not publicly posted' CCM."

A. I don't know.

Q. What does gender code mean?

A. I don't know.

Q. Do you know hot had significance of "B for both" is?

A. I do not.

Q. Who is Linda Simone Moore?

A. Who?

Q. So there's a sender up top here -- I'm sorry.

Leslie.

A. Moore-Simons.

Q. I need reading glasses. Leslie Moore-Simons. That's exactly right.

A. I don't know.

Q. Okay. Who is Susan Williams?

A. She works for Ashley Peterson in the pharmacy unit in the Bureau of Medicaid Policy.

Q. Okay. And who is Arlene Elliott? I'll just note the date that Arlene's email was sent was 8/21/2017.

A. Currently Arlene Elliott is in a different division at the Agency for Health Care Administration. But at this time, she was the AHCA administrator over the pharmacy policy section of the Bureau of Medicaid Policy.

Q. And what unit is she in now?

A. I don't know. She's no longer in the division of Medicaid.

Q. What division is she in?

A. I believe it's Health Quality Assurance.

Q. Do you know when she left her position in the Bureau of Medicaid Policy?

A. I believe it was spring or summer 2021. I'm not sure the exact date.

Q. Okay. Earlier in the exchange -- and yet dated later -- is the email dated April 20th, 2022, from Elica King-Wilson at Magellan. And she's included some language which she underlined and bolded. And it says, "All requests require vetting by AHCA before a final determination is made."

And it appears this is related to a final determination as to whether -- well, it says -- Leslie noted, "MMA does have an internal gender dysphoria criteria, which is attached."

MMA stands for?

A. I don't know in what context she's using it.

Q. Okay.

A. But to me, MMA would normally stand for managed medical assistance.

Q. I assume you're confused because this is coming from Magellan which is not a managed medical assistance program; is that right?

A. Yes. So I don't know if that's what she's referring to.

Q. And it says, "This internal document serves for GnRH analog use to delay puberty in adolescents with gender dysphoria." This document was provided by AHCA due to a fair hearing request received for Lupron for a recipient with this diagnosis" -- meaning gender

dysphoria. And it goes on with the underlying language that all of those requests -- coverage of Lupron for gender dysphoria -- need to be vetted by AHCA before a final determination is made.

Were you familiar with that process at all?

A. No. I don't know what process they were referring to.

Q. Would Ashley Peterson know?

A. I don't know. But she does work closely with Magellan.

Q. Okay. Did AHCA work with managed care plans to implement the exclusion in 1.050?

A. They were notified. But the specifics of how that communication happened, I can't recall.

MS. DEBRIERE: Okay. Can I have the SMMC Policy Transmittal relating to the Non-Coverage of Gender Dysphoria Treatment.

MS. DUNN: Do you want the policy or the emails?

MS. DEBRIERE: Could you do both.

MS. DUNN: Do you want them together?

MS. DEBRIERE: That would be great. But separate exhibits.

(Plaintiff's Exhibit No. 13 was marked for identification.)

(Plaintiff's Exhibit No. 14 was marked for identification.)

BY MS. DEBRIERE:

Q. So right now we're looking at an email that's Bates stamped DEF_000258835 to 000258838. It's an email from D.D. Pickle CC-ing you. And it's to Jason Weida.

In this -- I'm sorry. Looking specifically at an email dated August 22, 2022, from D.D. to Ashley Peterson and Matt Brackett. It states, "Ashley, Ann wants to include the 60-day language in the alert?"

What alert is D.D. Pickle referring to?

A. I believe it was the provider alert.

Q. And what's a provider alert?

A. It's the main way -- one of the main ways we communicate information to our providers and external stakeholders.

(Plaintiff's Exhibit No. 15 was marked for identification.)

BY MS. DEBRIERE:

Q. I'm handing you a document that's marked as Exhibit 15, called Florida Medicaid Health Care Alert Sign-Off Form, starting at Bates stamp DEF_000258839.

Is this the provider alert you were referring to?

A. Yes. It looks to be a provider alert regarding

the coverage of treatment for gender dysphoria.

MS. DEBRIERE: Okay. And then what was the transmittal?

MS. DUNN: It was 14.

BY MS. DEBRIERE:

Q. No. 14 -- can you look at that document. And that's Bates stamped DEF_000258833.

What is this document?

A. It looks to be a draft -- a policy transmittal.

Q. And who does that go to?

A. This specific one is marked to be sent to the medical assistance and specialty plans.

Q. Is that the final that was sent?

A. It does not appear so, no.

Q. Okay. How do you know that?

A. The policy transmittal number is not completed and it's not signed.

Q. Okay. Going back to the provider alert, was that the final that was sent?

A. I can't tell from this document if this was the final that was sent.

Q. Okay. Would you be able to tell from any of the versions whether it was the final?

A. Seeing the actual email alert would be how I would make sure. My team actually does not send out the

final provider alerts. So that's typically how I would look at the final version.

Q. Okay. And the policy transmittals and the provider alerts -- are those available on the agency's website? The finals?

A. Yes.

Q. Okay. So turning back to that email exchange where D.D. mentions you by name.

What is 60-day language?

A. I believe she's referring to the continuity of care.

Q. What is continuity of care?

A. It's a contract requirement for the plans to provide services for a period of time. I don't know if it's specific to when they change plans. I can't recall the exact contract language, but it's a contract provision.

Q. And are services previously being covered supposed to be continue being covered for 60 days according to the 60-day language?

A. I can't recall the exact parameters of the requirement.

Q. Do you recall why --

MR. PERKO: Counsel, we're getting on seven hours here.

BY MS. DEBRIERE:

Q. Do you recall why the 60-day language -- you wanted the 60-day language included in this alert?

A. I can't remember the conversation around this. And I can't speak for D.D.

Q. Well, D.D. is speaking for you; right?

The subject is "GD Policy Transmittal"; correct?

A. Yes.

Q. And what does "GD" stand for?

A. Based on the attachments, I would conclude that it is for gender dysphoria.

Q. Okay. And this would be discussion had after the rule was adopted excluding coverage of services for the treatment of gender dysphoria; correct?

A. Can you repeat that question.

Q. The date of this email is after the rule was adopted to exclude coverage of services for treatment of gender dysphoria.

A. I believe so.

Q. You don't recall why you thought it was important to have the 60-day language included in the alert?

A. I don't recall the specifics of the conversation. But I believe it was to ensure if there

was any current reimbursement or authorization that would apply.

Q. Current authorization of treatment of gender dysphoria?

A. Of the services listed in Rule 1.050, No. 7.

Q. Did any plans state to AHCA that they would continue coverage of the services excluded in the rule even though that rule had been adopted?

A. I don't know.

Q. Who would know that?

A. I don't know who it would have gone to. If there was a question, the communications typically go through the contract managers.

Q. Okay. Do you know if all plans have implemented the exclusion contained in the rule?

A. I don't know.

Q. Are you familiar with the variance and waiver process under Chapter 120?

A. Yes.

Q. Okay. What is the purpose of that statute?

MR. PERKO: Object to form; calls for a legal conclusion.

BY MS. DEBRIERE:

Q. What it the purpose of the variance and waiver process?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

MR. PERKO: Counsel, we're getting on seven hours here.

MS. DEBRIERE: All right. Let me just consult with my team for just a second.

(Brief recess.)

MS. DEBRIERE: We'll all set with direct.

Thank you for your time, Ms. Dalton.

MR. PERKO: I don't have any questions.

THE COURT REPORTER: Would you like to read or waive?

THE WITNESS: Read.

THE COURT REPORTER: Would you like to order at this time?

MS. DEBRIERE: Yes.

THE COURT REPORTER: Would anybody like to order a copy?

MR. PERKO: Yes.

(This deposition was concluded at 6:05 p.m.)

- - -

CERTIFICATE OF OATH

STATE OF FLORIDA:
COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, do hereby certify that ANN DALTON personally appeared before me on January 24, 2023 and was duly sworn and produced her ID badge as identification.

Signed this 30TH day of JANUARY, 2023.

GREG T. SMITH

Notary Public, State of Florida
My Commission No.: GG933698
Expires: March 21, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA:

COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, certify that I was authorized to and did stenographically report the deposition of ANN DALTON; that a review of the transcript was requested; and that the foregoing transcript, pages 6 through 175, is a true and accurate record of my stenographic notes.

I further certify that I am not a relative, employee, or attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 30TH day of JANUARY, 2023.

Greg T. Smith

GREG T. SMITH

KATHERINE J. DEBRIERE, ESQUIRE
DEBRIERE@FLORIDAHEALTHJUSTICE.ORG

January 30, 2023

RE: Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

The above-referenced transcript is available for review.

(The witness/You) should read the testimony to verify its accuracy. If there are any changes, (the witness/you) should note those with the reason on the attached Errata Sheet.

(The witness/You) should, please, date and sign the Errata Sheet and email to the deposing attorney as well as to Veritext at Transcripts-fl@veritext.com and copies will be emailed to all ordering parties.

It is suggested that the completed errata be returned 30 days from receipt of testimony, as considered reasonable under Federal rules*, however, there is no Florida statute to this regard.

If the witness fails to do so, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

*Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e).

Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

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Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____
(WITNESS NAME) DATE

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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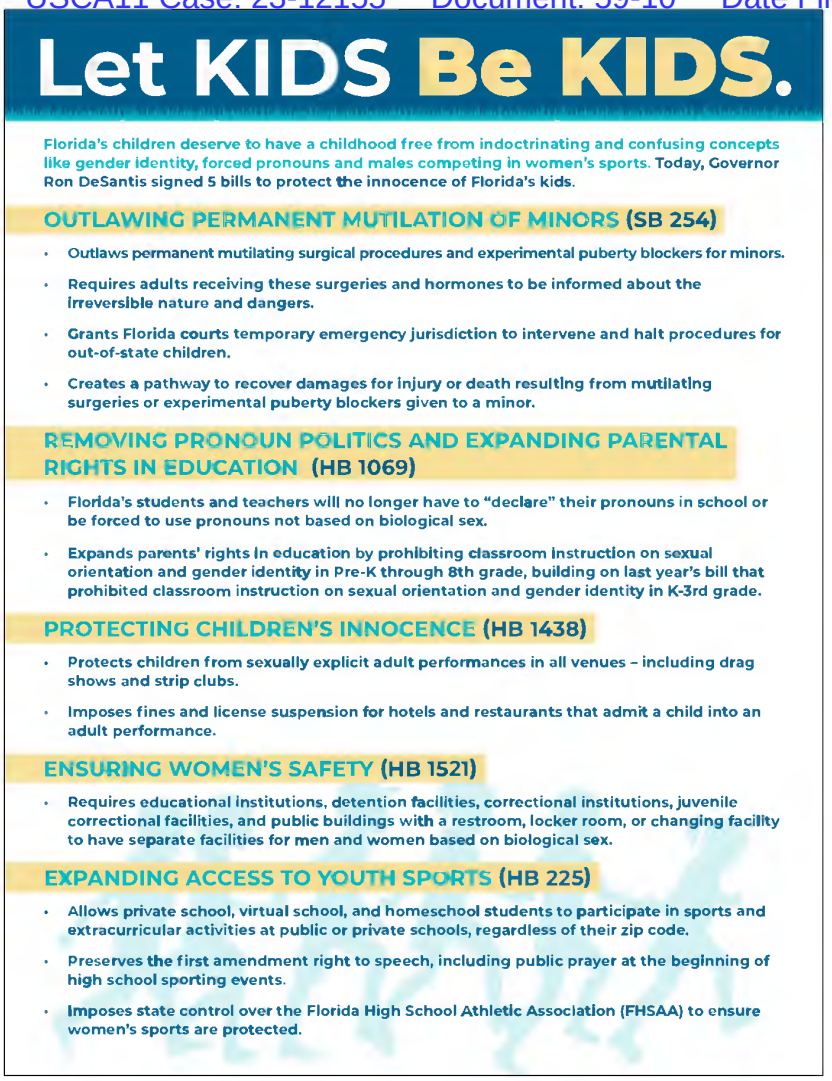
TAB 236-1

Governor Ron DeSantis Signs Sweeping Legislation to Protect the Innocence of Florida's Children

On May 17, 2023, in News Releases, by Staff

TAMPA, Fla. — Today, Governor Ron DeSantis signed the Let Kids Be Kids bill package to protect Florida's children from permanent mutilating surgical procedures, gender identity politics in schools, and attending sexually explicit adult performances. For more information about the bills signed today, click here.

Pl. Trial Ex. 365



Let KIDS Be KIDS.

Florida's children deserve to have a childhood free from indoctrinating and confusing concepts like gender identity, forced pronouns and males competing in women's sports. Today, Governor Ron DeSantis signed 5 bills to protect the innocence of Florida's kids.

OUTLAWING PERMANENT MUTILATION OF MINORS (SB 254)

- Outlaws permanent mutilating surgical procedures and experimental puberty blockers for minors.
- Requires adults receiving these surgeries and hormones to be informed about the irreversible nature and dangers.
- Grants Florida courts temporary emergency jurisdiction to intervene and halt procedures for out-of-state children.
- Creates a pathway to recover damages for injury or death resulting from mutilating surgeries or experimental puberty blockers given to a minor.

REMOVING PRONOUN POLITICS AND EXPANDING PARENTAL RIGHTS IN EDUCATION (HB 1069)

- Florida's students and teachers will no longer have to "declare" their pronouns in school or be forced to use pronouns not based on biological sex.
- Expands parents' rights in education by prohibiting classroom instruction on sexual orientation and gender identity in Pre-K through 8th grade, building on last year's bill that prohibited classroom instruction on sexual orientation and gender identity in K-3rd grade.

PROTECTING CHILDREN'S INNOCENCE (HB 1438)

- Protects children from sexually explicit adult performances in all venues – including drag shows and strip clubs.
- Imposes fines and license suspension for hotels and restaurants that admit a child into an adult performance.

ENSURING WOMEN'S SAFETY (HB 1521)

- Requires educational institutions, detention facilities, correctional institutions, juvenile correctional facilities, and public buildings with a restroom, locker room, or changing facility to have separate facilities for men and women based on biological sex.

EXPANDING ACCESS TO YOUTH SPORTS (HB 225)

- Allows private school, virtual school, and homeschool students to participate in sports and extracurricular activities at public or private schools, regardless of their zip code.
- Preserves the first amendment right to speech, including public prayer at the beginning of high school sporting events.
- Imposes state control over the Florida High School Athletic Association (FHSAA) to ensure women's sports are protected.

"Florida is proud to lead the way in standing up for our children," said **Governor Ron DeSantis**. "As the world goes mad, Florida represents a refuge of sanity and a citadel of normalcy."

"Thank you to Governor Ron DeSantis for continuing to implement legislation to keep our students safe and our schools focused on education, not indoctrination," said **Commissioner of Education Manny Diaz, Jr.** "Today's actions make it clear – educators in Florida are expected to teach our standards, and not interject their own opinions or worldview into the classroom. The Department will remain focused on teaching students core subjects, rather than woke gender ideology or inappropriate topics."

"Thank you Governor DeSantis for signing legislation that protects our children," said **Agency for Health Care Administration Secretary Jason Weida.** "Florida is following the science to elevate our standards of care to protect kids from harmful drugs and surgeries."

SB 254 – Treatments for Sex Reassignment:

- Prohibits sex reassignment surgeries and experimental puberty blockers for children.
- Requires adult patients who are receiving these medications or surgeries to be informed about the dangers and irreversible nature of these procedures and to give written, informed consent.
- Provides courts temporary emergency jurisdiction to step in and halt sex reassignment procedures for out-of-state children present in Florida.
- Creates a pathway for individuals to obtain damages when they were injured or killed after receiving sex reassignment surgeries or medications as minors.

HB 1069 protects students from having to declare their pronouns in school. Additionally, this bill expands parental rights in education by prohibiting classroom instruction on sexual orientation and gender identity in Pre-K through 8th grade.

HB 1438 protects children from sexually explicit performances in all venues. This bill prohibits a person from knowingly admitting a minor to an adult performance. Additionally, this legislation authorizes the Department of Business and Professional Regulation to fine, suspend, or revoke the operating or alcohol licenses of hotels or restaurants if they admit a child into an adult performance.

HB 1521 ensures that Florida's bathrooms, changing rooms, and locker rooms are safe places for women. The bill requires educational institutions, detention facilities, correctional institutions, juvenile correctional facilities, and public buildings with a restroom or changing facility to designate

separate facilities based on biological sex or to provide one-person unisex facilities.

The Governor also signed legislation to protect youth sports in Florida and ensure that all students can play sports without interference from extremist bureaucratic boards. HB 225 allows private school, virtual school, and home school students to participate in sports and other extracurricular activities at other public or private schools, regardless of zip code.

HB 225 also reorganizes the FHSAA Board of Directors to 13 members, instead of the current 16 members. Four members will be elected by school representative members while eight members will be appointed by the governor, and the final member will be the Commissioner of Education or his designee. This bill also allows teams to provide brief opening remarks, including prayers, before high school athletic contests.

###

Comments are closed.

Contact Governor DeSantis

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(850) 488-7146

Email Governor DeSantis

Email First Lady DeSantis

Email Lt. Governor Nuñez

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Scheduling Requests

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TAB 241

United States District Court

CIVIL MINUTES - TRIAL

Case No.: 4:22cv325-RH

Dates: May 9-11, 2023
Dates: May 17-19, 2023
Dates: May 22, 2023

AUGUST DEKKER et al. v. JASON WEIDA et al.

PROCEEDINGS: Bench Trial held. Ruling by Court: The Court's ruling will be made in a separate order to follow.

PRESENT: ROBERT L. HINKLE, U.S. DISTRICT JUDGE

Cindy Markley
Deputy Clerk

Megan Hague, Judy Gagnon
Court Reporters

Attorneys for Plaintiffs:
Omar Gonzalez-Pagan
Katherine DeBriere
Jennifer Altman
Carl Charles
Abigail Coursolle
Catherine McKee
Simone Chriss
Chelsea Dunn
Joseph Little
William Miller
Gary Shaw
Shani Rivaux

Attorneys for Defendants:
Mohammad Jazil
Gary Perko
Michael Beato

☐ Case called and continued to _____.
☒ COURT TRIAL
☐ JURY TRIAL. Jury impaneled and sworn in. See separate minutes for jury selection.
☐ Jury retires to deliberate at _____ on _____.
☐ Jury returns at ____ on _____.
☐ JURY VERDICT. See signed verdict.
☐ Jury polled ☐ Polling waived ☐ Mistrial declared
☒ FINDINGS BY COURT: Order to follow.
☐ JUDGMENT BY COURT for ☐ Plaintiff ☐ Defendant for $_____
☐ Findings, Conclusion of Law, Judgment to be prepared by ☐ Plaintiff ☐ Defendant
☐ Briefs to be filed ☐ Plaintiff ☐ Defendant ☐ Reply
☐ Continued to _____ for ☐ setting trial ☐ further trial

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

CIVIL MINUTES

JUDGE ROBERT L. HINKLE
Cindy Markley, Courtroom Deputy
Megan Hague, Official Court Reporter (May 9-11, May 22)
Judy Gagnon, Contract Court Reporter (May 17-19)

Case: 4:22cv325-RH
Legend: Plaintiff Attys: Omar Gonzalez-Pagan
Katherine DeBriere
Jennifer Altman
Carl Charles
Abigail Coursolle
Catherine McKee
Simone Chriss
Chelsea Dunn
Joseph Little
William Miller
Gary Shaw
Shani Rivaux
Defense Attys: Mohammad Jazil
Gary Perko
Michael Beato

Bench Trial – Day 1
DATE: May 9, 2023

9:00 Court in session
Opening statement by Plaintiffs (Gonzalez-Pagan)
9:18 Opening statement by Defense (Jazil)
9:21 Plaintiff moves to admit all joint exhibits (Gonzalez-Pagan)
9:21 Ruling by Court: Exhibits identified in ECF 219 are admitted.
9:23 Plaintiff Witness:
Dan Karasic – sworn, direct (DeBriere)
Plaintiff Exhibit 359 – previously admitted
Defendant Exhibit 16 – previously admitted
10:51 Court in recess

11:05 Court in session
Continued direct examination (DeBriere)
12:04 Cross examination (Jazil)
Defendant Exhibit 16 – previously admitted
Plaintiff Exhibit 45 – shown to witness
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 140 – shown to witness
1:07 Court in recess

2:11 Court in session
Continued cross examination (Jazil)
Defendant Exhibit 24 – previously admitted
Defendant Exhibit 28 – shown to witness
2:42 Redirect (DeBriere)
2:55 Court inquires of witness
3:15 Plaintiff Witness:
Daniel Evan Shumer – sworn, direct (Coursolle)
Plaintiff Exhibit 360 – previously admitted
3:39 Court in recess

3:47 Court in session
Continued direct (Coursolle)
5:05 Parties discuss legislation
5:13 Plaintiff expresses intent to move to amend the complaint (Gonzalez-Pagan)
5:14 Response by Defense (Jazil)
5:18 Court addresses the parties
5:26 Court in recess

Bench Trial – Day 2
DATE: May 10, 2023

9:01 Court in session
Parties discuss housekeeping matters
9:04 Cross examination of Dr. Shumer (Jazil)
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 188 – shown to witness
Plaintiff Exhibit 235 – previously admitted (not published)
Plaintiff Exhibit 236B – previously admitted (not published)
9:37 Redirect (Coursolle)
9:52 Court inquires of witness
9:58 Additional cross examination (Jazil)
10:00 Court in recess

10:10 Court in session
Plaintiff Witness:
Loren Sloan Schechter – sworn, direct (McKee)
Plaintiff Exhibit 362 – previously admitted
10:43 Cross examination (Perko)
Plaintiff Exhibit 34 – shown to witness
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 234A – previously admitted (not published)
10:56 Redirect (McKee)
10:56 Court inquires of witness
11:00 Plaintiff Witness:
Armand Herbert Matheny Antommaria – sworn, direct (Charles)
Plaintiff Exhibit 157 – shown to witness
Defendant Exhibit 24 – previously admitted
12:14 Court in recess

1:15 Court in session
Continued direct (Charles)
Defendant Exhibit 28 – shown to witness
2:18 Cross examination (Perko)
Plaintiff Exhibit 157 – shown to witness
Plaintiff Exhibit 5 – shown to witness
Defendant Exhibit 8 – shown to witness
2:35 Court inquires of witness
2:41 Plaintiff Witness:
Jeffrey A. English – sworn, direct (Altman)
Plaintiff Exhibit 18 – marked, ID'd, admitted
Defendant Exhibit 6 – marked, ID'd, admitted
Plaintiff Exhibit 30 – marked, ID'd, admitted
Plaintiff Exhibit 23 – previously admitted
Plaintiff Exhibit 238 – previously admitted
Plaintiff Exhibit 302 – shown to witness
3:34 Court in recess

3:50 Court in session
Continued direct (Altman)
3:54 Cross examination (Perko)
Plaintiff Exhibit 23 – previously admitted
4:01 Redirect (Altman)
4:04 Court inquires of witness
4:07 Plaintiff Witness:
Kellan Baker – sworn, direct (Dunn)
Plaintiff Exhibit 363 – previously admitted
Plaintiff Exhibit 142 – shown to witness
Plaintiff Exhibit 71 – marked, ID'd, admitted
5:06 Parties discuss schedule
5:15 Court in recess

Bench Trial – Day 3
DATE: May 11, 2023

9:00 Court in session
Cross examination of Dr. Baker (Beato)
Plaintiff Exhibit 23 – previously admitted
Defendant Exhibit 4 – previously admitted
9:06 Redirect (Dunn)
9:09 Statement to the Court by Plaintiffs regarding schedule (Gonzalez-Pagan)
9:11 Plaintiff Witness:
Johanna Olson-Kennedy – sworn, direct (Gonzalez-Pagan)
Plaintiff Exhibit 361 – previously admitted
Plaintiff Exhibit 141 – shown to witness
10:41 Court in recess

10:55 Court in session
Cross examination (Jazil)
Defendant Exhibit 16 – previously admitted
Plaintiff Exhibit 141 – shown to witness

Plaintiff Exhibit 164 – shown to witness
Plaintiff Exhibit 176 – shown to witness
11:20 Redirect (Gonzalez-Pagan)
11:23 Court inquires of witness
11:30 Additional redirect (Gonzalez-Pagan)
11:34 Plaintiff Witness:
Jane Doe – sworn, direct (Coursolle)
11:57 Cross examination (Jazil)
12:01 Court inquires of witness
12:03 Plaintiff Witness:
Brit Rothstein – sworn, direct (Chriss)
12:43 Cross examination (Jazil)
Plaintiff Exhibit 234 – previously admitted (not published)
12:48 Court in recess

1:50 Court in session
Plaintiff Witness:
August Dekker – sworn, direct (Charles)
2:44 Cross examination (Jazil)
Plaintiff Exhibit 237A – previously admitted (not published)
2:47 Redirect (Charles)
Plaintiff Exhibit 237A – previously admitted (not published)
2:51 Plaintiff Witness:
Jade Ladue – sworn, direct (DeBriere)
3:31 Parties discuss schedule
3:32 Ruling by Court: Trial will continue Wednesday, May 17, at 9:00 a.m.
3:33 Court in recess

Bench Trial – Day 4
DATE: May 17, 2023

9:00 Court in session
Plaintiff Witness:
Elliot Kale Edmiston – sworn, direct (Rivaux)
Plaintiff Exhibit 357 – previously admitted
9:35 Cross examination (Beato)
Defendant Exhibit 16 – previously admitted
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 351 – shown to witness
Plaintiff Exhibit 352 – shown to witness
Plaintiff Exhibit 354 – shown to witness
9:57 Court inquires of witness
10:02 Additional cross examination (Beato)
10:04 Plaintiff Witness:
Kim Hutton – sworn, direct (Little)
10:30 Cross examination (Perko)
10:31 Redirect (Little)
10:32 Court in recess

10:50 Court in session
10:51 Plaintiff Witness (by Zoom):
Aron Christopher Janssen – sworn, direct (Gonzalez-Pagan)
Plaintiff Exhibit 364 – previously admitted
11:45 Cross examination (Perko)
11:50 Redirect (Gonzalez-Pagan)
11:51 Court inquires of witness
11:54 Plaintiff addresses the court to clarify a previously admitted exhibit (Gonzalez-Pagan)
11:56 Response by Defense (Jazil)
11:59 Plaintiff moves to admit Plaintiff Exhibits 24, 21, 22, 74, 27, 28, 67, 62, 63, 295, 296, 330, 331, 332, 333, 291, 292, 292A, 313, 313A, 314, 315, 316, 254, 255, 263, 276, 346 (DeBriere)
Ruling by Court: Those exhibits are admitted with the exhibit of Plaintiff Exhibit 330.
12:31 Plaintiff moves to admit Plaintiff Exhibit 302 (Dunn)
12:32 Ruling by Court: Plaintiff Exhibit 302 is admitted.
12:32 Plaintiff moves to enter into evidence deposition designations (Dunn)
12:33 Ruling by Court: Those are admitted (Brackett, Dalton, Donovan). (Plaintiff will post them on the docket.)
12:36 Plaintiffs rest
Parties discuss possibility of amending complaint
12:43 Court in recess

1:45 Court in session
Defense Witness:
Paul William Hruz – sworn, direct (Perko)
Defendant Exhibit 29 – previously admitted
Defendant Exhibit 8 – shown to witness
Defendant Exhibit 9 – shown to witness
Defendant Exhibit 10 – shown to witness
Defendant Exhibit 11 – shown to witness
Defendant Exhibit 12 – shown to witness
Defendant Exhibit 13 – shown to witness
Defendant Exhibit 14 – shown to witness
2:55 Court inquires of witness
2:57 Cross examination (Rivaux)
Plaintiff Exhibit 46 – marked, ID'd, admitted
Plaintiff Exhibit 37 – marked, ID'd, admitted
Plaintiff Exhibit 38 – marked, ID'd, admitted
Plaintiff Exhibit 36 – marked, ID'd, admitted
Plaintiff Exhibit 39 – marked, ID'd, admitted
Plaintiff Exhibit 40 – marked, ID'd, admitted
Plaintiff Exhibit 41 – marked, ID'd, admitted
Plaintiff Exhibit 42 – marked, ID'd, admitted
Plaintiff Exhibit 45 – marked, ID'd, admitted
Plaintiff Exhibit 47 – marked, ID'd, admitted
Plaintiff Exhibit 48 – marked, ID'd, admitted
Plaintiff Exhibit 49 – marked, ID'd, admitted
3:40 Court in recess

