No. 23-12155

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

August Dekker et al.,
Plaintiffs-Appellees,

v.

Secretary, Florida Agency for Health Care Administration et al.,
Defendants-Appellants.

U.S. District Court for the Northern District of Florida, No. 4:22-cv-325
(Hinkle, J.)

APPELLANTS' APPENDIX – VOLUME VII OF XXI

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Dated: October 13, 2023

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at 140:5–141:24, 179:7-18.) He has publicly stated that his "primary research opportunities have involved studying sex offenders, mostly pedophiles and persons with other atypical sexualities whose behaviors led them into the legal system." (Swaminathan Decl., Ex. E; Swaminathan Decl., Ex. B at 140:5–141:24.)

At his deposition, Dr. Cantor admitted that he is not an endocrinologist, has not personally diagnosed any child or adolescent with gender dysphoria, has never personally treated any child or adolescent for gender dysphoria, and does not provide psychotherapy counseling to children or adolescents with gender dysphoria. (Swaminathan Decl., Ex. B at 179:1-14.) None of Dr. Cantor's professional roles have involved significant contact—or in many cases, any contact—with children or adolescents. During Dr. Cantor's fellowship at the Center for Addiction and Mental Health ("CAMH"), the average age of the patients he provided one-on-one therapy to was early 40s, the youngest being in their "late teens, early 20s." (*Id*. at 50:10-19.) Approximately 80 percent of the patients that Dr. Cantor saw at CAMH had been adjudicated as sex offenders. (*Id.* at 151:7-10.) When Dr. Cantor assumed his next professional role at Queen Elizabeth Hospital in Montreal, he did not provide psychotherapy to children or adolescents—he "predominantly worked with adults who came in with depression and anxiety disorders[.]" (*Id*. at 54:7-14.) Subsequently, while completing his post-doctoral studies within the law and mental health program, Dr. Cantor did not work with children and adolescents with gender dysphoria. (*Id*. at 61:4-8.) Dr. Cantor then became Senior Scientist at CAMH, where even while supervising the work of his interns, Dr. Cantor testified that he never worked directly with children or adolescents with gender dysphoria. (*Id*. at 68:22–69:2.) His supervision of the CAMH interns never involved research around puberty-delaying treatment prescribed to transgender adolescents nor hormone therapy prescribed to transgender adults. (*Id*. at 132:11-19.) In fact, in Dr. Cantor's current private practice, he has only

treated "about six to eight patents ages 16 to 18," and was unable to identify whether these patients were transgender or had gender dysphoria. (*Id*. at 179:15-18, 180:8-13.)

Dr. Cantor admitted at his deposition—as he must—that he has almost no experience researching and writing about or administering mental health treatment to transgender adolescents. Indeed, in the list of 64 articles he has authored or co-authored, only one even mentions transgender children ("The Recalled Childhood Gender Identity"), and Dr. Cantor was not a primary author of the article and did not himself carry out any portion of the study. (Swaminathan Decl., Ex. B at 102:8-14.)

In sum, Dr. Cantor is not recognized as an expert in providing treatment to transgender children or adolescents, does not have the requisite qualifications to provide treatment to transgender children or adolescents, has never treated nor delivered any psychiatric care to transgender children or adolescents in his day-to-day practice, has never written about or researched the provision of care to transgender children and adolescents, and has extremely limited experience working with children and adolescents in any capacity. (*Id*. at 179:4-14.) For all these reasons, Dr. Cantor is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of transgender children.

1. Dr. Cantor Admits That He Is Not Qualified To Offer Opinions On H.B. 3293 Or Transgender Athletes.

Astonishingly, Dr. Cantor admitted that he is not providing any testimony relating to the three purported governmental interests that the State of West Virginia ("State") asserts are advanced by H.B. 3293: 1) to protect women's sports; 2) to follow Title IX; and 3) to protect women's safety in female athletic sports. (Pl's SUF ¶ 59.) When asked whether he is "offering an expert opinion with respect to whether H.B. 3293 serves the interest of protecting women's

sports," Dr. Cantor responded he "[hadn't] been asked that, no." (Swaminathan Decl., Ex. B at 178:3-6.) When asked whether he is "offering an opinion with respect to whether H.B. 3293 serves the interest of following Title IX," Dr. Cantor responded that he "[hadn't] been asked that, no." (Swaminathan Decl., Ex. B at 178:7-10.) When asked whether he is "offering an opinion with respect to whether H.B. 3293 serves the interest of protecting women's safety in female athletic sports," Dr. Cantor again responded that he "[had not] been asked that, no." (Swaminathan Decl., Ex. B at 178:11-14.) When asked whether he has "any opinions on whether H.B. 3293 should apply to college athletes," Dr. Cantor responded that he has "no opinion in any direction." (Swaminathan Decl., Ex. B at 178:18-20.)

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The opinions expressed by Dr. Cantor are insufficiently tied to the facts of this case so that they will aid a factfinder in determining whether a categorical ban on transgender girls and women participating on girl's and women's sports team is lawful, and should therefore be excluded as irrelevant.

C. Dr. Cantor's Testimony Is Methodologically Unreliable And Unsupported By Science Or Medicine.

Expert testimony should only be admitted if its methodology is sufficiently reliable. *Sardis*, 10 F.4th at 281. Dr. Cantor's opinions fall far short of the reliability standard. Dr. Cantor's theory that "it remains entirely *plausible* that the psychotherapy [alone without] puberty blockers caused the improvements" in the mental health of transgender adolescents is pure speculation that has never been tested. (Swaminathan Decl., Ex. A at ¶ 54 (emphasis added).) But plausibility does not satisfy any standard for an expert opinion. Such speculative opinions should be excluded, especially given this Circuit's holding that "proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *see also Dunn v. Sandoz Pharms. Corp.*, 275 F.Supp.2d 672, 684 (M.D.N.C. 2003) ("[S]peculation is unreliable evidence and is inadmissible").

Dr. Cantor asserts without any evidence whatsoever that his views are accepted and shared by the amorphous and unspecific "scientific community." (Swaminathan Decl., Ex. B at 210:2-25.) Dr. Cantor asserts that "several scores" of people, comprised of individuals he is "in regular contact with," agree with his opinions as to withholding social transition in prepubertal children with gender dysphoria. (*Id.*) He admitted that his communications with these individuals, primarily sex researchers and sex therapists (none of whom specialize in care of transgender patients), are his "primary source" of evidence for the assertion that "practitioners support withholding social transition in prepubertal patients with gender dysphoria." (*Id.* at 211:4-15, 211:17-22.) Dr. Cantor's opinions thus are not rooted in science—they are personal opinions he

has formed through communications with groups of individuals who he is in routine contact with, and who are not practitioners specializing in the treatment of children and adolescents with gender dysphoria.[3]

Furthermore, Dr. Cantor fails to address how his experience and communications with other "sexologists"—which he claims are sufficient foundation for his opinions—leads to the conclusions he draws in this case. *See*, *e.g.*, *Cooper,* 259 F.3d at 200 (affirming the exclusion of an expert because he "asserted what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method."); *SAS Inst.*, 125 F. Supp. 3d at 589; *see also Nat'l Ass'n. for Rational Sexual Offense L.*, 2021 WL 736375, at *3 (excluding expert where offering party failed to establish how expert's "experience leads to his conclusions nor how those experiences have been reliably applied to the facts").

Another unreliable opinion presented by Dr. Cantor is that "the majority" of prepubertal children who experience gender dysphoria will cease to be transgender. (Swaminathan Decl., Ex. B at 191:11-24; 212:19-213:3 ("[R]esearch has unanimously shown that the majority of children with gender dysphoria desist – that is, cease to experience such dysphoria by or during puberty."). Dr. Cantor's only support for this concept is "11 studies listed on [his] blog." (Swaminathan Decl., Ex. B at 206:12–207:11.) Upon closer inspection, these sources are woefully inadequate to support his assertion. All of his sources suffer from the same malady: they purported to show desistance among children who were identified as having gender dysphoria under prior versions of the

[3] Even Defendants' other experts disagree with Dr. Cantor. Dr. Cantor opposes allowing transgender children to live in accordance with their gender identity, (Swaminathan Decl., Ex. B at 210:2-25), but Defendants' proposed expert, Dr. Stephen Levine, "cooperate[s] with" social transition and even has supported "people who already had social transition . . . in the face of their parents' objection." (Swaminathan Decl., Ex. H (Levine Dep.) at 141:7-11.)

American Psychiatric Association's Diagnostic and Statistical Manual ("DSM"). Those versions included a now-obsolete and overly broad diagnosis for "Gender Identity Disorder in Children," which differs in key ways from the current DSM-5 diagnostic criteria for "Gender Dysphoria in Children." As another expert in this matter explained, the older Gender Identity Disorder diagnosis did not require a finding that the child had a gender identity different from the sex assigned at birth. (Swaminathan Decl., Ex. D at 324:16–325:4.) As a result, those older studies tended to mischaracterize gender-nonconforming children as transgender. Such studies cannot be relied on to draw conclusions regarding "desistance" in prepubertal youth diagnosed with gender dysphoria.

Similarly, Dr. Cantor criticizes studies showing positive outcomes for transgender children who access puberty-delaying treatment as unreliable because there is "no method of separating how much of its result was due to psychotherapy versus due to medical intervention." (*Id*. at 252:6-10.) But this criticism is not meaningful: these studies nonetheless indicate that gender-affirming care leads to positive outcomes for transgender youth. (*See e.g.*, Swaminathan Decl., Ex. B at 233:1-10, 229:16-22.)

Chief among Dr. Cantor's many unreliable opinions is his assertion that wide disagreement exists about the appropriate treatment for gender dysphoria and that the SOC are not accepted by his amorphous and unspecified "scientific community." (Swaminathan Decl., Ex. A at ¶ 8(c).) Contrary to Dr. Cantor's personal feelings, which were formed as discussed above through communications with "several scores" of people who do not specialize in care of transgender patients, there ***is broad consensus*** about the appropriate treatment for gender dysphoria. All major medical associations endorse and follow the treatment protocols established by the WPATH in the SOC Version 7. (Swaminathan Decl., Ex. E ¶ 27.) This factual reality calls into serious question the reliability of this proffered opinion.

Additionally, Dr. Cantor's testimony directly contradicts the Fourth Circuit's recognition that "we now have modern accepted treatment protocols for gender dysphoria," which have been "[d]eveloped by the World Professional Association for Transgender Health (WPATH) . . . [and] represent the consensus approach of the medical and mental health community[.]" *Grimm,* 972 F.3d at 595. The Fourth Circuit recognizes these treatment protocols "as *the authoritative standards of care*," finding that "[t]here are no other competing, evidence-based standards . . . accepted by any nationally or internationally recognized medical professional groups." *Id.* at 595–96 (emphasis added) (quoting *Edmo*, 935 F.3d at 769).

1. Dr. Cantor's Assertions That Transgender Adolescents Are Receiving "Affirmation On Demand" And That Adolescents Transition Due To The "Unrealistic Expectation That Transition Will Help Them Fit In" Are Unsupported.

Dr. Cantor's most strikingly unreliable opinion is that "[b]ecause only a minority of gender dysphoric children persist in feeling gender dysphoric in the first place, 'transition-on-demand' . . . 'increases the probability of unnecessary transition and unnecessary medical risks.'" (Swaminathan Decl., Ex. B at 213:22–214:11.) Again, in making this broad and unfounded assertion, Dr. Cantor relies only on "those 11 studies" on his blog. (*Id*. at 215:17–217:19.) Dr. Cantor has no experience in his own practice with persistence or desistence in children with gender dysphoria, and he does not offer any support for this proposition from practitioners who actually treat gender dysphoria in children. (*Id.*)

When asked whether "any patient ever [came] to [him] asking for affirmation on demand," Dr. Cantor's response was "no." (*Id*. at 181:11-13.) When asked what his basis was for saying that providers are providing "affirmation on demand to children and adolescents with gender dysphoria," Dr. Cantor responded that his "only evidence" is from the following sources:

> "Through several venues. I get that information from parents, from people, you know, in society who e-mail me asking for help. There's a large number of media reports of it happening through the world, U.S., Canada and Europe. And there's now been – there are now several governmental entities, mostly in Europe, are now beginning more formal . . . investigations of it." (*Id*. at 181:14-25; 184:5-10.)

When asked whether he had ever spoken to providers who claim to provide affirmation on demand to children and adolescents with gender dysphoria, his response was "no." (*Id.* at 182:17-21.) When asked whether any provider at CAMH (his former employer) provides affirmation on demand, his response was again "no." *Id*. at 183:16-24. In other words, Dr. Cantor was unable to identify a single instance of a provider providing affirmation on demand, and his "evidence" is woefully inadequate to support any conclusion that such practice is occurring. Similarly, Dr. Cantor was unable to identify any scientific literature that demonstrates that providers are providing affirmation on demand to children and adolescents with gender dysphoria. (*Id*. at 184:11-14.)

Another stark example of Dr. Cantor's opinions failing to meet methodological reliability is his assertion that "a child experiencing depression from social isolation might develop hope – and the unrealistic expectation – that transition will help them fit in, this time as and with the other sex." (Swaminathan Decl., Ex. A at ¶ 69; Ex. B at 218:18–219:20.) Dr. Cantor himself admitted at his deposition that this "hypothesis hasn't been . . . tested," and therefore has no probative value. (Swaminathan Decl., Ex B at 219:15-20.)

None of Dr. Cantor's unsubstantiated hypotheses justify denying treatment to transgender adolescents, which is not at issue in this case regardless.

2. Dr. Cantor Testified That Transgender People Are One Of Three Things: Autogynephilic, Homosexual, Or Mistaken.

The Fourth Circuit has held conclusively that "just like being cisgender, being transgender is natural and is not a choice." *Grimm*, 972 F.3d at 594. The Fourth Circuit also acknowledges that "[b]eing transgender is also not a psychiatric condition, and implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." *Id.* (quotation marks omitted). By contrast, Dr. Cantor egregiously espouses that only three factors can "motivate a person to want to live as the other sex." (Swaminathan Decl., Ex. B at 143:8-10.) At his deposition, Dr. Cantor testified that "anyone who is transgender is transgender either due to autogynephilia,[4] homosexuality, or a mistake they've made as a . . . younger individual." (*Id*. at 145:7-15 ("[T]hat's the best summary we have of the – of the existing research").) Dr. Cantor asserted that homosexuality "can motivate a person to feel gender dysphoric" and "be the source of the desire to change." (*Id*. at 143:20-144:1.) In justifying his third theory, Dr. Cantor stated that young individuals "mistake the emotions that they're having to be gender dysphoria when they're actually motivated by something else, for example, a desire to not be associated with the sex that they would be biologically associated with." (*Id*. at 144:9-15.) Dr. Cantor's testimony is not only in direct conflict with Fourth Circuit precedent, but is a harmful, outlier opinion in the scientific community. Dr. Cantor does not believe that individuals can be transgender unless they fall into one of his three purported pathways. His views, which pathologize transgender people in stark contradiction to the Fourth Circuit's recognition that being transgender is a normal variation in human development, are irrelevant, harmful, and unfit for use by the Court.

[4] Autogynephilia refers to an extreme outlier hypothesis that transgender people become transgender out of a sense of sexual arousal. (*Id.* at 142:3-8.)

3. Dr. Cantor's Opinion That No Professional Organization Has Articulated A Meritorious Position Calling Into Question The Basis For The Act Directly Contradicts The Fourth Circuit's Holding In *Grimm*.

Dr. Cantor spends a great deal of time in his report critiquing the statements of preeminent medical and behavioral health organizations that recognize the standard of care for treating gender dysphoria. (Swaminathan Decl., Ex. A at ¶¶ 107–39.) Dr. Cantor's critiques, however, are misleading, misconstrue the current standards of care, and flout Circuit law. As just one example, Dr. Cantor quotes selectively from the Endocrine Society's clinical guidelines to misleadingly suggest that the guidelines recommend "address[ing] mental health issues *before* embarking on transition," and that they do "not endorse any affirmation-only approach." (Swaminathan Decl., Ex. A at ¶ 119–20 (emphasis added).) But this is incorrect. In fact, the guidelines affirmatively *recommend* that adolescents with gender dysphoria receive medical treatment and endorse "gender-affirming" care throughout. (*See, e.g.*, Swaminathan Decl., Ex. F at 3871 §§ 2.1-2.5 (recommending treatment with puberty-delaying medication and hormones).)

Dr. Cantor is additionally unqualified to opine on these professional organizations as he lacks any involvement with them. He testified that he is not a member of WPATH, has never advised the WPATH in any capacity, has never been involved in developing the SOC, and could not recall the most recent version of the SOC. (Swaminathan Decl., Ex. B at 203:1–204:24.) Similarly, Dr. Cantor is not a member of the Endocrine Society, was not involved in the development of the Endocrine Society guidelines in 2009 or in 2017, is not aware of the scientific literature conducted by the Endocrine Society in developing the guidelines, and does not hold himself out as an expert in how the guidelines were developed. (*Id.* at 201:8–202:19.)