3:55 Court in session
Continued cross examination (Rivaux)
Plaintiff Exhibit 43 – marked, ID'd, admitted

Defendant Exhibit 10 – shown to witness
Defendant Exhibit 13 – shown to witness
Plaintiff Exhibit 170 – shown to witness
4:19 Redirect (Perko)
Plaintiff Exhibit 38 – previously admitted
4:27 Defense moves to admit Defendant Exhibits 8-14 (Perko)
Ruling by Court: Those exhibits are admitted.
4:27 Court inquires of witness
4:50 Court in recess

Bench Trial – Day 5
DATE: May 18, 2023

9:01 Court in session
Defense Witness:
Stephen B. Levine – sworn, direct (Perko)
Defendant Exhibit 32 – previously admitted
9:50 Cross examination (Charles)
Defendant Exhibit 16 – previously admitted
10:35 Court in recess

10:50 Court in session
Continued cross examination (Charles)
11:06 Redirect (Perko)
11:15 Court inquires of witness
12:07 Court in recess

1:10 Court in session
Defense Witness:
Patrick Walter Lappert – sworn, direct (Jazil)
Defendant Exhibit 31 – previously admitted
1:27 Voir dire of witness by Plaintiff (Miller)
1:32 Continued direct (Jazil)
Defendant Exhibit 16 – previously admitted
1:52 Cross examination (Miller)
Plaintiff Exhibit 81 – shown to witness
Plaintiff Exhibit 135 – shown to witness
2:01 Defense Witness:
Kristopher Edward Kaliebe – sworn, direct (Perko)
Defendant Exhibit 30 – previously admitted
2:09 Voir dire of witness by Plaintiff (Gonzalez-Pagan)
2:15 Court inquires of witness
2:20 Continued direct (Perko)
2:35 Cross examination (Gonzalez-Pagan)
2:46 Court inquires of witness
2:53 Parties discuss schedule and other housekeeping matters
2:58 Ruling by Court: Motion to amend complaint is granted.
3:01 Parties discuss preliminary injunction in the Doe case
3:09 Ruling by Court: Motion for leave to amend the complaint in the Doe case is granted.
3:10 Court in recess

3:14 Court in session
Parties discuss preliminary injunction and temporary restraining order in the Doe case
3:26 Court in recess

Bench Trial – Day 6
DATE: May 19, 2023

10:20 Court in session
Defense Witness:
Ann Dalton – sworn, direct (Beato)
Plaintiff Exhibit 238 – previously admitted
10:35 Cross examination (Dunn)
Plaintiff Exhibit 29 – shown to witness
Plaintiff Exhibit 291 – previously admitted
Plaintiff Exhibit 321 – previously admitted
Plaintiff Exhibit 320 – previously admitted
Plaintiff Exhibit 292A – previously admitted
Plaintiff Exhibit 294 – previously admitted
Plaintiff Exhibit 295 – previously admitted
Plaintiff Exhibit 296 – previously admitted
Plaintiff Exhibit 297A – previously admitted
11:07 Court inquires of witness
11:14 Additional cross examination (Dunn)
11:15 Court in recess

11:20 Court in session
11:21 Defense Witness:
John Matthew Brackett – sworn, direct (Jazil)
Plaintiff Exhibit 23 – previously admitted
Defendant Exhibit 6 – previously admitted
Plaintiff Exhibit 329 – previously admitted
Plaintiff Exhibit 297A – previously admitted
Defendant Exhibits 1, 2, 3 – previously admitted
Plaintiff Exhibits 240, 242, 244 – previously admitted
Plaintiff Exhibit 326 – previously admitted
12:08 Cross examination (DeBriere)
Plaintiff Exhibit 141 – shown to witness
Plaintiff Exhibit 18 – previously admitted
Plaintiff Exhibit 166 – shown to witness
Plaintiff Exhibit 176 – shown to witness
Plaintiff Exhibit 151 – shown to witness
Plaintiff Exhibit 154 – shown to witness
Plaintiff Exhibit 155 – shown to witness
Plaintiff Exhibit 192 – shown to witness
Plaintiff Exhibit 23 – previously admitted
Plaintiff Exhibit 331 – previously admitted
Plaintiff Exhibit 284 – previously admitted
Plaintiff Exhibit 285 – previously admitted
Plaintiff Exhibit 303 – previously admitted
Plaintiff Exhibit 286A – previously admitted
Plaintiff Exhibit 291 – previously admitted

Plaintiff Exhibit 365 – marked, ID'd, admitted
12:57 Redirect (Jazil)
Defendant Exhibit 6 – previously admitted
Plaintiff Exhibit 176 – shown to witness
1:01 Court inquires of witness
1:09 Additional redirect (Jazil)
1:10 Additional cross examination (DeBriere)
1:11 Court in recess

Bench Trial – Day 7
DATE: May 22, 2023

9:00 Court in session
Defense Witness (by Zoom):
Sophie Kerttu Scott – sworn, direct (Jazil)
Defendant Exhibit 33 – previously admitted
9:13 Voir dire by Defense (Shaw)
9:18 Plaintiff moves to exclude witness testimony
9:21 Ruling by Court: The motion to exclude testimony in its entirety is denied.
9:25 Continued direct (Jazil)
9:57 Cross examination (Shaw)
10:15 Redirect (Jazil)
10:18 Court inquires of the witness
10:25 Defense rests
10:25 Court in recess

10:40 Court in session
10:43 Closing argument by Plaintiffs (Gonzalez-Pagan)
11:30 Closing argument by Defense (Jazil)
12:31 Rebuttal by Plaintiffs (Gonzalez-Pagan)
12:37 Ruling by Court: An order will follow.
12:40 Court adjourned

TAB 241-1

AO 187 (Rev. 7/87) Exhibit and Witness List

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF FLORIDA

AUGUST DEKKER et al.

v.

JASON WEIDA et al.

EXHIBIT LIST

Case Number: 4:22cv325-RH

PRESIDING JUDGE	PLAINTIFF ATTORNEYS	DEFENSE ATTORNEYS
Robert L. Hinkle	Omar Gonzalez-Pagan, Katherine DeBriere, et al.	Mohammad Jazil, Gary Perko, Michael Beato
HEARING DATE	**COURT REPORTERS**	**COURTROOM DEPUTY**
May 9-11, 2023 May 17-19, 2023 May 22, 2023	Megan Hague (May 9-11, May 22) Judy Gagnon (May 17-19)	Cindy Markley

PLTF. NO.	DFT. NO.	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS
				All exhibits were pre-filed on the docket
1		5/9/23	5/9/23	Defendants' Response to Pls' First Set of Request for Admissions
2		5/9/23	5/9/23	Defendants' Response to Pls' First Set of Interrogatories
3		5/9/23	5/9/23	Defendants' Response to Pls' Second Set of Interrogatories
4		5/9/23	5/9/23	Pls' First Set of Request for Admissions
18		5/10/23	5/10/23	AHCA GAPMS June 2022
19		5/9/23	5/9/23	Marstiller Letter to Wallace re AHCA June 2022 GAPMS
20		5/9/23	5/9/23	Fla. Admin. Code R. 59G-1.050
21		5/17/23	5/17/23	Fla. Admin. Code R. 59G-1.010
22		5/17/23	5/17/23	Florida Medicaid Definitions Policy (Aug. 2017)
23		5/9/23	5/9/23	Fla. Admin. Code R. 59G-1.035
		5/9/23	5/9/23	AHCA's Preferred Drug List, accessible at: https://ahca.myflorida.com/content/download/8681/file/PDL.pdf (online only); including but not limited to the criteria for testosterone: https://ahca.myflorida.com/content/download/6451/file/Testosterone_Criteria.pdf
		5/9/23	5/9/23	AHCA's Drug Criteria, accessible at: https://ahca.myflorida.com/medicaid/prescribed-drugs/drug-criteria (online only)
24		5/17/23	5/17/23	AHCA's Automated Prior Authorizations and Bypass Lists 01-2023
25		5/9/23	5/9/23	DRUGDEX listing for Testosterone
26		5/9/23	5/9/23	DRUGDEX listing for Estradiol
27		5/17/23	5/17/23	Prior Authorization Criteria - Testosterone
28		5/17/23	5/17/23	Agency Responses to Plaintiffs' Questions: March 1, 2023
30		5/10/23	5/10/23	Email communication between Jeffrey English and Devona Pickle – 3/22/22

33		5/9/23	5/9/23	DSM 5 Gender Dysphoria
36		5/17/23	5/17/23	AACAP Statement Responding to Efforts to Ban Care (Nov. 8, 2019)
37		5/17/23	5/17/23	AAFP – Care for Transgender Patients
38		5/17/23	5/17/23	AAP – Ensuring Comprehensive Care and Support
39		5/17/23	5/17/23	ACOG Committee Opinion on Health Care for Transgender Individuals (March 2021)
40		5/17/12	5/17/23	ACP – Attacks on Gender-Affirming and Transgender Health Care (May 3, 2022)
41		5/17/23	5/17/23	LGBT Health Disparities Policy, ACOP
42		5/17/23	5/17/23	AMA Letter to Nat'l Gov. Assoc. (April 26, 2021)
43		5/17/23	5/17/23	AMA/GLMA Issue Brief on health insurance coverage for gender-affirming care
45		5/17/23	5/17/23	APA, Guidelines for Psychological Practice with Transgender and Gender Non-conforming People
46		5/17/23	5/17/23	APA Resolution on Gender Identity Change Efforts (Feb. 2021)
47		5/17/23	5/17/23	APA Position Statement Trans and Gender Diverse Youth (July 2020)
48		5/17/23	5/17/23	APA Position Statement on Access to Care (July 2018)
49		5/17/23	5/17/23	Endocrine Society Transgender Health Position Statement
62		5/17/23	5/17/23	Ctrs. for Medicare & Medicaid Servs., EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents
63		5/17/23	5/17/23	Ctrs. for Medicare & Medicaid Servs., CMCS Informational Bulletin (July 21, 2022), https://www.medicaid.gov/federal-policy-guidance/downloads/cib07212022.pdf
64		5/9/23	5/9/23	Ctrs. for Medicare & Medicaid Servs., Decision Memo for Gender Dysphoria and Surgery (Aug. 20, 2016)
67		5/17/23	5/17/23	FDA, Understanding Unapproved Use of Approved Drugs "Off Label," (2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label
71		5/10/23	5/10/23	Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2576 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/boarddecisions/2014/dab2576.pdf
72		5/9/23	5/9/23	OASH, Gender-Affirming Care and Young People
74		5/17/23	5/17/23	SAMHSA, Moving Beyond Change Efforts (2023)
229		5/9/23	5/9/23	Template Notice of Adverse Benefit Determination
230		5/9/23	5/9/23	Template Notice of Plan Appeal Resolution
231		5/9/23	5/9/23	Sample AHCA Final Order – 20-FH0855
232		5/9/23	5/9/23	Medical records of August Dekker
234		5/9/23	5/9/23	Medical records of Brit Rothstein
234A		5/9/23	5/9/23	Medical records of Brit Rothstein
235		5/9/23	5/9/23	Medical records of K.F.
235A		5/9/23	5/9/23	Medical records of K.F.
236		5/9/23	5/9/23	Medical records of S.D.

236A		5/9/23	5/9/23	Medical records of S.D.
236B		5/9/23	5/9/23	Medical records of S.D.
236C		5/9/23	5/9/23	Medical records of S.D.
237		5/9/23	5/9/23	Dekker medical records
237A		5/9/23	5/9/23	Dekker medical records
238		5/9/23	5/9/23	GAPMS Decision Tree Checklist
239		5/9/23	5/9/23	GAPMS – GnRH for treatment of gender dysphoria
240		5/9/23	5/9/23	GAPMS – GnRH for treatment of gender dysphoria
241		5/9/23	5/9/23	GAPMS – Cross Sex Hormone Therapy – 5/20/2022
242		5/9/23	5/9/23	GAPMS – Cross Sex Hormone Therapy Report (edited) - 5/20/2022
243		5/9/23	5/9/23	GAPMS – Cross Sex Hormone Therapy – 11/2/2016
244		5/9/23	5/9/23	GAPMS – Gender Confirmation Surgery (incomplete) – 7/19/2017
250		5/9/23	5/9/23	AHCA review of research – 7/25/2016
254		5/17/23	5/17/23	Arlene Elliot email re GnRH coverage – 8/29/2016
255		5/17/23	5/17/23	Rebecca Borgert email regarding Endocrine Society guidelines – 8/29/2016
256		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for puberty suppression therapy – 8/31/2016
257		5/9/23	5/9/23	Special services criteria re GnRH coverage – 9/20/2016 (updated 11/17/17)
260		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for cross-sex hormone therapy – 11/2/2016
263		5/17/23	5/17/23	Draft GAPMS re gender-affirming surgery – 7/19/2017
264		5/9/23	5/9/23	Email exchange re Medicaid coverage of gender affirming surgery – June 2018
264A		5/9/23	5/9/23	Email exchange re Medicaid coverage of gender affirming surgery – June 2018
265		5/9/23	5/9/23	AHCA routing form tracking response to MCO question about Medicaid coverage of surgery – June 2018
266		5/9/23	5/9/23	AHCA document closing the project re responding to MCO question about Medicaid coverage of surgery – June 2018
272		5/9/23	5/9/23	Email from Andy Bardos to Andrew Sheeran re Cantor and legal research – 4/11/2022
273		5/9/23	5/9/23	Email forwarded by Andrew Sheeran from Ashley Lukis scheduling a call with James Cantor – 4/13/2022
274		5/9/23	5/9/23	Email from Andrew Sheeran to Miriam Grossman – 4/14/2022
275		5/9/23	5/9/23	Email exchange between Andrew Sheeran and Romina Brignardello Petersen – 4/18/2022
276		5/17/23	5/17/23	Email from Susan Williams to Shantrice Green re GAPMS on cross-sex hormone therapy – 4/20/2022
277		5/9/23	5/9/23	Email from Amy Zitiello to Vern Hamilton regarding FDOH guidance – 4/20/2022
277A		5/9/23	5/9/23	Email from Amy Zitiello to Vern Hamilton regarding FDOH guidance – 4/20/2022
279		5/9/23	5/9/23	Communication between Jason Weida and Dr. Michelle Cretella – 4/21/2025

280		5/9/23	5/9/23	Communication between Romina Brignardello-Petersen and Jason Weida regarding types of surgeries on which to focus – 4/25/2022
281		5/9/23	5/9/23	Communication between Jason Weida and Vern Hamilton regarding planned response to Dr. Zitiello's question about FDOH guidance – 4/29/2022
282		5/9/23	5/9/23	Draft GAPMS on gender affirming surgery (with handwritten notes) - May 2022
283		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283A		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283B		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283C		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283D		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283E		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
284		5/9/23	5/9/23	Jason Weida communication regarding articles provided to him by Dr. Van Mol – 5/6/2022
285		5/9/23	5/9/23	Dr. Van Mol communication with Jason Weida and Matthew Brackett about gender affirming care – 5/7/022
286		5/9/23	5/9/23	Dr. Van Mol's edits to June 2022 GAPMS memo – 5/13/2022
286A		5/9/23	5/9/23	Dr. Van Mol's edits to June 2022 GAPMS memo – 5/13/2022
286B		5/9/23	5/9/23	Dr. Van Mol's edits to June 2022 GAPMS memo – 5/13/2022
287		5/9/23	5/9/23	Text message from Jason Weida regarding Eknes-Tucker and James Cantor – 5/17/2022
288		5/9/23	5/9/23	Email from Shantrice Green to Susan Williams and Kelly Rubin regarding the GAPMS memo on cross-sex hormone therapy – 5/20/2022
289		5/9/23	5/9/23	Draft of GAPMS cross-sex hormone therapy memo – 5/20/2022
291		5/17/23	5/17/23	Email between Dr. Van Mol and Jason Weida regarding reimbursement – 5/21/2022
292		5/17/23	5/17/23	Invoices from Romina Brignardello-Petersen – 5/24/2022
292A		5/17/23	5/17/23	Invoices from Romina Brignardello-Petersen – 5/24/2022
294		5/9/23	5/9/23	Projected Rulemaking Timeline – June 2022
295		5/17/23	5/17/23	Gender Dysphoria/Transgender Health Care Non-Legislative Pathway – June 2022
296		5/17/23	5/17/23	Gender Dysphoria/Transgender Health Care Policy Pathway – June 2022
297		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for June 2022 GAPMS – 6/1/2022
297A		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for June 2022 GAPMS – 6/1/2022
298		5/9/23	5/9/23	Communication between Ashley Peterson and Jason Weida regarding an inventory of gender affirming care – 6/3/2022
298A		5/9/23	5/9/23	Communication between Ashley Peterson and Jason Weida regarding an inventory of gender affirming care – 6/3/2022
299		5/9/23	5/9/23	Email communication between AHCA and Magellan regarding coverage of GnRH to treat gender dysphoria

300		5/9/23	5/9/23	AHCA communication regarding the Special Services Criteria for puberty blockers – 6/10/2022
301		5/9/23	5/9/23	Communication between Jason Weida and Dr. Van Mol about a witness for the July 8th hearing – 6/14/2022
302		5/17/23	5/17/23	Email communication between Dr. Christopher Cogle and Jeffrey English – 6/27/2022
303		5/9/23	5/9/23	Communication regarding meeting between Miriam Grossman, Dr. Van Mol, Jason Weida, Andrew Sheeran, and Holtzman Vogel regarding July 8th hearing – 6/30/2022
304		5/9/23	5/9/23	Communication between Dr. Van Mol and AHCA - 7/2/2022
305		5/9/23	5/9/23	Brief of the July 8th rule hearing – 7/8/2022
306		5/9/23	5/9/23	Transcript from July 8th rule hearing – 7/8/2022
307		5/9/23	5/9/23	Email from Miriam Grossman – 7/10/2022
308		5/9/23	5/9/23	Email communications with Jason Weida and Dr. Van Mol – 7/14/2022
309		5/9/23	5/9/23	Communications regarding AHCA's development of public comment binder provided to the consultants – 7/19/2022
310		5/9/23	5/9/23	Invoice from Dr. Van Meter – 8/4/2022
311		5/9/23	5/9/23	Communication to Jason Weida regarding witnesses for a hearing – 8/10/2022
312		5/9/23	5/9/23	Invoices from Dr. Van Mol – 8/11/2022
313		5/17/23	5/17/23	Email communications regarding implementation of 59G-1.050(7) - 8/22/2022
313A		5/17/23	5/17/23	Email communications regarding implementation of 59G-1.050(7) - 8/22/2022
314		5/17/23	5/17/23	Communication between AHCA and EOG regarding planned communications about June 2022 GAPMS and 59G-1.050(7) - 8/22/2022
315		5/17/23	5/17/23	SMMC Policy Transmittal draft regarding non-coverage of gender dysphoria treatments – August 22, 2022
316		5/17/23	5/17/23	AHCA Medicaid Health Care Alert regarding prohibition on coverage for gender affirming care
317		5/9/23	5/9/23	AHCA draft response to media regarding gender affirming care – 9/1/2022
318		5/9/23	5/9/23	List of appeals for denials of hormone therapy – 12/19/2022
319		5/9/23	5/9/23	List of requests for surgery to treat gender dysphoria – 12/19/2022
320		5/9/23	5/9/23	AHCA After the Fact Request form for Quentin Van Meter – 6/13/2022
321		5/9/23	5/9/23	AHCA After the Fact Request form for Andre Van Mol – 5/26/2022
322		5/9/23	5/9/23	Draft of welcome/opening remarks for July 8th rule hearing
323		5/9/23	5/9/23	Endocrine Society public comment
324		5/9/23	5/9/23	Yale public comment
325		5/9/23	5/9/23	American Academy of Pediatrics public comment
326		5/9/23	5/9/23	Florida Medicaid, Comment Summary for Rule 59G-1.050 (20 pages)
327		5/9/23	5/9/23	Florida Medicaid, Comment Summary for Rule 59G-1.050 (17 pages)
328		5/9/23	5/9/23	Email communication between Van Mol and Weida and attachment
328A		5/9/23	5/9/23	Email communication between Van Mol and Weida and attachment

329		5/9/23	5/9/23	Florida Medicaid & G/TAT, Andrea Van Mol – May 2022
331		5/17/23	5/17/23	GAPMS – Scleral Contact Lenses
332		5/17/23	5/17/23	GAPMS – Fractional Exhaled Nitric Oxide
333		5/17/23	5/17/23	GAPMS – Breast Pump
334		5/9/23	5/9/23	Email from Miriam Grossman – July 7, 2022
335		5/9/23	5/9/23	Proposed media response from Brock Juarez to Taryn Fenske – 8/29/2022
337		5/9/23	5/9/23	Email communication between Van Meter and AHCA Counsel
338		5/9/23	5/9/23	AHCA Microsoft Teams Meeting Invite
340		5/9/23	5/9/23	AHCA Van Meter Invoice
341		5/9/23	5/9/23	HCA Hearing on General Medicaid Policy
342		5/9/23	5/9/23	Email communication between Devona Pickle and Van Meter
343		5/9/23	5/9/23	Email communication between consultants, counsel, and Van Meter
344		5/9/23	5/9/23	AHCA Teams Meeting Invites
344A		5/9/23	5/9/23	AHCA Teams Meeting Invites
345		5/9/23	5/9/23	Email communication between AHCA and consultants
346		5/17/23	5/17/23	Email communication between Sheeran and Brignardello-Petersen
347		5/9/23	5/9/23	Email communication between Van Mol and Weida
348		5/9/23	5/9/23	Van Mol comments to Alstott letter
350		5/9/23	5/9/23	Email communication between Cantor and Weida
355		5/9/23	5/9/23	Spreadsheet summarizing Florida Medicaid coverage
356		5/9/23	5/9/23	DOJ, Dear State Attorneys General Letter re Transgender Youth (March 31, 2022)
357		5/9/23	5/9/23	Curriculum Vitae of Dr. Kale Edmiston
358		5/9/23	5/9/23	Curriculum Vitae of Dr. Armand Antommaria
359		5/9/23	5/9/23	Curriculum Vitae of Dr. Dan H. Karasic
360		5/9/23	5/9/23	Curriculum Vitae of Dr. Daniel Shumer
361		5/9/23	5/9/23	Curriculum Vitae of Dr. Johanna Olson-Kennedy
362		5/9/23	5/9/23	Curriculum Vitae of Dr. Loren S. Schechter
363		5/9/23	5/9/23	Curriculum Vitae of Kellan E. Baker, Ph.D.
364		5/9/23	5/9/23	Curriculum Vitae of Dr. Aron Janssen
365		5/19/23	5/19/23	Press Release
	1	5/9/23	5/9/23	U.S. Health and Human Services Notice and Guidance on Care
	2	5/9/23	5/9/23	U.S. Health and Human Services Fact Sheet on Gender-Affirming Care

	3	5/9/23	5/9/23	U.S. Department of Justice Letter to State Attorneys General
	4	5/9/23	5/9/23	Centers for Medicare and Medicaid Services Decision Memo for Gender Dysphoria and Gender Reassignment Surgery
	5	5/9/23	5/9/23	Florida Department of Health Fact Sheet on Treatments for Gender Dysphoria
	6	5/10/23	5/10/23	Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (with attachments)
	8	5/17/23	5/17/23	Sweden's Care of Children and Adolescents with Gender Dysphoria, Summary of National Guidelines
	9	5/17/23	5/17/23	Finland's Recommendation of the Council for Choices in Health Care in Finland
	10	5/17/23	5/17/23	The Cass Review, Independent Review of Gender Identity Services for Children and Young People
	11	5/17/23	5/17/23	National Institute for Health and Care Excellence, Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria
	12	5/17/23	5/17/23	National Institute for Health and Care Excellence, Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria
	13	5/17/23	5/17/23	France's Academie Nationale de Medecine Press Release
	14	5/17/23	5/17/23	The Royal Australian and New Zealand College of Psychiatrists' Position Statement on Gender-Affirming Care
	16	5/9/23	5/9/23	WPATH Standards of Care, Version 8
	17	5/9/23	5/9/23	WPATH Standards-of-Care-Revision Team Criteria
	18	5/9/23	5/9/23	WPATH's Press Release Regarding Florida Department of Health
	19	5/9/23	5/9/23	WPATH's Statement of Opposition to Florida Draft Rule Banning Gender Affirming Care for Adolescents
	20	5/9/23	5/9/23	WPATH's Press Release on National and International Issues
	21	5/9/23	5/9/23	WPATH's Letter to Japanese Officials
	22	5/9/23	5/9/23	WPATH's Press Release Regarding New York Times Article
	23	5/9/23	5/9/23	WPATH Press Release on United Kingdom Matter
	24	5/9/23	5/9/23	Endocrine Society Guidelines on Treatments for Gender Dysphoria
	26	5/9/23	5/9/23	American Academy of Pediatrics, Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents
	29	5/9/23	5/9/23	Curriculum Vitae of Dr. Paul Hruz
	30	5/9/23	5/9/23	Curriculum Vitae of Dr. Kristopher Kaliebe
	31	5/9/23	5/9/23	Curriculum Vitae of Dr. Patrick Lappert
	32	5/9/23	5/9/23	Curriculum Vitae of Dr. Stephen Levine
	33	5/9/23	5/9/23	Curriculum Vitae of Dr. Sophie Scott
	34	5/9/23	5/9/23	Curriculum Vitae of Dr. Quentin Van Meter
	35	5/9/23	5/9/23	Curriculum Vitae of Dr. Joseph Zanga
	36	5/9/23	5/9/23	Curriculum Vitae of Dr. Michael Laidlaw

TAB A

CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2023, I filed a true and correct copy of the foregoing with the Clerk of the United States Court of Appeals for the Eleventh Circuit by using the appellate case filing CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan

No. 23-12155

In the United States Court of Appeals for the Eleventh Circuit

AUGUST DEKKER, BRIT ROTHSTEIN, SUSAN DOE, by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., by and through his parent and next friend, JADE LADUE,

Plaintiffs-Appellees,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, *et al.*,

Defendants-Appellants.

On Appeal from the U.S. District Court for the Northern District of Florida, No. 4:22-cv-00325, Honorable Robert L. Hinkle, District Judge

APPELLEES' APPENDIX
VOLUME 10 OF 10 (Tabs 230-4 – A)

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TABLE OF CONTENTS

Tab/Docket No.

VOLUME 1 OF 10

VOLUME 2 OF 10

VOLUME 3 OF 10

VOLUME 4 OF 10

VOLUME 5 OF 10

VOLUME 6 OF 10

VOLUME 7 OF 10

VOLUME 8 OF 10

VOLUME 9 OF 10

TAB 230-4 (continued)

think he has assisted Ashley's team with some questions or answering questions. And he's been available to assist with just different research projects.

Q. Was he involved at all with the categorical exclusion of treatment for gender dysphoria in developing the pharmacy coverage decisions related to that?

A. So when you ask that, you're specifically talking about the rule?

Q. I'm talking about the rule and the ways in which AHCA is implementing the rule.

A. I don't know to the extent -- I know that he assisted with research for the GAPMS report.

Q. Okay. And by GAPMS report, is that the report that is related to the categorical exclusion for treatment of gender dysphoria?

A. Yes.

Q. Why did Mr. Chen assist the pharmacy unit with the GAPMS report instead of the other pharmacists in the pharmacy policy unit? I'll strike that.

Why did Mr. Chen -- does the Canadian Prescription Drug Importation unit focus on pharmacy policies unrelated to the Canadian Prescription Drug Importation Program typically?

A. Since there's been such a long delay with the

federal approval of the Canadian Prescription Drug Importation Program, that team has assisted with various other projects within the bureau.

Q. Okay. Is that why Mr. Chen assisted with the GAPMS report for the exclusion of the treatment for gender dysphoria?

A. Yes.

Q. What types of services does AHCA develop coverage policies for? Actually -- I'm sorry; strike that. I apologize.

What does the Pharmacy Policy unit do?

A. Their job entails a lot of duties. Primarily they host and oversee the PNT and DUR meetings -- public meetings and the boards associated with that. They oversee the coverage policies specific to pharmacy. They assist with any contract language for the managed care contacts for pharmacy. They oversee the contract for our PBM contractor Magellan. Those are the primary duties.

Q. What does PBM stand for?

A. Pharmacy benefits manager.

Q. And what is that?

A. PBMs can have various duties. But the contract that I'm referring to is our rebate negotiation contract.

Q. Okay. And you said that PBM contract is with Magellan; is that correct?
A. Yes.
Q. Okay. What's DUR?
A. Drug Utilization Review Board.
Q. And I think you used one other acronym when you were discussing the public facing pharmacy meetings.
A. PNT.
Q. And what does that stand for?
A. I believe it's pharmaceuticals and therapeutics.
Q. Okay. And what is that?
A. All the responsibilities of that board are outlined in statute.
Q. Okay.
A. I can't think off the top of my head. But they meet quarterly. And we host those meetings and schedule them.
Q. Okay. A few more questions about Mr. Chen.
Is Mr. Chen a pharmacist?
A. I believe so.
Q. And is he the only pharmacist in the Canadian Prescription Drug Importation Program unit?
A. None of the other members of that team are pharmacists.

Q. So Mr. Chen is the only one?
A. Yes.
Q. Okay. Did any other pharmacist assist with the 2022 GAPMS relating to exclusion of treatment for gender dysphoria?
A. I don't know.
Q. What types of services does AHCA develop coverage policies for?
A. The coverage policies are -- outline the services that the State covers through the state plan -- Medicaid state plan or Medicaid waivers. So those are just any Medicaid related service.
Q. Does AHCA develop coverage policies for surgeries?
A. Yes.
Q. How about for prescription drugs?
A. Yes.
Q. Does AHCA develop coverage policies for every Medicaid service?
A. I don't know.
Q. Have you ever had a situation where a Medicaid recipient requests coverage for a service and there is no policy?
A. I personally have not, no.
Q. Okay. And what process does AHCA use to decide

whether to provide coverage of a Medicaid service?

A. That really depends on the specifics of what that service is.

Q. Does every service have a different process?

A. The process could vary based on what the service is that we are determining coverage for.

Q. Do you use the same process for developing pharmacy policy coverage?

A. I can't speak to the process or approach of the analysts. The process of promulgating the coverage policies into rule is always going to be in accordance with Chapter 120.

Q. During your time at AHCA, have you developed -- have you been involved in developing or has your team -- those you supervise -- been involved in developing new coverage policies to cover services?

A. Yes.

Q. Can you remember a specific service that you did that for?

A. Yes. We are currently in the process with promulgating the iBudget Waiver handbook. And as part of the updates to the handbook, one of those is to develop a new life skills development for Level 4 service. As part of that process, we also worked with our federal partners at CMS to get a waiver amendment

approved. That's a very recent example of a new service being developed.

Q. Do you have an example of a state plan service that you developed coverage for that's under current development?

A. Yes. We recently added some Puro Meno products to the DME fee schedule.

Q. And so in that instance, did you establish a coverage policy for those specific items of DME?

A. We did a coverage determination to determine if and how they could be included as a covered service as part of the DME service.

Q. And what is DME?

A. Durable medical equipment.

Q. And that includes medical supplies?

A. Yes.

Q. And Puro Meno would be a medical supply?

A. Yes.

Q. And you, to cover that service, incorporated it onto the fee schedule?

A. Yes.

Q. Did you do --

Okay. How did you assess whether to decide to incorporate Puro Meno into the fee schedule?

A. So I can't speak to all the steps that the

analyst -- the specific steps that they took. But just speaking overall, determined if we had the legislative and state plan authority to cover it; determined if it was -- if there would be a fiscal impact.

And we approach coverage like that example to, you know, try and make sure it's budget neutral since we are -- our coverage is driven by our general appropriations and our state general appropriations act. And then determined if and what types of updates would be needed to any of the Medicaid rules. That's the general process for determining that kind of coverage.

Q. So to make a coverage determination you look at your legislative authority -- authority under the state plan -- and you do a fiscal analysis and hope for budget neutrality. You check to see if there's any updates to Medicaid rules. Anything else?

A. Making sure that it's an allowable service under Medicaid, as well; which would entail that it meets all federal, state rules and regulations for coverage. But, like I said, all the details of the research that the team does -- I can't speak to exactly everything that they read or looked at.

Q. And if in that coverage determination you decide to cover that service, do you then incorporate it into the fee schedule?

A. In the example I gave, that's what we did, yes.
Q. Are there any situations where you would not incorporate it into the fee schedule?
A. Yes.
Q. What are those circumstances?
A. That would vary depending on what the actual request or coverage benefit is that we're looking.
Q. Can you think of an example?
A. Yes. Last legislative session, I believe it was, there was a specific language regarding the coverage of human donor milk and milk derivatives for inpatient use. Because it was under inpatient, that is a -- the reimbursement for that is different and isn't included in a fee schedule.
Q. Okay. That makes sense.
Once this coverage determination is made, do your responsibilities include reviewing that to determine whether to approve the decision?
A. Yes.
Q. And how do you go about doing that?
A. We usually meet with the team. We do a walkthrough, have discussions around the proposal and the recommendation. And then we put together -- depending on what the change is, put together a document to get approval from management -- upper management.

Q. Does that document have a specific title -- the same title every time?

A. No.

Q. How would you identify that document?

A. So if a fee schedule change was needed, there is a formal routing process for the rule promulgation process that would be routed through management and signed off on.

Q. Okay. Are there other documents that would be routed through management to be signed off on?

A. Yes.

Q. And what are the titles of those documents?

A. It depends on the situation. For example, we also have a steering committee at the agency for the division of Medicaid. And we call that a decision point that would be to the steering committee.

Q. Okay.

A. And the Medicaid director or agency leadership is part of that committee. And so that is also a way for us to get approval.

Q. For those coverage determinations that you reviewed and put together in a document for administrative review, who in the administration reviews that document?

A. Depends on what that is. So for administrative

rule -- that needs to be signed off by several agency leadership; including the general counsel, the agency secretary for a proposed rule. So it would depend on what the final document is who the final signatory would be.

Q. Distinct from implementation of the coverage determination, is there a review by the administration of just whether to cover the Medicaid service?

A. It depends on what the specific circumstances are.

Q. Okay. Can you think of an example of the administration reviewing a determination of whether to cover a service?

A. Can you be more specific? So the waiver example I used a while back would be signed to submit the waiver -- the iBudget waiver -- with the changes. That would have been signed by the Medicaid director prior to submission to federal CMS.

Q. How long have you been involved in the process of doing coverage determination?

A. Since my time at AHCA.

Q. Okay. So since -- I'm trying to take notes here. So since August of 2018?

A. January of 2018.

Q. January of 2018. Thank you.

And when you're making coverage determinations, you coordinate with AHCA rules unit if a rule change is needed; is that right?

A. Yes.

Q. Okay. Under what bureau does the AHCA rules unit fall?

A. Under the Bureau of Medicaid Policy.

Q. Okay. So under your unit?

A. In the bureau.

Q. I'm sorry. Under you're bureau?

A. Yes.

Q. And you coordinate with AHCA's pharmacy policy unit; which falls under your -- the pharmacy policy unit falls under your bureau as well; is that right?

A. Yes.

Q. Okay. Do you coordinate with other bureaus in developing coverage determinations?

A. Yes.

Q. Which ones?

A. All the bureaus in the division work closely together. And there have been some recent changes with that structure. But speaking prior to those changes, the Bureau of Medicaid Program Finance would be probably be the primary bureau; because they assist with determining or setting our fee schedules and our rates

and the methodologies and doing fiscal impact analyses -- data analytics -- Medicaid data analytics.

As part of the whole development package, we talk to all the bureaus because plan management operations can be affected if there is an update to the contracts. The Bureau of Medicaid Quality who monitors and oversees the provision of services through those contracts -- and they have various other duties. But depending on what the change is, we would communicate with most of the bureaus within the division.

Q. Okay. You just mentioned some recent changes in terms of that structure. What are those recent changes?

A. The Bureau of Medicaid Finance and Medicaid Data Analytics are reporting directly to Tom. And Plan Management Operations, Quality, and Policy are reporting directly to Brian Meyer.

Q. And why is that a change?

A. Previously I had been reporting directly to Tom Wallace.

Q. Is Brian Meyer's position a new one?

A. I don't know all the details of those changes.

Q. Okay. Who made the decision to make those changes?

A. I don't know.

Q. Okay. Who oversees the rules unit?
A. Cole Giering is program administrator of the rules unit.
Q. How long has he been in that position?
A. I'm not sure exactly. But it was since I've been bureau chief.
Q. Okay. So --
A. August of 2021.
Q. Thank you.
Do you coordinate -- in making coverage determinations, do you coordinate with the chief medical officer for AHCA?
A. Yes.
Q. Who is that?
A. Dr. Christopher Cogal.
Q. Can you describe how you coordinate with him, what that process looks like.
A. Again, it really depends on the specific question or policy we're reviewing. But it would consist of meetings or discussions.
Q. What types of things would you discuss?
A. So, for example -- I'm going to go back to the two examples of recent activity. So he wasn't involved in the iBudget Waiver changes at all. But for the human donor milk, he assisted when we had originally done the

legislative bill analysis when the legislation was first proposed. And so for the development of how to implement the changes, he was consulted. I don't know the specific conversation, but I do know that he was involved in that process.

Q. On what kind of expertise do you rely on him for? What kind of input does he provide in the process? Is it medical in nature?

A. I don't know.

Q. Okay.

A. To the extent -- I know he's an available resource for the team. But I don't know to the extent that -- of his involvement.

Q. When he gets involved, is it through a formal process? Or is it just a decision to reach out and ask him for advice? How would you characterize it?

A. From my experience at the bureau level, it's been more informal. I know that there have been -- he's been formally asked to review bill analysis or -- but how that process works, I don't know.

Q. Okay. Are there people under you who are more likely to communicate with Dr. Cogal?

A. I believe there's staff that communicate with him more than others, yes.

Q. What staff are those?

A. Ashley Peterson has been meeting with him on some projects lately. Again, it really depends on the project. But we are working with him on continuous glucose monitoring -- questions around coverage there. And Jesse Bottcher and his team.

Q. When you say Jesse Bottcher and his team, would that include the GAPMS process?

A. His team is responsible for it.

Q. In coordinating with Dr. Cogal -- in the coordination between Mr. Bottcher's team and Dr. Cogal, would that include the GAPMS process?

A. I don't know the extent to which he is involved in that.

Q. Okay. To your knowledge, has he ever been involved in that?

A. I don't know specifically.

Q. Have you and Dr. Cogal and anyone from Mr. Bottcher's team ever met to discuss the GAPMS process?

A. The process, yes. When I first took the role, we had met to talk through the process. But I can't remember the specific conversation.

Q. Okay. Switching gears a bit. When I use the term "Florida Medicaid managed care plan," do you know what it means?

A. Yes.
Q. What does that term mean?
A. Those are the managed care plans that the agency contracts with to provide the services through the managed care delivery model.
Q. Do Medicaid managed care plans have their own coverage policies?
A. The agency's coverage policies are incorporated into the managed care plan contracts by reference. And there are requirements outlined in the contract with how the managed care plans have to provide services.
Q. Are you aware of managed care plans having their own policies that incorporate Florida Medicaid's policies?
A. I don't know.
Q. Have you ever seen a copy of a Florida Medicare managed care plan document that discusses the coverage of a Florida Medicaid service?
A. I reviewed the plans' member handbooks or enrollee handbooks. And I've seen their resources available on their websites that weigh out what they cover. I can't remember if I've ever seen an official document titled "Coverage Policy."
Q. So my question is: Have you ever seen a document from a Medicaid managed care plan -- formal or

informal, it doesn't matter -- with information that contains the criteria used to determine if Florida Medicaid will cover a service?

A. I believe that information is in the handbooks. But I can't recall any specific documents drafted by the plans.

Q. What unit would be responsible for communicating with managed care plans about their coverage of Florida Medicaid services?

A. That would depend if they had a question for the agency on the agency's coverage of a covered service or a contractually required service. Those most likely would be sent to Medicaid policy.

Q. Okay.

A. To review.

MS. DEBRIERE: Okay. Yes. Definitely. Just a couple more questions, if that's okay.

BY MS. DEBRIERE:

Q. Are you okay Ms. Dalton?

A. Yes.

Q. Who would review those questions? Who specific -- like, what specific individuals?

A. It would depend on what the question was.

Q. Okay. If the managed care plan doesn't have a question, is there any process that exists that just

involves overseeing whether a Medicaid managed care plan is covering a Florida Medicaid service?

A. The Bureau of Plan Management Operations is the bureau that oversees the adherence to the contract. All the contract managers for the individual plans are housed there. So if it was a compliance question on if the managed care plan was following the requirements in the contract, that would be Plan Management Operations most likely who would be the first point of contact for the plans.

Q. Okay. Can MCOs create their own guidelines for implementing AHCA coverage policies?

A. I don't know.

Q. Who would know that?

A. It would be in the contracts.

Q. Okay.

A. The parameters around what their materials are allowed to contain and if the materials have to be reviewed and approved by the agency.

Q. Okay. And that would be the Bureau of Planned Management Operations who does that -- takes on that role? And if not, then who?

A. I believe it would depend on what the materials being reviewed are. Just like with reporting -- there are different report owners in different bureaus within

the division of Medicaid that review compliance with the -- the plan's compliance with the contracts. But the first point of contact for submitting those materials and making sure that they're submitted would be through Plan Management Operations.

Q. And who is that bureau chief? Remind me.

A. Pam Hall.

Q. Okay. One last question. Are you aware that MCOs have their own guidelines for specific types of Medicaid services?

A. I can't speak to that. I don't know.

Q. Do you know who would know?

A. Are you asking if it's a required -- or if they're allowed to --

Q. No. I'm just asking if you're aware. So are you aware that they have their own --

MR. PERKO: Asked and answered.

MS. DEBRIERE: -- criteria guidelines?

THE WITNESS: I would have to review the contract.

BY MS. DEBRIERE:

Q. Okay. So is that a no, you are not aware as we sit here today without having anything in front of you?

A. Correct. I don't know without seeing a specific example or reviewing the contract.

Q. Okay. Do you want to take a break?
A. Yes.
(Brief recess.)
BY MS. DEBRIERE:
Q. Ms. Dalton, just briefly -- when we took a break, did you discuss this deposition with anyone?
A. No.
Q. Did you discuss it with your attorneys?
A. Just briefly.
Q. Okay. When I use the term "quality improvement organizations" or QIOs, do you know what I mean?
A. Yes.
Q. What does that term mean?
A. Quality improvement organization.
Q. Yeah. Is eQHealth a QIO?
A. Yes.
Q. And what do they do?
A. I don't know the whole scope. But their main function in their contract with the agency is the -- to do prior authorization for fee for service services.
Q. Okay. What does prior authorization mean?
A. It's a utilization management tool to ensure that the services are in their scope, authorized, and appropriate.
Q. By "appropriate," what do you mean?

A. That the service that's being requested is allowable and delivered within the parameters of the Medicaid program.

Q. Who makes the request for prior authorization?

A. I don't know the details of how the process works.

Q. Okay. By parameters, do you mean the parameters set by AHCA's coverage policies?

A. Yes. And administrative rule.

Q. Okay. Is administrative rule distinct from a coverage policy?

A. Yes. Not all of the administrative rules incorporate a coverage policy by reference.

Q. Okay. So an example of that would be the definition of medical necessity -- would be an administrative rule that sets out the parameters for coverage but does not include a specific coverage policy?

A. The definition of medical necessity is actually in the definitions policy -- which is a document incorporated by reference into the text of the administrative rule.

Q. Okay. Do QIOs like eQHealth -- do they have their own coverage criteria they rely on?

A. Yes.

Q. Do you coordinate with QIOs regarding those coverage criteria?

A. I personally do not.

Q. Does anybody on your team?

A. The eQHealth contract is housed in the Bureau of Medicaid Quality.

Q. Okay.

A. So they would be a lead in managing of that contract and communicating with the vendor. But I do know that we have communicated with them in the past -- the Bureau of Medicaid Policy has.

Q. What types of things have you communicated about in the past?

A. The first example that comes to mind is recently the agency opened the definitions rule policy and did communicate that that rule was being opened with eQHealth.

Q. Okay. Are MCOs and QIOs bound by AHCA's coverage policies?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: As I stated before, the contract for the managed care plans incorporates the coverage policies by reference. And the plans are not allowed to be more restrictive than the coverage

policies. I don't know the specific language off the top of my head with the requirements of how they adhere to the policies. But that is in the contract.

BY MS. DEBRIERE:

Q. Okay. So the MCO's obligation to adhere to AHCA's coverage policies is set forth in the contract?

A. Yes.

Q. Okay. What about QIOs?

A. I don't know the specific language off the top of my head. But that information is also in the contracts on how the managed care plans' contracted QIO vendors are expected to operate.

Q. Okay. Is there a formal approval process for the QIO's coverage criteria?

A. I don't know.

Q. Is Magellan a QIO?

A. I don't know.

Q. Okay. Does Magellan conduct prior authorization of Florida Medicaid services?

A. I don't know.

Q. Does Magellan review the request of a Medicaid recipient to authorize prescription drug services in the Fee for Service program?

A. I don't know.

Q. Do you know what -- do you know if Magellan plays any role in determining coverage of pharmacy services under Florida Medicaid?

A. I believe the agency has a contract with them to adjudicate the claims. But I don't know the scope of that contract.

Q. What do you mean by adjudicate the claims?

A. I don't know the whole scope of that process or the contract.

Q. When you just use that phrase, what did you mean by that?

A. That they're involved in the reimbursement process.

Q. Okay. And would the reimbursement process involve determining the eligibility for the service itself?

A. I don't know the extent of that process.

Q. Would anybody at AHCA know or be able to answer that question?

A. I don't know.

Q. Moving back to coverage determinations undertaken by your bureau, who is the final decisionmaker as to whether AHCA will adopt that coverage determination?

A. Can you repeat the question.

Q. So earlier we were talking about your bureau undertaking coverage determinations of Florida Medicaid services; correct?

A. Yes.

Q. Who is -- before AHCA or anyone at AHCA can act on that determination, who is the final decisionmaker?

A. Again, it depends on the circumstances. And I can only speak to the signatory of who needs to be -- to officially sign off. But the example I used before for a federal authority submission, that would be whoever was designated from the agency as the Medicaid director or the Medicaid state plan approver.

Q. Okay.

A. And then administrative rule to actually complete the promulgation process. That's actually signed off by the head of the agency, which here would be our secretary.

Q. Okay. When coverage policies are promulgated, are there multiple drafts of those policies? Are there ever multiple drafts of those policies?

A. Can you repeat the question.

Q. When you're developing a coverage policy, are there multiple drafts?

A. It would it depend on what the change was.

Q. So there are times when coverage policies have

multiple drafts?

A. Yes.

Q. And how do you track any changes to those policies during the drafting process?

A. So specific to the coverage policy, we typically use a document called a revisions template; which tracks the changes being proposed.

Q. Okay. Is there a limit to the people who can make changes to the revisions document?

I'm sorry; the revision just tracks who has made the changes; is that right?

A. So it tracks what the old policy said, what the new changes are, if there's a reason for the change. I'm not sure if it includes who the requester of the change is.

Q. Okay. Does it record who is making the change?

A. I can't recall if that's on the template.

Q. Is anybody at AHCA allowed to make a change?

A. So for most of the coverage policies, there's a subject matter expert assigned to that program area who any changes would filter through. And then they have to work with the rules unit who is actually making the changes to the coverage policy and promulgating that through the rulemaking process.

Q. Okay. Just switching quickly to some specific

Medicaid services. Are coverage policies regarding surgery adopted into rule?

A. Yes.

Q. And are they in handbooks or a handbook?

A. I don't believe it's one specific handbook.

Q. Do you remember the names of any of the handbooks they are contained in?

A. We have a transplant services coverage policy.

Q. Okay.

A. Which I would consider inclusive of surgical. We have an inpatient services coverage policy. Without seeing the list of policies, I can't recall off the top of my head.

Q. Give me one second.

Would coverage policies about surgeries be in the Ambulatory and Surgical Center Services Policy?

A. I don't know the content of that policy off the top of my head.

Q. Okay. You said inpatient hospital services would contain surgery policies?

A. I don't know all the content in the policy without looking at it. But it...

Q. If it mentions surgery in the handbook, is it going to have a coverage policy related to it?

How would you know if a handbook covered

surgery or contained a surgery coverage policy in it?

A. I would have to read the handbook. Depending on what the specific question was, what type of surgery.

Q. Okay. What about prescription drug coverage policies? Are those adopted into rule?

A. I believe there is a rule specific to pharmacy policies and prescription drugs, yes.

Q. Okay. And then I'm just going to flip my computer around here and go to this page. We're looking at what's titled Agency for Health Care Administration Drug Criteria. AHCA.myFlorida.com/Medicaid/prescribed_drug_criteria.shtml.

And I assume, Ms. Dalton, I'm seeing here -- are you just seeing a list of drug criteria?

A. Yes.

Q. Is this an exhaustive list of the drug criteria that AHCA relies on?

A. I don't know.

Q. Who would know that?

A. Ashley Peterson and her team may be able to confirm.

Q. Okay. And why wouldn't this be an exhaustive list?

MR. PERKO: Object to form.

THE WITNESS: I'm not personally very familiar with this page.

MR. PERKO: Counsel, for the record, can we read the URL.

MS. DEBRIERE: Absolutely. Well, I think I -- Gary, do I not know what a URL is?

MR. PERKO: The website address.

MS. DEBRIERE: So I think we read most of it. But I can start with https://AHCA.myFlorida.com/Medicaid/prescribed_drug/drug_criteria.shtml.

MR. PERKO: Thank you.

MS. DEBRIERE: Absolutely.

BY MS. DEBRIERE:

Q. Do you know what categorical exclusion means?

MR. PERKO: I'm going to object to form. I guess I'm a bit confused, Counsel. You already defined what categorical exclusion means at the beginning of this deposition.

MS. DEBRIERE: Well, that's categorical exclusion -- you're right, Counsel. It contained the statement "categorical exclusion"; just categorical exclusion of a very specific set of services. The treatment for --

MR. PERKO: That wasn't the definition at the

beginning. But go ahead.

BY MS. DEBRIERE:

Q. How about this, Ms. Dalton: Can you provide an example of a categorical exclusion under Medicaid?

A. I can't think of an example. I'm familiar with the term. I cannot think of an example.

Q. Okay. I'm trying to think of one too.

Does AHCA -- does Florida Medicaid cover private duty nursing service for individuals over the age of 21?

A. Not through the state plan.

Q. Okay. Do they cover it through home and community based services with a Medicaid waiver?

A. Yes.

Q. Okay. And if Florida Medicaid does not cover private duty nursing services for individuals over 21 under the Medicaid state plan, is that a categorical exclusion?

A. Yes.

Q. And does the agency categorically exclude any Medicaid service for beneficiaries under the age of 21?

A. Can you repeat the question.

Q. I'm sorry. Bear with me one second, Ms. Dalton. I'll come back to that.

Do your responsibilities include ensuring that

coverage policies meet the standards under EPSDT?

A. The Bureau of Medicaid Policy doesn't oversee the monitoring of the adherence to the policies or the provision of services. In terms of ensuring that the policy language complies with the federal EPSDT requirements, yes.

Q. And how do you ensure that compliance when developing coverage policies?

A. It depends on the specific coverage policy. But the majority of the service specific coverage policies include language incorporating EPSDT by reference and language from the federal regulation.

Q. Generally speaking, what is that EPSDT requirement?

A. That the State must provide all medically necessary services to children ages under 21.

Q. Does the State have to provide a service under EPSDT to a Medicaid recipient under 21 if that service is experimental?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Do you know what I mean when I say experimental?

A. Yes.

Q. So same question. Does the State have to

provide coverage to children under age 21 if that health service is considered experimental?

MR. PERKO: Object to form.

THE WITNESS: The State is allowed to develop its own definition of medically necessary or medical necessity; which Florida has done and promulgated in administrative rule. And part of that definition does include the parameters by which a service would not be determined medically necessary; and, therefore, not required under the EPSDT.

BY MS. DEBRIERE:

Q. Okay. And that definition of medical necessity includes the requirement that the service not be experimental; correct?

A. I cannot recall the exact definition off the top of my head. But that is in -- promulgated in the definition coverage policy.

Q. When you say that is --

A. The definition of medical necessity.

MS. DEBRIERE: Okay. We can mark -- I have a copy of the rule so you can reference it. We can mark that as Exhibit 3. And that's 59G-1.010.

We might have forgotten to put a copy in. If we did, it's my fault.

MS. DUNN: I have a copy right here.

(Plaintiff's Exhibit No. 3 was marked for identification.)

MS. DUNN: Yeah. It's right there. Last definition on that page.

THE WITNESS: It doesn't seem to be the whole --

MS. DUNN: It's not.

MS. DEBRIERE: It's not. We ended it at "N," because it's a very large coverage policy and we are trying to save some trees.

BY MS. DEBRIERE:

Q. So if you look at the definition of "medically necessary" or "medical necessity," does that contain a requirement that the service not be experimental?

A. Yes.

Q. And so under EPSDT, can the agency deny a medical service to a child under 21 if they deem it to be experimental?

A. Yes.

Q. Okay. Who is responsible for compliance with EPSDT? Is it a specific person?

A. I don't know who is responsible.

Q. Is it someone within your bureau regarding EPSDT as it relates to the development of coverage policies?

A. There isn't a specific person in my bureau, no.
Q. Are there any written guidelines about ensuring compliance with EPSDT with developing coverage policies?
A. Can you repeat.
Q. Are there any written guidelines relied on to determine whether a coverage policy complies with EPSDT, other than that contained in the Federal Medicaid Act?
A. I don't know specific -- all the specific documents that the analysts rely on when developing the coverage policy. But as part of that process, the expectation is to review the federal guidelines and statute and other rules and regulations of governing the Medicaid program to ensure that the coverage policy adheres to the Medicaid program federally and state.
Q. And that's an expectation of the staff within your bureau?
A. Yes. It's the common practice when approaching research regarding changes to the policy -- a policy.
Q. Okay. When I use the term "comparability," do you know what I mean as it's laid out in regulations implemented in the Federal Medicaid Act?
A. You may have to give me some more context.
Q. So under the Federal Medicaid Act, there is a requirement that state agencies who administer Medicaid do so in a way that all Medicaid recipients receive

comparable services. Are you familiar with that requirement?

A. Vaguely sounds familiar.

Q. Is your bureau required to be familiar with that requirement in developing coverage policies?

A. I can't speak to that without more information.

Q. Okay. Is there anyone who can speak to the requirement -- is there anyone who can speak to ensuring that the policy comply with comparability under the Federal Medicaid Act?

A. So, again, I think it really would depend on what the specific question is regarding or which specific coverage policy. As I said before, a lot of the coverage policies have a specific subject matter expert with knowledge of that service area. So it just really would depend.