Dr. Cantor's attack on these professional organizations also defies this Circuit's recognition that they constitute the "*leading* medical, public health, and mental health organizations" regarding treatment for transgender adolescents. *Grimm*, 972 F.3d at 594 n.1 (emphasis added). *Grimm* relied heavily on the amici curiae brief submitted by many of the same organizations to explain the treatment protocols for transgender adolescents, citing these organizations as "our foremost medical, mental health, and public health organizations." *Id.* at 612; *see also id.* at 594–613 (citing the amici curiae brief nine times).

4. Dr. Cantor Has Offered Harmful Opinions Related To Transgender People And Has Been Removed From Respectable Scientific Societies For Posting Disrespectful Material.

Dr. Cantor is unfit to provide testimony in this case given his history of promulgating disturbing and offensive content about transgender people.[5] In Dr. Cantor's blogpost, Sexology Today, for example, Dr. Cantor suggests that transgender people are "atypical," and writes that "only very few trans kids still want to transition by the time they are adults. Instead, they generally turn out to be ***regular*** gay or lesbian folks." (Swaminathan Decl. Ex. G; Ex. B at 187:17–188:9 (testifying that "non-regular gay or lesbian folks" are people "with a paraphilia or with a fetish that makes the determination of their sexual orientation a bit moot"); Ex. B at 188:15–189:1 (testifying that "if a child's gender dysphoria were to persist and they continued to want to transition by the time they are adults," that would be "atypical") (emphasis added).)

[5] Dr. Cantor was a member of the Society for the Scientific Study of Sexuality, a group dedicated to "forward[ing] and promot[ing] the conduct and dissemination of sex research," for twenty-seven years. (Swaminathan Decl., Ex. A. at 96; Ex. B at 284:19-22; 287:11-13.) After his twenty-seven-year membership, Dr. Cantor was suspended and removed from the society's online forum after its Board determined that Dr. Cantor had violated one of its guidelines by posting "disrespectful" content relating to transgender people. (Swaminathan Decl., Ex. B. at 288:10-13 ("[T]hey told me what I said they deemed to be disrespectful"); 288:16-18 ("Q . . . [D]id what you say deal with issues relating to transgender people or gender dysphoric people? A. Yes.")

D. Dr. Cantor's Report, Opinions, And Testimony Lack Probative Value And Are Thus Inadmissible Under Federal Rule Of Evidence 403.

Finally, the Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the issues, or result in misleading testimony. Fed. R. Evid. 403. As noted above, Dr. Cantor offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Consideration of his testimony would waste time and create confusion. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the veracity of Plaintiffs' gender identity, gender dysphoria diagnosis, and other experiences—issues unrelated to whether transgender girls and women should be allowed to participate on girls' and women's sports teams in West Virginia. Accordingly, Dr. Cantor's testimony fails to satisfy the requirements of Federal Rule of Evidence 403 and should be excluded.

CONCLUSION

WHEREFORE, based on the foregoing, Plaintiff respectfully request that this Court grant the instant motion and exclude all of Dr. Cantor's purported expert testimony because it is not admissible under *Daubert* and the Federal Rules of Evidence.

Dated: May 12, 2022

Respectfully submitted,
/s/ *Loree Stark*

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and mother, HEATHER JACKSON, *Plaintiff*, v. WEST VIRGINIA STATE BOARD OF EDUCATION, HARRISON COUNTY BOARD OF EDUCATION, WEST VIRGINIA SECONDARY SCHOOL ACTIVITIES COMMISSION, W. CLAYTON BURCH in his official capacity as State Superintendent, DORA STUTLER in her official capacity as Harrison County Superintendent, and THE STATE OF WEST VIRGINIA, *Defendants*, and LAINEY ARMISTEAD, *Defendant-Intervenor*.	Civil Action No. 2:21-cv-00316 Hon. Joseph R. Goodwin

CERTIFICATE OF SERVICE

I, Loree Stark, do hereby certify that on this 12th day of May, 2022, I electronically filed a true and exact copy of ***Plaintiff's Memorandum of Law in Support of Motion to Exclude the Expert Testimony of James M. Cantor*** with the Clerk of Court and all parties using the CM/ECF System.

/s/ Loree Stark
Loree Stark
West Virginia Bar No. 12936

EXHIBIT N

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. PATRICK W. LAPPERT

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Plaintiffs respectfully submit this memorandum of law in support of their motion to exclude the expert testimony of Dr. Patrick W. Lappert.

INTRODUCTION[1]

Dr. Lappert holds himself out as being board-certified in both plastic surgery and general surgery. He is neither: his certification in plastic surgery lapsed in 2018, and he has not been board-certified in surgery since ***2002***. Moreover, in his entire career, Dr. Lappert has never performed a single surgical procedure to treat gender dysphoria—which is not surprising, since he considers those procedures to be "intentional mutilation" and "child abuse." Dr. Lappert has no reliable basis to opine about gender-affirming surgery, and his purported expert opinions about those procedures should be excluded.

And Dr. Lappert's opinions outside of surgery are even more ripe for exclusion. Straying far afield from his surgical experience, Dr. Lappert gives a smorgasbord of opinions that he is not qualified to provide, and for which he has no basis. For example, he criticizes how organizations like the World Professional Association for Transgender Health ("WPATH") and the Endocrine Society have developed guidelines for diagnosis and treatment of gender dysphoria, despite admitting that he does not know the first thing about how those guidelines were created. He speculates about whether puberty-blocking treatment is appropriate for adolescents, even though he is not an endocrinologist and he admits "that's not [his] area of expertise." He criticizes the process by which patients are

[1] Unless otherwise noted, all emphasis is added, and all citations, alterations, and ellipsis are omitted. Exhibits referenced herein are attached to the concurrently-filed Declaration of Dmitriy Tishyevich.

diagnosed with gender dysphoria, despite admitting that he has "very limited psychiatric / psychological knowledge," is not "a licensed mental healthcare provider of any kind," and is not qualified to make this diagnosis himself. And he also offers rank speculation about patients with gender dysphoria who "detransition" or experience "regret," even though he concedes he has no reliable data to quantify these phenomena. These and other of Dr. Lappert's many non-surgery opinions are both unreliable and irrelevant, and they should all be excluded accordingly.

Dr. Lappert's deposition also made clear that he is certainly not a dispassionate expert who will offer neutral "specialized knowledge" to "help the trier of fact to understand the evidence," as Rule 702 contemplates. Far from it. In addition to calling gender-affirming surgery "intentional mutilation," Dr. Lappert says that parents who talk to their children about gender identity issues are "sexualizing them" and "grooming" them for abuse. He accuses doctors who provide gender-affirming treatment of being part of a "Transgender Treatment Industry" cabal—a term that he concedes is certainly not "commonly used" in his professional field, and is instead "idiosyncratic" to his report. He has given inflammatory presentations on gender-affirming surgery, opining that performing these surgeries is a "moral violation" for physicians and that "changing a person's sex is a lie." He tours the country, urging state legislatures to outlaw gender-affirming treatment for minors. And he also thinks that states should "criminally prosecute doctors" that provide this critically-needed treatment—even though ***every*** reputable

medical organization in the country, including his own professional society, has said that such treatment is medically necessary and appropriate.

Even if Dr. Lappert's opinions were reliable under Rule 702 (and they are not), and even if they had any minimal probative value (and they do not), that value would be far outweighed by unfair prejudice and confusion of the issues under Rule 403. For these reasons, and as explained below, all of Dr. Lappert's opinions should be excluded.

LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on the trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021). As the Fourth Circuit recently reaffirmed, "the importance of the gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283.

"The proponent of the testimony must establish its admissibility by a preponderance of proof." *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019). The first step is to determine if the expert is qualified to give the proffered opinion, which requires examining the expert's professional qualifications and "full range of experience and training." *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012). If the expert is not qualified, the testimony should be excluded. *See SMD Software, Inc. v. EMove, Inc.*, 945 F. Supp. 2d 628, 639 (E.D.N.C. 2013).

Even if the expert is qualified, the court must consider the relevancy of the expert's testimony as "a precondition to admissibility." *Sardis*, 10 F.4th at 282. To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id.* at 281. "If an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded." *Id.*

The opinion must also be based on a reliable foundation, with the inquiry focusing on the expert's "principles and methodology" to assess whether it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Id.* at 281-82. In evaluating reliability, courts consider, among other things, whether: (1) the theory "can be and has been tested"; (2) has been "subjected to peer review and publication"; (3) "the known or potential rate of error"; and (4) "whether the technique is generally accepted in the scientific community." *Id.* at 281.

When an expert relies upon experience and training rather than a specific methodology, the application of the *Daubert* factors is more limited. *See Freeman v. Case Corp.*, 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). In those cases, courts consider: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015).

Finally, the Fourth Circuit has cautioned that although the trial court has "broad latitude" to determine reliability, it must still engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even rigorous cross-

examination is not a substitute for the court's gatekeeping role. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017).

ARGUMENT

I. Dr. Lappert Is Not Qualified to Offer Any of His Purported Opinions.

An expert witness must have "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). "[Q]ualifications alone do not suffice," however. *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999); *Patel ex rel. Patel v. Menard, Inc.*, 2011 WL 4738339, at *1 (S.D. Ind. Oct. 6, 2011). Even "a supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant." *Clark*, 192 F.3d at 759 n.5.

Moreover, "an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise." *Martinez v. Sakurai Graphic Sys. Corp.*, 2007 WL 2570362, at *2 (N.D. Ill. Aug. 30, 2007); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352, 1369 (11th Cir. 2014).

Importantly, this qualification inquiry is subject-specific, because "[g]eneralized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge." *Martinez*, 2007 WL 2570362, at *2. "For example, no medical doctor is automatically an expert in every medical issue merely because he or she has graduated from medical school or has achieved

certification in a medical specialty." *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994). Dr. Lappert fails these requirements, for reasons below.

A. Dr. Lappert Has Never Performed Gender-Affirming Surgery and Is Not Qualified to Opine on Such Procedures.

Dr. Lappert's report represents that he is "Board Certified in Surgery and Plastic Surgery." (Ex. 1 at 1.) This is not true. As he admitted, his "plastic surgery board certificate expired at the end of 2018." (Ex. 2 at 23.) His "board certification in surgery" expired "in 2002"; thus, he has not "been board-certified in surgery" for "over nineteen years." (*Id.* at 31-32.)

These are not trivial fibs, because physicians are not allowed to hold themselves out as board-certified unless they actually have a ***current*** board certificate. The American Board of Plastic Surgeons unequivocally prohibits such misrepresentations, stating that "when a physician misrepresents certification status," as Dr. Lappert did here, "ABPS may notify local credentialing bodies, licensing bodies, law enforcement agencies, and others." (*Id.* at 30; Ex. 3 at 3.) And the American Board of Surgery takes a similarly dim view of such misrepresentations, as Dr. Lappert also acknowledged. (Ex. 2 at 32 (agreeing it does not "surprise [him] that the [ABS] does not allow doctors to represent that they are board-certified in surgery unless they have a current board certificate.").)

Setting aside these misrepresentations about his credentials, Dr. Lappert is also not qualified to give expert opinions about gender-affirming surgery for a more basic reason: he has never even performed a single such procedure. He admitted that he has "never

performed facial feminization surgery" or "facial masculinization surgery" for any transgender patient. (*Id.* at 167.) The same is true for "transfeminine top surgery" and "chest reconstruction surgery." (*Id.* at 167.) He has also never "performed a vaginoplasty" nor "metoidioplasty." (*Id.* at 167-68.) In short, Dr. Lappert has "***never*** performed ***any kind*** of gender-affirming surgery in transgender patients." (*Id.* at 168; *id.* at 151 ("I have never treated a patient with gender dysphoria surgically.").) He was also emphatic that he would never perform such surgeries, because he personally does not "see them as beneficial" and thinks that they are "incorrect treatments." (*Id.* at 150.)

Dr. Lappert has not published any research on gender-affirming surgery either. He agreed that he has "not published any original research in peer-reviewed literature within the ***last 23 years***" at all—and of the six total articles that he did publish a quarter-century ago, not one was on gender-affirming surgeries for patients with gender dysphoria. (*Id.* at 129; *see id.* at 130-134.)

As a substitute for first-hand experience, Dr. Lappert cites a handful of studies in his report about supposed complications from gender-affirming surgery. But reading studies does not make one an expert. That is just the sort of "generalized knowledge of a particular subject" that courts have rejected as a qualification under Rule 702. *Martinez*, 2007 WL 2570362, at *2. As with the disqualified expert in *Lebron* who "reached his opinion . . . by relying on studies," reading literature is not enough. 772 F.3d at 1369.

It is also telling that the Code of Ethics of the American Society of Plastic Surgeons ("ASPS") prohibits members from giving this kind of unfounded testimony.[2] Section IV of that Code of Ethics says that "to help limit false, deceptive and/or misleading testimony, Members serving as expert witnesses ***must***: 1. Have ***recent and substantive experience*** (as defined in the Glossary of the Code) in the area in which they testify[.]" (Ex. 4 at 6.) The Glossary, in turn, defines "recent and substantive experience" to mean (among other requirements) that the member "has performed the specific procedure in question within three (3) years of the date of being retained as an expert witness." (*Id.* at 8.)

Dr. Lappert fails these requirements. Far from having actually performed any of the gender-affirming procedures that he criticizes in his report (*see* Ex. 1 at 29-39)—***ever***, let alone within the last three years—Dr. Lappert was emphatic that he would never perform such surgeries because he does not "see them as beneficial." (Ex. 2 at 150.) To be sure, the ASPS Code of Ethics is not a substitute for the Court's Rule 702 inquiry. But the fact that the ASPS prohibits members from providing these kinds of ill-informed expert opinions precisely to "help limit false, deceptive, and/or misleading [expert] testimony" from being offered in court (Ex. 4 at 6) should give the Court serious pause, to say the least, about allowing Dr. Lappert's testimony.

[2] Dr. Lappert resigned from ASPS around the time his board certification lapsed (Ex. 2 at 100-101), but he was a member from 1997 to 2017, and he agreed that ASPS is a "reputable organization" to which "93 or so percent of all plastic surgeons" in the country belong. (*Id.* at 102-103.)

B. Dr. Lappert Has No Basis to Offer Opinions on Topics Outside of Plastic Surgery.

Dr. Lappert also offers a grab-bag of opinions on topics far outside his field of plastic surgery—including endocrinology (*e.g.*, opining whether puberty-blocking agents and cross-sex hormones like testosterone are appropriate treatments for gender dysphoria), psychiatry (*e.g.*, criticizing how patients are diagnosed with gender dysphoria), and more.

Dr. Lappert has no qualifications or any other basis to give any of these opinions, and they all should be excluded. For example, he has no basis to opine about purported risks of puberty-blocking treatments, given that he agreed that he is "not an endocrinologist" and has "no specialized training or expertise in endocrinology." (Ex. 2 at 153, 204.) He also has "never prescribed any puberty-blocking drugs of any kind"; and indeed, he admitted: "I ***do not*** consider myself an expert in that area" and "that's not my area of expertise." (*Id.* at 201, 203.)

The same is true for Dr. Lappert's opinions on cross-sex hormone treatments—given that he admits that he has "never prescribed cross-sex hormones for treatment of gender dysphoria," and that he has "no firsthand experience with advising [his] patients about potential risks and benefits" of such treatment. (*Id.* at 214.) Here, again, Dr. Lappert conceded that he does not "hold [himself] out as an expert in endocrinology," and that he does not plan to offer "any expert opinions in endocrinology in this case because that's outside [his] scope of expertise." (*Id.* at 204.) All of his purported opinions related to endocrinology should be excluded accordingly.

Dr. Lappert also has no qualifications—or any other basis—to opine about diagnosis or treatment of mental conditions. He admits that he has "very limited psychiatric/psychological knowledge"; he is "not a psychiatrist" or "a licensed mental healthcare provider of any kind"; and in his "professional day-to-day practice," he "do[es] not diagnose mental health conditions of any kind." (*Id.* at 68, 153-54.)[3] Thus, as Dr. Lappert conceded, "for any patient that presents to [him] with a mental health condition," he would "send them to someone who is . . . trained in how to diagnose mental health conditions."). (*Id.* at 157.) And after all of these admissions, he also conceded that he "do[es] not hold [himself] out as an expert in ***diagnosing*** mental health conditions outside, potentially, of body dysmorphic disorder," and that he also does "not have special[ized] training or expertise in ***treating*** mental health conditions." (*Id.* at 75.)

In short, while Dr. Lappert does not even have the relevant expertise to opine about gender-affirming surgery, he certainly does not have the expertise to "waltz into the courtroom" and mislead a factfinder with purported expert testimony about endocrinology, psychiatry, or anything else. *See Clark*, 192 F.3d at 759 n.5. So at the very least, all of his opinions outside of plastic surgery should be excluded.