Q. Okay. I'm just going to make myself a note.

What is the purpose -- turning back to Exhibit 3 and the definition of medical necessity -- what's the purpose of AHCA's medical necessity standard?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Does AHCA's medical necessity standard have a purpose?

MR. PERKO: Object to form.

THE WITNESS: I don't know what you mean.
BY MS. DEBRIERE:
Q. What is the purpose of the definition of medical necessity?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. What do you use it for?
A. The definition is relied on a lot. Most of the service specific coverage policies refer and incorporate by reference the definitions policy and make a statement that the service must be medically necessary as part of the requirement for reimbursement.
Q. If a Medicaid recipient makes a request for a Medicaid service, in order for that service to be authorized, does it have to be medically necessary?
A. Yes.
Q. Do managed care plans rely on AHCA's medical necessity standard in their prior authorization process?
A. I can't recall the exact contract language. But, yes.
Q. And what about QIOs?
A. I don't know.
Q. Regardless of the method in which Medicaid is delivering the service -- fee for service or managed care -- in order for that surface to be authorized, does

it have to be medically necessary?

A. I don't know the details of the actual authorization process. I do know that the expectation from policy prospective is that the services have to be provided in accordance with the agency's coverage policies and administrative rules.

Q. And that includes the definition of medical necessity?

A. Yes.

Q. If AHCA finds that a Medicaid service is experimental, would AHCA or a contractor or managed care plan still review whether service meets other portions of AHCA's medical necessity definition?

A. I don't know the extent of their review.

Q. What about your review at AHCA for fee service?

A. Again, I don't know eQHealth or QIO vendors' process.

Q. Do all Florida Medicaid services require prior authorization?

A. I don't know. I don't believe so.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 4, which is the GAPMS Report on Cross-Sex Hormone Therapy, dated May -- I believe we did the May version.

So what I'm showing you is Bates stamped

beginning at Defendant 00126105. I should pull out my own copy.

And that continues through, Court Reporter -- this one is not Bates stamped. It's weird. This one doesn't have a copy. This copy is not Bates stamped. But it is entitled Cross-Sex Hormone Therapy GAPMS Determination Report With Recommendation.

That's very odd. Very odd. I don't think it's a huge deal.

(Plaintiff's Exhibit No. 4 was marked for identification.)

BY MS. DEBRIERE:

Q. So on the last two pages, Ms. Dalton, starting at "Coverage policy" -- and it starts, "Federal regulations."

"Federal regulations for Medicaid..." and continues on through the definition of medical necessity --

MR. PERKO: Can you give a page number.

MS. DEBRIERE: Oh, yes. Thank you, Gary.

So page 8, 9, and a tiny bit of the top of 10.

THE WITNESS: I'm there.

BY MS. DEBRIERE:

Q. Take all the time you need to read it. And

afterwards, if you can tell me if this is an accurate portrayal of the standard used to determine Florida Medicaid coverage for prescription drugs.

MR. PERKO: Do you have another copy?

Thank you.

BY MS. DEBRIERE:

Q. I think it starts at the top of page 8 -- middle of page 8. So reviewing that standard, is that what's used to determine whether Florida Medicaid will cover a prescription drug?

A. Can you direct me more to where you're referring. I read both pages 8 and 9, and I don't think I can speak to the specifics of all this information.

Q. Okay. When reviewing whether to cover a prescription drug, does AHCA look at -- here on page 8 it says AHCA is -- "The program is required to asses data on drug use against predetermined standards consistent with the following compendia." And then it lists three types of compendia and the peer reviewed medical literature. Is that an accurate statement of AHCA policy?

A. I don't know.

Q. Who would know that?

A. I don't know if I can speak for them. But I would ask one of the pharmacists.

Q. Would you ask Ashley Peterson? Or would you ask one of the pharmacists that works under her?

A. I specifically would go to Ashley, as she's my direct report. And then she would research the question for me.

Q. Okay. Would research involve asking one of her pharmacists?

A. I don't know. I can't speak for her process.

Q. So going to page 9, top of the page says, "In order to be reimbursed by Medicaid, a drug must be medically necessary."

Is that the same as the definition contained in the 59G-1.010 that we just reviewed -- Exhibit 3?

A. I don't understand what you mean by the same.

Q. Does medically necessary mean the same as the definition in the definitions policy?

A. I would think so.

Q. Okay. And it is, "Either prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in the Medicaid Act or prior authorized by a qualified clinical specialist approved by that agency."

Is this an accurate recitation of the standard AHCA uses to authorize prescription drug coverage?

A. I don't know.

Q. Would Ashley Peterson know that information -- her or her team?

A. I would think so, yes.

Q. Okay. The next thing it says, "The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows." And then it lists three criteria.

Reading over that statement, are these currently the criteria AHCA uses in authorizing drugs for off label purposes?

A. Again, I don't know.

Q. Would Ashley Peterson know the answer to that question?

A. I would think her team would, yes.

Q. Is this the type of information -- looking at this, is this the type of information that would be contained in a coverage policy adopted in rule?

A. I'm not sure.

Q. Why aren't you sure? What's throwing you about it?

A. I don't know the content of the rules off the top of my head.

Q. But I think my question is a little different. So does this appear to be the type of information that would be contained in a coverage policy adopted into

rule?

A. I can't speak to that. I don't know because of the reason I stated. I will say the coverage policies traditionally do not repeat regulation or requirements or information that are found elsewhere; for example, in Florida statute or in federal regulation. And each coverage policy is structured somewhat similarly, but does contain very different information. So I don't know if this is information that's found off the top of my head in one of our policies.

Q. Okay. I think you -- do all prescription drugs require prior authorization to be reimbursed by Medicaid?

A. I don't know.

Q. Who would know that?

A. I would think Ashley Peterson and her team. Or it might be available on the information on our website regarding pharmacy policy and authorization criteria.

Q. Okay. So Ms. Peterson would be familiar with authorization criteria for prescription drugs?

A. Yes. Or she would know where to look.

Q. Okay. Specifically related to pharmacy coverage policies, how are they developed?

A. The coverage of the pharmacy services is a little different than the other coverage policies. I

don't know all the details that go from the analysts into the developments. But because there is different statutory requirements -- Florida statutory requirements around pharmacy services, including the PNT and DUR board -- the process for overseeing the coverage of pharmacy services is a little different.

Q. In reviewing whether a prescription drug requires a coverage policy -- strike that.

Do you use the GAPMS process to determine pharmacy coverage -- to determine whether coverage of a prescription drug is experimental?

A. I don't know specifically for determining if a prescription drug is experimental. I don't know.

Q. When you develop coverage policies in your bureau, does that include a determination as to whether a service is experimental?

A. So the coverage policies are drafted specific to the covered services that we've been approved to provide.

Q. Okay.

A. By the federal government. So that is the driving factor on how we would initially approach the coverage and organize or draft a coverage policy asserting a service that we are authorized to provide.

Q. So separate and apart from developing coverage

policies, the responsibilities of your bureau also include determining whether a service is experimental; is that correct?

A. So that would be part of the GAPMS process that is outlined in administrative rule.

Q. Okay. Do you use the GAPMS process for prescription drugs?

A. Without researching or consulting others on the team for a specific example, I don't know the interplay between the different authorities and how that works.

Q. Which team is responsible for the GAPMS process?

A. That position is within the Medicaid -- Bureau of Medicaid Policy.

Q. Earlier speaking about teams under the bureau, which teams is responsible for the GAPMS process?

A. Jesse Bottcher is the manager over the position that is primarily responsible for the GAPMS process.

Q. Are there any other teams that are primarily responsible for the GAPMS process? Or is it only Jesse's team?

A. So in terms of listing that as a primary responsibility on a job description, that would be Jesse's team.

Q. Should the people on Jesse's team be aware of

every GAPMS process that's undertaken?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: So as the bureau chief of Policy, I do try to keep staff within the bureau aware of everything that's happening within the bureau -- especially when a determination has been made. Jesse's team would definitely need to be aware, because there could be potential impacts with a specific service coverage policy. But I do think every circumstance is different. So I can't say just in a general statement to your question.

BY MS. DEBRIERE:

Q. Would it be typical for Jesse's team to not be aware of a GAPMS report being developed?

A. I can't say if it would be typical. I have not overseen very many GAPMS in my time as bureau chief.

Q. So as the bureau chief with Jesse's team being primarily responsible for GAPMS, would you as that chief endeavor to ensure that Jesse's team was aware of all GAPMS reports being written?

A. Yes. We meet the managers on -- my direct reports and I meet regularly at least twice a week for an hour and discuss projects that are going on with each team and provide updates. So the ongoing bureau

activities are regularly discussed with the management team.

Q. Okay. Do you know what a drug compendium is?

A. I recognize the term, but don't think I can define it.

Q. Do you know which compendia are listed in the Federal Medicaid Act?

A. No.

Q. I'm just going to screen share again. I'm showing right now on my screen -- the URL is https://AHCA.myFlorida.com/Medicaid/prescribed_drug/pharm_thera/pdf/PDL.pdf. The title of this document is Preferred Drug List, Effective January 21st, 2023.

Do you know what the preferred drug list is?

A. Yes.

Q. What is it?

A. It's list of drugs developed that the managed care plans must adhere to. And it has to do with rebate negotiations and is recommended by the PMT committee.

Q. Perhaps you just answered this. But who develops the PDL?

A. The agency.

Q. What is the PMT committee's role in it?

A. Per statute, they make recommendations to the agency.

Q. Okay. Does the DUR have any role in developing the PDL?

A. I don't know. I don't believe so.

Q. And this PDL applies to managed care plans; is that correct?

A. And fee for service.

Q. Okay. So on here -- I'm going to have to do Control+F. Pardon; one second.

It's very small. So tell me if you need to make it any bigger.

Okay. On here you will see the drug estradiol -- e-s-t-r-a-d-i-o-l -- listed. And there is many versions here starting at it looks like this line continuing all the way down until we hit norethindrone AC. So the fact that estradiol is lied on the PDL, does that mean Florida Medicaid will cover it if the eligibility criteria are met? Excuse me. Scratch that.

Since estradiol is listed on this PDL, does it mean that Florida Medicare will cover it?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. If any drug is listed on the PDL, does that mean Florida Medicaid will cover it?

A. I don't know the interplay between the PDL and

the other rules and regulations covering pharmacy services.

Q. Okay. Over in this column at the top of page, it reads "Clinical PA required." And it also has a column for a minimum and a maximum age. What does clinical PA required mean?

A. Operationally, I don't know.

Q. Do you know it in any other version?

A. I understand the words. But I don't know in the context of the program or the PA process what that means.

Q. What does "PA" stand for?

A. Prior authorization.

Q. Okay. Is it possible that clinical PA -- so if we scroll down to estradiol -- this version with a minimum of an age of zero, maximum age of 999 -- and it says "no" under the column of clinical PA required, do you know what that means?

A. No.

Q. Who would know that?

A. Ashley Peterson and her team are lead on this.

Q. Do you know what it means to have a minimum age column? Why that's significant or why it's on there?

A. Specific to this document, no.

Q. Same with maximum age?

A. No, I don't know the reason why it's on there.
Q. Since you've been at the agency -- January 2018?
A. Yes.
Q. How many GAPMS processes have you been involved in?
A. Two completed. And maybe one or two discussions.
Q. How many pending?
A. I don't know.
Q. Do you know currently how many GAPMS are pending?
A. Clarify "pending."
Q. Why don't you tell me what you meant by completed.
A. Two that have been signed by agency leadership.
Q. Okay. And how many reports are in the stage of being written and not yet signed?
A. I don't know.
Q. To be clear, though, as bureau chief you meet weekly with Jesse Bottcher and his team who are primarily responsible for GAPMS.
A. I meet weekly with Jesse Bottcher and my team.
Q. Okay.
A. I don't regularly meet with the individual

teams, but with the managers.

Q. When you meet with Jesse, do you discuss GAPMS?

A. Not routinely. We have before.

Q. What are the other responsibilities of Jesse's team?

A. The three managers under Jesse each have units that are responsible for the developments of the service specific coverage policies. His team also oversees the eligibility policy and the provider enrollment policy, updates all the fee schedules -- so works closely with fiscal agent operations to ensure updates are made to the MMIS system and with Medicaid program financing the development of fee schedules. And that's the bulk of their responsibilities.

Q. So when you're meeting with Jesse weekly, what are you discussing about his team?

A. It depends on what -- the highest priority assignments are usually up first; things that are due that week.

Q. Okay. So you do not routinely discuss GAPMS -- that was your testimony just a second ago?

A. Yes. I wouldn't say that it's a subject that we discuss at every meeting or routinely at our individual meetings, no.

Q. And you organize what you discuss based on what

has the highest priority?

A. Yes, typically.

Q. Okay. How familiar with you with the GAPMS process?

A. In terms of all the research and everything that goes into developing, I'm not as familiar. But I am familiar with the routing process, the rule, the authority for that process.

Q. Okay. So just generally, what does AHCA use the GAPMS process for?

A. So if the agency receives a request for coverage -- typically that's how the process would be initiated. If the coverage was determined to not be something that the agency could proceed with -- possibly adding to the fee schedule or incorporating into a service definition -- then the GAPMS process would be used.

Q. Okay. How is the GAPMS process initiated?

A. I believe it's a rule how to.

Q. Would it be helpful if you had the rule in front of you?

A. Yes.

MS. DEBRIERE: Okay. Let's mark that as Exhibit 5. That's Rule 59G-1.035.

(Plaintiff's Exhibit No. 5 was marked for

identification.)
BY MS. DEBRIERE:
Q. So how is GAPMS initiated?
A. A request is submitted to the health services research inbox in the Medicaid Policy Bureau.
Q. Who can submit a request to that inbox?
MR. PERKO: Object to form.
THE WITNESS: I believe anyone can.
BY MS. DEBRIERE:
Q. Okay. Is that the only way that a request is submitted for AHCA to undertake a GAPMS?
A. No.
Q. What are other ways?
A. So in the contracts with the plans, there's also language on how a managed care plan can submit a request to the agency for review -- not necessarily through the health services inbox. I can't recall the exact direction. But there's also the opportunity for the clients to request a review.
Q. When that review is requested, is it -- is the standard process used? Is the standard GAPMS process used?
A. I'm not sure. I believe it may be expedited. But I'm not sure to the specifics of the process.
Q. Who would be most familiar with that process?

A. Either Jesse Bottcher or Jeffrey English.
Q. Okay. So you mentioned managed care plans can submit a request -- or anyone can submit a request through the health services inbox. Are there any other ways that a request can be submitted to the agency to undertake a GAPMS?
A. Yes.
Q. And what are those ways?
A. I don't know all the ways. But I can't think of us not approaching the process if we received a request outside of getting it specifically through the health services research inbox.
Q. How often --
A. Which is -- I'm hesitating because I couldn't see us not -- like, refusing to complete the process if it was received another way.
Q. How often does that happen?
A. So, like I said before, in my time as bureau chief, there haven't very many finalized GAPMS. Or that process has not been a part of my day-to-day work. So I'm not sure.
Q. Okay. So you cannot recall another way that a GAPMS request came to the agency, other than through a managed care plan or the health services inbox?
A. So for the most recent GAPMS report, that was a

request from -- I believe it was the secretary. But I don't know if it went through the inbox specifically or not.

Q. Okay. So that's another way that the GAPMS process can be requested -- is through the secretary?

A. That's the way that it has been.

Q. Okay. How many times?

A. I don't know.

Q. And when you say the most recent GAPMS report, do you mean the GAPMS report related to gender dysphoria?

A. Yes.

Q. When that request came in through the secretary, did the secretary identify why she was making that request?

And, I'm sorry, do you mean Secretary Marstiller?

A. Yes.

Q. Okay. Did she identify why she was making that request?

A. I can't recall the contents of the specific request.

Q. Did the request come -- who did the request from Marstiller go to?

A. I don't know.

Q. How did you find out about it?
A. I just can't remember if I was sent the letter in an email. But it was then discussed by my manager.
Q. And that manager was? Is?
A. At the time was Jason Weida, who is the assistant deputy secretary.
Q. And did you receive the letter from Secretary Marstiller before that discussion occurred?
A. Yes.
Q. And how long between receiving the letter and having -- how long past between receiving that letter and having that conversation with Mr. Weida?
A. I don't remember.
Q. Was it, like, hours? A day? Several days? Within the same week?
A. I don't remember.
Q. Okay. Was that discussion just between you and Mr. Weida? Or were there other people?
A. I don't remember in the initial conversation if there was anybody with me.
Q. Okay. Was it -- where did it take place?
A. I believe it was in Jason's office.
Q. Okay. Did Jason ask you to come to his office to have the conversation? How were you notified of the meeting?

A. I don't remember. We had standing meetings in his office; he was my -- or I was his direct report. So I don't remember if it was part of that when we were talking about assignments and priorities or separate. I can't remember.

Q. What was Mr. Weida's position at the time at the agency?

A. He was the assistant deputy secretary for Medicaid policy and quality.

Q. And then who is in that position prior to him?

A. I think Shevaun Harris.

Q. Okay.

A. There was a gap in between. But I think she was the last person.

Q. Okay. And who took that position after Mr. Weida?

A. That position is currently vacant.

Q. Okay. And has Brian Meyer ever held that position?

A. No.

Q. Okay. Prior to your meeting with Mr. Weida but after your received the request from Secretary Marstiller, did you communicate with anybody else about the request?

A. Can you repeat the question.

Q. Between the time that you received the request from Secretary Marstiller -- the letter -- and meeting with Mr. Weida, did you have a conversation with anyone else about the request?

A. I don't believe so.

Q. Okay. Were you surprised to see the request?

A. No.

Q. Why not?

A. Medicaid Policy -- I think we're unique in that bureau because no one day is exactly the same. There's always something new coming out from the federal government, from legislative action, from leadership. So I think that's kind of part of the job of being the bureau chief of Medicaid policy.

Q. Okay. What was -- when you met with Mr. Weida, did you develop a plan about how to honor the Secretary's request?

A. Yes.

Q. And what was that plan?

A. The team that was going to work on it was the Canadian Prescription Drug Importation Plan team; following the regular GAPMS process in terms of research and report and development.

Q. Did you identify who was going to be on that team?

A. Yes.
Q. And who did you identify?
A. Matt Brackett, Nai Chen, and D.D. Pickle.
Q. As part of that plan -- and to be clear, the secretary's request was specifically a request to undertake a GAPMS investigation?
A. Yes; to review through that process.
Q. Okay. And the team identified was Brackett, Chen -- and I forgot the --
A. Their manager, D.D. Pickle.
Q. D.D. Pickle. Thank you.
So you previously testified that the team primarily responsible for GAPMS was led by Jesse Bottcher. Why was Jesse Bottcher not part of the team to undertake this GAPMS?
A. So there was several factors considered. Matt Brackett has worked with the bureau a long time and previously had the position responsible for -- primarily responsible for the GAPMS. D.D. Pickle has also been with the bureau and agency a very long time. So I would say that the historical knowledge, the bandwidth -- having bandwidth to focus on completing the GAPMS -- were probably the two biggest factors.
Q. When you say bandwidth, what do you mean?
A. So that team -- their primary responsibility is

the Canadian Prescription Drug Importation Program, which is not approved federally. So our ability to move forward with the day-to-day operations and implementation of that program is stalled. Due to that, that team has been available to assist in other areas within the bureau when needed.

Q. Was the team that's primarily responsible for GAPMS -- were they overwhelmed with doing GAPMS at the time?

A. I don't know.

Q. But you used the fact that Mr. Brackett and D.D.'s team generally would have a lot of time to work on GAPMS as a deciding factor to pick the team for this report; is that right?

A. Yes.

Q. But you didn't first check whether the team that's primarily responsible for GAPMS would have the time to do the report?

A. No.

Q. Okay. How long has Mr. Chen been with the agency?

A. I don't remember.

Q. Would you classify him -- as you did Ms. Pickle and Mr. Brackett -- as being with the agency for a long time?

A. No.
Q. So he did not have that historical knowledge that Mr. Brackett and Ms. Pickle have with the agency?
A. No.
Q. And that was a deciding factor in picking the team?
A. Yes.
Q. When you met with Mr. Weida to pick this team, did Mr. Weida suggest the names or did you?
A. I believe I did.
Q. Okay. Other than the length of time at the agency and bandwidth, what criteria -- did Mr. Weida give you any criteria in terms of picking the team?
A. I don't think so, no.
Q. Did you use any other factors other than the length of time at the agency and bandwidth to select this team?
A. I think it's still the same as historical knowledge. But I have worked very closely with D.D. and Matt in my various positions. I knew Matt had some knowledge of previous similar requests, as well extensive knowledge of the standard GAPMS process. And it was a team of three that was available. So I think that still kind of historical knowledge and bandwidth were really the biggest factors.

Q. You said Mr. Brackett had experience with previous similar requests. What were those previous similar requests?

A. I believe there was a GAPMS request in the past before my time with the agency that had to do with hormone treatment.

Q. Would it be -- and it was hormone treatment. When you say a similar request, was it for GAPMS?

A. Yes.

Q. Would it have been the cross-sex hormone therapy GAPMS that is Exhibit 4?

A. No.

Q. How do you know?

A. The date on this. The one I was thinking of was much earlier before my time.

Q. Before your time -- do you have any sense of when that might be?

A. Maybe 2016 or 2017.

Q. Do you know who the Governor of Florida was in 2016 or 2017? I'm sorry. It's not a test, I promise.

Was it Rick Scott?

A. Yes.

Q. Okay. And was the interim secretary at the time at AHCA, was it Justin Senior?

A. Yes.

Q. And was Beth Kidder there at that time at AHCA?
A. Yes.
Q. And all of those people are listed on this Exhibit 4 --
A. So my document has Beth Kidder crossed out and looks to be a draft document from May 20th, 2022.
Q. Is there a name that replaced Beth Kidder on that?
A. Ashley Peterson.
Q. Okay. Do you know when Ashley Peterson joined AHCA?
A. I believe it was 2021.
Q. Okay. And is it --
MR. PERKO: Counsel, it's 1:30. Are we going to stop for lunch?
MS. DEBRIERE: We can if you want to.
MR. PERKO: Do you want to? It's up to you.
THE WITNESS: At some point.
MS. DEBRIERE: That's fine. Can I just finish up here real quick.
BY MS. DEBRIERE:
Q. So is it possible that this document was created in 2017?
A. I'm looking at a document that has track changes that appear to be since then. But I don't know.

Q. Why do those track changes appear to be since then?

A. Since the date was updated to May 20th, 2022.

Q. Okay. There's some editing in the column. It's very faint. Can you see it?

A. Yes.

Q. And the initials of editor appear to be GS.

A. Yes.

Q. Do you have any idea who that would be?

A. No.

Q. Do you know anybody here with the initials GS?

A. I'm sure somebody here has those initials, but I don't know off the top of my head.

Q. So Mr. Brackett was involved with a GAPMS related to cross-sex hormone therapy, but it wasn't necessarily this one; is that right?

A. I don't know the level of his involvement, but I know that he had some knowledge or knew about it.

Q. Okay. Did he do any other GAPMS related to the treatment of gender dysphoria?

A. I don't know.

Q. Mr. Chen -- did he have any previous experience with GAPMS?

A. I don't know.

Q. Ms. Pickle -- has she had any previous

experience with GAPMS?
A. I don't know.
Q. And you've explained why Mr. Brackett, Ms. Pickle, and Mr. Chen were selected for the team. Why was Mr. Bottcher not selected?
A. I can't recall all the details of the decision. But Jesse Bottcher's team is one of the busiest in the bureau, and has a lot of time sensitive work that they are constantly working on. So I think that had something to do with it, since he is the manager of an entire section.
Q. I think you had previously testified there weren't a lot of GAPMS pending at the time this request come through; is that right?
A. I didn't know the bandwidth or the workload.
Q. Okay. You didn't know the bandwidth. So you didn't know if, for example, Mr. English had the bandwidth to handle the GAPMS report?
A. No.
Q. Do you want to take a break?
A. Yes.
(Brief recess.)
BY MS. DEBRIERE:
Q. Previously before break we were talking about the selection of Mr. Brackett to be on the GAPMS report

team for gender dysphoria. And you mentioned that he had drafted previous similar GAPMS in the past. And I believe you used the example of cross-sex hormones.

Were there any other similar requests that he drafted related to gender dysphoria in the past?

MR. PERKO: Object to form.

THE WITNESS: Just to clarify, I'm not sure if he drafted it.

MS. DEBRIERE: I'm sorry; yes.

THE WITNESS: I know he had some historical knowledge of previous GAPMS.

MS. DEBRIERE: Okay.

THE WITNESS: So can you repeat your question.

BY MS. DEBRIERE:

Q. Did he have hysterical knowledge of previous GAPMS related to gender dysphoria?

A. Outside of the one that I referred to earlier?

Q. No, including that one.

A. Yes, I believe he had some historical knowledge of previous GAPMS.

Q. Other than the one you referenced earlier, are you aware of any other GAPMS that he was involved in related to gender dysphoria?

A. I don't know the extent of all the GAPMS he was involved in.

Q. Also earlier when you were discussing your responsibilities under GAPMS, you mentioned routing.

A. Yes.

Q. Can you describe that a little bit.

A. As the bureau chief of Bureau of Medicaid Policy, any official documents that leave the bureau are usually reviewed by me. And so routing process is the hierarchy of reviewers through wherever the final reviewer or signatory or approver. That's what I was referring to by routing process.

Q. Okay. Does every GAPMS report have a routing process?

A. Yes.

MS. DEBRIERE: Okay. Can I have the 2016 GAPMS routing form. And we'll mark it as Exhibit 6.

MS. DUNN: I can tell from this exhibit that when we printed these the Bates numbering got cut off. So I will look it up and read --

MS. DEBRIERE: That's a bummer.

MS. DUNN: I know.

(Plaintiff's Exhibit No. 6 was marked for identification.)

BY MS. DEBRIERE:

Q. Okay. So do you recognize this document?

A. Not this specific document. But this appears

to be a policy routing and tracking form.

Q. And is that form the same as the form you currently use to track -- to route and track?

A. Sometimes.

Q. What other forms do you use?

A. Prior to the pandemic, we used this form primarily. Since returning to the office there have been different variations of routing and tracking forms developed for different teams or documents -- types of documents.

Q. Do you use the same routing and tracking form for GAPMS?

A. So I've only approved two GAPMS in my time. And I can't remember if this was the -- this format was what was used to route it to me.

Q. Okay. But there was a form used to route it to you when you approved -- when you approved your two GAPMS?

A. I believe so.

Q. Okay. And on this GAPMS form, it says prepared by Monique Johnson. What does it mean to be prepared by? Was the form prepared by Ms. Johnson? Or was the GAPMS report prepared by Ms. Johnson?

A. I don't know.

MS. DEBRIERE: Okay. Could I see the 2022

GAPMS. This will be Exhibit 7.

(Plaintiff's Exhibit No. 7 was marked for identification.)

BY MS. DEBRIERE:

Q. So I'm handing you -- and Gary will want to take a look at it too -- again, the first page of the document is entitled "Medicaid Policy Routing and Tracking Form." If you go through the entire document, it should also include the June 20, 2022, GAPMS report on treatment of gender dysphoria.

MR. PERKO: I believe it was June 2nd.

MS. DEBRIERE: June 2nd. Excuse me.

BY MS. DEBRIERE:

Q. So looking at the document -- the first page, is this the Medicaid Policy Routing and Tracking Form that was associated with the GAPMS report on the treatment of gender dysphoria?

A. Yes.

Q. How do you know?

A. These are my initials.

Q. Okay. So you've seen this before?

A. Yes.

Q. I do want to point out "prepared by" here. What does that mean?

A. That Matt Brackett prepared the routing

package.

Q. Okay. Did he also prepare the GAPMS report itself?

A. Yes.

Q. Do you know if the person who prepares the routing and tracking form -- if they are the person who also prepares the GAPMS report?

A. Can you repeat the question.

Q. The person who prepares the Medicaid Policy Routing and Tracking Form, do they also prepare the GAPMS report itself?

A. I don't know how all the team members are instructed to fill out the report or -- I'm sorry -- fill out the tracking form.

Q. Is there any other way to determine who has prepared a GAPMS report?

A. I don't know. But speaking in general assignments -- these forms are used for other assignments. And there are a lot of assignments that are done collaboratively. So, yeah. I don't know specifically how else you would know just looking at documentation.

Q. Would that information be contained on an AHCA shared drive?

A. It's possible.

Q. Okay. Is there a reason the GAPMS report doesn't identify an author on the report?
A. I don't know.
Q. Okay. A couple other things. On the section line here, it says Canadian Prescription Drug Importation Program. But we have established this was the routing and tracking form for the GAPMS report related to the treatment of gender dysphoria. Are those two things related?
A. So the Canadian Prescription Drug Importation Program is the section of who developed the report. And it lets us know how the hierarchy of the routing should go through the management levels within the bureau and outside.
Q. So it was the Canadian Prescription Drug Importation unit who prepared the GAPMS report on the treatment for gender dysphoria?
A. So that's what I would interpret this section -- why it's listed there next to this section. It's the section responsible for routing and lets us know the hierarchy of the management.
Q. Okay. And then just looking down at the "Reviewed by and Routing Timelines," the start date is June 1st, 2022, for everybody except Mr. Wallace; who has a date of June 2nd, 2022. And the end date is June

1st, 2022, except for Mr. Wallace. Does that indicate that you Mr. Weida and Ms. Pickle all reviewed the report and signed off on it on the same day?

A. That the official routing and the signature occurred on the same day, yes.

Q. What do you mean by official routing?

A. So the date that this form and the final routing package was ready for signature.

Q. And what was continued in the final routing package?

A. I believe it was just the report.

Q. Okay. So the final report -- what was being tracked through this routing and tracking form?

A. Yes.

Q. Were there any attachments to the final report that were also reviewed?

A. The expert witness reports were also reviewed. But I can't remember if they were included in this routing package at the same time.

Q. Who reviewed those final expert reports?

A. I don't remember.

Q. Did you review them?

A. I don't remember if I reviewed them all. But I had seen them -- at least some of them. I can't remember if I reviewed them all formally.

Q. Okay. Turning just back to the general GAPMS process. Is the GAPMS process ever initiated to assess existing coverage of Medicaid services?

A. Can you repeat the question.

Q. Is the GAPMS process ever used to assess existing coverage of Medicaid services?

A. I don't know specifically.

Q. Okay. Who would know that?

A. Are you asking if it ever has or ever would?

Q. Ever would.

Would Ms. Pickle know that?

A. So my personal experience with the GAPMS process is somewhat limited. But it is such a unique process. I feel it's hard to answer that without each situation or each request that we would get would be unique, because that process is dealing with questions that fall outside of something that's easily answered policy question.

MS. DEBRIERE: Have we entered the GAPMS rule into evidence yet? Can we do that now. And that's to be 59G-1.0 -- I thought we had. Oh, it's 5. Okay. Sorry. That's my fault.

MR. PERKO: That's fine.

BY MS. DEBRIERE:

Q. So a couple questions about the language of the

rule. First under (1)(b), "health services" is defined as diagnostic tests, therapeutic procedures, or medical devices or technologies.

Under what category would prescription drugs fall in this definition?

A. I don't know.

Q. You are familiar with the GAPMS rule, though; correct?

A. Yes. I've read the GAPMS rule.

Q. Would prescription drugs fall under any of these categories?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I wasn't part of the original drafting of this rule text. So in order to interpret the policy, I would need to do research.

BY MS. DEBRIERE:

Q. Who would you ask?

A. I would probably start with Ashley Peterson.

Q. Okay. And going down to 3, the second sentence -- "The public may request that a health service be considered for coverage under the Florida Medicaid program by submitting a request."

What does this sentence mean to you?

A. There's much room for interpretation. It says

the public may request a public health service be considered for coverage.

Q. Does this sentence mean that the public may request that Florida Medicaid consider whether to exclude a service previously covered?

MR. PERKO: I'm going to object to form.

THE WITNESS: So I think it could. Not only do we update the coverage policies to include new services, but we do change the scope of a service as part of that process. So if there was a question that was not clear within the scope of the service, I can see how that might apply.

Or the example that you used earlier with a service that's only provided to under 21. If that service was -- if we received a request to make that service available for over 21. So I can think of examples where it wouldn't have to be a new service.

BY MS. DEBRIERE:

Q. Does this rule cover a public's request to take a service away?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know?

A. Public -- that would be a legal interpretation

or policy interpretation that would need consultation with the agency for me to answer.

Q. As the bureau chief of Medicaid Policy, you're responsible for developing coverage policies; correct?

A. I oversee the teams that develop coverage policies, yes.

Q. And you are responsible for overseeing the teams that develop administrative rules to implement those coverage policies; correct?

A. Yes.

Q. So you would be responsible for understanding how rules that implement coverage policies should be interpreted.

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Is it your responsibility to understand the content of this rule?

A. Yes.

Q. Okay. But you can't tell me how to interpret that second sentence in Subpart 3?

A. So if we received a request and I wasn't clear on the authority, there's several steps I would take to confirm that the agency's position is we have authority -- which would be to review any other applicable laws or regulations; would be to consult with

my team and with agency management and perhaps with legal if I was not sure whether a specific question or scenario that was received. We may not have the authority to take an action.

Q. So when reading the second sentence in Subpart 3 -- "The public may request a health service be considered for coverage" -- in order to understand what that sentence means, would you undertake any of the steps you just described?

A. It would depend on the exact question. If I wasn't clear with what the request was and how that authority applied, then I would take further steps to make sure that I understood how the rule applied to the request.

Q. Did you do that for -- okay. Okay. Let me make a note.

In the legal consultation part, it trigged me to remember just a housekeeping question. At lunch did you speak with your attorneys --

A. No.

Q. -- about the deposition?

A. No.

Q. Okay. Does the GAPMS process typically look at an individual service when you're undertaking analysis?

A. I don't know.

MS. DEBRIERE: Okay. Can I have either the Van Mol or Van Meter ATF. It doesn't matter. And we'll mark that as Exhibit 8.

(Plaintiff's Exhibit No. 8 was marked for identification.)

BY MS. DEBRIERE:

Q. So at the top of the page you have a -- did you approve this document?

A. Yes.

Q. Okay. So under "Reason for Occurrence," it says, "On April 20th, 2022, the Bureau of Medicaid Policy received a request for a time-sensitive analysis of service coverage. While such requests are typically for a single service or good --" Is that a correct statement?

A. I don't know.

Q. But you wrote this?

A. No. I signed this.

Q. Okay. Were you the one making the request?

A. No.

Q. Who was making the request?

A. Devona Pickle.

Q. Okay. Before you sign something, do you have to agree with the language contained therein?

A. Yes.

Q. So at the time you signed this, you agreed with the statement that such requests are typically for a single service or good?

A. Yes.

Q. Okay. But now you don't know if GAPMS are typically used for a single service or good?

A. My experience with GAPMS is limited. And I trust the expertise of my staff. And one of the reasons I asked or had recommended that this team be responsible was because of their historic knowledge of the GAPMS process.

Q. And when you say that, that includes D.D. Pickle; correct? You trust her expertise on the GAPMS process?

A. Yes.

Q. Okay. Are you aware of a standard operating procedure used for the GAPMS process?

A. I've heard mention of it. But I don't believe I've ever seen it.

Q. Who did you hear mention of it from?

A. I can't remember. Either Matt or Jesse.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 9, which is the GAPMS Decision Tree Checklist.

(Plaintiff's Exhibit No. 9 was marked for

identification.)
BY MS. DEBRIERE:
Q. Do you recognize this document, Ms. Dalton?
A. I believe I've seen this before.
Q. Do you know what it's used for?
A. I believe this was developed to determine if a request just goes through the coverage determination process or should be handled as a GAPMS.
Q. Okay. And tell me the difference between a coverage determination and something that needs to go through the GAPMS.
A. I don't know everything that goes into how that decision is concluded. But in general, a coverage determination is when it's very clear that the agency has the authority to add a service and that it meets all of the agency's rules and -- for example, an optional state plan service that the agency currently doesn't cover but is clearly allowed through federal CMS would be a coverage determination. Where the GAPMS process is driven by the rule you referenced earlier that describes when it's not clearly meeting all the requirements and laid out in the current coverage policies.
Q. So much earlier in the deposition you gave an example of a coverage determination of a medical supply for -- was it Amino Foods?

A. Puro Meno.
Q. Puro Meno Foods. Why didn't you use the GAPMS process for that? Did you use the GAPMS process for that?
A. No.
Q. Why not?
A. Because the agency already covered similar products.
Q. Okay. Was that the only factor in determining whether to assess it using GAPMS?
A. I don't remember the conversations with the team when I was briefed on the recommendation.
Q. Was a GAPMS Decision Tree Checklist done for Puro Meno Foods?
A. I don't believe so. I never saw one, no.
Q. Okay. Who undertakes the process to fill out the decision tree?
A. I don't know.
MS. DEBRIERE: I apologize. Can we take just a two-minute break.
MR. PERKO: Sure.
(Brief recess.)
BY MS. DEBRIERE:
Q. Do you know how to interpret the answers on a decision tree checklist?

A. No, I don't believe I've ever seen one filled out.

Q. Okay. There's a space here that says "GAPMS Topic." What would go in that space? Do you know?

A. I don't know.

Q. Would a decision tree checklist be generated for every GAPMS request that comes in?

A. I don't know.

Q. Who would know that?

A. I don't know. I don't know if this is still the internal process. I don't know.

Q. Who would know whether it was still the internal process?

A. Jesse Bottcher.

Q. Okay. Would the members of Jesse Bottcher's team also know?

A. No, I don't think anyone currently on his team would know.

Q. How about anybody previously on his team -- I'm sorry; back up.

So no one on Jesse Bottcher's team is in charge of the GAPMS process?

A. The GAPMS position is currently vacant.

Q. Would anybody who was in charge of the GAPMS process at some point know whether the decision tree

checklist is used in the GAPMS process?
A. I don't know.
Q. And there's only one position that would know that, and that is currently vacant; correct?
A. I believe so, yes.
Q. And what is that position called?
A. I believe it's a Government Analyst II.
Q. And so there's just that one position in charge of knowing the GAPMS process?
A. As far as I know, yes.
Q. Okay. We touched on this a bit earlier. Does AHCA use the GAPMS process for prescription drugs?
A. I don't know.
Q. When you were giving an example of similar requests that Mr. Brackett handled for GAPMS, the example you gave was cross hormone therapy; correct?
MR. PERKO: Object to form.
THE WITNESS: I believe that was the example I gave.
BY MS. DEBRIERE:
Q. And what is cross-sex hormone? What is a hormone?
A. I don't think I can recite the clinical definition.
Q. Is the hormone a prescribed drug?

A. I believe so.
Q. So then you're aware of one instance in which GAPMS was used for determining -- for assessing a prescription drug?
A. Yes.
Q. But you don't know generally if GAPMS is used to assess prescription drugs?
A. My knowledge of GAPMS is limited. So to speak in generalities -- but I do see where in 2016 there was the GAPMS on hormone suppression.
Q. Okay. Is GAPMS the only method AHCA relies on to determine whether a Medicaid service is experimental?
A. I don't know. I know we have a clinical trials coverage policy. So there may be circumstances where it's clear that coverage would be -- that coverage policy or the clinical trials rule would apply. And I don't know all the details of how the QIO vendors -- what that process, all that entails.
Q. Whether the QIO venders would determine whether something is experimental?
A. Or if it was clear the clinical trial policy would apply instead. So I don't know to the extent of if there could possibly be.
Q. What is the clinical trials policy?
A. It's a rule that outlines the agency's coverage

for recipients participating in a clinical trial.

Q. And what does that type of authorization entail?

A. I don't know the specifics.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should be excluded?

A. Can you repeat the question.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should not be covered?

A. I don't know the specifics. But if, for example, a pharmaceutical is not FDA approved, there would be perhaps, like, a different process where it wouldn't have to go through the process.

Q. What is the significance of a drug being FDA approved for the purposes of coverage?

A. I don't know the details.

Q. What do you know about it?

A. I believe there's federal requirements on if a drug is not FDA approved -- there is certain coverage requirements.

Q. Do you know if that relates to the compendia we were earlier talking about?

A. I don't know.

Q. Okay. If AHCA is determining whether a production drug is experimental, does AHCA consider whether the drug is FDA approved?

A. I believe so.

Q. If a particular use for a drug has been FDA approved, can AHCA deem the drug experimental for that use?

A. Can you repeat the question.

Q. If a particular use for a drug has been FDA approved, can AHCA deem that drug experimental for that use?

MR. PERKO: I'm going to object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. But FDA approval bears on a determination as to whether AHCA will cover a drug; is that correct?

A. Yes, I think it's considered.

Q. If it's not -- if a drug is not FDA approved, are there circumstances under which AHCA will still cover the drug?

A. I don't know. But I think there is federal regulations around what's allowable.

Q. In the Federal Medicaid Act?

A. I believe.

Q. You mentioned just a second ago, a clinical

trials coverage policy. Where does that policy live?
A. In Rule Class 59G on our website.
Q. If it's not there where would we find it?
A. In the Florida Administrative Code.
Q. It should be in Chapter 59G?
A. But it should be on our website.
Q. Okay. And it is adopted as a rule?
A. Yes.
Q. Okay. Once AHCA reaches a decision through the GAPMS process, describe the implementation of that decision.
A. So, again, in my experience -- I've only been bureau chief for two finalized decisions that were different. And I can't remember all the steps to implementation. But once a determination of any coverage is made, then there's a process of how to notify the public. There's a process for notifying the plans of changes if it affects the plans. There's a process of making sure that the -- any other associated rules that may be impacted are updated.
Q. Anything else?
A. If a training is needed, it depends on what it is. But there could be other.
Q. Who would you train?
A. So, again, just speaking generally -- the

managed care plans; the public; if it's fee for service, the providers; especially if it has to do with submitted claims.

Q. What are the two final reports that you have overseen as bureau chief?

A. So it was the GAPMS that we're discussing today.

Q. And, again, that's the one that relates to treatment of gender dysphoria?

A. Yes. And then the -- I can't remember the exact name of the other GAPMS. But it was through a managed care plan request.

Q. Was it an expedited GAPMS?

A. I don't believe so.

Q. Do you remember what the service was at issue?

A. I do not.

Q. Okay. And the process for an expedited GAPMS, that's different from the traditional GAPMS process?

A. I'm not sure of the differences outside of the timeframe.

Q. Is it different as to how you would inform the public about it?

A. I don't know. I can't recall what steps we took after notifying the plans of the final decision.

Q. Okay. Through the traditional GAPMS process --

do you have any GAPMS right now that are in the final stages?

A. No.

Q. Okay. And you don't know how many requests are currently pending?

A. I don't know.

Q. So the last GAPMS that was finalized was in June of 2022?

A. Yes.

Q. Okay. And now we're in February of 2023. And there's no GAPMS that are ready for finalization at this point?

A. I don't know what stages of development they are.

Q. Okay. Is there anything on your desk to review?

A. I don't know. I don't remember if I have anything pending.

Q. Okay. When you were meeting with Mr. Weida about the June 2022 GAPMS report related to the treatment for gender dysphoria, that report had not been drafted; correct?

A. Sorry. Can you repeat that.

Q. Yeah. Absolutely. So earlier you spoke to meeting with Mr. Weida once you received the request

from the secretary to undertake the GAPMS for treatment of gender dysphoria; do you remember?

A. Yes.

Q. During that meeting had the GAPMS report been drafted yet? I know it seems like a silly question. But I'm asking at face value.

At the time you met with Mr. Weida, had the GAPMS report been drafted yet?

A. The GAPMS report I was discussing with him? No.

Q. Okay. But you have a good memory of that report before it was even drafted; is that right? You were able to recount details to me about discussing that report about before it had been drafted; is that right?

A. Throughout the process there had been discussions. But I don't know if I remember all the details.

Q. What I'm wondering is just why that report sticks out in your mind, but now you can't recount any other GAPMS reports that are pending. Is there a reason for that?

A. I have a lot of documentS in my queue at any one time. And it's really on the onus of the analyst -- part of their job responsibilities -- to make sure assignments are completed and finalized and routed and

closed. So because there was discussion and updates on the status and progress of the report -- and it was not that long ago -- I remember having conversations about the report.

Q. There are GAPMS reports pending right now, though; right?

A. I don't know. I don't know what the GAPMS queue is right now.

Q. Okay. So you don't know if there's anything in the queue right now?

A. Correct.

Q. But you do remember details about the GAPMS report related to treatment of gender dysphoria?

A. Details on the process?

Q. Yeah.

A. Yes.

Q. Okay. When I say "rulemaking process," do you understand what I'm referring to?

A. Yes.

Q. And do your current responsibilities at AHCA include the rulemaking process?

A. Yes.

Q. Can you describe those responsibilities.

A. I review drafts of the coverage policy and the documents that go along with the rule promulgation

process. I sometimes participate in the public meetings and review provider alerts or other notices associated with the process.

Q. Anything else?

A. Not that I can think of.

Q. Okay. Do you ever review public comment associated with the rule?

A. It depends.

Q. So you have before?

A. More in my old role as the AHCA administrator.

Q. Okay. Can you remind me the dates you were in that role.

A. August 2018 to August 2021.

Q. And in your previous roles at AHCA as well as DOEA, you had rulemaking responsibilities; is that right?

A. DOEA was more of the drafting of the policy and not the promulgation process.

Q. Okay.

A. And then AHCA has been more on the promulgation process -- administrative process.

Q. So you'd say you had experience with Florida agency rulemaking?

A. Yes.

Q. When I say "rule workshop," do you understand

what I'm referring to?

A. Yes.

Q. When I say "rule hearing," do you understand what I'm referring to?

A. Yes.

Q. What is the difference?

A. Chapter 120 has different public meetings outlined in different stages of the process. The workshop as we use it here is primarily for the rule development stage of the administrative process. And the hearing occurs at the proposed rule stage.

Q. Okay. When you say the development of the rule, does that mean generally the rule language itself has not yet been drafted or proposed?

A. It depends.

Q. Okay. So is there a difference between workshop and hearing?

A. They're both public meetings meant to garner input from the public and make the public aware of the changes. But per Chapter 120, there are differences because of the different stages of the process.

Q. Okay. Why was there no public workshop held for the rule development of the change to Rule 1.050 excluding the treatment for gender dysphoria?

A. I don't know.

Q. Were you here were when that happened?
You were?
A. Yes.
Q. Okay. While here, have you had public comment on rule workshops for other rules?
A. Can you repeat the question.
Q. Since you've been here at AHCA, have you -- let me ask this question: When the rule was developed to exclude treatment of gender dysphoria per 1.050, were the you bureau chief for Medicaid Policy?
A. When the rule was promulgated?
Q. Well, when you were having the -- when you noticed the proposed rule and had the rule hearing.
A. For this specific rule?
Q. Yes.
A. Yes.
Q. Okay. In your role as bureau chief, have you ever -- in your role as bureau chief, have you been involved in rule workshops for other rules?
A. Yes.
Q. So why weren't you involved in the rule workshop for the exclusion of treatment for gender dysphoria; do you know?
A. I can't remember. I believe I was out of town.
Q. Okay. If you weren't out of town, would you

have been involved in it?

A. I don't remember the discussion around that. But I'm not always involved in the workshops or rules.

Q. How is that determined?

A. It depends on the circumstances and the content of the rule. But I can't remember the specific conversation when that was determined.

Q. Was there a public workshop for the exclusion of the treatment for gender dysphoria? There was only a public hearing; correct?

A. I know there was only one public meeting. I can't remember.

Q. Generally what's the process for planning a rule hearing?

A. We determine a date, a location, and who will be in attendance. And the date and location is included in the notice.

Q. And when you say who will be in attendance, who does that mean?

A. Who the subject matter experts or other agency staff will conduct the public meeting.

Q. Okay. And what do you mean by subject matter expert?

A. So I think I described it a little before how for most of the coverage areas there is a specific

analyst responsible for the development of that policy. So, for example, if there was a change to respiratory services, whoever that suggest matter expert or analyst is would typically be present at the workshop since they have the in-depth knowledge on the changes being proposed.

Q. Is that person always a person employed by the agency?

A. The subject matter expert for all our coverage policies are individuals employed with the agency.

Q. Okay. Are there any written protocols regarding the planning of a rule hearing?

A. I know we've developed process maps and procedures. But I don't know the details of planning a hearing specifically and how detailed those documents are on that process.

Q. What's a process map? What does that entail or detail?

A. There's a graphic that was created before my time that -- it's a real nice layout of the administrative rulemaking process.

Q. Okay.

A. And so it has -- it's a graphic, and it's one page. So it's easy to put on your wall.

Q. And your responsibilities include sometimes

attending rule hearings?

A. Yes.

Q. Since you've been the bureau chief, how many rule hearings have you attended?

A. I don't think I've attended any hearings.

Q. As a State agency employee -- either at DOEA or AHCA -- how many rule hearings have you attended?

A. So at DOEA I attended several AHCA rule hearings in the audience. In my previous position with the agency, I think it was only a handful.

Q. Does that mean five?

A. Yes; I'd say five or less.

Q. Okay. Who else from AHCA attends rule hearings? Let me ask this: Are there AHCA staff who attend rule hearings as part of their job description -- they have to be at every rule hearing?

A. I don't know if that's actually in the job descriptions. But Cole and his team -- since they set up the workshop or hearing or the public meeting -- their responsibilities include making sure they have the speaker list, making sure that everybody is escorted into the building, that the speakers can be heard. So they're in attendance for all of the public meetings.

Q. Okay. And do you know if they have any protocol off which they operate -- written protocol for

conducting the hearing?

A. I believe there's an internal process and process map. But I don't know the details off the top of my head what's included in that document.

Q. Is it the rules unit that is in possession of that document?

A. I would think so, yes.

Q. Okay. In your experience, aside from the agency who attends the hearing?

A. From the public?

Q. I mean, I think that would be the only other option; right?

What types of people from the public?

MR. PERKO: Object to form.

THE WITNESS: That would really depend on what the change is and who is impacted.

BY MS. DEBRIERE:

Q. In your experience attending public hearings -- rule hearings -- are there typically more than 25 people from the public that show up at the rule hearing?

A. I would say yes. Especially since the hearings are now -- have a virtual option. The majority of them are virtual and in person.

Q. Are there typically more than 25 people who show up in person?

A. So I haven't participated in all of them. In the last few that I participated in, there was not 25.

Q. In the last one you participated in how many were there?

A. Less than ten.

Q. Does AHCA ever invite specific persons from the public to attend the rule hearings?

A. Yes.

Q. And how do they do that invite?

A. A provider alert is sent out to the providers. Usually that goes along with the FAR notice that was posted and the public was noticed. If it's a sister agency, it might be by email. So if we believe a rule might impact a sister agency, we might reach out specifically.

Q. So other than posting the public notice and the FAR provider alerts and emails to potentially impacted sister agencies, is there any other way the agency invites specific people to attend the hearing?

A. I believe we sent calendar invites before.

Q. To what people? How did you decide on sending calendar invites?

A. The specific example I'm thinking of is a sister agency for the iBudget handbook. We invited ADP to participate and sent them a meeting invite so they

can block that time.

Q. Okay. Have you ever invited Medicaid recipients other than through the public notice to attend a rule hearing?

A. I don't know, outside of the public notice process.

Q. In your experience?

A. I personally have not.

Q. Okay. Do any State agencies in hosting a rule hearing, do they arrange for transportation for individuals from the public to attend that hearing?

MR. PERKO: Object to form.

THE WITNESS: I can't speak for any other agency. I don't know.

BY MS. DEBRIERE:

Q. What about at DOEA? Did that ever happen?

A. I don't believe I ever participated in an actual public meeting hosted by DOEA.

Q. That's right. You said that.

What about AHCA? Are you aware of AHCA ever arranging transportation for individuals from the public to attend a hearing?

A. Not that I'm aware of.

Q. Are you aware of anyone from the public being paid to attend a hearing?

A. No.
Q. Are you aware of anyone who is a subject matter expert being paid to attend a hearing?
A. I know we've reimbursed the subject matter experts. But I'm not sure if that was specifically -- attending the hearing was specifically included.
Q. And these are subject matter experts that are employed with the agency?
A. I don't know how that process works. But they're not full-time employees with the agency. I believe it's like consultants.
Q. Okay. What's the average length of a hearing?
A. I don't know the average. I know our public meetings typically range between 30 minutes and two hours.
Q. Okay. On average how many comments do agencies receive for a rule hearing? Is there an average?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Do you think 100 comments is a lot of public comments to receive at a hearing?
MR. PERKO: Same objection.
THE WITNESS: I really don't know.
BY MS. DEBRIERE:

Q. In your experience, does a State agency ask outside legal counsel to attend and perhaps in rule hearings?

A. Can you repeat the question.

Q. In your experience, does a State agency normally ask that outside legal counsel attend a rule hearing?

A. I don't know.

Q. When you planned this last rule hearing, did you ask outside legal counsel to attend?

A. Can you specify which hearing.

Q. Yeah. There was a hearing a couple of weeks ago on the change to the medical necessity definition.

A. Yes. The workshop.

Q. Workshop. Did you ask outside legal counsel to attend that workshop?

A. I personally did not.

Q. Did outside legal counsel attend that workshop?

A. I don't believe so.

Q. And have you ever attended a rule hearing where outside legal counsel was asked to participate in?

A. I can't recall if that circumstance has ever happened.

Q. So it's not usually -- it's not the standard course of things for outside legal counsel to attend?

A. Correct.

Q. All right. Turning to the exclusion for treatment of gender dysphoria under Rule 59G-1.050. Prior to the adoption of this exclusion, did any coverage policies regarding any of the services listed there -- sorry. Strike that.

Prior to the adoption of the exclusions set forth -- I'm not sure you're looking at the right rule. 59G-1.050. Exhibit 2. It would help me to tell you the exhibit number. And then it's Subpart 7.

So prior to the adoption of that rule -- that Subpart 7 -- did any coverage policies exist regarding the services that are now subject to that exclusion?

A. Can you repeat that question.

MS. DEBRIERE: Court Reporter, can you read back that last question.

(The preceding question was read back by the reporter.)

THE WITNESS: There was not a specific coverage policy for services for the treatment of gender dysphoria.

BY MS. DEBRIERE:

Q. Does that mean those services were never covered to treat gender dysphoria by Florida Medicaid?

A. I don't believe there was any policy language

that specifically outlined coverage of the services listed in this section.

Q. If there was no specific policy language, does that then mean those services were not covered to treat gender dysphoria by Florida Medicaid?

A. I don't know the extent to what providers were reimbursed for providing the services.

Q. So even if there wasn't a coverage policy specifically related to these services, it's possible that Florida Medicaid was covering the services for the treatment of gender dysphoria?

A. It's possible Florida Medicaid reimbursed for these.

Q. Are there circumstances in which AHCA might not have an explicit or affirmative coverage policy, but would consider a request for a service on a case-by-case basis?

A. Can you repeat the question.

Q. Are there circumstance in which AHCA might not have an explicit coverage policy regarding those services -- or any service -- but would consider a request for a service on a case-by-case basis?

A. I don't know specifically if it's case-by-case basis. But I believe that the plans -- that some of the request from the managed care plans may be specific to a

request for a specific coverage. So when plans request for a GAPMS to be provided, it could be being driven by a specific case.

Q. Okay. So even though a coverage policy does not exist regarding the coverage of a specific service, there are circumstances in which AHCA might still cover that service?