[3] Dr. Lappert said he feels qualified to identify a potential diagnosis of body dysmorphia, and to then "offer referral for psychiatric/psychological support and evaluation" to those patients. (Ex. 2 at 72.) Body dysmorphic disorder is a distinct condition from gender dysphoria, however, that "is primarily characterized by an excessive preoccupation with a perceived defect or flaw in appearance that others cannot see or would judge as slight in appearance." (Ex. 17 at 1; Ex. 2 at 71 ("They see a defect that you don't see.").)

II. Dr. Lappert's Opinions on Topics Outside of Gender-Affirming Surgery Do Not "Fit" the Disputed Issues, Are Unreliable, Or Both.

An expert's testimony should only be admitted if it is reliable. And "proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018).

Even if the testimony is reliable, the court must still "satisfy itself that the proffered testimony is relevant to the issue at hand, for that is a precondition to admissibility." *Sardis*, 10 F.4th at 282. "The test for relevance, or fit, considers whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F. Supp. 3d 837, 846 (W.D.N.C. 2016).

This case turns on whether Defendants' exclusion of coverage for gender-confirming health care treatments violates Plaintiffs' rights under the equal protection clause, Title VII, and Section 1557 of the Affordable Care Act. Many of Dr. Lappert's opinions are both unreliable and irrelevant to this inquiry, as described below.

A. Far from Being Generally Accepted, Dr. Lappert's Opinions Have Been Rejected by the Scientific Community.

General acceptance is a reliability factor, *Nease*, 848 F.3d at 229, and the fact that a particular theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594. Dr. Lappert asserts that gender-affirming surgical and hormonal treatments "have not been accepted by the relevant

scientific communities" (Ex. 1 at 40), but this is not true. In fact, it is Dr. Lappert's opinions that are on the scientific fringe, to say the least.

Another court found as much just last year in addressing a challenge to Arkansas' state-law ban on gender-affirming treatment for minors, where Dr. Lappert had offered virtually identical opinions to support that ban. *Brandt v. Rutledge*, 4:21-cv-450 (E.D. Ark.); Ex. 2 at 33-34; Ex. 5 (Lappert *Brandt* Declaration). In *Brandt*, Dr. Lappert asserted that "'[g]ender affirming' treatments are experimental," which he agreed was "basically the same opinion that [he] offered in this case." (Ex. 2 at 35.) Drs. Hruz and Levine had also submitted similar declarations in *Brandt* in support of the ban. (*See id.* at 33-34.)

The *Brandt* court preliminarily enjoined the ban on August 2, 2021 (Ex. 6), squarely rejecting these opinions. That court recognized that "the consensus recommendation of medical organizations is that the ***only*** effective treatment for . . . gender dysphoria is to provide gender-affirming care," citing briefs from organizations like the American Medical Association, American Academy of Pediatrics, and many more. (*Id.* at 6 n.3; Br. of Am. Med. Ass'n, et al. (ECF No. 131 (expressing same views in this case).) *Brandt* also found that "gender-affirming treatment is supported by medical evidence that has been subject to rigorous study," and that "***every*** major expert medical association recognizes that gender-affirming care for transgender minors may be medically appropriate and necessary to improve the physical and mental health of transgender people." (Ex. 6 at 7-8.)

As Dr. Lappert admitted, *Brandt*'s findings were "contrary to the opinions that [he] offered." (Ex. 2 at 39.) And as he also agreed, "every major expert medical association

disagrees with [him] because they've all taken [the] position that this treatment is in fact medically necessary." (*Id.* at 40; *see also id.* (agreeing the same is true regarding Drs. Hruz and Levine).) In fact, Dr. Lappert admits that there are at least "18 different professional medical organizations" that "take[] the view that's contrary to the opinions that [he] and Dr. Hruz and Dr. Levine are offering" here, testifying that "there's a consensus of consensus on this, exactly." (*Id.* at 42.)

That consensus also includes Dr. Lappert's own former association, the ASPS. While he says that gender-affirming surgery is experimental, the ASPS said the exact opposite in a February 2021 statement—stating that it "***firmly believes*** that plastic surgery services can help gender dysphoria patients align their bodies with whom they know themselves to be," and promising to "continue its efforts to advocate across state legislatures for full access to medically necessary transition care." (Ex. 8 at 3.) So as Dr. Lappert admitted, the ASPS also "does not agree with [his] opinions that gender-affirming surgery is experimental." (Ex. 2 at 112-13.)

And it is not just professional medical associations either. ***Every major insurer*** in the country also says that gender-affirming surgical and hormonal treatments are medically necessary, as Dr. Lappert also admitted. (Ex. 2 at 334-38 & Ex. 9 at 2 (BCBS North Carolina policy, stating that "[s]ervices for gender affirming surgery and hormone therapy may be considered medically necessary when the criteria below are met"); Ex. 2 at 427-28 & Ex. 10 at 1 (similar for Aetna); Ex. 2 at 430-33 & Ex. 11 (similar for Cigna); Ex. 2 at 434-39 & Ex. 12 (similar for UnitedHealthCare).)

In short, this overwhelming consensus confirms that far from being generally accepted, Dr. Lappert's opinions are fringe and unreliable.

B. Dr. Lappert's Critiques of WPATH, Endocrine Society Guidelines, DSM-V, and Other Organizations' Positions Are Unreliable.

Aware that his views are contrary to those of every major medical society and professional organization, Dr. Lappert tries to dismiss every single one of them as partisan—part of the same supposed "Transgender Treatment Industry" that he crusades against. For example, he contends that the "WPATH, APA, AAP," and "AMA" all supposedly rely on a "non-scientific" methodology, and that the guidelines and position statements issued by every one of those organizations are "political" and are "not the product of a reliable scientific method." (Ex. 1 at 10-11.)

These opinions are—again—not generally accepted, to put it mildly. Just recently, the Fourth Circuit confirmed that the WPATH guidelines in particular "represent the consensus approach of the medical and mental health community" and "have been recognized by various courts, including [the Fourth Circuit], as the authoritative standards of care." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020). "There are ***no*** other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups," in fact. *Id.* at 595-596.

Dr. Lappert's deposition further confirmed that his critiques are baseless *ipse dixit* because he admitted that he has no idea how any of these standards of care were actually developed, and on what scientific basis. Take WPATH SOC Version 7 ("WPATH7"), for example. Dr. Lappert admits that he has "not been involved with the development" of

WPATH7; he does not "know what kind of scientific literature [review] the WPATH conducted as part of drafting" WPATH7; he does not know what kind of "peer review" or "outside experts" or "public comments" the WPATH may have relied on in developing WPATH7, or how many "different drafts" the WPATH7 went through, or "what may have gone on during [WPATH] meetings or conferences" to discuss the development of WPATH7. (Ex. 2 at 184-87.) And after these admissions, Dr. Lappert unsurprisingly conceded that he is "***not an expert*** in how Version 7 of the WPATH was developed." (*Id.* at 188.) The same is true for WPATH SOC Version 8. (*Id.* at 189 (agreeing he does not "hold [himself] out as an expert on how Version 8" is being developed).)

The same is also true with respect to Dr. Lappert's critiques of other standards of care and position statements:

- Endocrine Society Guidelines for Treatment of Gender Dysphoria: Dr. Lappert does not know when these guidelines "were initially published" or "last revised"; he was "not involved with the[ir] development"; he does not know "what kind of scientific literature review" went into that development; thus, he agrees he is "***not an expert*** in how the Endocrine Society developed the original 2009 guidelines" or "the 2017 updates" (Ex. 2 at 195-200);

- DSM-5: Dr. Lappert has "not been involved with the development of DSM-5"; does not know "what kind of scientific literature review was done" during that development; does not know what went on during "different meetings or conferences" to "discuss that development"; thus, he "do[es] ***not*** have expert firsthand knowledge of how the DSM-5 was developed" (*id.* at 190-93);

- AMA Position Statement on Gender-Affirming Treatment: Dr. Lappert "do[es] not know how the AMA came to issue this consensus statement" and has "no personal knowledge what scientific literature they reviewed"; thus, he has "***no idea*** . . . how the AMA came to reach this consensus statement" (*id.* at 47-48);

- American Academy of Pediatrics Position Statement on Gender-Affirming Treatment: has no "personal knowledge" of how the AAP adopted this statement (*id.* at 48).

In the end, Dr. Lappert agreed more broadly that he does "not have firsthand knowledge of how ***any*** of those organizations came to reach these positions," and that he "do[es] not know what scientific literature they relied on." (*Id.* at 49-50.) He should not be allowed to mislead a factfinder with these unfounded *ipse dixit* critiques. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

C. Dr. Lappert's Opinions About the Need for Randomized Clinical Trials Are Unreliable.

A key component of Dr. Lappert's opinions is that surgical and hormone gender-affirming treatments are supposedly experimental because they are unsupported by results from randomized clinical trials ("RCTs"). (*See, e.g.*, Ex. 1 at 5 (arguing that "properly conducted [RCTs] and long-term treatment outcome studies" are necessary to make "experimental procedures actual, proven treatments"). But his deposition confirmed that these critiques are baseless because he agreed that: (1) it is common for surgeons to perform procedures unsupported by RCT results; and (2) in any event, it is not possible to conduct RCTs for hormonal or surgical gender-affirming treatments.

First, RCTs in surgery are exceedingly rare. The ASPS's Plastics and Reconstructive Surgery Journal—which Dr. Lappert agreed is the "premier peer-reviewed source for current information on reconstructive and cosmetic surgery" (Ex. 2 at 296)—confirms as much. As a 2019 study found, in 2018, "only ***2.1 percent*** of all publications" in the ASPS Journal "were level 1 [*i.e.*, RCT] evidence"; "in 2008 and 2013, those

percentages were ***0.3*** and ***1.7 percent*** respectively," as he also agreed. (*Id.* at 299, 302; Ex. 7 (Sugrue study)). Given this paucity of RCTs, Dr. Lappert unsurprisingly conceded that surgeons in the real world do not actually wait for RCT results before deciding that a particular procedure is non-experimental. (Ex. 2 at 294-95 (agreeing it is "not uncommon for plastic surgeons to perform procedures that are not supported by results from an RCT").) In fact, he ***himself*** does not even "think it's necessary for a surgical procedure to be supported by results from a[n] . . . RCT before it can be considered effective." (*Id.* at 285.) Rule 702 demands that experts apply "the same level of intellectual rigor [in the courtroom] that characterizes the practice of an expert in the relevant field." *Cooper*, 259 F.3d at 200. Here, though, Dr. Lappert tries to impose an impossible RCT-based standard that he concedes surgeons in the real world—including himself—do not actually apply.

Second, it is not possible to perform RCTs for gender-affirming surgery or hormonal treatment. Dr. Lappert conceded this too: he agreed "it is not possible to perform RCTs for some surgical procedures because you can't blind the patient or the investigator to what the procedure is" (meaning, it is impossible to do the surgery without the patient and the investigator knowing that it was done)—including for "phalloplasty," "metoidioplasty," and more generally for all types of what is "colloquially known as bottom surgery." (Ex. 2 at 315-16.) He also agreed the same is true for "puberty-blocking hormones," since they cause "observable physical effects"; thus, "it's not possible to do an RCT for puberty-blocking hormones" either. (*Id.* at 316-18.) And he also conceded that the same is true for

cross-sex hormones, because those also cause "physical effects" and thus "it's not possible to design a double-blind RCT" for those treatments. (*Id.* at 318-19.)

Given all this, Dr. Lappert should not be permitted to offer his misleading opinion that gender-affirming surgery and hormone treatments are experimental in the absence of RCT support.

D. Dr. Lappert's Speculation About "Detransitioners," "Regret" and "Social Contagion" Is Unreliable.

Dr. Lappert also opines that some patients will "drop out of transitioning or reverse the process" (so-called "detransitioners"); others will experience "regret" after surgery; and yet others supposedly develop gender dysphoria as a result of "social contagion" like "peer group, social media, [and] YouTube role modeling." (Ex. 1 at 21-22, 40.)

None of this passes *Daubert* muster. To start, none of these opinions are even remotely connected to Dr. Lappert's experience as a plastic surgeon, given that he studiously avoids performing gender-affirming surgical procedures due to his personal beliefs, and has "never treated a single patient for gender dysphoria." (Ex. 2 at 150-51; *SAS Inst., Inc.*, 125 F. Supp. 3d at 589 (when an expert relies on experience, he must show how his "experience leads to the conclusion reached" and "why that experience is a sufficient basis for the opinion").)

Next, Dr. Lappert's own report makes clear that these are all speculative hypotheses at best. For instance, he admits that the extent of "social contagion" is unknown, writing: "a currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by . . . social contagion and social pressure processes." (Ex. 1 at 40

(underlining in original).) He also wrote the same thing about "desistance" and "regret," stating that these phenomena have "to my knowledge ***not been quantified or well-studied***." (*Id.* at 21 (emphasis in original).)

Dr. Lappert's deposition confirmed that these opinions are pure guesswork. He conceded that he is "not aware of any peer-reviewed studies that quantifies the number of people" affected by social contagion, and that "we don't know the numbers." (Ex. 2 at 367-38; *id.* at 373 ("At present, we're ***hypothesizing*** about the actual cause.").) The same was true for his "regret" opinions. (*Id.* at 329 (agreeing "there's no data available on the percentage of people" treated for "gender dysphoria who experience regret.").

But "the courtroom is not the place for scientific guesswork, even of the inspired sort." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *accord, e.g.*, *Small v. WellDyne, Inc.*, 927 F.3d 169, 176-77 (4th Cir. 2019) (expert testimony "must not be based on belief or speculation"). Dr. Lappert's speculation about regret, de-transitioning, and social contagion should be excluded accordingly.

E. Dr. Lappert's Opinions About Risks Communicated to Plaintiffs Are Unreliable.

Dr. Lappert also purports to opine about what risks were or were not communicated to individual Plaintiffs before they started gender dysphoria treatment. (*See, e.g.*, Ex. 1 at 50 (for C.B., asserting there is no evidence that "the parents were counseled concerning" risks of "off-label use of puberty blocker"); *id.* (opining there was a "failure to obtain proper informed consent" for Plaintiff "CT-F").)

There is no basis for these opinions either. Dr. Lappert "did not meet with any of the plaintiffs" and has "never spoken" with any of them about what risks their doctors discussed. (Ex. 2 at 417-18.) He was "not present in any meetings that any of these plaintiffs may have had with their mental health professionals," or their "endocrinologists," or their "surgeons"; thus, outside of reviewing medical records, he has no idea "what was said or not said during those meetings." (*Id.* at 418-19.) With no reliable basis to say what was or was not communicated during these meetings, Dr. Lappert should not be permitted to create confusion with this speculation. *See, e.g.*, *Small*, 927 F.3d at 176-77.

III. Dr. Lappert's Opinions Are Based on His Personal Beliefs Rather than Science.

Reliability is a flexible inquiry, under which "courts must ensure that an expert's opinion is based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Sardis*, 10 F.4th at 281. There is ample evidence that Dr. Lappert's opinions are so tainted by his strong personal views against gender-affirming care as to make those opinions unreliable. To be clear, Plaintiffs do not seek to impugn whatever moral or religious views Dr. Lappert may hold. But because those views plainly inform the opinions that he offers here—indeed, they seem to be the main driver of those opinions—they are something the Court should consider in assessing their reliability.

Dr. Lappert readily admits that he has "strong personal opinions on whether doctors should be providing gender-affirming treatment to minors." (Ex. 2 at 79.) That's putting it mildly. He has urged state legislatures in Utah, Arkansas, Alabama, and Texas (at least) to pass laws that would ban doctors from being able to provide this medical care for

adolescents. (*Id.* at 57, 61-62; *id.* at 54-55 (agreeing he has "actively lobbied to get these kinds of bans passed").) For example, he spoke in favor of the ban before the Alabama legislature and "publish[ed] an op-ed" that urged the legislature to protect what he called "gender-confused children." (Ex. 2 at 77, 64, 76 & Ex. 14.) He likewise threw his support behind a similar proposed ban in Utah—arguing to the legislature that "you can't change a person's sex," and that "all that is happening is that the patient is undergoing an intentional mutilation in order to create a counterfeit appearance of the other sex." (Ex. 13 at 5).

Dr. Lappert was unapologetic about these opinions at his deposition. He testified that he "absolutely" stands by them, and that he "absolutely" considers "gender reassignment surgery to be an intentional mutilation." (Ex. 2 at 60.) What's more, he also wants doctors who perform these gender-affirming surgeries to be "criminally prosecute[d]"—agreeing that he thinks "that's a good idea." (*Id.* at 52.)

And even though Dr. Lappert was understandably more careful in how he phrased his expert report—avoiding inflammatory language that he uses outside of litigation, like calling gender-affirming care "intentional mutilation"—sometimes the mask slips. For instance, his report accuses every single doctor and organization who oppose his views of being part of some made-up "Transgender Treatment Industry." That is obviously not "a commonly used term in the field of treatment and diagnosis of gender dysphoria," as he admitted; instead, it is "idiosyncratic" to his report. (*Id.* at 21-22.)