A. Yes.

And I apologize. On your last question I think I heard you specific about GAPMS, which is what I answered. So I apologize.

Q. That's okay. No, that's fine. You're referring to not the last question, but the question before that; is that right?

A. Yes.

Q. Okay. But your response on that last question, you understood the question?

A. Yes.

Q. Okay. Will Florida Medicaid cover an EPSDT service if that service is experimental?

A. So in order for an EPSDT service to be covered, it has to meet the definition of medical necessity.

Q. And that medical necessity definition includes the requirement that the service not be experimental?

A. Yes.

Q. Okay. So you received a request from Secretary Marstiller via email to engage in a GAPMS regarding treatment for gender dysphoria; correct?
A. I can't remember if it was email.
Q. Right. But you received the request somehow?
A. Yes.
Q. And roughly when was that; do you remember?
A. I don't remember.
Q. And then the next step was speaking with Mr. Weida about the letter?
A. Yes.
Q. And developing the plan as to who was going to --
A. Yes. Developing how the process would work.
Q. Were all the decisions reached in that one meeting with Mr. Weida?
MR. PERKO: Object to form.
THE WITNESS: No.
BY MS. DEBRIERE:
Q. Okay. So after that meeting with Mr. Weida, what happened next?
A. I can't remember the exact timeline of events. I know we met at some point with the Canadian Prescription Drug Importation team.
Q. And they were the ones who were put in charge

of doing this GAPMS?
A. Yes.
Q. Okay.
A. And there was several conversations following that.
Q. Were those conversations limited to yourself, Mr. Brackett, Mr. Chen, and Ms. Pickle? Or were there other people involved?
A. I can't remember the chronology. I know after the report and then into the rulemaking Cole Giering was brought into the conversation. Legal counsel -- there was conversations with the experts.
Q. Who were the experts?
A. I can't remember all their names. I don't know if we have that list here.
Q. Did you ever personally speak with any of the experts?
A. No.
Q. Are all the experts listed here on what would be will be your Exhibit 7 on page 45?
A. I believe so, yes.
Q. Was a Dr. Von Mol ever involved as an expert?
A. I believe so.
MS. DEBRIERE: And let me just mark this as Exhibit 10.

(Plaintiff's Exhibit No. 10 was marked for identification.)

BY MS. DEBRIERE:

Q. And this is a document -- an After the Fact Request Form Under 35K. This form is indicating what?

A. Consultant services for vendor name Andre Van Mol.

Q. And what kind of consulting services did Dr. Van Mol provide?

A. I don't know all the details of that -- what the contractor provided. But it was as part of the GAPMS process.

Q. Okay. Why was it time sensitive? It indicates on that form it was time sensitive. Why?

A. I don't know why the request was time sensitive.

Q. Who would know that?

A. I don't know.

Q. Okay. At any time throughout the process did you feel like there was an urgency to the development of the report and rule?

A. Yes. The time sensitive nature was communicated.

Q. By?

A. I don't know remember if it was in the original

request or if it was later in conversations with leadership. I can't remember exactly who. But I think the expectation to follow the process but work as quickly as possible was apparent.

Q. Okay. But you cannot provide me an explanation as to why it was identified as time sensitive?

A. Correct.

Q. I believe we already marked ATF to Dr. Van Meter as Exhibit 8.

Dr. Van Mol -- do you know if he attended the rule hearing for the exclusion of treatment for gender dysphoria?

A. I don't know.

Q. Okay. What does this document, Exhibit 8, indicate to you?

A. An approval for consultant services for vendor named Quintan Van Meter.

Q. Okay. And what kind of services did he provide in exchange for that reimbursement?

A. Consultant services.

Q. Consulting on what?

A. As part of the GAPMS process.

Q. Do you know what specific stages he provided consultation on?

A. I don't.

Q. Do you know whose idea it was to use him?
A. I don't.
Q. Do you know whose idea it was to retain any of the outside experts?
A. No.
Q. Was it internal to AHCA, that decision? Did someone at AHCA decide to retain outside experts?
A. I don't know.
Q. Who would have made that decision?
MR. PERKO: Asked and answered.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Are you aware of AHCA retaining outside experts for any other GAPMS report?
A. I don't know.
Q. Other than Dr. Van Meter and Dr. Van Moll -- I'm sorry.
Was there a Dr. Grossman involved in the process?
A. Yes.
Q. And what was Dr. Grossman's role?
A. I believe it was the same -- consultant services.
Q. For the development of the report?
A. Yes.

Q. Okay. Do you know if they were reimbursed to participate in the hearing?
A. I don't know.
Q. Okay. Were any of the -- other than Dr. Van Mol and Dr. Van Meter -- was Dr. Brignardello-Petersen reimbursed by AHCA for consultant services related to the development of the exclusion of treatment for gender dysphoria?
A. I don't know off the top of my head.
Q. What about Dr. James Cantor?
A. I don't know off the top of my head without consulting if there was an invoice.
Q. Is that true for all the experts?
A. I can't remember how exactly the contracts -- the contracted services were reimbursed.
Q. Were they reimbursed?
A. They were.
Q. Looking at Van Meter's form -- why did you sign that form for a $34,000 reimbursement if you didn't know what Van Meter was doing?
MR. PERKO: I'm going to object to form.
THE WITNESS: So I know that Van Meter was consulting as part of the project. I just don't know throughout the process all the specific details of that consultation.

BY MS. DEBRIERE:

Q. Would you assume each expert listed was similarly compensated for the amount that Dr. Van Meter and Van Mol were compensated?

A. I'm not going to assume. Just looking at the two invoices, they are very different.

Q. In what ways?

A. This one has a not to exceed amount. And then this one has as dollar amount.

Q. Okay. Is that the only way they're different?

A. No.

Q. How else are they different?

A. The one for Quinton Van Meter has specific information regarding his MFMP registration.

Q. What is MFMP?

A. My Florida Market Place.

Q. Okay. Any other ways that they're different?

A. Some of the other language is different. The dates are different. But aside from that, no.

Q. How often do you approve an After the Fact Request Form for reimbursement of outside expertise?

A. Not often.

Q. How many times have you done it for expertise not related to the treatment of gender dysphoria?

A. I can't recall if I actually approved the

invoice; but I believe there was a consultant for the Canadian Prescription Drug Importation Program at one point. And I just can't remember the time.

Q. Is that the only time you can remember?

A. Yes.

Q. Okay. So when you were approving these forms that don't come across your desk often, do they strike you as something that needed careful review?

A. The invoice itself?

Q. The reason for reimbursement.

A. Yes. But the invoice itself seems pretty straightforward that a reimbursement based on services provided -- that had already been provided would be signed.

Q. Did you do a carful review of the reason for reimbursement?

MR. PERKO: Object to form.

THE WITNESS: I guess I'm not sure what you mean by careful review. I personally was not involved in all of the consultation services provided. But I did meet with the team and knew that services were provided.

BY MS. DEBRIERE:

Q. Prior to you receiving this request for reimbursement, did you know these experts were being

relied on for consultation?
A. Yes.
Q. Did you have to approve that request?
A. I don't know if there was a request initiating the services. I don't remember.
Q. Was there a need to approve the decision to rely on outside experts?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. Was there a requirement that consulting with outside experts be approved prior to the consultation?
MR. PERKO: Object to form.
THE WITNESS: Can you repeat that question.
BY MS. DEBRIERE:
Q. Was there -- who consulted with the outside experts?
A. Again, I don't know the extent of what the consultation services were or who all was part of that.
Q. In order for them to -- in order for the team to develop the GAPMS report -- who wrote it -- in order for them to consult with outside experts, did it require your approval?
A. I don't recall ever approving them.
Q. And the team relying on outside experts to write the GAPMS report on gender dysphoria, did it

require the approval of D.D. Pickle?

MR. PERKO: Object to form.

THE WITNESS: I can't recall how the formal process was initiated.

And I do want to say relying on experts -- there was a lot of additional research done as well as part of the GAPMS process. So I wanted to clarify that.

BY MS. DEBRIERE:

Q. But part of writing the report was consulting with these outside experts; correct?

A. Yes.

Q. And you don't know who made the decision to consult with those experts; is that right?

A. Correct.

Q. Whoever made the decision -- we don't know who that is. But whoever made the decision, did they require approval before they could implement that decision?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. As the bureau chief who oversees the team who wrote this GAPMS report, did you have an expectation that they would come to you for approval to

consult with outside experts that would then be paid?
A. Can you repeat that.
Q. As the bureau chief, the person who oversees the team that wrote the GAPMS report on treatment for gender dysphoria, did you have an expectation that they first ask you permission before they consulted with outside experts who charged for their services?
A. No.
Q. Why didn't you have that expectation?
A. I can't really answer that, as I was not part of the decision to consult with the experts.
Q. Who was part of the decision?
A. I don't know.
Q. But you know you were not part of it. Okay.
At the bottom of the After the Request Form, it states -- for Dr. Van Mol, which is Exhibit 10 -- it states supervisor approval is required. What does that mean?
A. In the routing hierarchy for approval.
Q. Approval of what?
A. For invoices for My Florida Marketplace. I'm the direct supervisor of D.D. Pickle.
Q. So your approval is required for D.D. Pickle to pay this bill?
A. Yes.

Q. Okay. But your approval was not required for D.D. Pickle to incur this bill?

MR. PERKO: Object to form.

THE WITNESS: I don't remember if there was a formal approval to initiate the services.

BY MS. DEBRIERE:

Q. Did you have to have approval to authorize this payment to Dr. Van Mol?

A. I can't remember. I don't know where this goes next in the routing.

Q. Okay. Did you ask permission to approve this from anyone?

A. I can't remember a specific conversation. But I knew it was approved by the agency to consult with -- to have the consultant services.

Q. Okay. Related to that, the last sentence is -- how did you know that?

A. How did I know what? Can you repeat that.

Q. I think you had responded that you knew the agency had approved it. And so my question was: How did you know that?

A. I don't remember the specific conversation. But I do know that it was approved by leadership.

Q. And how do you know that?

A. There must have been a conversation. I just

can't remember an exact -- if there was an exact conversation or a document I signed. I can't remember.

Q. Okay. Do you remember who you had the conversation with or had the document signed by?

A. I don't remember.

Q. The last sentence under that first paragraph, it says, "Verification of the availability of funding and approval from executive leadership was obtained prior to any work being conducted for this project."

Who was that executive leadership?

A. The majority of my discussions were with my direct supervisor. But Tom Wallace ultimately signed the report. And I don't know outside of that who all was involved.

Q. Do you need a break?

A. Yeah.

(Brief recess.)

BY MS. DEBRIERE:

Q. Who decided the amount in those forms?

A. I don't know how the amount was negotiated.

Q. Did you follow up on the amount being requested -- ask any questions about it?

A. I can't remember if I asked any questions. But, again, as it states on the form -- the availability of funding approval for leadership.

Q. So you think whoever that leadership was had approved that amount?
A. I don't know how the reimbursement for the services was negotiated.
Q. Okay. So you didn't ask any questions about the amount or what it was being used for?
MR. PERKO: Object to form.
THE WITNESS: I knew what it was being used for. But I can't remember if I asked any questions about the amount.
MS. DEBRIERE: Okay.
THE WITNESS: I can't recall any.
BY MS. DEBRIERE:
Q. Are there any subject matter experts for the services listed in that exclusion that are full-time employees with the agency?
MR. PERKO: Object to form.
THE WITNESS: I don't believe so, since the services outlined in the policy were not clearly outlined in any existing coverage policy that would have had any subject matter expert assigned to the coverage policy.
BY MS. DEBRIERE:
Q. Do you have a subject matter expert in surgery?
A. I don't know if it's one person or more than

one. We have an area that's responsible for the coverage policies we talked about earlier that contain coverage for surgical procedures.

Q. So you have a subject matter expert for outpatient hospital services?

A. Yes.

Q. And do you have a subject matter expert for inpatient hospital services?

A. I don't know if it's the same person.

Q. Okay. But do you have a subject matter expert in inpatient, it just might be the same person?

A. There's a team responsible for oversight of those policies, yes.

Q. Was that team involved in the development of this GAPMS report?

A. Not to my knowledge. But I can't speak to all of the research and activities that were part of the completion of the project.

Q. Who is that team -- that team that are the suggest matter experts in inpatient and outpatient hospital services?

A. That would be John Matson under Jesse Bottcher who is responsible for primary and preventive surgeries, including dental.

Q. Okay. You had mentioned before the break that

you had communications about the development of the GAPMS report with legal counsel; is that correct?

A. I believe so. I can't remember if it was part of the report or part of the rule. I know for sure with the rulemaking process that legal is involved in that process normally. And they were in this instance as well.

Q. Did that legal include outside counsel?

A. I don't know. I don't remember meeting with outside counsel.

Q. Okay. You don't remember with meeting with Holtzman & Vogel, the law firm?

A. No.

Q. Did you communicate with any other State agencies like the Florida Department of Health about the GAPMS report?

A. I personally did not.

Q. Did anybody at the Agency for Health Care Administration?

A. I don't know.

Q. Did you communicate -- were there any communications between AHCA and the Governor about the development of this report?

A. I don't know.

Q. Did you personally communicate with the

Governor's office about the development of this report?

A. No.

Q. Did you personally communicate with the Governor's office about the exclusion of treatment for gender dysphoria?

A. No.

Q. Were there any communications between AHCA and people that provided public comment at the hearing?

A. I'm sorry; can you repeat the question.

Q. Were there any communications between AHCA -- prior to the hearing, were there any communications between AHCA and the people who provided public comment at the hearing?

A. I don't know.

Q. Did you personally communicate with anyone who provided public content at the hearing prior to the hearing?

A. No.

Q. Was anyone at AHCA aware that specific people would provide public content at the hearing prior to the hearing?

A. I don't know.

Q. Were you aware that there were any specific members of the public who would provide public comment at the hearing prior to the hearing?

A. No.
Q. The person who is identified as authoring the GAPMS report on gender dysphoria is Matt Brackett; correct?
A. Yes, he was the primary author.
Q. Do you recall a meeting between you, Mr. Weida, and Mr. Bottcher discussing who the author of the report would be?
A. I don't remember if Jesse was in any of the conversations.
Q. Okay. Did Jesse ever express a concern to you about someone -- anyone on his team drafting the GAPMS report on gender dysphoria treatment?
A. Prior to?
Q. At any time.
A. Can you say that again.
Q. Did Mr. Bottcher ever express to you concerns over someone on his team drafting the GAPMS report on the treatment for gender dysphoria?
A. Not that I can recall.
Q. Was the GAPMS decision tree used before you decided to undertake the GAPMS analysis that is contained in the June 2022 report?
A. I don't know.
Q. Who would have that information?

Did Secretary Marstiller in her letter to Tom Wallace -- did she direct Tom Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.

THE WITNESS: I can't recall the details of the letter.

MS. DEBRIERE: Me neither. Do we have a copy?

MS. CHRISS: It's the last page right there. It's Attachment A.

MS. DEBRIERE: Oh. It's the very back of Exhibit --

MR. PERKO: It's not attached to ours.

MS. DEBRIERE: Okay.

MS. DUNN: Why don't you pull it off and mark it as a separate exhibit.

MS. DEBRIERE: So we'll mark the letter from Simone Marstiller dated April 10th, 2022, as Exhibit 11. And that's Attachment A to the June 2022, GAPMS report related to the treatment for gender dysphoria.

(Plaintiff's Exhibit No. 11 was marked for identification.)

BY MS. DEBRIERE:

Q. So in this letter is Secretary Marstiller directing Mr. Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.
THE WITNESS: Yes.
BY MS. DEBRIERE:
Q. Do you think that Secretary Marstiller undertook a decision tree prior to writing this letter and sending it to Mr. Wallace?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Has the secretary of AHCA ever personally completed a decision tree on the GAPMS process?
A. I don't know.
Q. Would it be unusual if the secretary of AHCA completed a decision tree on the GAPMS process?
A. I don't know.
Q. Looking at the GAPMS report itself, does it contain a fiscal analysis?
A. I don't know off the top of my head.
Q. Yeah. No, take your time.
A. No, I do not see a fiscal analysis.
Q. Do you see anything related to cost effectiveness?
A. No.
Q. Do you know why that was not included?
A. No.

Q. Is budget neutrality in reaching a GAPMS decision important?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I know that that's something when determining a coverage determination that is taken into consideration. But specific to the GAPMS process, I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know that? Would the person responsible for writing GAPMS reports know that?

A. Yes. Or Jesse Bottcher or Matt Brackett.

Q. Or Jeff English?

A. Yes.

Q. Who decided which services would be assessed in the GAPMS report?

A. I don't know.

Q. So typically a request comes in from the public for a specific service. In this instance, the request came from the secretary; correct?

A. Yes.

Q. So would it have been the secretary who decided which services should be assessed?

A. I can't recall how the decision was made. I do know that that was part of conversations we had during this process. But I can't recall exactly how the

decision was finalized.

Q. Was there ever a discussion about narrowing the types of services to be included?

A. I don't recall specifically. I know that the coverage of behavioral health services was something that was always covered. But outside of that specifically, I can't remember.

Q. Was there ever any discussion about undertaking the GAPMS process for a set of services simultaneously as opposed to a single service?

A. Can you clarify.

Q. In the discussions about writing the report or assessing the services, were there ever any concerns raised about undertaking the process for a set of services as opposed to a single one?

A. I don't recall specifically.

Q. Was there any discussion about EPSDT?

A. I can't remember if it was specific to the development of the report or the rulemaking more specifically. But I believe there was.

Q. And what was discussed?

MR. PERKO: I'm going to object for a second. Did that include counsel? Did those discussions include counsel?

THE WITNESS: Yes.

MR. PERKO: And who was that?
THE WITNESS: I don't remember.
MR. PERKO: But it did include counsel?
THE WITNESS: I believe it was a discussion on the rulemaking with counsel.
MR. PERKO: I'm going to instruct the witness not to answer.
BY MS. DEBRIERE:
Q. Were all discussions had in front of counsel about EPSDT?
A. I don't remember.
Q. How about comparability?
MR. PERKO: I'll ask you the same thing.
THE WITNESS: Can you remind me what you're referencing when you say comparability. I think you mentioned that at the very beginning of the day.
MS. DEBRIERE: Comparability is a requirement under the Federal Medicaid Act in the administration of the coverage of the Medicaid services.
THE WITNESS: I don't recall.
BY MS. DEBRIERE:
Q. Were there communications with the Centers for Medicare and Medicaid Services about AHCA's decision to assess whether the services listed in the exclusion were experimental?

A. I don't know. I personally did not have any conversations.

Q. Who communicates with CMS about those kinds of things?

A. Those kinds of things, you mean changes in coverage?

Q. Does CMS ever reach out to AHCA about concerns they have about an action that they're taking related to Medicaid coverage?

A. Yes.

Q. Who would be the point person at AHCA to have those conversations?

A. So if an update to a federal authority were needed, that would be either Catherine Mcgrath or myself.

Q. Okay. You would not have had -- have you had any conversations with CMS about the GAPMS report related to the treatment of gender dysphoria?

A. No.

Q. Has Catherine?

A. Not to my knowledge.

Q. Have you had any conversations with CMS about the exclusion of the treatment for gender dysphoria as contained in Rule 59G-1.050?

A. I have not.

Q. Has Catherine?
A. Not to my knowledge.
Q. Has anybody else at AHCA?
A. I don't know.
Q. Okay. You mentioned a second ago that you weren't sure if you were talking about EPSDTs as it related to the report or the rulemaking. When you make that distinction, are you referring the writing of the report versus the adoption of the rule?
A. Yes.
Q. Okay. How was it decided that the conclusions from the GAPMS report should be adopted into rule?
A. I'm trying to remember the specific conversations. But I do believe those were conversations with counsel as well.
Q. Okay. The expedited GAPMS that you were involved in from start to finish, was that decision adopted into rule?
A. It was just one other GAPMS. And I don't believe any rule update was needed for that one.
Q. Why was a rule update needed for this GAPMS report?
MR. PERKO: If that's discussion with counsel, I will instruct you not to answer.
THE WITNESS: Because there was not any policy

language that clearly explained the coverage, it was determined that developing policy language was the best approach. Anything past that was -- how that process went was conversation with counsel.

BY MS. DEBRIERE:

Q. How often in your day-to-day in making decisions in your job do you have to consult with legal counsel?

A. Often.

Q. Okay. So does that mean -- okay. Like, every day?

A. I would say the majority of days.

Q. Okay.

A. And I'll just specify. I have some sort of contact or interaction with legal counsel.

Q. On most days?

A. Yes. And, again, because the rule promulgation does require review and some other documents we route are managed care contracts also route through legal. Just to give you examples of why it's quite often.

Q. They're all contacts with legal counsel about things related to the doing of your job?

A. The development of policy and -- yes.

Q. Okay. So there was -- you said there was -- the reason that it needed to be adopted into rule is

because there was no clear coverage policy on the services at issue; is that correct?

A. I can't remember all the factors that went into the decision. But I believe that was one of the factors when it was assessed that there was no coverage policy specific to the treatment of gender dysphoria.

Q. Were there existing coverage guidelines?

A. Not to my knowledge.

Q. At the time were you aware of existing pharmacy policies related to the treatment of gender dysphoria?

A. At what time? Can you specify.

Q. It was 2017/2016.

A. I was not with the agency in 2016. So I would not have been part of any development of policy at that time.

Q. But when you were deciding whether to adopt this exclusion into the rule, did you do any review of existing coverage guidelines or past coverage decisions?

A. I believe we did. But I can't recall the specifics.

Q. Did you review past GAPMS reports regarding the treatment of gender dysphoria?

A. I believe we did.

Q. And why weren't they enough to establish the coverage policy?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. 59G-1.050, Subpart 7 -- it bans Medicaid coverage for puberty blockers, hormones and surgery if done so to treat gender dysphoria; correct?

A. It covers that Medicaid does not cover those services for the treatment of gender dysphoria; correct.

Q. Does it distinguish between adults and children?

A. No.

Q. So the exclusion applies equally to both children and adults; is that correct?

A. Yes.

Q. Okay. And it excludes Medicaid coverage for puberty blockers and hormones and surgery to treat gender dysphoria, but it does not exclude Medicaid coverage for those services to treat other diagnoses; is that correct?

A. Correct.

Q. And I just forgot you answer; I apologize. Were you involved in the rule hearing held on July 8th regarding the exclusion set forth in 1.050?

A. No.

Q. Were you aware that outside legal counsel

participated in that hearing?

A. I don't know if I was made aware prior to today. I can't remember.

Q. At rule hearings you've been in in the past, do the State agencies have a panel of subject matter experts who respond to public comment during the hearing?

A. I can't cite the specific language, but it's actually required per Chapter 120 that the agency has subject matter experts who can speak to the contents of whatever is being discussed at a public meeting available.

Q. Other than the July 8th hearing, are you aware of any time that any agency has retained outside subject matter experts to participate on that panel?

A. I'm not aware of any.

Q. To your knowledge is this the only time AHCA has created a slogan to advertise the conclusion in its GAPMS memo?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Are you aware of the slogan "Let kids be kids"?

A. I've seen the website, yes.

Q. In your experience has AHCA ever designed a website page for any other rule adoption?

A. I can't remember if it was specific to rule adoption. But I can think of a couple of examples where we created web pages for policy updates; for example, for home and community based settings rule that was an administrative rule as well as a federal rule. There's a specific external web page for updates regarding that and information on that rule.

When we received the American Rescue Act funding approval, we created a web page with information on that funding and what those funding could be used for. So I feel like it's pretty common for us to update our external website when there's important information to communicate.

Q. In those other examples, did AHCA ever develop a slogan to go along with those web pages?

A. Not in the examples that I used, I don't think.

Q. Did they issue press releases?

A. The American Rescue Act funding may have had one. But I can't remember.

Q. Okay. Just going back quickly. My co-counsel has pointed out to me that in Chapter 120 it says that at the rule hearing agency staff must be available but not an expert. Do you think maybe you were confusing that requirement that an expert needs to be available under 120?

A. I think it says an agency staff with knowledge.

Q. Okay. "Ensure that staff are available to explain the agency's proposal and to respond to questions or comments regarding the rule." Is that the provision you were --

A. Yes.

Q. -- thinking of? Okay.

Typically when AHCA decides not to cover a particular service, where is that information included?

MR. PERKO: Object to form.

THE WITNESS: I think it depends on the policy. Each policy has different exclusions, if there are any, with the service. Or most of the coverage policies include a section specific to exclusions.

MS. DEBRIERE: Most of the policies? Is that what you said? I apologize.

THE WITNESS: Most of the coverage policies.

BY MS. DEBRIERE:

Q. Okay. And those coverage policies are service specific policies?

A. The examples I was thinking of, yes, were service specific coverage policies and include -- I can't remember exactly what section in the example of where to find that in the coverage policy. But, yes, it would include exclusion specific to the coverage that's

being described in the policy.

Q. Okay. The exclusion on the treatment of gender dysphoria, is it in a service specific coverage policy?

A. No. This is a general Medicaid policy. But it does include coverage information including what Florida Medicaid reimburses for and what it does not.

Q. Does it speak to the exclusion of any other services under Florida Medicaid but those services excluded for the treatment of gender dysphoria?

A. Yes.

Q. Which ones?

A. No. 4 is an example. (4)(b), that speaks to that Florida Medicaid does not cover continuous services after the emergency has been alleviated.

Q. Is that a specific service? Or is that the length of time for any service?

A. I apologize. It's emergency service. It's under the section for emergency Medicaid.

Q. But, again, is that speaking to the coverage of any service deemed emergency?

A. It's specific to emergency services provided to aliens who meet all Florida Medicaid eligibility requirements except for citizenship.

Q. It says an exclusion under Subpart 7 speaks specifically to the exclusion of sex reassignment

surgeries; correct?

A. Services for the treatment of gender dysphoria.

Q. But only three services.

A. Four.

Q. What are examples of procedures that alter primary or secondary sexual characteristics that are not related to surgery?

A. I don't know.

Q. Just going back to the surgery, why not include that in service specific policies that discuss surgery?

A. Can you repeat the question.

Q. Looking at the exclusion of sex reassignment surgeries, why was that not included in the coverage policies related to surgeries that we discussed earlier?

A. I don't recall the specific conversation on how it was decided that this was the most appropriate policy. And I do believe that most of that conversation was with counsel.

Q. So same question for puberty blockers. Why wouldn't you include that in a pharmacy coverage policy?

A. I don't know.

Q. And Subpart 7's subject line is "Gender Dysphoria"; correct?

A. Yes.

Q. And that's a diagnosis?

A. I don't know clinically the definition.
Q. We've been talking about the treatment of gender dysphoria; right?
A. Yes.
Q. So in order to exclude treatment of gender dysphoria, it would be the exclusion of a treatment for a diagnosis; correct?
A. Yes. But I can't speak to the specifics of the diagnosis or what that means in clinical terms.
Q. Okay. For the July 8th hearing, do you know how many public comments were submitted?
A. I don't know.
Q. Do you know if it was more than 100?
MR. PERKO: Asked and answered.
THE WITNESS: I know it was a lot.
BY MS. DEBRIERE:
Q. Okay. And do you know how long it took AHCA to review and consider the comments before adopting the final rule?
A. I don't know the length of time. But I know that all the public comments were reviewed.
Q. Who reviewed them?
A. I know Cole Giering did. I don't know if anybody else -- if anybody else did.
Q. Okay. So after the July 8th hearing up until

the final adoption of the rule, other than reviewing and considering public comment, what else did AHCA do before adopting the rule?

A. Can you repeat the question.

Q. So after the July 8th hearing up until the final adoption of the rule, other than reviewing public comment, what other activities did AHCA undertake in deciding to adopt the rule?

A. I don't know. I can't remember specific to this rule. But after it's been determined there's no changes needed to the rule, the filing for adoption would be the next step.

Q. How do you reach that decision that no changes should be made?

MR. PERKO: Object to form.

THE WITNESS: There's various factors involved in that decision. And it really depends on the specific circumstances.

MS. DEBRIERE: Okay. I don't know what it would be labeled, but do you have an exhibit -- it's an email from Ms. McGriff to Magellan.

MS. CHRISS: Yes. The email exchange between Magellan and AHCA.

MS. DEBRIERE: Thank you.

Court Reporter, just for your reference what we

just marked as Exhibit 12 is Bates stamped DEF_00288753 to 000288756.

(Plaintiff's Exhibit No. 12 was marked for identification.)

BY MS. DEBRIERE:

Q. So Magellan is emailing several people at AHCA. And she says, "Attached are the internal criteria not publicly posted."

What are the internal criteria?

A. I don't know.

Q. Does Magellan rely on internal criteria for the coverage of Medicaid services?

A. I don't know.

Q. What does "CCM" mean? It's right after that sentence. "Attached are the internal criteria 'not publicly posted' CCM."

A. I don't know.

Q. What does gender code mean?

A. I don't know.

Q. Do you know hot had significance of "B for both" is?

A. I do not.

Q. Who is Linda Simone Moore?

A. Who?

Q. So there's a sender up top here -- I'm sorry.

Leslie.

A. Moore-Simons.

Q. I need reading glasses. Leslie Moore-Simons. That's exactly right.

A. I don't know.

Q. Okay. Who is Susan Williams?

A. She works for Ashley Peterson in the pharmacy unit in the Bureau of Medicaid Policy.

Q. Okay. And who is Arlene Elliott? I'll just note the date that Arlene's email was sent was 8/21/2017.

A. Currently Arlene Elliott is in a different division at the Agency for Health Care Administration. But at this time, she was the AHCA administrator over the pharmacy policy section of the Bureau of Medicaid Policy.

Q. And what unit is she in now?

A. I don't know. She's no longer in the division of Medicaid.

Q. What division is she in?

A. I believe it's Health Quality Assurance.

Q. Do you know when she left her position in the Bureau of Medicaid Policy?

A. I believe it was spring or summer 2021. I'm not sure the exact date.

Q. Okay. Earlier in the exchange -- and yet dated later -- is the email dated April 20th, 2022, from Elica King-Wilson at Magellan. And she's included some language which she underlined and bolded. And it says, "All requests require vetting by AHCA before a final determination is made."

And it appears this is related to a final determination as to whether -- well, it says -- Leslie noted, "MMA does have an internal gender dysphoria criteria, which is attached."

MMA stands for?

A. I don't know in what context she's using it.

Q. Okay.

A. But to me, MMA would normally stand for managed medical assistance.

Q. I assume you're confused because this is coming from Magellan which is not a managed medical assistance program; is that right?

A. Yes. So I don't know if that's what she's referring to.

Q. And it says, "This internal document serves for GnRH analog use to delay puberty in adolescents with gender dysphoria." This document was provided by AHCA due to a fair hearing request received for Lupron for a recipient with this diagnosis" -- meaning gender

dysphoria. And it goes on with the underlying language that all of those requests -- coverage of Lupron for gender dysphoria -- need to be vetted by AHCA before a final determination is made.

Were you familiar with that process at all?

A. No. I don't know what process they were referring to.

Q. Would Ashley Peterson know?

A. I don't know. But she does work closely with Magellan.

Q. Okay. Did AHCA work with managed care plans to implement the exclusion in 1.050?

A. They were notified. But the specifics of how that communication happened, I can't recall.

MS. DEBRIERE: Okay. Can I have the SMMC Policy Transmittal relating to the Non-Coverage of Gender Dysphoria Treatment.

MS. DUNN: Do you want the policy or the emails?

MS. DEBRIERE: Could you do both.

MS. DUNN: Do you want them together?

MS. DEBRIERE: That would be great. But separate exhibits.

(Plaintiff's Exhibit No. 13 was marked for identification.)

(Plaintiff's Exhibit No. 14 was marked for identification.)

BY MS. DEBRIERE:

Q. So right now we're looking at an email that's Bates stamped DEF_000258835 to 000258838. It's an email from D.D. Pickle CC-ing you. And it's to Jason Weida.

In this -- I'm sorry. Looking specifically at an email dated August 22, 2022, from D.D. to Ashley Peterson and Matt Brackett. It states, "Ashley, Ann wants to include the 60-day language in the alert?"

What alert is D.D. Pickle referring to?

A. I believe it was the provider alert.

Q. And what's a provider alert?

A. It's the main way -- one of the main ways we communicate information to our providers and external stakeholders.

(Plaintiff's Exhibit No. 15 was marked for identification.)

BY MS. DEBRIERE:

Q. I'm handing you a document that's marked as Exhibit 15, called Florida Medicaid Health Care Alert Sign-Off Form, starting at Bates stamp DEF_000258839.

Is this the provider alert you were referring to?

A. Yes. It looks to be a provider alert regarding

the coverage of treatment for gender dysphoria.

MS. DEBRIERE: Okay. And then what was the transmittal?

MS. DUNN: It was 14.

BY MS. DEBRIERE:

Q. No. 14 -- can you look at that document. And that's Bates stamped DEF_000258833.

What is this document?

A. It looks to be a draft -- a policy transmittal.

Q. And who does that go to?

A. This specific one is marked to be sent to the medical assistance and specialty plans.

Q. Is that the final that was sent?

A. It does not appear so, no.

Q. Okay. How do you know that?

A. The policy transmittal number is not completed and it's not signed.

Q. Okay. Going back to the provider alert, was that the final that was sent?

A. I can't tell from this document if this was the final that was sent.

Q. Okay. Would you be able to tell from any of the versions whether it was the final?

A. Seeing the actual email alert would be how I would make sure. My team actually does not send out the

final provider alerts. So that's typically how I would look at the final version.

Q. Okay. And the policy transmittals and the provider alerts -- are those available on the agency's website? The finals?

A. Yes.

Q. Okay. So turning back to that email exchange where D.D. mentions you by name.

What is 60-day language?

A. I believe she's referring to the continuity of care.

Q. What is continuity of care?

A. It's a contract requirement for the plans to provide services for a period of time. I don't know if it's specific to when they change plans. I can't recall the exact contract language, but it's a contract provision.

Q. And are services previously being covered supposed to be continue being covered for 60 days according to the 60-day language?

A. I can't recall the exact parameters of the requirement.

Q. Do you recall why --

MR. PERKO: Counsel, we're getting on seven hours here.

BY MS. DEBRIERE:

Q. Do you recall why the 60-day language -- you wanted the 60-day language included in this alert?

A. I can't remember the conversation around this. And I can't speak for D.D.

Q. Well, D.D. is speaking for you; right?

The subject is "GD Policy Transmittal"; correct?

A. Yes.

Q. And what does "GD" stand for?

A. Based on the attachments, I would conclude that it is for gender dysphoria.

Q. Okay. And this would be discussion had after the rule was adopted excluding coverage of services for the treatment of gender dysphoria; correct?

A. Can you repeat that question.

Q. The date of this email is after the rule was adopted to exclude coverage of services for treatment of gender dysphoria.

A. I believe so.

Q. You don't recall why you thought it was important to have the 60-day language included in the alert?

A. I don't recall the specifics of the conversation. But I believe it was to ensure if there

was any current reimbursement or authorization that would apply.

Q. Current authorization of treatment of gender dysphoria?

A. Of the services listed in Rule 1.050, No. 7.

Q. Did any plans state to AHCA that they would continue coverage of the services excluded in the rule even though that rule had been adopted?

A. I don't know.

Q. Who would know that?

A. I don't know who it would have gone to. If there was a question, the communications typically go through the contract managers.

Q. Okay. Do you know if all plans have implemented the exclusion contained in the rule?

A. I don't know.

Q. Are you familiar with the variance and waiver process under Chapter 120?

A. Yes.

Q. Okay. What is the purpose of that statute?

MR. PERKO: Object to form; calls for a legal conclusion.

BY MS. DEBRIERE:

Q. What it the purpose of the variance and waiver process?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

MR. PERKO: Counsel, we're getting on seven hours here.

MS. DEBRIERE: All right. Let me just consult with my team for just a second.

(Brief recess.)

MS. DEBRIERE: We'll all set with direct.

Thank you for your time, Ms. Dalton.

MR. PERKO: I don't have any questions.

THE COURT REPORTER: Would you like to read or waive?

THE WITNESS: Read.

THE COURT REPORTER: Would you like to order at this time?

MS. DEBRIERE: Yes.

THE COURT REPORTER: Would anybody like to order a copy?

MR. PERKO: Yes.

(This deposition was concluded at 6:05 p.m.)

- - -

CERTIFICATE OF OATH

STATE OF FLORIDA:
COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, do hereby certify that ANN DALTON personally appeared before me on January 24, 2023 and was duly sworn and produced her ID badge as identification.

Signed this 30TH day of JANUARY, 2023.

GREG T. SMITH

Notary Public, State of Florida
My Commission No.: GG933698
Expires: March 21, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA:

COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, certify that I was authorized to and did stenographically report the deposition of ANN DALTON; that a review of the transcript was requested; and that the foregoing transcript, pages 6 through 175, is a true and accurate record of my stenographic notes.

I further certify that I am not a relative, employee, or attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 30TH day of JANUARY, 2023.

Greg T. Smith

GREG T. SMITH

KATHERINE J. DEBRIERE, ESQUIRE
DEBRIERE@FLORIDAHEALTHJUSTICE.ORG

January 30, 2023

RE: Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

The above-referenced transcript is available for review.

(The witness/You) should read the testimony to verify its accuracy. If there are any changes, (the witness/you) should note those with the reason on the attached Errata Sheet.

(The witness/You) should, please, date and sign the Errata Sheet and email to the deposing attorney as well as to Veritext at Transcripts-fl@veritext.com and copies will be emailed to all ordering parties.

It is suggested that the completed errata be returned 30 days from receipt of testimony, as considered reasonable under Federal rules*, however, there is no Florida statute to this regard.

If the witness fails to do so, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

*Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e).

Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

E R R A T A S H E E T

PAGE_____ LINE_____ CHANGE_____
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REASON_____

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____
(WITNESS NAME) DATE

d

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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Inquiries about Veritext Legal Solutions' confidentiality and security policies and practices should be directed to Veritext's Client Services Associates indicated on the cover of this document or at www.veritext.com.

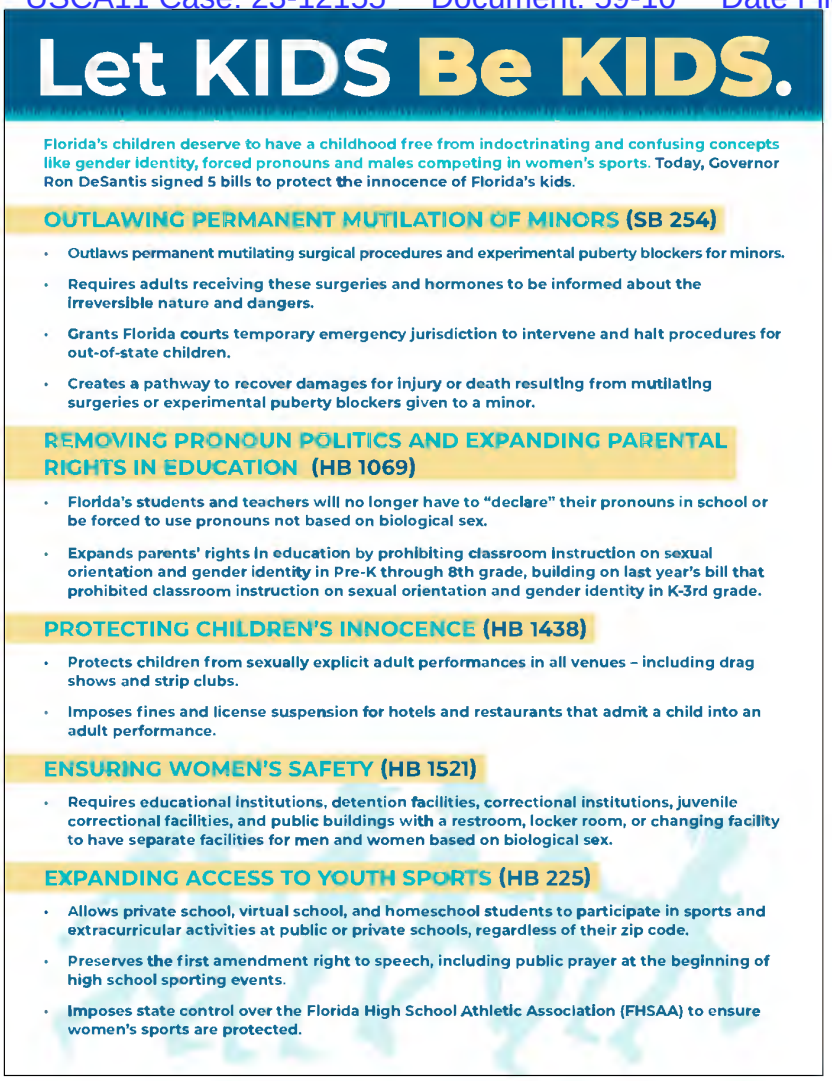
TAB 236-1

Governor Ron DeSantis Signs Sweeping Legislation to Protect the Innocence of Florida's Children

On May 17, 2023, in News Releases, by Staff

TAMPA, Fla. — Today, Governor Ron DeSantis signed the Let Kids Be Kids bill package to protect Florida's children from permanent mutilating surgical procedures, gender identity politics in schools, and attending sexually explicit adult performances. For more information about the bills signed today, click here.

Pl. Trial Ex. 365



Let KIDS Be KIDS.

Florida's children deserve to have a childhood free from indoctrinating and confusing concepts like gender identity, forced pronouns and males competing in women's sports. Today, Governor Ron DeSantis signed 5 bills to protect the innocence of Florida's kids.

OUTLAWING PERMANENT MUTILATION OF MINORS (SB 254)

- Outlaws permanent mutilating surgical procedures and experimental puberty blockers for minors.
- Requires adults receiving these surgeries and hormones to be informed about the irreversible nature and dangers.
- Grants Florida courts temporary emergency jurisdiction to intervene and halt procedures for out-of-state children.
- Creates a pathway to recover damages for injury or death resulting from mutilating surgeries or experimental puberty blockers given to a minor.

REMOVING PRONOUN POLITICS AND EXPANDING PARENTAL RIGHTS IN EDUCATION (HB 1069)

- Florida's students and teachers will no longer have to "declare" their pronouns in school or be forced to use pronouns not based on biological sex.
- Expands parents' rights in education by prohibiting classroom instruction on sexual orientation and gender identity in Pre-K through 8th grade, building on last year's bill that prohibited classroom instruction on sexual orientation and gender identity in K-3rd grade.

PROTECTING CHILDREN'S INNOCENCE (HB 1438)

- Protects children from sexually explicit adult performances in all venues – including drag shows and strip clubs.
- Imposes fines and license suspension for hotels and restaurants that admit a child into an adult performance.

ENSURING WOMEN'S SAFETY (HB 1521)

- Requires educational institutions, detention facilities, correctional institutions, juvenile correctional facilities, and public buildings with a restroom, locker room, or changing facility to have separate facilities for men and women based on biological sex.

EXPANDING ACCESS TO YOUTH SPORTS (HB 225)

- Allows private school, virtual school, and homeschool students to participate in sports and extracurricular activities at public or private schools, regardless of their zip code.
- Preserves the first amendment right to speech, including public prayer at the beginning of high school sporting events.
- Imposes state control over the Florida High School Athletic Association (FHSAA) to ensure women's sports are protected.

"Florida is proud to lead the way in standing up for our children," said **Governor Ron DeSantis**. "As the world goes mad, Florida represents a refuge of sanity and a citadel of normalcy."

"Thank you to Governor Ron DeSantis for continuing to implement legislation to keep our students safe and our schools focused on education, not indoctrination," said **Commissioner of Education Manny Diaz, Jr.** "Today's actions make it clear – educators in Florida are expected to teach our standards, and not interject their own opinions or worldview into the classroom. The Department will remain focused on teaching students core subjects, rather than woke gender ideology or inappropriate topics."

"Thank you Governor DeSantis for signing legislation that protects our children," said **Agency for Health Care Administration Secretary Jason Weida.** "Florida is following the science to elevate our standards of care to protect kids from harmful drugs and surgeries."

SB 254 – Treatments for Sex Reassignment:

- Prohibits sex reassignment surgeries and experimental puberty blockers for children.
- Requires adult patients who are receiving these medications or surgeries to be informed about the dangers and irreversible nature of these procedures and to give written, informed consent.
- Provides courts temporary emergency jurisdiction to step in and halt sex reassignment procedures for out-of-state children present in Florida.
- Creates a pathway for individuals to obtain damages when they were injured or killed after receiving sex reassignment surgeries or medications as minors.

HB 1069 protects students from having to declare their pronouns in school. Additionally, this bill expands parental rights in education by prohibiting classroom instruction on sexual orientation and gender identity in Pre-K through 8th grade.

HB 1438 protects children from sexually explicit performances in all venues. This bill prohibits a person from knowingly admitting a minor to an adult performance. Additionally, this legislation authorizes the Department of Business and Professional Regulation to fine, suspend, or revoke the operating or alcohol licenses of hotels or restaurants if they admit a child into an adult performance.

HB 1521 ensures that Florida's bathrooms, changing rooms, and locker rooms are safe places for women. The bill requires educational institutions, detention facilities, correctional institutions, juvenile correctional facilities, and public buildings with a restroom or changing facility to designate

separate facilities based on biological sex or to provide one-person unisex facilities.

The Governor also signed legislation to protect youth sports in Florida and ensure that all students can play sports without interference from extremist bureaucratic boards. HB 225 allows private school, virtual school, and home school students to participate in sports and other extracurricular activities at other public or private schools, regardless of zip code.

HB 225 also reorganizes the FHSAA Board of Directors to 13 members, instead of the current 16 members. Four members will be elected by school representative members while eight members will be appointed by the governor, and the final member will be the Commissioner of Education or his designee. This bill also allows teams to provide brief opening remarks, including prayers, before high school athletic contests.

###

Comments are closed.

Contact Governor DeSantis

Executive Office of Governor Ron DeSantis
400 S Monroe St
Tallahassee, FL 32399

(850) 488-7146

Email Governor DeSantis

Email First Lady DeSantis

Email Lt. Governor Nuñez

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TAB 241

United States District Court

CIVIL MINUTES - TRIAL

Case No.: 4:22cv325-RH

Dates: May 9-11, 2023
Dates: May 17-19, 2023
Dates: May 22, 2023

AUGUST DEKKER et al. v. JASON WEIDA et al.

PROCEEDINGS: Bench Trial held. Ruling by Court: The Court's ruling will be made in a separate order to follow.

PRESENT: ROBERT L. HINKLE, U.S. DISTRICT JUDGE

Cindy Markley
Deputy Clerk

Megan Hague, Judy Gagnon
Court Reporters

Attorneys for Plaintiffs:
Omar Gonzalez-Pagan
Katherine DeBriere
Jennifer Altman
Carl Charles
Abigail Coursolle
Catherine McKee
Simone Chriss
Chelsea Dunn
Joseph Little
William Miller
Gary Shaw
Shani Rivaux

Attorneys for Defendants:
Mohammad Jazil
Gary Perko
Michael Beato

☐ Case called and continued to _____.
☒ COURT TRIAL
☐ JURY TRIAL. Jury impaneled and sworn in. See separate minutes for jury selection.
☐ Jury retires to deliberate at _____ on _____.
☐ Jury returns at ____ on _____.
☐ JURY VERDICT. See signed verdict.
☐ Jury polled ☐ Polling waived ☐ Mistrial declared
☒ FINDINGS BY COURT: Order to follow.
☐ JUDGMENT BY COURT for ☐ Plaintiff ☐ Defendant for $_____
☐ Findings, Conclusion of Law, Judgment to be prepared by ☐ Plaintiff ☐ Defendant
☐ Briefs to be filed ☐ Plaintiff ☐ Defendant ☐ Reply
☐ Continued to _____ for ☐ setting trial ☐ further trial

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

CIVIL MINUTES

JUDGE ROBERT L. HINKLE
Cindy Markley, Courtroom Deputy
Megan Hague, Official Court Reporter (May 9-11, May 22)
Judy Gagnon, Contract Court Reporter (May 17-19)

Case: 4:22cv325-RH
Legend: Plaintiff Attys: Omar Gonzalez-Pagan
Katherine DeBriere
Jennifer Altman
Carl Charles
Abigail Coursolle
Catherine McKee
Simone Chriss
Chelsea Dunn
Joseph Little
William Miller
Gary Shaw
Shani Rivaux
Defense Attys: Mohammad Jazil
Gary Perko
Michael Beato

Bench Trial – Day 1
DATE: May 9, 2023

9:00 Court in session
Opening statement by Plaintiffs (Gonzalez-Pagan)
9:18 Opening statement by Defense (Jazil)
9:21 Plaintiff moves to admit all joint exhibits (Gonzalez-Pagan)
9:21 Ruling by Court: Exhibits identified in ECF 219 are admitted.
9:23 Plaintiff Witness:
Dan Karasic – sworn, direct (DeBriere)
Plaintiff Exhibit 359 – previously admitted
Defendant Exhibit 16 – previously admitted
10:51 Court in recess

11:05 Court in session
Continued direct examination (DeBriere)
12:04 Cross examination (Jazil)
Defendant Exhibit 16 – previously admitted
Plaintiff Exhibit 45 – shown to witness
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 140 – shown to witness
1:07 Court in recess

2:11 Court in session
Continued cross examination (Jazil)
Defendant Exhibit 24 – previously admitted
Defendant Exhibit 28 – shown to witness
2:42 Redirect (DeBriere)
2:55 Court inquires of witness
3:15 Plaintiff Witness:
Daniel Evan Shumer – sworn, direct (Coursolle)
Plaintiff Exhibit 360 – previously admitted
3:39 Court in recess

3:47 Court in session
Continued direct (Coursolle)
5:05 Parties discuss legislation
5:13 Plaintiff expresses intent to move to amend the complaint (Gonzalez-Pagan)
5:14 Response by Defense (Jazil)
5:18 Court addresses the parties
5:26 Court in recess

Bench Trial – Day 2
DATE: May 10, 2023

9:01 Court in session
Parties discuss housekeeping matters
9:04 Cross examination of Dr. Shumer (Jazil)
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 188 – shown to witness
Plaintiff Exhibit 235 – previously admitted (not published)
Plaintiff Exhibit 236B – previously admitted (not published)
9:37 Redirect (Coursolle)
9:52 Court inquires of witness
9:58 Additional cross examination (Jazil)
10:00 Court in recess

10:10 Court in session
Plaintiff Witness:
Loren Sloan Schechter – sworn, direct (McKee)
Plaintiff Exhibit 362 – previously admitted
10:43 Cross examination (Perko)
Plaintiff Exhibit 34 – shown to witness
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 234A – previously admitted (not published)
10:56 Redirect (McKee)
10:56 Court inquires of witness
11:00 Plaintiff Witness:
Armand Herbert Matheny Antommaria – sworn, direct (Charles)
Plaintiff Exhibit 157 – shown to witness
Defendant Exhibit 24 – previously admitted
12:14 Court in recess

1:15 Court in session
Continued direct (Charles)
Defendant Exhibit 28 – shown to witness
2:18 Cross examination (Perko)
Plaintiff Exhibit 157 – shown to witness
Plaintiff Exhibit 5 – shown to witness
Defendant Exhibit 8 – shown to witness
2:35 Court inquires of witness
2:41 Plaintiff Witness:
Jeffrey A. English – sworn, direct (Altman)
Plaintiff Exhibit 18 – marked, ID'd, admitted
Defendant Exhibit 6 – marked, ID'd, admitted
Plaintiff Exhibit 30 – marked, ID'd, admitted
Plaintiff Exhibit 23 – previously admitted
Plaintiff Exhibit 238 – previously admitted
Plaintiff Exhibit 302 – shown to witness
3:34 Court in recess

3:50 Court in session
Continued direct (Altman)
3:54 Cross examination (Perko)
Plaintiff Exhibit 23 – previously admitted
4:01 Redirect (Altman)
4:04 Court inquires of witness
4:07 Plaintiff Witness:
Kellan Baker – sworn, direct (Dunn)
Plaintiff Exhibit 363 – previously admitted
Plaintiff Exhibit 142 – shown to witness
Plaintiff Exhibit 71 – marked, ID'd, admitted
5:06 Parties discuss schedule
5:15 Court in recess

Bench Trial – Day 3
DATE: May 11, 2023

9:00 Court in session
Cross examination of Dr. Baker (Beato)
Plaintiff Exhibit 23 – previously admitted
Defendant Exhibit 4 – previously admitted
9:06 Redirect (Dunn)
9:09 Statement to the Court by Plaintiffs regarding schedule (Gonzalez-Pagan)
9:11 Plaintiff Witness:
Johanna Olson-Kennedy – sworn, direct (Gonzalez-Pagan)
Plaintiff Exhibit 361 – previously admitted
Plaintiff Exhibit 141 – shown to witness
10:41 Court in recess

10:55 Court in session
Cross examination (Jazil)
Defendant Exhibit 16 – previously admitted
Plaintiff Exhibit 141 – shown to witness

Plaintiff Exhibit 164 – shown to witness
Plaintiff Exhibit 176 – shown to witness
11:20 Redirect (Gonzalez-Pagan)
11:23 Court inquires of witness
11:30 Additional redirect (Gonzalez-Pagan)
11:34 Plaintiff Witness:
Jane Doe – sworn, direct (Coursolle)
11:57 Cross examination (Jazil)
12:01 Court inquires of witness
12:03 Plaintiff Witness:
Brit Rothstein – sworn, direct (Chriss)
12:43 Cross examination (Jazil)
Plaintiff Exhibit 234 – previously admitted (not published)
12:48 Court in recess

1:50 Court in session
Plaintiff Witness:
August Dekker – sworn, direct (Charles)
2:44 Cross examination (Jazil)
Plaintiff Exhibit 237A – previously admitted (not published)
2:47 Redirect (Charles)
Plaintiff Exhibit 237A – previously admitted (not published)
2:51 Plaintiff Witness:
Jade Ladue – sworn, direct (DeBriere)
3:31 Parties discuss schedule
3:32 Ruling by Court: Trial will continue Wednesday, May 17, at 9:00 a.m.
3:33 Court in recess

Bench Trial – Day 4
DATE: May 17, 2023

9:00 Court in session
Plaintiff Witness:
Elliot Kale Edmiston – sworn, direct (Rivaux)
Plaintiff Exhibit 357 – previously admitted
9:35 Cross examination (Beato)
Defendant Exhibit 16 – previously admitted
Defendant Exhibit 24 – previously admitted
Plaintiff Exhibit 351 – shown to witness
Plaintiff Exhibit 352 – shown to witness
Plaintiff Exhibit 354 – shown to witness
9:57 Court inquires of witness
10:02 Additional cross examination (Beato)
10:04 Plaintiff Witness:
Kim Hutton – sworn, direct (Little)
10:30 Cross examination (Perko)
10:31 Redirect (Little)
10:32 Court in recess

10:50 Court in session
10:51 Plaintiff Witness (by Zoom):
Aron Christopher Janssen – sworn, direct (Gonzalez-Pagan)
Plaintiff Exhibit 364 – previously admitted
11:45 Cross examination (Perko)
11:50 Redirect (Gonzalez-Pagan)
11:51 Court inquires of witness
11:54 Plaintiff addresses the court to clarify a previously admitted exhibit (Gonzalez-Pagan)
11:56 Response by Defense (Jazil)
11:59 Plaintiff moves to admit Plaintiff Exhibits 24, 21, 22, 74, 27, 28, 67, 62, 63, 295, 296, 330, 331, 332, 333, 291, 292, 292A, 313, 313A, 314, 315, 316, 254, 255, 263, 276, 346 (DeBriere)
Ruling by Court: Those exhibits are admitted with the exhibit of Plaintiff Exhibit 330.
12:31 Plaintiff moves to admit Plaintiff Exhibit 302 (Dunn)
12:32 Ruling by Court: Plaintiff Exhibit 302 is admitted.
12:32 Plaintiff moves to enter into evidence deposition designations (Dunn)
12:33 Ruling by Court: Those are admitted (Brackett, Dalton, Donovan). (Plaintiff will post them on the docket.)
12:36 Plaintiffs rest
Parties discuss possibility of amending complaint
12:43 Court in recess