Dr. Lappert has also worked closely with the Alliance Defending Freedom ("ADF"), an organization he agreed has "moral objections" to gender-affirming healthcare. (*Id.* at

83, 82.) Among other things, he attended an ADF conference that discussed the "poverty of [experts] who are willing to testify" about these anti-gender-affirming treatments. (*Id.* at 90-91.) Attendees at that conference "were asked whether they would be willing as participate as expert witnesses"; not coincidentally, Dr. Lappert became an expert witness for the first time after attending that conference. (*Id.* at 91.)

Dr. Lappert's report also unapologetically misgenders individual Plaintiffs—"referring to [them] in a way that doesn't align with their gender"—because in Dr. Lappert's view, he is "obliged to honor objective biological realities" (*id.* at 447), which is to say that he does not believe that a person's birth-assigned sex can ever be changed. (*See also id.* at 448 ("I think it's essential that we stick to the biological reality that . . . biological sex is ***immutable***.").)

And then there are Dr. Lappert's many public interviews and presentations where he crusades against gender-affirming care. These include, for example, his views that the religious conception of "the human person" "defines the 'end' of medical and surgical care." (Ex. 2 at 459.) They also include his opinions that "changing a person's sex is a lie and also a moral violation for a physician," and that gender-affirming surgery is "diabolical in every sense of the word." (*Id.* at 464 & Ex. 16 at 1, 7; Ex. 2 at 465 (agreeing that he "hold[s] those views"). And finally, these also include his inflammatory views that parents who "discuss[] gender identity issues with children" are "sexualizing them" (Ex. 2 at 462), and that these conversations are "grooming a generation" for abuse. (*Id.* at 461 & Ex. 15 (Dr. Lappert's presentation titled "Transgender Surgery & Christian Anthropology") at 23;

see also Ex. 16 at 1, 2 (another interview with Dr. Lappert titled "Plastic surgeon: sex-change operation 'utterly unacceptable' and a form of 'child abuse'"; reporting that "regarding children, Lappert said, sexualizing them at a young age with these ideas is grooming them for later abuse.").)

These are obviously not neutral, well-reasoned scientific opinions by a dispassionate expert. It is moral opprobrium masquerading as science, and it should be excluded as such.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Lappert's opinions in full.

Dated: February 2, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 6,250 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: February 2, 2022

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all registered users.

Dated: February 2, 2022

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EXHIBIT O

UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF F WASHINGTON

AT TACOMA

C.P., by and through his parents, Patricia Pritchard and Nolle Pritchard and PATRICIA PRITCHARD,

Plaintiffs,

vs.

BLUE CROSS BLUE SHIELD OF ILLINOIS,

Defendant.

No. 3:20-cv-06145-RJB

ZOOM VIDEO DEPOSITION UPON ORAL EXAMINATION

OF

MICHAEL LAIDLAW

9:00 a.m.

September 2, 2022

REPORTED BY: Pat Lessard, CCR #2104

A P P E A R A N C E S

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ALSO PRESENT:

MR. PATRICK NORTON, Videographer

MICHAEL LAIDLAW, being duly sworn, testified upon oath, as follows:

E X A M I N A T I O N

BY MR. GONZALEZ-PAGAN:

Q. All right. I think we're good to proceed.

Good morning, Dr. Laidlaw, thank you for joining us today. It's afternoon for me; I'm in New York.

A. Okay.

Q. Are you in California today?

A. Correct.

Q. Okay. So as you might have heard, I represent the plaintiffs in this matter and I will be asking you some questions about your opinions in this case.

A. Okay.

Q. First I just want to go over some ground rules for the deposition which will make it easier for everyone and most importantly for our court reporter.

You understand that you're under oath today, is that correct?

A. Yes.

Q. We cannot speak at the same time because the court reporter needs to be able to take down what each of us says.

where a researcher, say a medical doctor, is a researcher, there are patients that collect data, say temperature and blood tests, and then draw up a journal article and have it published with all of their observations and those sorts of thing.

If we could call that primary research, as opposed to, say, a meta-analysis where there are a number of different studies that have already been done -- if you want to call those primary research -- and then someone comes up with a conclusion based on those other studies.

Q. (By Mr. Gonzalez-Pagan) Thank you. That's very helpful.

So what I'm trying to do is for us to have an understanding of what we're talking about so that --

A. Sure.

Q. -- so we can have some questioning about it.

A. Yes.

Q. So I'm trying to establish a distinction between original research, okay, where there's collection of data, right --

A. Yes.

Q. -- and the observations being done by the researcher, versus secondary research which is based

on existing publications and preexisting data.

I think that's the distinction that you were drawing in your answer as well, is that correct?

A. Yes.

Q. So would you be comfortable with that understanding, that shared understanding of -- do you know what I mean by primary research?

A. Yes, I understand your meaning.

Q. Have you performed any primary research?

A. Yes.

Q. On what? On what matters?

A. There were two studies. One was a magnesium study that had to -- we're looking for an association of low magnesium leading to osteoporosis.

And the other study was regarding thyroid cancer where we were looking at thyroid globulin tumor markers and how they correlated with ultrasound findings of the neck.

Q. And when did you perform this research?

A. This was during my -- it may have begun during my -- I think it began during my residency and then I continued into fellowship.

Q. Have you performed any primary research regarding gender dysphoria?

A. No.

Q. Have you performed any primary research relating to transgender people?
A. No.
Q. Have you performed any primary research relating to gender identity?
A. No.
Q. Do you have any peer-reviewed publications?
A. Yes.
Q. Do you have a copy of your CV with you?
A. No.
Q. I will show you what's been marked as Exhibit 2.
A. Okay.
Q. And this is a copy of your CV, right?
Well, it's not showing yet. This is a copy of your CV, right?
A. Yes. It's the one we looked at earlier.
Q. And you have here a section titled "Research, Publications, and Expert Witness Work," is that right?
A. Yes.
Q. And we can scroll through it but just go area by area.
Can you tell me which the -- within the screen showing right now which of these publications

THE VIDEOGRAPHER: We're going off the record at 10:00 a.m.

(Recess.)

THE VIDEOGRAPHER: We're back on the record at 10:07 a.m.

Q. (By Mr. Gonzalez-Pagan) We left off discussing your publications. Do you recall that, Dr. Laidlaw?

A. Yes, I do.

Q. Just to sum up, none of your publications pertaining to gender dysphoria are based on original primary research, is that correct?

A. That's correct.

Q. And with the exception of the piece in the Journal of Bioethics none of your publications pertaining to gender dysphoria are peer-reviewed?

A. Well, a number are published in peer-reduced journals.

Q. Sorry. The Letters to the Editor, is that right?

A. The Letters to the Editors are in peer-reviewed journals, yes.

Q. We've established that you have a private practice dedicated to endocrinology, is that correct?

A. That's correct.

you're providing him to align his body with his sex assigned at birth to be treatment for gender dysphoria?

A. No. This is a treatment for testosterone deficiency.

Q. How long have you been seeing this person?

A. I think I first saw him in May.

Q. So then let me reask the prior question now that we have some further clarification.

A. Yes.

Q. Beyond the patient for whom you provided that one prescription of estrogen, have you provided any patient with care as treatment for their gender dysphoria?

A. No.

Q. Have you monitored any patient undergoing gender affirming medical treatment?

A. When you say "monitor," do you mean monitor specifically for effects of that treatment?

Q. Yes. Or worked with, like a patient that is undergoing medical care and you're overseeing in some way their laboratories, their care.

A. I've had patients with gender dysphoria that I'm seeing for other reasons that I'm monitoring their laboratory or imaging, stuff like that.

Q. But you're not treating them yourself for gender dysphoria, is that right?
A. Correct.
Q. Have you ever conducted a review of medical necessity as an insurance company employee or as an external reviewer?
A. No.
Q. All right. Let's talk a little bit about your report.
A. Okay.
Q. And by "a little," I mean the bulk of the next conversation.
A. Okay. I kind of figured.
Q. What did you do to prepare your report?
A. To prepare my report?
Q. Yes.
A. Let's see. I reviewed -- I reviewed the materials from paragraph ten.
I looked at -- spent a lot of time with medical records and the clinical visit notes and laboratories and so forth of Dr. Hatfield and Dr. Kyllo.
Yeah, I read through the expert declarations and looked to build my report based on those items.
Q. Does the report we have, your report which

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

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

SUPPLEMENTAL EXPERT DECLARATION OF LOREN S. SCHECHTER, M.D.

I, Loren Schechter, pursuant to 28 U.S.C. §1746, declare as follows:

1. I have been retained by counsel for the Plaintiffs as an expert in the above-captioned lawsuit. I previously submitted an expert witness declaration [Dkt. No. 11-4] ("Schechter Dec.") in connection with Plaintiffs' motion for a preliminary injunction in this case.

2. I submit this declaration to respond to points raised in the declaration of Patrick W. Lappert, M.D. [Dkt. No. 49-1 App. 557-90] ("Lappert Dec."), which Defendants submitted in connection with their response to Plaintiffs' motion for a preliminary injunction.

3. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original declaration. In preparing this declaration, I was provided with and reviewed the following additional case-specific materials: Expert Declaration of Patrick W. Lappert, MD, with attachments.

4. I have personal knowledge of the matters stated in this supplemental declaration.

5. I note that since I submitted my prior declaration, WPATH has published version 8 of the Standards of Care.[1] While version 8 does contain important updates with respect to gender-affirming surgery, it does not change the substance of any of the opinions I expressed in my previous declaration.

6. Dr. Lappert continues to misunderstand that gender dysphoria is a valid medical diagnosis. *See* Schechter Dec. ¶ 37. Because he does not accept gender dysphoria as a diagnosis, it is no surprise that Dr. Lappert disagrees that surgery is an appropriate reconstructive treatment. But his views on the appropriateness of surgery and other medical interventions to treat gender dysphoria fall far outside of the medical mainstream.

[1] E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, Int'l J. of Transgender Health S1 (2022), https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644.

American Plastic Surgery Society Levels of Evidence

7. Dr. Lappert discusses the American Society of Plastic Surgeons Levels of Evidence extensively, suggesting that because there are Level IV and V studies supporting gender-affirming surgical procedures, these surgeries are not established as safe, effective, or accepted. Lappert Dec. ¶¶ 25-27, 55. As I described in my prior declaration, there are practical and ethical limitations on conducting studies in clinical medicine, especially in surgery. Schechter Dec. ¶¶ 54-56. That does not mean that studies with lower levels of evidence are not useful to inform clinical decision making.

8. In fact, Dr. Lappert ignores that the quality of the evidence supporting gender-affirming surgeries is similar to that supporting many common plastic surgeries. For example, Dr. Lappert points to his experience performing surgery to treat cleft palate and craniofacial differences. Lappert Dec. ¶¶ 8, 10. However, there are only a small number of studies providing Level 1 evidence for that treatment.[2] Scientific ratings of evidence generally employ extremely high standards that are not satisfied for many commonly-

[2] *See, e.g.*, Jonathan M. Bekisz, *A Review of Randomized Controlled Trials in Cleft and Craniofacial Surgery*, 29 J. of Craniofacial Surgery 219 (2018).

prescribed treatments and procedures.[3] Such ratings do not mean that the treatment is unsupported in the literature and clinical practice, or that it is not medically necessary. The level of evidence does not always speak to the quality of the research, including because conducting prospective, randomized, double-blind, placebo-controlled studies is not always the optimal or appropriate choice for a particular research question, and in some areas, is not feasible or ethical. *See* Schechter Dec. ¶¶ 54-56.

9. Dr. Lappert is also wrong to suggest that studies are the only way for surgeons to determine the appropriate course of treatment for a particular condition. Critical review of the scientific literature is certainly an important component as to how surgeons evaluate whether a particular procedure is generally safe and effective and whether it is appropriate or recommended for an individual patient. But in addition to considering the literature en masse, we must also account for our own clinical experience and that of our colleagues, as well as our patients' experiences and input. Here, the existing literature, taken as a whole, combined with my own experience and that of many colleagues,

[3] *See, e.g.*, Bernard T. Lee, et al., *Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps*, Plastic and Reconstructive Surgery, 140(5):651e-664e (Nov. 2017); doi: 10.1097/PRS.0000000000003768.

indicates that gender affirming surgery is a safe and effective treatment for individuals with gender dysphoria.

10. In fact, since I submitted my prior declaration, a higher level study has been published showing that in transgender and nonbinary adolescents and young adults, top surgery is associated with low complication rates and improved chest dysphoria, gender congruence, and body image satisfaction.[4] That study adds to the body of evidence supporting the use of gender affirming surgery in patients with gender dysphoria.

Surgery, Like All Medicine, Is An Evolving Field

11. Dr. Lappert focuses on the evolution of treatment for gastric ulcers to support his claims that using Level 4 and 5 evidence to support surgical treatment "can result in grave missteps." Lappert Dec. ¶ 27. But as Dr. Lappert notes, once Level 1 and 2 studies demonstrated that gastric ulcers could be treated with medications, the standard of care changed. This is common in medicine. As the research and clinical evidence evolves, treatment evolves in turn.[5] For example, we previously counseled patients that the only way to lose weight was through dietary changes. Now, we use surgical interventions, such

[4] *See* Mon Ascha et al., Top Surgery and Chest Dysphria Among Transmasculine and Nonbinary Adolescents and Young Adults, JAMA Pediatrics (Sept. 26, 2022), doi:10.1001/jamapediatrics.2022.3424 .
[5] *See, e.g.*, Conor M. Sugrue et al., *Levels of Evidence in Plastic and Reconstructive Surgery Research: Have We Improved Over the Past 10 Years?,* 7 Plast. Reconstruct. Surg. Global Open e2408 (2019).

as bariatric surgery, to treat obesity in certain situations. Notably, Dr. Lappert does not – and cannot – point to any research showing that treatment other than gender-affirming care is effective for gender dysphoria.

Reconstructive Surgeries

12. Dr. Lappert misconstrues the distinction between reconstructive and cosmetic surgery. He suggests that a mastectomy performed to treat gender dysphoria is cosmetic because it "will produce a degradation or loss of two essential human functions, namely: sexual arousal, and breast feeding." Lappert Dec. ¶¶ 42. Here, he makes at least two incorrect assumptions. First, research, as well as my clinical experience, shows that gender-affirming mastectomy is associated with an increase in sexual satisfaction.[6] Second, not all patients view breastfeeding as a desirable function. What is more, Dr. Lappert ignores that a mastectomy performed to treat breast cancer will likewise result in the inability to breast feed. So, his assertion that any procedure that causes a loss of function is cosmetic cannot be correct.

13. Dr. Lappert later suggests that the difference between reconstructive surgery (which he states that insurance will cover) and cosmetic

[6] *See, e.g.*, Cori A. Agarwal et al., *Quality of Life Improvement After Chest Wall Masculinization in Female-To-Male Transgender Patients: A Prospective Study Using the BREAST-Q and Body Uneasiness Test*, 71 Journal of Plastic, Reconstructive & Aesthetic Surgery 651-657 (2018).

surgery (which he states that insurance will not) turns on pathology reports, using breast reduction surgery and surgery to treat gynecomastia as examples. Lappert Dec. ¶¶ 47-48. But, for both of those procedures, the American Society of Plastic Surgeons states that symptomatology – not pathology reports – is the important determinant for insurance coverage.[7]

14. As I described in my prior declaration, it is the underlying diagnosis that distinguishes a reconstructive procedure from a cosmetic one. Schechter Dec. ¶¶ 33-37. Gender-affirming surgery is considered medically necessary, reconstructive surgery when performed in accordance with the WPATH Standards of Care because it is clinically indicated to treat the underlying diagnosis of gender dysphoria. Schechter Dec. ¶¶ 34-35.

15. Ultimately, Dr. Lappert classifies gender-affirming procedures as cosmetic because he does not believe that gender dysphoria is a valid diagnosis for which surgery is necessary, pointing to the lack of "objective" tests for the condition. Lappert ¶¶ 31, 42, 47-48. *See also* Lappert ¶ 51 (stating that the condition of a cancer patient "is far more grievous" than the condition of a

[7] *See* American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Reduction Mammaplasty (2021), https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2021-reduction-mammaplasty.pdf; American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Gynecomastia, https://www.plasticsurgery.org/documents/Health-Policy/Positions/Gynecomastia_ICC.pdf.

person with gender dysphoria). That belief conflicts with the consensus of the medical community. Schechter Dec. ¶¶ 22, 28.

16. In addition, his reliance on "objective" tests is misplaced. What he considers to be objective tests – an x-ray, pathology report, or lab value – are open to interpretation. It is not uncommon to have conflicting opinions regarding an x-ray or a pathology report. In addition, while various tests may be considered in regards to establishing a diagnosis, the tests are usually interpreted within the clinical context. For example, x-ray reports typically include the phrase "clinical correlation is recommended." Finally, Dr. Lappert ignores that once a diagnosis is established, treatment then depends on a discussion with the patient. That discussion includes information from the literature, but also includes other clinical considerations, such as the patient's values, preferences, choices, and autonomy, which Dr. Lappert disregards. For example, while Dr. Lappert references complex oropharyngeal reconstruction, *see* Lappert Dec. ¶ 51, he fails to acknowledge that there are other methods for treating and/or reconstructing this complex defect, as there are other techniques for reconstructing genitalia to treat gender dysphoria. Thus, while Dr. Lappert may be describing his preferred approach to patient care, that approach does not reflect the clinical reality of medicine in 2022.

Informed Consent and Mental Health

17. It is not uncommon for patients needing surgery for a wide variety of conditions to have been diagnosed with mental health conditions; this includes transgender patients. Dr. Lappert claims that surgery of any kind is inappropriate for someone with a behavioral health condition such as autism, depression, or anxiety. Lappert Dec. ¶¶ 43. But patients with these and other mental health conditions regularly and appropriately consent (and assent, as described below) to surgical care. Generally, these conditions do not prevent patients from understanding the procedure, the risks and complications of the procedure, and the benefits that they can reasonably expect to achieve from surgery. Rather, in some cases, surgeons and their colleagues will work with patients in a capacity referred to as "prehabilitation" to address mental health conditions and psychosocial considerations that could impact surgical results.[8] The WPATH Standards of Care are consistent with that approach. *See* Schechter Dec. ¶ 31.

18. Dr. Lappert also misunderstands the informed consent process for minors, claiming they "by definition are not competent to consent." Lappert Dec. ¶ 43. When individuals under age 18 seek any surgery, including gender

[8] *See* James Durrand et al., *Prehabilitation*, 19 Clin. Med. 458-64 (2019).

affirming surgery, it is their parent or guardian that must provide informed consent. Of course, the adolescent must also assent to gender confirming surgery.

19. In sum, not all people with gender dysphoria need, want or are candidates for surgery. However, in appropriately-selected and prepared people, surgery is safe, effective, and medically necessary. *See* Schechter Dec. ¶ 26-28.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 6th day of October, 2022.

Loren S. Schechter, M.D.

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

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

SUPPLEMENTAL EXPERT DECLARATION OF
DR. DAN H. KARASIC, M.D.

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have personal knowledge of the matters stated in this supplemental declaration.

3. I submit this declaration to respond to points raised in the declarations of Dr. Andre Van Mol, Dr. Michael K. Laidlaw, Dr. James Cantor, Dr. G. Kevin Donovan, Dr. Geeta Nangia, and Dr. Kristopher Kaliebe, which Defendants submitted in connection with their response to Plaintiffs' motion for a preliminary injunction.

4. I have personal knowledge of the matters stated in this supplemental declaration.

5. I previously submitted an expert witness declaration [Dkt. 11-3] in support of Plaintiffs' motion for a preliminary injunction in this case.

6. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original declaration.

7. Since I submitted my prior declaration, WPATH has published version 8 of the *Standards of Care for the Health of Transgender and Gender Diverse People* ("WPATH SOC-8").[1]

8. The SOC-8 is based upon a more rigorous and methodological evidence-based approach than previous versions. (Coleman, et al., 2022). This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Its recommendations are evidence-based, informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. The process for development of the SOC-8 incorporated recommendations on clinical practice guideline

[1] E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, Int'l J. of Transgender Health S1 (2022), https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644.

development from the National Academies of Medicine and The World Health Organization. Its recommendations were graded using a modified GRADE methodology (Guyatt, et al., 2011), considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.

9. While SOC-8 includes important updates, it does not change the substance of any of the opinions I expressed in my previous declaration. Indeed, SOC-8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery, as medically appropriate and necessary treatments for gender dysphoria, based on an individual patient's needs.

REBUTTAL TESTIMONY

10. The opinions expressed and critiques outlined in my original declaration apply to the various new declarations submitted in support of defendants' response to the motion for a preliminary injunction. Below, I outline some additional critiques based on my review of these declarations.

Rebuttal to Dr. Van Mol

11. In his declaration, Dr. Van Mol sets up a straw man of "self-diagnosis" and "affirmation on demand." Dr. Van Mol states that WPATH supports "self-diagnosis" and "treatment on demand." In fact, WPATH Standards of Care 8 requires a diagnosis when used in local contexts, which in the United States is

Gender Dysphoria under the DSM 5-TR. Diagnoses for care are made by clinicians caring for patients.

12. Dr. Van Mol provides no evidence of "affirmation on demand" leading to poor outcomes, citing instead papers in which patients with gender dysphoria were given DSM diagnoses by clinicians.

13. Dr. Van Mol mentions the *interim* report by Dr. Hillary Cass in the United Kingdom and the closure of the Tavistock clinic in the UK. He fails to mention that the report recommends more access to care, based on a regional rather than single centralized model for the entire country, and that two clinics will be opened to replace Tavistock, with more to come, with the intent of expanding access to care for transgender youth.

14. Dr. Van Mol's efforts to separate UK policy from WPATH SOC-8 recommendations are incorrect. SOC-8 benefitted from the leadership of several UK-based clinicians and academicians, like Dr. Jon Arcelus, MD, co-editor of SOC-8, Dr. Christina Richards, PhD, chapter lead of the Assessment chapter, and Dr. Walter Bouman, MD, who oversaw the SOC 8 process as WPATH president.

15. Dr. Van Mol cites an opinion in Bell v. Tavistock that was overturned on appeal regarding the legal capacity of minors to consent for medical treatment in the UK. In Florida and most other states, however, it is parents or legal guardians

who consent for minors' care. WPATH SOC-8 provides guidance on clinicians assessing the cognitive maturity for minors to assent for care, but consent is by parents or adult guardian.

16. Dr. Van Mol cites Dhejne, et al. (2011), for the proposition that suicide rates were higher in the 324 patients who received gender affirming surgery from 1973-2003, than in the general population. However, Dr. Dhejne herself notes that the study does not compare those that had surgery with those that did not, so it really does not measure the effectiveness of care. In the last 15 years of the 30-year study, there was no statistical difference in suicide rates, and the total number of suicides over 30 years were 10 in trans people versus 5 in general population control.

17. Dr. Van Mol relies heavily on statements by others who oppose gender-affirming care, rather than on data and studies themselves. These provide no counter to the many studies that provide evidence of the benefits of gender-affirming care, including those discussed or cited in my original declaration.

Rebuttal to Dr. Laidlaw

18. Dr. Laidlaw states that Gender Dysphoria was a rare condition in children and adolescents. There is little data on the frequency of those meeting the Gender Dysphoria in Children criteria over time as the diagnosis has only existed in its current criteria since 2013. The current diagnosis of Gender Dysphoria in

Children was preceded by the diagnosis of Gender Identity Disorder of Childhood contained in prior versions of the DSM, like the DSM-IV, which included a broader population of gender diverse children.

19. Moreover, population surveys asking adolescents their gender identity are a recent phenomenon, and include larger numbers, but not evidence of substantial change when the same population has been surveyed over time. As WPATH SOC-8 notes, the Littman study of social contagion has significant limitations—only parents, not gender-dysphoric youth were surveyed, and recruited from websites concerned about social contagion, and the results have not been replicated.

20. Dr. Laidlaw also uses old studies of desistance in pre-pubertal youth to argue against treatment of youth in adolescence. The newest cited study (Singh 2012) includes data from youth in the Toronto clinic from as far back as the 1970s. These older studies included pre-pubertal gender diverse youth who only met broader, obsolete diagnostic criteria that did not require the youth to have a transgender identity, and included some youth who had no diagnosis at all. In any event, in the same clinics following these youth in Toronto and in Amsterdam, if gender dysphoria was present in adolescence, it was treated with puberty blockers and hormones.

21. Regarding sexual functioning in those given puberty blockers early in development, van der Meulen, et al. (2022) reported that from long-term follow up of the Dutch cohort who received puberty blockers at Tanner stages 2 and 3, when surveyed as adults after gender affirming surgery, 81% of trans women were able to orgasm, a higher percentage than those who received gender-affirming treatment that started later in adolescence. Thus, from available data, the use of puberty blockers early in adolescence did not harm sexual functioning.

22. Regarding fertility, effects of gender-affirming care on fertility are discussed with parents and the adolescent before starting gender-affirming care. Some youth and their parents choose to preserve fertility through sperm or ova and have financial resources to do so. This is part of the equation of weighing risks and benefits. Moreover, many trans people retain reproductive capacity and some bear children. While fertility concerns are taken seriously by youth, their parents, and treatment providers, these deeply personal decisions are made by families and their doctors, not the state.

23. Lastly, Dr. Laidlaw purports to review the clinical cases of the plaintiffs, without having met or examined them. He attempts to make clinical recommendations, based on partial records, that they should not receive gender-affirming care. Dr. Laidlaw lacks the training and experience in transgender care or

mental health to make these recommendations. This is compounded by his making clinical recommendations for those who are not his patients and whom he has not examined, and by making false assumptions in each case. Making these clinical recommendations is highly speculative and inappropriate.

Rebuttal to Dr. Cantor

24. Dr. Cantor attempts to counter the statement in my declaration that the sole contemporary American longitudinal study, by Olson, et al. (2022) shows very low desistance rates. He uses a study by Singh, et al. (2021) to claim there is recent evidence of high desistance. In fact, though Singh was recently published, it is a study of feminine boys from as far back as 1975, with a mean year of evaluation of 1989. This overlaps with other reports of these feminine boys from the same Toronto clinic, who received the now obsolete Gender Identity Disorder of Childhood, if they received any diagnosis. While the feminine prepubertal boys in this study predominately identified as gay and bisexual men as adults, patients in the same clinic who had gender dysphoria continuing into adolescence were treated with puberty blockers and hormones.

25. Dr. Cantor disputes my statement that transgender identity is not a paraphilic disorder. Transgender identity is not a paraphilic disorder nor itself a mental disorder. The American Psychiatric Association, in its list of mental

disorders, states that the Gender Dysphoria diagnosis is based on "distress, not identity per se." (DSM-5, APA 2013). DSM-5 further states in the Paraphilic Disorders chapter that those with a paraphilic disorder "Do not report an incongruence between their experienced gender and assigned gender nor a desire to be of the other gender."

Rebuttal to Dr. Donovan

26. Dr. Donovan replies to my ethical concerns about forced detransition by cutting off the current care received by transgender people on Medicaid by stating that gender-affirming care should include provisions for detransitioners. In fact, WPATH provides training on working with detransitioners, and has included detransition in SOC-8. However, this volitional detransition by choice, an uncommon occurrence that should be taken seriously by health professionals, is a very different ethical concern than forcing large numbers of poor and disabled people off care involuntarily. I am surprised that Dr. Donovan seems unable to distinguish between these very different circumstances.

Rebuttal to Dr. Nangia

27. Dr. Nangia, who has practiced in State College, Pennsylvania and Greenville South Carolina, reports to have seen over a thousand youth with gender dysphoria or transgender identity in her 15 years of practice. These high numbers

are very suspect and are not typical for a general psychiatric practice. By comparison, the UCSF Child and Adolescent Gender Center, a specialty clinic providing gender-affirming medical care which attracts referrals from across the country and around the world, has only seen approximately 2,000 gender diverse and transgender youth in its 10 years of existence, and treated approximately 1,200 with puberty blockers and hormones. For Dr. Nangia to have cared for over 1,000 transgender and gender dysphoric youth, she would have to had one of the largest psychiatric practices caring for trans youth in the United States, and yet has not previously reported on this cohort. Notwithstanding her claim, I was unfamiliar with Dr. Nangia prior to reading her declaration and I have practiced as a psychiatrist in this field for over 30 years.[2]

28. Without elaboration, Dr. Nangia claims her patients have not benefitted from gender-affirming care. Four of the largest gender clinics, UCSF, Children's Hospital of Los Angeles, Northwestern, and Boston Children's first reported at the WPATH Biennial Symposium in Montreal on a cohort of 315 transgender

[2] According to the Williams Institute, the estimated population of transgender youth (ages 13-17) is only 3,200 in South Carolina and 10,000 in Pennsylvania. (Herman, et al., 2022). Pennsylvania has well-established and recognized multidisciplinary gender clinics like the ones at Children's Hospital of Philadelphia and UPMC Children's Hospital of Pittsburgh. Similarly, South Carolina has a multidisciplinary pediatric transgender clinic at MUSC Children's Health.

adolescents that were followed for two years after starting gender-affirming hormones, who showed improvement on mental health measures and on body congruence. Again, without elaboration, Dr. Nangia reports that her patients have regretted gender-affirming medical treatment. A study of 209 gender-affirming mastectomies in transmasculine adolescents under 18, performed at Kaiser Permanente Northern California from 2013 to 2020, showed a regret rate of 1%. (Tang, et al., 2022).

29. Dr. Nangia mentions a doubling of estimates of the number of transgender youth by the Williams institute. This increase is in large part because of a change in methodology, from just using the Behavior Risk Factor Surveillance System (BRFSS) to using both the BRFSS and the Youth Risk Behavior Survey (YRBS). The YRBS is a survey of high school students that includes large urban school systems, including the San Francisco Unified School District. It has higher estimates than the BRFSS, which has been relatively stable over time.

CONCLUSION

30. There is a large and growing body of evidence, as well as a consensus of experts in the just published WPATH Standards of Care Version 8, that demonstrate the benefits and medical necessity of gender affirming care to people with gender dysphoria.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and corrected.

Executed this 6th day of October 2022.

Dan H. Karasic, M.D.

EXHIBIT A

Supplemental Bibliography

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

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REBUTTAL DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. My background and credentials are detailed in my previous declaration submitted September 11, 2022 (ECF 11-5). My CV is attached as Exhibit A of that declaration.

3. I submit this rebuttal declaration to address aspects of Dr. Andre Van Mol's declaration submitted by Defendants in support of their opposition to Plaintiffs' Motion for Preliminary Injunction (ECF 49, Appendix Attachment 6).[1] Because there are many issues with Dr. Van Mol's declaration, I do not address

[1] I will refer to Dr. Van Mol's declaration with parenthetical citations in the text to page numbers in the appendix filed by Defendants at ECF 49-1.

every point he makes or every study or article that he cites. Instead, I focus on his declaration's major shortcomings: Dr. Van Mol's lack of experience in gender-affirming medical care or bioethics, his persistent mischaracterization of the evidence for gender-affirming medical care, and his erroneous statements regarding the ethics of clinical research and informed consent. I reserve the right to supplement my opinions as the case proceeds.

4. To begin, Dr. Van Mol is not an expert on the topics involved in this litigation, specifically gender-affirming medical care and the treatment of gender dysphoria in adolescents and adults. He does not report any formal training in bioethics beyond what he would have received as a medical student and resident, nor does he report any employment as a bioethicist. He is a board-certified family physician in full-time practice. This makes Dr. Van Mol one of over 100,000 board-certified family physicians in the United States.[2] Dr. Van Mol does not indicate that he previously provided or currently provides medical care to individuals with gender dysphoria in his clinical practice. He does not have any academic appointments and reports only "six peer-reviewed commentaries and letters." He is, in fact, the author of only a single peer reviewed article whose topic, health-care reform, [3] is not

[2] About the American Board of Family Medicine. American Board of Family Medicine. Accessed October 5, 2022. Available at https://www.theabfm.org/about.
[3] Van Mol A. Health-care reform's great expectations and physician reality. *Ann Pharmacother*. 2010;44(9):1492-5.

germane to gender-affirming medical care or the treatment of gender dysphoria. His other five publications are letters to the editor.[4] While major medical journals perform peer-review of submitted manuscripts, they do not generally peer review letters to the editor. Dr. Van Mol does not offer any evidence to that his letters were "peer-reviewed" in the common meaning of this term. His characterization of these letters is, therefore, misleading. Finally, rather than stating his own opinions in his declaration, Dr. Van Mol quotes extensively from others, including another expert witness retained by the Defendants, Dr. James Cantor.

5. Many of Dr. Van Mol's responses to my initial declaration fail to address the issues that I raised, and instead attempt to misdirect the reader. For example, instead of responding directly to my pointing out that there are other common medical diagnoses that do not require confirmatory laboratory or radiographic studies, Dr. Van Mol instead asserts alleged risks of gender-affirming

[4] Van Mol A. Premature termination of life is not palliative care. *Chest*. 2013;143(1):279; Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline". *J Clin Endocrinol Metab*. 2019;104(3):686-687; Van Mol A, Laidlaw MK, Grossman M, McHugh PR. Gender-affirmation surgery conclusion lacks evidence. *Am J Psychiatry*. 2020;177(8):765-766; Rosik CH, Sullins DP, Schumm WR, Van Mol A. Sexual orientation change efforts, adverse childhood experiences, and suicidality. *Am J Public Health*. 2021;111(4):e19-e20; Laidlaw MK, Van Mol A, Van Meter Q, Hansen JE. Letter to the Editor From Laidlaw et al: "Erythrocytosis in a large cohort of transgender men using testosterone: A long-term follow-up study on prevalence, determinants, and exposure years." *J Clin Endocrinol Metab*. 2021;106(12):e5275-e5276.

medical care (App. 527) and instead of responding to my point that observational studies may be sufficient evidence upon which to base recommendations, Dr. Van Mol asserts that gender dysphoria is not a disease (App. 542). Furthermore, rather than attempt to refute my opinion that it is health care providers who make the diagnosis of gender dysphoria, Dr. Van Mol asserts, "The problem is that proper, extensive psychological evaluation and support of the gender dysphoric patient and family both is not assured or even consistent (App. 524)."

6. Contrary to Dr. Van Mol's unsupported assertion, clinical practice guidelines for the treatment of gender dysphoria are clear regarding the evaluation which should be performed prior to initiating gender-affirming medical care. The Endocrine Society's criteria for gender-affirming hormone therapy for adolescents include "A qualified [mental health professional] has confirmed that: the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria" and "any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment."[5] It is not new or surprising that medical providers feel pressure from themselves, patients, families, and society to alleviate patients' pain

[5] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

and suffering whether it is caused by gender dysphoria or another medical condition. It is, however, providers' responsibility, as professionals, to make sound treatment recommendations.

7. Dr. Van Mol's sole empirical evidence for his claims that evaluation and support of patients diagnosed with gender dysphoria is not "assured or consistent" comes from only two clinics, one in London, England and the other in New South Wales, Australia (App. n. 3, 6). Without conceding that there is significant nonadherence to clinical practice guidelines in these two clinics, there are other, more appropriate ways to address such alleged concerns, rather than withdrawing funding for gender-affirming medical care. Dr. Van Mol does not point to evidence of nonadherence in Florida or provide arguments that withdrawing funding is the appropriate response to alleged nonadherence.

8. With respect to my opinion that "off-label" uses of medications to treat gender dysphoria, like gonadotropin releasing hormone (GnRH) analogs, estrogen, and testosterone, does not mean they are experimental, untested, or unsafe, Dr. Van Mol again misrepresents my opinion by responding that "Safe and effective for a given approved indication should not be assumed to mean safe and effective for any other (App. 532)." The Defendants maintain that because these medications are being used off label, they are experimental and not safe and effective, which is false. GAPMS Memo at 8, 14, 16, 19, 21; Attachment G at 4. In my declaration, I cite

independent evidence of the safety and efficacy of the use of medications "off-label" to treat gender dysphoria (ECF 11-5, at ¶¶ 22, 33-34).

9. Dr. Van Mol claims that, because additional research is purportedly needed regarding gender-affirming medical care, such care should be denied to Florida Medicaid beneficiaries. It is not possible for clinicians to tell their patients with gender dysphoria, or any other clinical condition whose treatment is currently based on a similar level of evidence, to come back later when more evidence is available. Clinicians must make treatment recommendations based on the best, currently available evidence. For example, clinical trials frequently have restrictive inclusion and exclusion criteria to improve their methodological rigor. Clinicians must subsequently determine whether to recommend the intervention to a patient with the same condition who would not have been eligible for the clinical trial. An example is fetal surgery for spina bifida in a pregnant person with a body mass index greater than 35 kg/m^2. Additional research would be beneficial for most medical conditions.

10. As I detailed in my declaration, clinical practice guidelines for medical conditions other than gender dysphoria are also frequently based on similar, "low-quality" evidence. Other clinical practice guidelines also include qualifications, e.g., the guideline does not establish a standard of care. This simply indicates that clinicians must use their best clinical judgment in applying the guideline to

individual patients. Defendants are not, however, withdrawing coverage from all conditions whose clinical practice guidelines are based on a similar level of evidence or that make similar qualifications.

11. There are prospective observational trials that support the safety and efficacy of gender-affirming medical care. Immediately after the publication of these studies, providers and potential participants could still have had the clinical equipoise necessary to ethically conduct a randomized, placebo-controlled trail, e.g, they may have had genuine uncertainty about whether or not to use puberty blockers in adolescents. The reason why a randomized, placebo-controlled trial was not performed at that time is multifactorial including the lack of government or industry funding. With additional clinical experience, many potential investigators and participants no longer have equipoise. Other types of randomized, controlled trials may nonetheless be beneficial, such as trials comparing different dosing regimens.[6] Prospective observational studies, e.g., studies of the incidence of side-effects, may also contribute to patient care.

12. It is important to reiterate that even if a randomized, placebo-controlled trial of puberty blockers had been performed, it would not have provided "high quality" evidence in the way that Dr. Van Mol inaccurately suggests. Although

[6] Burinkul S, Panyakhamlerd K, Suwan A, Tuntiviriyapun P, Wainipitapong S. Anti-androgenic effects comparison between cyproterone acetate and spironolactone in transgender women: A randomized controlled trial. *J Sex Med*. 2021;18(7):1299-1307.

randomized trials are initially assigned the grade "high," this initial grade is decreased to "moderate" if there are serious limitations in the study's quality, and to "low" if there are very serious limitations. Criteria for quality include the adequacy of allocation, concealment, blinding, and follow up.[7] In the case of placebo-controlled trials of gender-affirming medical care, it is not possible to prevent the investigators or the participants from knowing whether a participant has been assigned to the intervention or the control group. Participants and investigators would know based on whether the participant develops secondary sexual characteristics or what type of characteristics the participant develops. Dr. Van Mol insists on a type of evidence that is neither ethically nor methodologically possible.

13. It is surprising that while Dr. Van Mol asserts additional research is necessary, he is critical of the ongoing, prospective observational study of gender-affirming medical care of adolescents in the United States (U.S.). Funding for The Impact of Early Medical Treatment in Transgender Youth study was approved on a competitive basis by the Eunice Kennedy Shriver National Institute of Child Health & Human Development and the study protocol was approved by the Institutional Review Boards at the four participating hospitals.[8]

[7] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. Jun 19 2004;328(7454):1490.
[8] Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of early medical treatment for transgender youth: Protocol for the Longitudinal, Observational Trans Youth Care study. *JMIR Res Protoc.* 2019;8(7):e14434.

14. With respect to informed consent, Dr. Van Mol quotes European authors incorrectly implying that minors, rather than their parents or legal guardians, provide informed consent for gender-affirming medical care in the U.S. (App. 549-550). Dr. Van Mol also mischaracterizes a legal case from the United Kingdom (U.K.), Bell vs. The Tavistock and Portman NHS Foundation Trust, in support of his claims regarding informed consent (App. 550). In England and Wales, individuals 16- years-old and older are presumed to have the capacity to consent to medical treatment and those under 16 can consent if they possess sufficient understanding and intelligence to understand fully what is proposed. Although the court questioned the capacity of adolescents under age 16 to consent for gender-affirming medical care and suggested a role for the court in authorizing care for older adolescents, this ruling was later overturned by the Court of Appeal, [9] a fact that Dr. Van Mol conveniently fails to mention.

15. Dr. Van Mol, again quoting others, asserts that there is no established standard for informed consent and that practice varies considerably (App. 549). There are, in fact, well established standards of informed consent. Although states differ in the standard they utilize to determine if the disclosure of potential benefits and risks is adequate (the professional practice or the rational person standard), the

[9] Thornton J. Court upholds Gillick competence in puberty blockers case. *Lancet*. 2021; 398(10307):1205-1206.

standard is well established within individual states.[10] Again, Dr. Van Mol provides no empirical evidence of practice variation in Florida and, even if he were to, there are preferable ways to address such variation, were it to exist, other than completely withdrawing coverage for one type of medical care.

16. With respect to Dr. Van Mol's assertion that the Florida Medicaid Rule is non-discriminatory, the references that he cites do not support his claim (App. 553-54). As stated in above, the U.K. High Court's opinion in Bell v. Tavistock was overturned on appeal and therefore cannot be used for support as Dr. Van Mol attempts to do. The National Institute of Health and Care Excellence (NICE) reviews of puberty blockers and cross-sex hormones are systematic reviews of the literature[11] and, while they grade the quality of the evidence, they do not make treatment recommendations. The Swedish Agency of Health Technology Assessment and Assessment of Social Services report is a scoping review (a review which identifies knowledge gaps or the scope of a body of literature, clarifies concepts, or investigates research conduct)[12] and again does not make treatment recommendations. Instead of banning or defunding gender-affirming medical care,

[10] Murray B. Informed consent: What must a physician disclose to a patient? *Virtual Mentor*. 2012;14(7):563-6.
[11] Cook DJ, Greengold NL, Ellrodt AG, Weingarten SR. The relation between systematic reviews and practice guidelines. *Ann Intern Med*. 1997;127(3):210-6.
[12] Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. 2018;18(1):143.

the U.K. and Sweden are reorganizing the delivery of gender-affirming medical care into regional interdisciplinary clinics and supporting research on gender-affirming medical care. For example, in her interim report, Dr. Hilary Cass recommends, "regional centres should be developed, as soon as feasibly possible, to become direct service providers, assessing and treating children and young people who may need specialist care, as part of a wider pathway."[13] To the best of my knowledge, neither the U.K., Sweden, Finland, nor France is banning or defunding gender-affirming medical care.

17. Dr. Van Mol fails to reference any evidence for his claim that "There are alternative treatments of mental health natures which are at least as effective. And without the harms of hormonal and surgical interventions (App. 555)." Such claims are based on case reports or anecdotes[14] which represent a lower level of evidence than prospective observational studies. Recall that Dr. Van Mol asserts

[13] Cass H. Independent review of gender identity services for children and young people: Interim report. February 2022. Accessed October 5, 2022. Available at https://cass.independent-review.uk/publications/interim-report/.

[14] D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One size does not fit all: In support of psychotherapy for gender dysphoria. *Arch Sex Behav*. 2021;50(1):12; Levine SB. Transitioning back to maleness. *Arch Sex Behav*. 2018;47(4):1295-1300; Schwartz D. Clinical and ethical considerations in the treatment of gender dysphoric children and adolescents: When doing less is helping more. *J Infant Child Adolesc Psychother.* 2021;20(4):439-449; Zucker KJ. The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-confirming children" by Temple Newhook et al. (2018). *Int J Transgenderism.* 2018;19(2):238-9.

prospective observational studies, let alone case reports or anecdotes, are an unacceptable level of evidence to support gender-affirming medical treatments.

18. Dr. Van Mol's declaration provides no substantive reasons for me to alter my conclusions that treatment for gender dysphoria is not experimental and is consistent with generally accepted professional medical standards including standards for informed consent. I remain of the opinion that there is not a sound medical or ethical basis for excluding such care from coverage by Florida Medicaid and so doing is inconsistent with the program's other medical coverage decisions.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on October 7, 2022

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

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

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

SUPPLEMENTAL EXPERT DECLARATION OF
DR. JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have personal knowledge of the matters stated in this supplemental declaration.

3. I submit this declaration to respond to points raised in the declarations of Dr. Michael M. Laidlaw, M.D., Dr. Andrew Van Mol, M.D., and Dr. James Cantor (attachments 4, 6, and 11 to Defendants' Appendix), which Defendants submitted in connection with their response to Plaintiffs' motion for a preliminary injunction.

4. I have personal knowledge of the matters stated in this supplemental declaration.

5. I previously submitted an expert witness declaration [Dkt. 11-2] in support of Plaintiffs' motion for a preliminary injunction in this case.

6. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original declaration.

7. Since I submitted my prior declaration, WPATH has published version 8 of the *Standards of Care for the Health of Transgender and Gender Diverse People* ("SOC8").[1] Importantly, SOC8 is based on the best available science and expert professional consensus in transgender health; its recommendation statements were developed based on data derived from independent systematic literature reviews, background reviews, and expert opinions; and its grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability of these.

8. While SOC8 contains important updates with respect to gender-affirming surgery, it does not change the substance of any of the opinions I expressed

[1] E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, Int'l J. of Transgender Health S1 (2022), https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644.

in my previous declaration. Indeed, SOC8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery as treatment for gender dysphoria, based on an individual patient's needs.

9. In preparing this supplemental declaration, I relied on my training and years of research and clinical experience, as set out in my curriculum vitae attached to my original declaration, and on the materials listed therein; the materials referenced in my original declaration and listed in the bibliography attached thereto; and on the materials referenced herein and the supplemental bibliography attached as Exhibit A. reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

REBUTTAL TESTIMONY

Rebuttal to Dr. Laidlaw

10. Dr. Laidlaw utilizes many of the same arguments against gender affirmation that are presented in the reports that were attached to GAPMS Memo and which I have addressed in my original declaration. These include his arguments about the high desistence rates of children, the inability of adolescents and their parents to make informed decisions, social contagion theory, lack of good quality

data, blockers and social transition as gateways to gender affirming medical treatment and an overemphasis on the secondary sex characteristics as reproductive tools.

11. Dr. Laidlaw does not include the most recent study examining persistence, that also has the largest sample size: Kristina R. Olson, Lily Durwood, Rachel Horton, Natalie M. Gallagher, Aaron Devor; Gender Identity 5 Years After Social Transition, Pediatrics, August 2022; 150 (2): e2021056082. 10.1542/peds.2021-056082. This study demonstrated that 94% of the transgender youth in this study continued to have a transgender identity five years after enrollment.

12. From his declaration, it is evident that Dr. Laidlaw does not work with transgender youth, nor does he have a good understanding of the care, as illustrated by the points below.

13. In many places throughout his report, Dr. Laidlaw references the use of "high dose" hormones. Nowhere does he provide a definition of "high dose."

14. Dr. Laidlaw writes: "There are also serious concerns regarding liver dysfunction: "Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may

rupture] —all potentially life-threatening complications" (Actavis Pharma, 2018). (Laidlaw Dec. at 20.) The source document Dr. Laidlaw relies on describes these side effects of liver dysfunction as related to the use of 17alpha-AAS, Methyltestosterone, Oxandrolone, Oxymetholone and Stanozolol. These are not medications routinely used in gender-affirming care. Masculinization is achieved with testosterone esters, most commonly, testosterone cypionate. Someone who practices this medicine would know this.

15. Similarly, Dr. Laidlaw writes: "Moreover, "[s]tudies ... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms." (Laidlaw Dec. at 22.) Again, if he was familiar with the care, he would be aware that testosterone doses for masculinization are not even close to the "medium" dosing described above. In fact, most commonly patients are being prescribed 60-100 mg a week.

16. Dr. Laidlaw repeatedly presents irrelevant data in order to create confusion and incite fear. He presents source data with very few subjects, or quotes studies with statistics that sound alarming, but does not accurately represent the

absolute risk of potential side effects. Additionally, he fails to mention the positive medical side effects of hormones.

17. For example, Dr. Laidlaw writes that "Breast cancer is a relatively uncommon problem of the male. However the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen." (Laidlaw Dec. at 23.) The source document he relies on says on its first page that "The absolute risk of breast cancer in transgender people remains low, and therefore following breast cancer screening guidelines for cisgender people seems sufficient for transgender people using hormone treatment."

18. Breast cancer risk is higher among transgender women compared to cisgender males, but lower than cisgender women. The fact that transgender individuals adopt a similar health risk profile to their cisgender counterparts is not surprising. Accordingly, transgender men have a lower risk of breast cancer than cisgender men.

19. Neither a practitioner in gender care, nor a researcher, Dr. Laidlaw further demonstrates his lack of understanding about transgender adolescent development when he writes about the apparent "impairment of sexual function" by relying on an episode of the TLC reality show "I am Jazz," where the protagonist of the show, Jazz, visited a surgeon and discussed sexual function. (Laidlaw Dec. at

16). If Dr. Laidlaw had experiencing caring for transgender youth, he would not distill the experiences of all transgender girls treated with puberty-delaying medication in early puberty to two sentences from a reality TV show on TLC. Many transgender girls have difficulty with masturbation because of a disconnection between themselves and their genitals. It takes conversation and education to help patients develop comfort with self-pleasure. Many patients do get over this discomfort and have both sexual sensation and orgasm.

20. Dr. Laidlaw further asserts that the psychosocial development of transgender youth treated with puberty blockers "will be necessarily stunted as they are not developing with their peers" and that "[t]his is a permanent harm as the time cannot be regained." (Laidlaw Dec. at 17.) This assertion completely discounts the understanding that pubertal trajectories vary between individuals.

21. Pubertal development has a wide variation among individuals. Puberty in people assigned male at birth typically begins anywhere from age 9 to age 14, and sometimes does not complete until past 18. For people assigned female at birth, puberty typically ranges from age 8 to age 17.

22. If a 13-year-old cisgender female had not yet started puberty, we would not give them exogenous hormones so that they were peer concordant with the

majority of their peers simply because they are on the later side of the normal range for puberty commencement.

23. Protocols used for the treatment of transgender youth tend to put the start of puberty using exogenous hormones in the latter third of typical puberty for the sex consistent with their identity, but nothing outside of the typica range.

24. Dr. Laidlaw also asserts that "there are unknown, but likely negative consequences to blocking normal puberty with respect to brain development." Dr. Laidlaw's assertion based on pure supposition. What is known is that untreated gender dysphoria has a tremendously negative impact on the quality of life and functioning of adolescents.

25. Finally, it should be noted that Dr. Laidlaw's commentary regarding the specific course of care of the plaintiffs is not reliable and highly suspect. It is inappropriate for Dr. Laidlaw to offer a recommendation about the specific course of care for plaintiffs when he has neither met nor treated these patients and is basing his recommendations on an incomplete and partial view of their medical history. Moreover, Dr. Laidlaw does not appear to be experienced in the provision of gender-affirming care and does not offer any recommendation for the treatment of people's gender dysphoria, including plaintiffs.

26. More specifically, in his comments about plaintiffs, Dr. Laidlaw makes references to doses of testosterone but only mentions the concentration of the suspension (200 mg/mL) not the *actual* dose. Dr. Laidlaw also repeatedly points out the coexistence of mental health concerns, including anxiety, depression, and ADHD. These are very common diagnoses in adolescents at large, and it is well-documented that youth with gender dysphoria have even higher rates of anxiety and depression likely *as a result of* their gender dysphoria. Moreover, there is no reason that youth with coexisting anxiety, depression and ADHD should be denied care related to gender dysphoria.

27. Dr. Laidlaw also unabashedly declares professionals "unfit" to provide both diagnoses of gender dysphoria and medical treatment of gender dysphoria. This is not only an appalling display of unprofessionalism, it demonstrates his lack of understanding about how multidisciplinary teams function in the care of transgender youth. He has no personal knowledge of these providers' training and leans on his own "hierarchy of professionals" that places medical doctors at the top to deem whether or not people are qualified to be doing the work they are doing. This declaration from a provider who clearly does not practice in this field of medicine is unprecedented.

28. Dr. Laidlaw's suggestion that medical services related to gender dysphoria for plaintiffs, who he has not met nor treated, should be discontinued is misinformed and dangerous.

29. Dr. Laidlaw is not an expert in the care of transgender youth, nor is he an investigator in transgender care or any other topic. His CV consists largely of letters to the editor, speeches advocating against transgender youth care, and providing unsubstantiated "expert testimony" in cases such as these.

Rebuttal to Dr. Van Mol

30. Much of Dr. Van Mol's declarations draws upon the existing testimony from others, such as Dr. Stephen Levine and Dr. James Cantor. Dr. Van Mol does not care for transgender patients, and has a clear bias given his listed credentials.

31. The American College of Pediatricians, the Council on Adolescent Sexuality and the Christian Medical & Dental Associations and the Alliance Defending Freedom have historically opposed transgender rights, including access to gender-affirming care, and LGBTQ rights more broadly.

32. Dr. Van Mol refers to the closing of the Tavistock Clinic in the United Kingdom as a justification for denying care to youth with gender dysphoria in Florida. But the closure is not intended to end the provision of gender-affirming care (as Dr. Van Mol and Dr. Laidlaw) would have one believe. It was based on

issues such as long waitlists that were documented by Dr. Hillary Cass's "independent review of gender identity services for children and young people" in the United Kingdom.

33. To the contrary, the closure is based on a recommendation by Dr. Hillary Cass to move to a "regionalised service delivery model," that is meant to "*improve access*, networked care, research capacity and workforce development." Simply put, gender-affirming care for youth with gender dysphoria is not being discontinued. Indeed, England's National Health Service has stated that, "The aim is to close the Tavistock clinic [the Gender and Identity Development Service (Gids)] by spring 2023, moving to the new provider model through specialist children hospitals" and noted that the youth "being seen by the Tavistock (and those on waiting lists) will be transferred to a new provider over the course of that time."

34. Dr. Van Mol also repeats the assertion that the use of psychological treatment for patients with gender dysphoria is not proven to be inferior to medical interventions, which is outlandish given the decades of research, scientific study, and clinical experience we now have. In 1966, Harry Benjamin noted in "The Transsexual Phenomenon" that while transsexualism is primarily considered a psychiatric disorder, it is refractory to psychiatric intervention. Over the past 50 years, mental health professionals who have attempted to treat gender dysphoria with

psychological interventions that have been unsuccessful. (Olson-Kennedy Dec. at ¶¶ 110-11.)

35. Dr. Van Mol also presents the same arguments about gender-affirming care, particularly for youth, is purportedly experimental and that there is no good quality evidence because of the lack of an untreated control group. I have addressed these concerns in my original declaration. (Olson-Kennedy Dec. at ¶¶ 68-88.) Dr. Van Mol's assertion here is based on the belief that the control group would have access to psychological interventions. But as, as stated above, this is not true and has proven to be unsuccessful. Additionally, participants would have to choose to be in a study in which they could receive no medical intervention. There are distinct issues that I have outlined in my previous testimony regarding the feasibility of RCTs in this context.

36. Finally, Dr. Van Mol omits the importance of clinician experience and patient values in the construct of evidence-based medicine, as noted in my original declaration (Olson-Kennedy Dec. at ¶¶ 85-88).

Rebuttal to Dr. Cantor

37. In my original declaration, I discussed at length the challenges of using a grading system to identify research as "high quality" and of the importance of clinical experience and patient values in the practice of evidence-based medicine. I

am not disputing that the research discussed by Dr. Cantor does not reach a grading of high quality, but that RCTs (the "gold standard" of high-quality evidence) are not feasible based on the challenges posed in adolescent gender care research.

38. Dr. Cantor reasserts that mental health therapy alone can improve the mental health of patients with gender dysphoria. (Cantor Dec. ¶ 33.) But gender dysphoria is characterized by the clinically significant distress that results from the incongruence between a person's gender identity and sex assigned at birth. No study has demonstrated that mental health therapy alone is a successful mechanism to manage gender dysphoria.

39. Dr. Cantor also takes issue with my discussion of Harry Benjamin's work based on the fact that the seminal text *The Transsexual Phenomenon* does not mention children. But the Rule at issue in this case prohibits coverage of gender-affirming care for adults and minors alike. Moreover, while I did not represent the quote was referring to children, in fact, Harry Benjamin did care for adolescents. (Dear Doctor Benjamin; Letters from Transsexual Youth, International Journal of Transgenderism Vol 10, 2008) There is no reference to whether or not youth are included in his sentiment, but given that he did care for adolescents, it is likely that he includes them in this sentiment.

CONCLUSION

40. The testimony of Dr. Van Mol and Dr. Laidlaw exposes that neither of these defendants have experience in the care of transgender adolescents.

41. While it is true that the field of transgender youth care is a growing field, there is ample clinical experience and data to demonstrate the positive impact of medical interventions in the care of youth with gender dysphoria, and to cut off access to this care would have a detrimental impact on a very vulnerable population.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and corrected.

Executed this 7th day of October 2022.

Johanna Olson-Kennedy, M.D., M.S.

EXHIBIT A

Supplemental Bibliography

SUPPLEMENTAL BIBLIOGRAPHY

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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

NOTICE OF SCRIVENER'S ERROR AND FILING OF SUPPLEMENTAL DECLARATION TO CORRECT ERROR

NOTICE is hereby given that Jade Ladue's declaration filed in support of Plaintiffs' Motion for Preliminary Injunction (ECF. 11-9) contains a scrivener's error. Plaintiffs therefore file an amended declaration along with this Notice to correct the error.

Respectfully submitted this 10th day of October 2022.

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CERTIFICATE OF SERVICE

I hereby certify that, on October 10, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

/s/ Jennifer Altman
Jennifer Altman

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	No. 4:22-cv-325-RH-MAF

SUPPLEMENTAL DECLARATION OF JADE LADUE

I, Jade Ladue, hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.

2. In my prior declaration filed in support of Plaintiffs' Motion for Preliminary Injunction on September 12, 2022, I stated that K.F.'s first appointment with the Gender Multispecialty Service (GeMS) Program at Boston Children's Hospital was September 13, 2015. (ECF 11-9, ¶16). That statement included a scrivener's error. The correct date for K.F.'s first appointment with the GeMS Program is September 13, 2017.

I declare under penalty of perjury that the foregoing is true and correct. Executed this ___ day of October 2022.

Respectfully Submitted,

Jade Ladue

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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER et al.,

Plaintiffs,

v. CASE NO. 4:22cv325-RH-MAF

SIMONE MARSTILLER et al.,

Defendants.
_____/

ORDER DENYING A PRELIMINARY INJUNCTION

The State of Florida recently adopted a rule barring Medicaid payment for specific categories of treatment for gender dysphoria: puberty blockers, hormone therapy, and surgeries. The plaintiffs assert the rule is unconstitutional, violates the Affordable Care Act's nondiscrimination provision, and violates the federal Medicaid statute. The plaintiffs have moved for a preliminary injunction based only on the Constitution and ACA, not based on the Medicaid statute. This order confirms and briefly summarizes the ruling announced on the record at the conclusion of a hearing on the motion.

I

Medicaid is a jointly funded federal-state program that provides medical care for patients of limited economic means. *See Harris v. James*, 127 F.3d 993, 996 (11th Cir. 1997). Federal law makes some services mandatory but allows states to "place appropriate limits" based on "such criteria as medical necessity or on utilization control procedures." 42 C.F.R. § 440.230(d); *see also Rush v. Parham*, 625 F.2d 1150, 1156 (5th Cir. 1980). States may "set reasonable standards" for "medical necessity." *Garrdio v. Dudek*, 731 F.3d 1152, 1155 (11th Cir. 2013).

Exercising this authority, Florida has long barred payment for physician services that are "clinically unproven [or] experimental." Fla. Stat. § 409.905(9). If there is a difference between "clinically unproven" and "experimental," it makes no difference for purposes of this order. For convenience, when discussing the Florida statute, this order uses the term "experimental," without also referring to "clinically unproven." This is consistent with the way the parties have briefed the issues.

The statute is unquestionably valid, at least on its face. The controlling question in this litigation is whether applying the provision to the gender-dysphoria treatments at issue violates the United States Constitution or federal law.

II

As a prerequisite to a preliminary injunction, a plaintiff must establish a substantial likelihood of success on the merits, that the plaintiff will suffer irreparable injury if the injunction does not issue, that the threatened injury outweighs whatever damage the proposed injunction may cause a defendant, and that the injunction will not be adverse to the public interest. *See, e.g.*, *Charles H. Wesley Educ. Found., Inc. v. Cox*, 408 F.3d 1349, 1354 (11th Cir. 2005); *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc).

III

In *Rush v. Parham*, 625 F.2d 1150 (5th Cir. 1980), a Medicaid beneficiary challenged Georgia's refusal to pay for gender-affirming surgery. The state said the surgery was experimental and thus not medically necessary. The district court ruled that the surgery was necessary because the plaintiff's physician said so—that the state was bound by the physician's opinion. Not surprisingly, the Fifth Circuit disagreed.

The Fifth Circuit remanded the case to the district court to determine two things: first, whether Georgia had a policy prohibiting payment for experimental services when it first rejected the plaintiff's application; and second, if it did, "whether its determination that transsexual surgery is experimental is reasonable." *Id*. at 1157. The court said this second question—whether the state's determination

"is" reasonable, would be controlled on remand by "current medical opinion, regardless of the prevailing knowledge at the time of plaintiff's application." *Id*. at 1157 n.13.

Rush is binding authority in the Eleventh Circuit. *See Bonner v. City of Prichard*, 661 F.2d 1206, 1207 (11th Cir. 1981) (en banc). The remand instructions were the Fifth Circuit's square holding. The case dealt only with surgery, not puberty blockers or hormone therapy, but the same principles apply. The decision thus sets out a roadmap for further proceedings in this court—the same roadmap the district court was required to follow in *Rush*.

There is, however, one difference. This record provides no basis to doubt that Florida prohibited payment for experimental services when the plaintiffs submitted their applications. This was the first of the two questions on remand in *Rush*. The second question thus will be controlling here: whether, based on current medical knowledge, the state's determination that these treatments are experimental is reasonable.

If the state has reasonably determined these treatments are experimental, the refusal to pay for them under the Medicaid program is unconstitutional or violates the ACA nondiscrimination provision only if the state pays for other, equivalently experimental treatments. The plaintiffs will face a difficult task to show that any other treatment is equivalently experimental, because it will be difficult to establish

two things: first, an equivalence between any Florida-Medicaid-eligible service and these treatments for this diagnosis, or second, an equivalence of current medical knowledge between these treatments and any Florida-Medicaid-eligible service. The plaintiffs' suggestion that their diagnoses can be ignored so that equivalence can be established merely by showing that the same procedures are provided for other diagnoses will not do—a treatment that is well established in one circumstance may be experimental in another. The record does not show that the plaintiffs are likely to prevail on this issue.

If, on the other hand, the state has not reasonably determined the treatments are experimental, the state will be required to pay for the treatments under the Medicaid program, and there will be no need to reach the constitutional issue. *See generally Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 341, 345-46 (1936) (Brandeis, J., concurring) (setting out fundamental principles of constitutional adjudication, including that, "The Court will not 'anticipate a question of constitutional law in advance of the necessity of deciding it' ") (quoting earlier authorities in part); *see also Lyng v. Nw. Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445 (1988) ("A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them."), *quoted with approval in Williamson v. Brevard Cnty.*, 928 F.3d 1296, 1316-17 (11th Cir. 2019); *Hayburn's Case*, 2 U.S. 408

(1792) (forbidding federal courts from rendering advisory opinions or making determinations that are subject to revision by the executive branch).

In short, the case is likely to rise or fall on the Medicaid claim. The plaintiffs have not moved for a preliminary injunction on that claim. They have not shown a likelihood of success on the merits on the constitutional and ACA claims, because it is likely that the plaintiffs will lose those claims (if they lose the Medicaid claim) or that the other claims will not be reached (if the plaintiffs win the Medicaid claim).

IV

An equally important basis for denying the plaintiffs' motion is that they have not shown they will suffer irreparable harm in the absence of a preliminary injunction. This is so for two reasons.

First, the record does not include medical testimony that the plaintiffs need the treatments at issue and will suffer irreparable harm if it is not provided before the scheduled trial. A factfinder could perhaps conclude, from the plaintiffs' own testimony, that they will suffer irreparable harm, but I do not make that finding on that basis at this time.

Second, the defendants have represented, in opposition to the plaintiffs' motion, that Florida law does not flatly prohibit Medicaid payment for the treatments at issue, and that instead, the plaintiffs may be able to obtain payment

under Florida Statutes § 120.542. That statute allows an agency to grant a variance or waiver from an otherwise uniformly applicable rule. The defendants equated this to the emerging approach in some European countries, where treatment of this kind is available, just not as readily available as in years past. If a plaintiff qualifies for a variance under § 120.542—as one or more of them well might if, as the defendants have said, the challenged rule mirrors the cited European approach—the plaintiff will not suffer irreparable harm. The defendants' representation is a basis for this order denying a preliminary injunction and will bind the defendants as the case goes forward.

V

A note should be added about what this case does *not* involve. The question presented is only whether Medicaid must *pay* for the treatments at issue. The case does not involve the markedly different question whether a state could *prohibit* treatments of this kind. Florida does not prohibit the treatments.

VI

The bottom line is this. The Medicaid claim is likely to control the outcome of this litigation. The plaintiffs have not moved for a preliminary injunction on that claim. And they have not established that they will suffer irreparable harm if a preliminary injunction does not issue, partly because they have not sought a variance or waiver.

For these reasons and those set out on the record at the conclusion of the preliminary-injunction hearing,

IT IS ORDERED:

The preliminary-injunction motion, ECF No. 11, is denied.

SO ORDERED on October 24, 2022.

s/Robert L. Hinkle
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

SIMONE MARSTILLER, et al.,

Defendants.
_____/

ANSWER

Pursuant to Rule 8(b) of the Federal Rules of Civil Procedure, Defendants, SIMONE MARSTILLER, in her official capacity as Secretary of the Florida Agency of Health Care Administration, and the FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION hereby answer the allegations of the Complaint filed by Plaintiffs, August Dekker, legally known as Kori Dekker, BRIT ROTHSTEIN, SUSAN DOE, a minor, by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., a minor by and through his parent and next friend, JADE LADUE. The numbered Paragraphs of this Answer correspond to the numbered Paragraphs of the Complaint. Defendants deny any and all allegations of the Complaint, whether express or implied, that are not specifically admitted, qualified, or denied by this Answer. The headings included in the Complaint are quoted for consistency and ease of reference only and any allegations in the headings are specifically denied.

INTRODUCTION

1. The first sentence of Paragraph 1 states Plaintiffs' legal position and therefore requires no response. Defendants deny the second and third sentence of this Paragraph.

2. Denied.

3. Admitted that the Agency for Health Care Administration adopted Rule 59G-1.050(7). The remaining allegations and conclusions, as well as the characterizations of Rule 59G-1.050(7), contained in Paragraph 3 are denied.

4. Denied.

5. Defendants admit the allegation in the first sentence of Paragraph 5, but deny the allegations in the second sentence.

6. Denied.

7. Denied.

8. Denied.

9. Denied.

10. Denied.

11. Denied.

12. Paragraph 12 contains Plaintiffs' description of the relief requested in this lawsuit; therefore no response is required.

A. Plaintiffs

Plaintiff August Dekker

13. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 13 and on that basis deny them.

Plaintiff Brit Rothstein

14. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 14 and on that basis deny them.

Plaintiff Susan Doe

15. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 15 and on that basis deny them.

Plaintiff K.F.

16. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 16 and on that basis deny them.

B. Defendants

17. Admitted.

18. Admitted.

JURISDICTION AND VENUE

19. Admitted.

20. Defendants deny that Plaintiffs are entitled to declaratory or injunctive relief.

21. Admitted.

22. Admitted.

FACTUAL BACKGROUND

23. Denied.

24. Denied.

25. Admitted that some individuals experience incongruence between their sex and their perception of themselves; otherwise denied.

26. Denied.

27. Admitted.

28. Denied.

29. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 29 and on that basis deny them.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Admitted to the extent that gender dysphoria is a mental condition; otherwise denied.

35. Defendants deny that the listed medical and mental health groups are "leading"; otherwise admitted.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Admitted as to the position of WPATH and Endocrine Society. Denied that the treatments referenced in Paragraph 40 are medically necessary.

41. Denied.

42. Denied.

43. Admitted that some transgender individuals pursue legal transition. The characterization of "many" is vague and therefore denied.

44. Denied.

45. Denied that hormone therapy and surgery are medically necessary treatments for gender dysphoria.

46. Denied.

47. The WPATH Standards of Care speak for themselves. Defendants deny the allegation in the first sentence of this Paragraph that medical interventions are medically necessary and appropriate after transgender youth reach puberty. Defendants deny the allegations in the second sentence as a categorial description of how gender dysphoria is treated in every case.

48. Defendants deny that puberty delaying medications minimizes and potentially prevents any heightened gender dysphoria associated with puberty.

49. Defendants deny the allegations of this Paragraph to the extent they are contrary to the Agency for Healthcare Administration's ("AHCA's") Generally

Accepted Professional Medical Standards Determination for Gender Dysphoria ("GAPMS Determination").

50. Denied.

51. Admitted that surgery might be sought by transgender people after puberty; otherwise denied.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 56 and on that basis deny them.

57. Denied.

B. The Medicaid Act and Florida's Medicaid Program

i. Medicaid Coverage

58. The statutory provisions cited in Paragraph 58 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

59. The statutory provision cited in Paragraph 59 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

60. The statutory provisions cited in Paragraph 60 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

61. The statutory provision and regulations cited in Paragraph 61 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

62. The statutory provision cited in Paragraph 62 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

63. The statutory provision cited in Paragraph 63 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

64. The statutory provisions cited in Paragraph 64 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

65. The statutory provision cited in Paragraph 65 speak for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

ii. <u>The Medicaid EPSDT Requirements</u>

66. The statutory provisions cited in Paragraph 66 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

67. . The statutory provisions cited in Paragraph 67 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

68. The federal regulatory guidance cited in Paragraph 68 speak for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

69. The statutory provisions cited in Paragraph 69 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

70. The statutory provisions cited in Paragraph 70 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

71. The statutory provisions cited in Paragraph 71 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

72. The statutory provisions cited in Paragraph 72 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

73. The statutory provision cited in Paragraph 73 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

74. The regulation cited in Paragraph 74 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

iii. The Medicaid Comparability Requirements

75. The statutory provision cited in Paragraph 75 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

76. The regulation cited in Paragraph 76 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

77. The regulation cited in Paragraph 77 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

iv. Florida's Medicaid Program

78. The statutory provision and regulations cited in Paragraph 78 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

79. The statutory provision cited in Paragraph 79 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

80. The federal register provisions cited in Paragraph 80 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

81. The regulations cited in Paragraph 81 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

82. The regulations cited in Paragraph 82 speak for themselves, and all allegations inconsistent with their terms are denied. Otherwise denied.

83. The regulation cited in Paragraph 83 speaks for itself, and all allegations inconsistent with its terms are denied. Otherwise denied.

84. Admitted that Rule 59G-1.050, F.A.C. as amended became effective August 21, 2022. Otherwise, denied.

85. Admitted that Rule 59G-1.050, F.A.C. as amended became effective August 21, 2022. Otherwise, denied.

C. Defendants adopt the Challenged Exclusion and Target Transgender Medicaid Beneficiaries for Discrimination. (DENIED)

86. Denied that the Florida Department of Health ("FDOH") guidelines are "misleading and factually inaccurate"; otherwise admitted.

87. Admitted that the FDOH guidelines are non-binding; otherwise denied.

88. Admitted.

89. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 89 and on that basis deny them.

90. The referenced letter to the editor speaks for itself. Defendants deny the substance of the quoted statements.

91. The referenced letter to the editor speaks for itself. Defendants deny that "[t]hese national and international guidelines are the result of careful deliberation and examination of the evidence by experts, including pediatricians, endocrinologists, psychologists and psychiatrists."

92. Admitted.

93. Denied.

94. Denied.

95. Admitted that AHCA published the GAPMS Determination on June 2, 2022. Denied that AHCA published a "political" webpage with "misleading 'fact-checking' of HHS's guidance" or any "false assertions."

96. Denied that the GAPMS Determination included "wrong[]" conclusions; otherwise admitted.

97. Denied that scare quotes should be used for the term "'assessments.'" Otherwise, admitted.

98. Denied.

99. Admitted that the GAPMS Determination included an expert report by Dr. Quentin Van Meter; otherwise argumentative and denied.

100. Admitted that the GAPMS Determination included an expert report by Dr. James Cantor. The referenced judicial decision speaks for itself.

101. Admitted that the GAPMS Determination included an assessment by Dr. Romina Brignardello-Peterson. Admitted that Dr. Brigardello has no experience treating gender dysphoria. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the remaining allegations in Paragraph 101 and on that basis deny them.

102. Admitted that the GAPMS Determination included an assessment by Dr. Patrick Lappert. The referenced judicial decision speaks for itself.

103. Admitted.

104. Denied that the Proposed Rule "goes beyond" FDOH Guidance, which does not deal with Medicaid coverage; otherwise admitted that the rule denies Medicaid coverage for certain treatments for gender dysphoria.

105. Denied that "thousands" of comments were submitted by individuals, organizations, and medical professionals in opposition to the rule. Comments were submitted by a total of approximately 1,300 individuals, organizations and medical professionals both in support and in opposition to the Proposed Rule.

106. Admitted.

107. Admitted that the hearing was set for 3:00 p.m., on Friday, July 8, 2022, and that it featured a panel of experts; otherwise denied.

108. Denied.

109. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 109 and on that basis deny them.

110. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 110 and on that basis deny them.

111. Defendants deny that any participants at the public hearing were "flown in from out of state" or "bussed" in by AHCA or that AHCA "allowed" stickers to be passed out. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in Paragraph 111 and on that basis deny them.

112. Denied that "thousands" of written comments were submitted in opposition to the rule. Comments were submitted by a total of approximately 1,300 individuals and organizations both in support and in opposition to the Proposed Rule. Denied that the nature of the proceedings was biased. Admitted that written comments were submitted and that individuals testified at the public hearing both in support and in opposition to the proposed rule; otherwise denied.

113. Admitted that comments were submitted by a group of professors from Yale Law School, the Yale School of Medication, University of Texas Southwestern, and the University of Alabama at Birmingham. Denied that those comments refuted conclusions behind the GAPMS Determination or that any such conclusions are unscientific.

114. The referenced comments speak for themselves. Defendants deny the conclusions of the comments as summarized in Paragraph 114.

115. Admitted that the group of professors submitted a report entitled "A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria." The document speaks for itself, but Defendants deny that the GAPMS Determination is misleading.

116. The comments of the American Academy of Pediatrics speak for themselves. Defendants deny the substance of the comments and any allegation that the GAPMS Determination was issued for "discriminatory reasons."

117. The comments of the Endocrine Society speak for themselves. Defendants deny the substance of the comments.

118. Any interviews with researchers speak for themselves. Defendants deny that Defendants misinterpreted or misrepresented any studies to justify the GAPMS Determination.

119. Admitted that the Proposed Rule was filed for final adoption on August 1, 2022. Defendants deny the remaining allegations of this Paragraph.

120. Admitted.

121. Admitted.

122. Denied.

123. Denied that there is an established scientific and medical consensus that the four specified services are frequently medically necessary, safe, and effective for treating gender dysphoria. Defendants deny all other allegations in this Paragraph.

124. Denied.

125. Denied.

126. Admitted that some of these events occurred although they are mischaracterized; denied that any were related to the GAPMS Determination.

127. Denied.

D. The Plaintiffs

Plaintiff August Dekker

128. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

129. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

130. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

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149. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

150. Denied.

Plaintiff Brit Rothstein

151. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

152. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

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177. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

Plaintiff Susan Doe

178. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

179. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

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Plaintiff K.F.

216. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

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250. Defendants lack information or knowledge sufficient to formulate an opinion as to the truth of the allegations in this Paragraph and on that basis deny them.

CLAIMS FOR RELIEF

COUNT I
Deprivation of Equal Protection in Violation of the Fourteenth Amendment of the U.S. Constitution

(All Plaintiffs Against Defendant Simone Marstiller)

251. Defendants incorporate by reference their responses to Paragraphs 1-250 of the Complaint.

252. Admitted.

253. This Paragraph characterizes Plaintiffs' claims and therefore requires no response. However, Defendants deny that Plaintiffs are entitled to any relief sought.

254. Denied.

255. This Paragraph states a legal conclusion and therefore requires no response. If a response is required, Defendants deny the allegation in this Paragraph.

256. This paragraph states a legal conclusion and therefore requires no response. If a response is required, Defendants deny the allegation in this Paragraph.

257. Denied.

258. The first sentence of this Paragraph states a legal conclusion and therefore requires no response. If a response is required, Defendants deny the allegation in this Paragraph. This paragraph states a legal conclusion and therefore requires no response. If a response is required, Defendants deny the allegation in this Paragraph. All other allegations in this Paragraph are denied.

259. Denied.

260. Denied.

261. Denied.

262. Denied.

263. Denied.

264. Denied.

265. Denied.

COUNT II
Discrimination on the Basis of Sex in Violation of Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116

(All Plaintiffs Against AHCA)

266. Defendants incorporate by reference their responses to Paragraphs 1-250 of the Complaint.

267. The referenced statute speaks for itself.

268. This paragraph states a legal conclusion and therefore requires no response. If a response is required, Defendants deny the allegations in this Paragraph.

269. The statutory provisions cited in Paragraph 269 speak for themselves, and all allegations inconsistent with their terms are denied.

270. This paragraph states a legal conclusion and therefore requires no response. If a response is required, Defendants deny the allegations in this Paragraph.

271. This paragraph states a legal conclusion and therefore requires no response. If a response is required, Defendants deny the allegations in this Paragraph.

272. Denied.

273. Denied.

274. Denied.

COUNT III
Violation of the Medicaid Act's EPSDT Requirements,
42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r)(5)

(Plaintiffs Brit Rothstein, Susan Doe, and K.F. Against Defendant Marstiller)

275. Defendants incorporate by reference their responses to Paragraphs 1-250 of the Complaint.

276. The referenced statutory provisions speak for themselves.

277. Denied.

COUNT IV
Violation of the Medicaid Act's Comparability Requirements,
42 U.S.C. § 1396a(a)(10)(i)

(All Plaintiffs Against Defendant Marstiller)

278. Defendants incorporate by reference their responses to Paragraphs 1-250 of the Complaint.

279. The referenced statutory provision speaks for itself.

280. Denied.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the requested relief.

Respectfully submitted by:

/s/ Mohammad O. Jazil
Mohammad O. Jazil (FBN: 72556)
Gary V. Perko (FBN: 855898)
Michael Beato (FBN: 1017715)
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Fax No.: (540) 341-8809

Dated: October 26, 2022

Counsel for Defendants Secretary Marstiller and Florida Agency for Healthcare Administration

CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2022, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

Doc. 108

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,	)	
	)	
Plaintiffs,	)	Case No: 4:22cv325
	)	
v.	)	Tallahassee, Florida
	)	January 26, 2023
JASON WEIDA, et al.,	)	
	)	10:35 AM
Defendants.	)	
_____	)	

TRANSCRIPT OF TELEPHONIC MOTION PROCEEDINGS
BEFORE THE HONORABLE ROBERT L. HINKLE
UNITED STATES CHIEF DISTRICT JUDGE
(Pages 1 through 62)

Court Reporter: MEGAN A. HAGUE, RPR, FCRR, CSR
111 North Adams Street
Tallahassee, Florida 32301
megan.a.hague@gmail.com

Proceedings reported by stenotype reporter.
Transcript produced by Computer-Aided Transcription.

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Tallahassee, Florida 32301

P R O C E E D I N G S

(Call to Order of the Court at 10:35 AM on Thursday, January 26, 2023.)

THE COURT: Good morning. This is Judge Hinkle. We are starting a little late because Mr. Jazil had a hearing in another court and it ran over, and I understand that. So here we go.

I've read the motion and been through the attachments and read the declaration that the defense submitted in response, Mr. Brackett's declaration. I've got a couple of preliminary matters, and then we can work through the various production requests.

Let me start just on terminology. There will certainly be some discussion of the GAPMS report. I'm going to pronounce that "GAPMS," treat the P as silent. I don't know how you people have been doing it, but it just seems to make it one syllable -- it works better -- and in the transcript it will show up as all caps G-A-P-M-S, but be pronounced as if the P is silent.

Then the one issue that seems to me to address before we start going through the individual items, if I have it right, the defense asserts that communications with experts who submitted reports prior to issuance of the GAPMS report are within the work product privilege because litigation was anticipated. Essentially, if I have it right, the defense says,

we didn't -- we didn't get these reports for use in promulgating the rule, for use in deciding what the rule should be. We got the reports -- we communicated with these experts because we anticipated litigation. That's what I draw from Mr. Brackett's declaration.

Mr. Jazil, let me tell you, I have two responses to that. The first one doesn't make much difference and the second one goes right to the heart of it. The first one that doesn't make much difference is this: Mr. Brackett says, Well, we knew there was going to be litigation because they told us at that the hearing. Well, what they told you at the hearing doesn't explain what you did before the hearing. And so the fact that somebody said at the hearing that if you promulgate this rule there is going to be litigation, doesn't tell one anything about why experts were retained earlier. That doesn't make a lot of difference.

The second problem, though, seems to me to be of importance. If what you're telling me is, We didn't retain these people to decide what the rule should be; we just retained them because we thought there might be a lawsuit later, then I want to make sure that this is what you're going to tell an administrative law judge at ACHA if there is a rule challenge. Because it seems to me that position is virtually an admission that you violated the governing rule that deals with how you promulgate these standards.

Administrative Code Rule 59G-1.01 says that to determine whether health service is consistent with generally accepted medical standards, the agency shall consider -- shall consider -- and then there is a list of various things, and one is recommendations or assessments by clinical or technical experts in the subject or field.

Well, if what you are telling me is that's not what you did, then it seems to me you just basically admitted that you didn't properly promulgate the rule.

So let's start by having you tell me how it is that you can withhold these materials without admitting that you violated the rule.

MR. JAZIL: Yes, Your Honor.

And, Your Honor, I want to make clear that the reports were submitted for a dual purpose: One was to support the rulemaking; the other was to help give us grounding in any future administrative rule challenge or federal district court rule challenge. That's number one, Your Honor. It was a dual purpose. It was not a single purpose.

Secondly, Your Honor, there was a letter from the Department of Justice, March 31st, 2022, where the Department of Justice wrote to the States and said that, We are reminding you that you've got to provide all these gender-affirming care services, and if you don't, you might violate a host of federal statutes. And that was submitted along with Mr. Brackett's

declaration, and it was part of the GAPMS process, Your Honor.

So there was a statement during the rule hearing that what we are doing is unconstitutional, that what we are doing violates the law. But separate and apart from that, there was a letter from the Department of Justice suggesting that if the states, including Florida, don't follow through on providing certain of these services, we might be in violation of federal law. So there was a predicate document before the hearing which suggested that litigation was over the horizon.

And, Your Honor, secondly, to answer your question, there was a dual purpose for the reports. The reports from the experts support the conclusion that Mr. Brackett, the author of the GAPMS memo, reached. And -- pardon me, Your Honor, I'm getting over COVID. And the dual purpose, Your Honor, so it was for rulemaking in the subsequent litigation which was sure to follow on this highly charged issue. So I note that.

And, Your Honor, furthermore, under Florida law, as I understand it, I can claim work product protection for something if it is done for dual purposes. Under federal law, Your Honor, in the Eleventh Circuit, my understanding of the law is that there is no consensus view on whether or not something can be produced for dual purpose or must primarily be produced for litigation for the federal work product privilege to apply.

So I hope I've answered Your Honor's questions.

THE COURT: What was the primary purpose for which you

dealt with those experts?

MR. JAZIL: Your Honor, the primary purpose was to buttress the rule, the rule which was delving into an issue -- that complicated issue of scientific debate. So that was --

THE COURT: Had you already decided what the rule was going to be, or were you going to listen to these people?

MR. JAZIL: Your Honor, we were going to listen to these people. They were hired to provide their expert perspective on this. And Mr. Brackett considered that as the author of the GAPMS report.

THE COURT: All right. Tell me how Dr. Van Mol, who I think is the person who was at the public hearing and responded -- kind of rebutted anybody who spoke against the proposed rules -- how are his notes of that hearing protected?

He's