1:45 Court in session
Defense Witness:
Paul William Hruz – sworn, direct (Perko)
Defendant Exhibit 29 – previously admitted
Defendant Exhibit 8 – shown to witness
Defendant Exhibit 9 – shown to witness
Defendant Exhibit 10 – shown to witness
Defendant Exhibit 11 – shown to witness
Defendant Exhibit 12 – shown to witness
Defendant Exhibit 13 – shown to witness
Defendant Exhibit 14 – shown to witness
2:55 Court inquires of witness
2:57 Cross examination (Rivaux)
Plaintiff Exhibit 46 – marked, ID'd, admitted
Plaintiff Exhibit 37 – marked, ID'd, admitted
Plaintiff Exhibit 38 – marked, ID'd, admitted
Plaintiff Exhibit 36 – marked, ID'd, admitted
Plaintiff Exhibit 39 – marked, ID'd, admitted
Plaintiff Exhibit 40 – marked, ID'd, admitted
Plaintiff Exhibit 41 – marked, ID'd, admitted
Plaintiff Exhibit 42 – marked, ID'd, admitted
Plaintiff Exhibit 45 – marked, ID'd, admitted
Plaintiff Exhibit 47 – marked, ID'd, admitted
Plaintiff Exhibit 48 – marked, ID'd, admitted
Plaintiff Exhibit 49 – marked, ID'd, admitted
3:40 Court in recess

3:55 Court in session
Continued cross examination (Rivaux)
Plaintiff Exhibit 43 – marked, ID'd, admitted

Defendant Exhibit 10 – shown to witness
Defendant Exhibit 13 – shown to witness
Plaintiff Exhibit 170 – shown to witness
4:19 Redirect (Perko)
Plaintiff Exhibit 38 – previously admitted
4:27 Defense moves to admit Defendant Exhibits 8-14 (Perko)
Ruling by Court: Those exhibits are admitted.
4:27 Court inquires of witness
4:50 Court in recess

Bench Trial – Day 5
DATE: May 18, 2023

9:01 Court in session
Defense Witness:
Stephen B. Levine – sworn, direct (Perko)
Defendant Exhibit 32 – previously admitted
9:50 Cross examination (Charles)
Defendant Exhibit 16 – previously admitted
10:35 Court in recess

10:50 Court in session
Continued cross examination (Charles)
11:06 Redirect (Perko)
11:15 Court inquires of witness
12:07 Court in recess

1:10 Court in session
Defense Witness:
Patrick Walter Lappert – sworn, direct (Jazil)
Defendant Exhibit 31 – previously admitted
1:27 Voir dire of witness by Plaintiff (Miller)
1:32 Continued direct (Jazil)
Defendant Exhibit 16 – previously admitted
1:52 Cross examination (Miller)
Plaintiff Exhibit 81 – shown to witness
Plaintiff Exhibit 135 – shown to witness
2:01 Defense Witness:
Kristopher Edward Kaliebe – sworn, direct (Perko)
Defendant Exhibit 30 – previously admitted
2:09 Voir dire of witness by Plaintiff (Gonzalez-Pagan)
2:15 Court inquires of witness
2:20 Continued direct (Perko)
2:35 Cross examination (Gonzalez-Pagan)
2:46 Court inquires of witness
2:53 Parties discuss schedule and other housekeeping matters
2:58 Ruling by Court: Motion to amend complaint is granted.
3:01 Parties discuss preliminary injunction in the Doe case
3:09 Ruling by Court: Motion for leave to amend the complaint in the Doe case is granted.
3:10 Court in recess

3:14 Court in session
Parties discuss preliminary injunction and temporary restraining order in the Doe case
3:26 Court in recess

Bench Trial – Day 6
DATE: May 19, 2023

10:20 Court in session
Defense Witness:
Ann Dalton – sworn, direct (Beato)
Plaintiff Exhibit 238 – previously admitted
10:35 Cross examination (Dunn)
Plaintiff Exhibit 29 – shown to witness
Plaintiff Exhibit 291 – previously admitted
Plaintiff Exhibit 321 – previously admitted
Plaintiff Exhibit 320 – previously admitted
Plaintiff Exhibit 292A – previously admitted
Plaintiff Exhibit 294 – previously admitted
Plaintiff Exhibit 295 – previously admitted
Plaintiff Exhibit 296 – previously admitted
Plaintiff Exhibit 297A – previously admitted
11:07 Court inquires of witness
11:14 Additional cross examination (Dunn)
11:15 Court in recess

11:20 Court in session
11:21 Defense Witness:
John Matthew Brackett – sworn, direct (Jazil)
Plaintiff Exhibit 23 – previously admitted
Defendant Exhibit 6 – previously admitted
Plaintiff Exhibit 329 – previously admitted
Plaintiff Exhibit 297A – previously admitted
Defendant Exhibits 1, 2, 3 – previously admitted
Plaintiff Exhibits 240, 242, 244 – previously admitted
Plaintiff Exhibit 326 – previously admitted
12:08 Cross examination (DeBriere)
Plaintiff Exhibit 141 – shown to witness
Plaintiff Exhibit 18 – previously admitted
Plaintiff Exhibit 166 – shown to witness
Plaintiff Exhibit 176 – shown to witness
Plaintiff Exhibit 151 – shown to witness
Plaintiff Exhibit 154 – shown to witness
Plaintiff Exhibit 155 – shown to witness
Plaintiff Exhibit 192 – shown to witness
Plaintiff Exhibit 23 – previously admitted
Plaintiff Exhibit 331 – previously admitted
Plaintiff Exhibit 284 – previously admitted
Plaintiff Exhibit 285 – previously admitted
Plaintiff Exhibit 303 – previously admitted
Plaintiff Exhibit 286A – previously admitted
Plaintiff Exhibit 291 – previously admitted

Plaintiff Exhibit 365 – marked, ID'd, admitted
12:57 Redirect (Jazil)
Defendant Exhibit 6 – previously admitted
Plaintiff Exhibit 176 – shown to witness
1:01 Court inquires of witness
1:09 Additional redirect (Jazil)
1:10 Additional cross examination (DeBriere)
1:11 Court in recess

Bench Trial – Day 7
DATE: May 22, 2023

9:00 Court in session
Defense Witness (by Zoom):
Sophie Kerttu Scott – sworn, direct (Jazil)
Defendant Exhibit 33 – previously admitted
9:13 Voir dire by Defense (Shaw)
9:18 Plaintiff moves to exclude witness testimony
9:21 Ruling by Court: The motion to exclude testimony in its entirety is denied.
9:25 Continued direct (Jazil)
9:57 Cross examination (Shaw)
10:15 Redirect (Jazil)
10:18 Court inquires of the witness
10:25 Defense rests
10:25 Court in recess

10:40 Court in session
10:43 Closing argument by Plaintiffs (Gonzalez-Pagan)
11:30 Closing argument by Defense (Jazil)
12:31 Rebuttal by Plaintiffs (Gonzalez-Pagan)
12:37 Ruling by Court: An order will follow.
12:40 Court adjourned

TAB 241-1

AO 187 (Rev. 7/87) Exhibit and Witness List

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF FLORIDA

AUGUST DEKKER et al.

v.

JASON WEIDA et al.

EXHIBIT LIST

Case Number: 4:22cv325-RH

PRESIDING JUDGE	PLAINTIFF ATTORNEYS	DEFENSE ATTORNEYS
Robert L. Hinkle	Omar Gonzalez-Pagan, Katherine DeBriere, et al.	Mohammad Jazil, Gary Perko, Michael Beato
HEARING DATE	**COURT REPORTERS**	**COURTROOM DEPUTY**
May 9-11, 2023 May 17-19, 2023 May 22, 2023	Megan Hague (May 9-11, May 22) Judy Gagnon (May 17-19)	Cindy Markley

PLTF. NO.	DFT. NO.	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS
				All exhibits were pre-filed on the docket
1		5/9/23	5/9/23	Defendants' Response to Pls' First Set of Request for Admissions
2		5/9/23	5/9/23	Defendants' Response to Pls' First Set of Interrogatories
3		5/9/23	5/9/23	Defendants' Response to Pls' Second Set of Interrogatories
4		5/9/23	5/9/23	Pls' First Set of Request for Admissions
18		5/10/23	5/10/23	AHCA GAPMS June 2022
19		5/9/23	5/9/23	Marstiller Letter to Wallace re AHCA June 2022 GAPMS
20		5/9/23	5/9/23	Fla. Admin. Code R. 59G-1.050
21		5/17/23	5/17/23	Fla. Admin. Code R. 59G-1.010
22		5/17/23	5/17/23	Florida Medicaid Definitions Policy (Aug. 2017)
23		5/9/23	5/9/23	Fla. Admin. Code R. 59G-1.035
		5/9/23	5/9/23	AHCA's Preferred Drug List, accessible at: https://ahca.myflorida.com/content/download/8681/file/PDL.pdf (online only); including but not limited to the criteria for testosterone: https://ahca.myflorida.com/content/download/6451/file/Testosterone_Criteria.pdf
		5/9/23	5/9/23	AHCA's Drug Criteria, accessible at: https://ahca.myflorida.com/medicaid/prescribed-drugs/drug-criteria (online only)
24		5/17/23	5/17/23	AHCA's Automated Prior Authorizations and Bypass Lists 01-2023
25		5/9/23	5/9/23	DRUGDEX listing for Testosterone
26		5/9/23	5/9/23	DRUGDEX listing for Estradiol
27		5/17/23	5/17/23	Prior Authorization Criteria - Testosterone
28		5/17/23	5/17/23	Agency Responses to Plaintiffs' Questions: March 1, 2023
30		5/10/23	5/10/23	Email communication between Jeffrey English and Devona Pickle – 3/22/22

33		5/9/23	5/9/23	DSM 5 Gender Dysphoria
36		5/17/23	5/17/23	AACAP Statement Responding to Efforts to Ban Care (Nov. 8, 2019)
37		5/17/23	5/17/23	AAFP – Care for Transgender Patients
38		5/17/23	5/17/23	AAP – Ensuring Comprehensive Care and Support
39		5/17/23	5/17/23	ACOG Committee Opinion on Health Care for Transgender Individuals (March 2021)
40		5/17/12	5/17/23	ACP – Attacks on Gender-Affirming and Transgender Health Care (May 3, 2022)
41		5/17/23	5/17/23	LGBT Health Disparities Policy, ACOP
42		5/17/23	5/17/23	AMA Letter to Nat'l Gov. Assoc. (April 26, 2021)
43		5/17/23	5/17/23	AMA/GLMA Issue Brief on health insurance coverage for gender-affirming care
45		5/17/23	5/17/23	APA, Guidelines for Psychological Practice with Transgender and Gender Non-conforming People
46		5/17/23	5/17/23	APA Resolution on Gender Identity Change Efforts (Feb. 2021)
47		5/17/23	5/17/23	APA Position Statement Trans and Gender Diverse Youth (July 2020)
48		5/17/23	5/17/23	APA Position Statement on Access to Care (July 2018)
49		5/17/23	5/17/23	Endocrine Society Transgender Health Position Statement
62		5/17/23	5/17/23	Ctrs. for Medicare & Medicaid Servs., EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents
63		5/17/23	5/17/23	Ctrs. for Medicare & Medicaid Servs., CMCS Informational Bulletin (July 21, 2022), https://www.medicaid.gov/federal-policy-guidance/downloads/cib07212022.pdf
64		5/9/23	5/9/23	Ctrs. for Medicare & Medicaid Servs., Decision Memo for Gender Dysphoria and Surgery (Aug. 20, 2016)
67		5/17/23	5/17/23	FDA, Understanding Unapproved Use of Approved Drugs "Off Label," (2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label
71		5/10/23	5/10/23	Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2576 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/boarddecisions/2014/dab2576.pdf
72		5/9/23	5/9/23	OASH, Gender-Affirming Care and Young People
74		5/17/23	5/17/23	SAMHSA, Moving Beyond Change Efforts (2023)
229		5/9/23	5/9/23	Template Notice of Adverse Benefit Determination
230		5/9/23	5/9/23	Template Notice of Plan Appeal Resolution
231		5/9/23	5/9/23	Sample AHCA Final Order – 20-FH0855
232		5/9/23	5/9/23	Medical records of August Dekker
234		5/9/23	5/9/23	Medical records of Brit Rothstein
234A		5/9/23	5/9/23	Medical records of Brit Rothstein
235		5/9/23	5/9/23	Medical records of K.F.
235A		5/9/23	5/9/23	Medical records of K.F.
236		5/9/23	5/9/23	Medical records of S.D.

236A		5/9/23	5/9/23	Medical records of S.D.
236B		5/9/23	5/9/23	Medical records of S.D.
236C		5/9/23	5/9/23	Medical records of S.D.
237		5/9/23	5/9/23	Dekker medical records
237A		5/9/23	5/9/23	Dekker medical records
238		5/9/23	5/9/23	GAPMS Decision Tree Checklist
239		5/9/23	5/9/23	GAPMS – GnRH for treatment of gender dysphoria
240		5/9/23	5/9/23	GAPMS – GnRH for treatment of gender dysphoria
241		5/9/23	5/9/23	GAPMS – Cross Sex Hormone Therapy – 5/20/2022
242		5/9/23	5/9/23	GAPMS – Cross Sex Hormone Therapy Report (edited) - 5/20/2022
243		5/9/23	5/9/23	GAPMS – Cross Sex Hormone Therapy – 11/2/2016
244		5/9/23	5/9/23	GAPMS – Gender Confirmation Surgery (incomplete) – 7/19/2017
250		5/9/23	5/9/23	AHCA review of research – 7/25/2016
254		5/17/23	5/17/23	Arlene Elliot email re GnRH coverage – 8/29/2016
255		5/17/23	5/17/23	Rebecca Borgert email regarding Endocrine Society guidelines – 8/29/2016
256		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for puberty suppression therapy – 8/31/2016
257		5/9/23	5/9/23	Special services criteria re GnRH coverage – 9/20/2016 (updated 11/17/17)
260		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for cross-sex hormone therapy – 11/2/2016
263		5/17/23	5/17/23	Draft GAPMS re gender-affirming surgery – 7/19/2017
264		5/9/23	5/9/23	Email exchange re Medicaid coverage of gender affirming surgery – June 2018
264A		5/9/23	5/9/23	Email exchange re Medicaid coverage of gender affirming surgery – June 2018
265		5/9/23	5/9/23	AHCA routing form tracking response to MCO question about Medicaid coverage of surgery – June 2018
266		5/9/23	5/9/23	AHCA document closing the project re responding to MCO question about Medicaid coverage of surgery – June 2018
272		5/9/23	5/9/23	Email from Andy Bardos to Andrew Sheeran re Cantor and legal research – 4/11/2022
273		5/9/23	5/9/23	Email forwarded by Andrew Sheeran from Ashley Lukis scheduling a call with James Cantor – 4/13/2022
274		5/9/23	5/9/23	Email from Andrew Sheeran to Miriam Grossman – 4/14/2022
275		5/9/23	5/9/23	Email exchange between Andrew Sheeran and Romina Brignardello Petersen – 4/18/2022
276		5/17/23	5/17/23	Email from Susan Williams to Shantrice Green re GAPMS on cross-sex hormone therapy – 4/20/2022
277		5/9/23	5/9/23	Email from Amy Zitiello to Vern Hamilton regarding FDOH guidance – 4/20/2022
277A		5/9/23	5/9/23	Email from Amy Zitiello to Vern Hamilton regarding FDOH guidance – 4/20/2022
279		5/9/23	5/9/23	Communication between Jason Weida and Dr. Michelle Cretella – 4/21/2025

280		5/9/23	5/9/23	Communication between Romina Brignardello-Petersen and Jason Weida regarding types of surgeries on which to focus – 4/25/2022
281		5/9/23	5/9/23	Communication between Jason Weida and Vern Hamilton regarding planned response to Dr. Zitiello's question about FDOH guidance – 4/29/2022
282		5/9/23	5/9/23	Draft GAPMS on gender affirming surgery (with handwritten notes) - May 2022
283		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283A		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283B		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283C		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283D		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
283E		5/9/23	5/9/23	Jason Weida communication regarding report from Romina Brignardello-Petersen – 5/5/2022
284		5/9/23	5/9/23	Jason Weida communication regarding articles provided to him by Dr. Van Mol – 5/6/2022
285		5/9/23	5/9/23	Dr. Van Mol communication with Jason Weida and Matthew Brackett about gender affirming care – 5/7/022
286		5/9/23	5/9/23	Dr. Van Mol's edits to June 2022 GAPMS memo – 5/13/2022
286A		5/9/23	5/9/23	Dr. Van Mol's edits to June 2022 GAPMS memo – 5/13/2022
286B		5/9/23	5/9/23	Dr. Van Mol's edits to June 2022 GAPMS memo – 5/13/2022
287		5/9/23	5/9/23	Text message from Jason Weida regarding Eknes-Tucker and James Cantor – 5/17/2022
288		5/9/23	5/9/23	Email from Shantrice Green to Susan Williams and Kelly Rubin regarding the GAPMS memo on cross-sex hormone therapy – 5/20/2022
289		5/9/23	5/9/23	Draft of GAPMS cross-sex hormone therapy memo – 5/20/2022
291		5/17/23	5/17/23	Email between Dr. Van Mol and Jason Weida regarding reimbursement – 5/21/2022
292		5/17/23	5/17/23	Invoices from Romina Brignardello-Petersen – 5/24/2022
292A		5/17/23	5/17/23	Invoices from Romina Brignardello-Petersen – 5/24/2022
294		5/9/23	5/9/23	Projected Rulemaking Timeline – June 2022
295		5/17/23	5/17/23	Gender Dysphoria/Transgender Health Care Non-Legislative Pathway – June 2022
296		5/17/23	5/17/23	Gender Dysphoria/Transgender Health Care Policy Pathway – June 2022
297		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for June 2022 GAPMS – 6/1/2022
297A		5/9/23	5/9/23	AHCA GAPMS routing and tracking form for June 2022 GAPMS – 6/1/2022
298		5/9/23	5/9/23	Communication between Ashley Peterson and Jason Weida regarding an inventory of gender affirming care – 6/3/2022
298A		5/9/23	5/9/23	Communication between Ashley Peterson and Jason Weida regarding an inventory of gender affirming care – 6/3/2022
299		5/9/23	5/9/23	Email communication between AHCA and Magellan regarding coverage of GnRH to treat gender dysphoria

300		5/9/23	5/9/23	AHCA communication regarding the Special Services Criteria for puberty blockers – 6/10/2022
301		5/9/23	5/9/23	Communication between Jason Weida and Dr. Van Mol about a witness for the July 8th hearing – 6/14/2022
302		5/17/23	5/17/23	Email communication between Dr. Christopher Cogle and Jeffrey English – 6/27/2022
303		5/9/23	5/9/23	Communication regarding meeting between Miriam Grossman, Dr. Van Mol, Jason Weida, Andrew Sheeran, and Holtzman Vogel regarding July 8th hearing – 6/30/2022
304		5/9/23	5/9/23	Communication between Dr. Van Mol and AHCA - 7/2/2022
305		5/9/23	5/9/23	Brief of the July 8th rule hearing – 7/8/2022
306		5/9/23	5/9/23	Transcript from July 8th rule hearing – 7/8/2022
307		5/9/23	5/9/23	Email from Miriam Grossman – 7/10/2022
308		5/9/23	5/9/23	Email communications with Jason Weida and Dr. Van Mol – 7/14/2022
309		5/9/23	5/9/23	Communications regarding AHCA's development of public comment binder provided to the consultants – 7/19/2022
310		5/9/23	5/9/23	Invoice from Dr. Van Meter – 8/4/2022
311		5/9/23	5/9/23	Communication to Jason Weida regarding witnesses for a hearing – 8/10/2022
312		5/9/23	5/9/23	Invoices from Dr. Van Mol – 8/11/2022
313		5/17/23	5/17/23	Email communications regarding implementation of 59G-1.050(7) - 8/22/2022
313A		5/17/23	5/17/23	Email communications regarding implementation of 59G-1.050(7) - 8/22/2022
314		5/17/23	5/17/23	Communication between AHCA and EOG regarding planned communications about June 2022 GAPMS and 59G-1.050(7) - 8/22/2022
315		5/17/23	5/17/23	SMMC Policy Transmittal draft regarding non-coverage of gender dysphoria treatments – August 22, 2022
316		5/17/23	5/17/23	AHCA Medicaid Health Care Alert regarding prohibition on coverage for gender affirming care
317		5/9/23	5/9/23	AHCA draft response to media regarding gender affirming care – 9/1/2022
318		5/9/23	5/9/23	List of appeals for denials of hormone therapy – 12/19/2022
319		5/9/23	5/9/23	List of requests for surgery to treat gender dysphoria – 12/19/2022
320		5/9/23	5/9/23	AHCA After the Fact Request form for Quentin Van Meter – 6/13/2022
321		5/9/23	5/9/23	AHCA After the Fact Request form for Andre Van Mol – 5/26/2022
322		5/9/23	5/9/23	Draft of welcome/opening remarks for July 8th rule hearing
323		5/9/23	5/9/23	Endocrine Society public comment
324		5/9/23	5/9/23	Yale public comment
325		5/9/23	5/9/23	American Academy of Pediatrics public comment
326		5/9/23	5/9/23	Florida Medicaid, Comment Summary for Rule 59G-1.050 (20 pages)
327		5/9/23	5/9/23	Florida Medicaid, Comment Summary for Rule 59G-1.050 (17 pages)
328		5/9/23	5/9/23	Email communication between Van Mol and Weida and attachment
328A		5/9/23	5/9/23	Email communication between Van Mol and Weida and attachment

329		5/9/23	5/9/23	Florida Medicaid & G/TAT, Andrea Van Mol – May 2022
331		5/17/23	5/17/23	GAPMS – Scleral Contact Lenses
332		5/17/23	5/17/23	GAPMS – Fractional Exhaled Nitric Oxide
333		5/17/23	5/17/23	GAPMS – Breast Pump
334		5/9/23	5/9/23	Email from Miriam Grossman – July 7, 2022
335		5/9/23	5/9/23	Proposed media response from Brock Juarez to Taryn Fenske – 8/29/2022
337		5/9/23	5/9/23	Email communication between Van Meter and AHCA Counsel
338		5/9/23	5/9/23	AHCA Microsoft Teams Meeting Invite
340		5/9/23	5/9/23	AHCA Van Meter Invoice
341		5/9/23	5/9/23	HCA Hearing on General Medicaid Policy
342		5/9/23	5/9/23	Email communication between Devona Pickle and Van Meter
343		5/9/23	5/9/23	Email communication between consultants, counsel, and Van Meter
344		5/9/23	5/9/23	AHCA Teams Meeting Invites
344A		5/9/23	5/9/23	AHCA Teams Meeting Invites
345		5/9/23	5/9/23	Email communication between AHCA and consultants
346		5/17/23	5/17/23	Email communication between Sheeran and Brignardello-Petersen
347		5/9/23	5/9/23	Email communication between Van Mol and Weida
348		5/9/23	5/9/23	Van Mol comments to Alstott letter
350		5/9/23	5/9/23	Email communication between Cantor and Weida
355		5/9/23	5/9/23	Spreadsheet summarizing Florida Medicaid coverage
356		5/9/23	5/9/23	DOJ, Dear State Attorneys General Letter re Transgender Youth (March 31, 2022)
357		5/9/23	5/9/23	Curriculum Vitae of Dr. Kale Edmiston
358		5/9/23	5/9/23	Curriculum Vitae of Dr. Armand Antommaria
359		5/9/23	5/9/23	Curriculum Vitae of Dr. Dan H. Karasic
360		5/9/23	5/9/23	Curriculum Vitae of Dr. Daniel Shumer
361		5/9/23	5/9/23	Curriculum Vitae of Dr. Johanna Olson-Kennedy
362		5/9/23	5/9/23	Curriculum Vitae of Dr. Loren S. Schechter
363		5/9/23	5/9/23	Curriculum Vitae of Kellan E. Baker, Ph.D.
364		5/9/23	5/9/23	Curriculum Vitae of Dr. Aron Janssen
365		5/19/23	5/19/23	Press Release
	1	5/9/23	5/9/23	U.S. Health and Human Services Notice and Guidance on Care
	2	5/9/23	5/9/23	U.S. Health and Human Services Fact Sheet on Gender-Affirming Care

	3	5/9/23	5/9/23	U.S. Department of Justice Letter to State Attorneys General
	4	5/9/23	5/9/23	Centers for Medicare and Medicaid Services Decision Memo for Gender Dysphoria and Gender Reassignment Surgery
	5	5/9/23	5/9/23	Florida Department of Health Fact Sheet on Treatments for Gender Dysphoria
	6	5/10/23	5/10/23	Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (with attachments)
	8	5/17/23	5/17/23	Sweden's Care of Children and Adolescents with Gender Dysphoria, Summary of National Guidelines
	9	5/17/23	5/17/23	Finland's Recommendation of the Council for Choices in Health Care in Finland
	10	5/17/23	5/17/23	The Cass Review, Independent Review of Gender Identity Services for Children and Young People
	11	5/17/23	5/17/23	National Institute for Health and Care Excellence, Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria
	12	5/17/23	5/17/23	National Institute for Health and Care Excellence, Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria
	13	5/17/23	5/17/23	France's Academie Nationale de Medecine Press Release
	14	5/17/23	5/17/23	The Royal Australian and New Zealand College of Psychiatrists' Position Statement on Gender-Affirming Care
	16	5/9/23	5/9/23	WPATH Standards of Care, Version 8
	17	5/9/23	5/9/23	WPATH Standards-of-Care-Revision Team Criteria
	18	5/9/23	5/9/23	WPATH's Press Release Regarding Florida Department of Health
	19	5/9/23	5/9/23	WPATH's Statement of Opposition to Florida Draft Rule Banning Gender Affirming Care for Adolescents
	20	5/9/23	5/9/23	WPATH's Press Release on National and International Issues
	21	5/9/23	5/9/23	WPATH's Letter to Japanese Officials
	22	5/9/23	5/9/23	WPATH's Press Release Regarding New York Times Article
	23	5/9/23	5/9/23	WPATH Press Release on United Kingdom Matter
	24	5/9/23	5/9/23	Endocrine Society Guidelines on Treatments for Gender Dysphoria
	26	5/9/23	5/9/23	American Academy of Pediatrics, Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents
	29	5/9/23	5/9/23	Curriculum Vitae of Dr. Paul Hruz
	30	5/9/23	5/9/23	Curriculum Vitae of Dr. Kristopher Kaliebe
	31	5/9/23	5/9/23	Curriculum Vitae of Dr. Patrick Lappert
	32	5/9/23	5/9/23	Curriculum Vitae of Dr. Stephen Levine
	33	5/9/23	5/9/23	Curriculum Vitae of Dr. Sophie Scott
	34	5/9/23	5/9/23	Curriculum Vitae of Dr. Quentin Van Meter
	35	5/9/23	5/9/23	Curriculum Vitae of Dr. Joseph Zanga
	36	5/9/23	5/9/23	Curriculum Vitae of Dr. Michael Laidlaw

TAB A

CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2023, I filed a true and correct copy of the foregoing with the Clerk of the United States Court of Appeals for the Eleventh Circuit by using the appellate case filing CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan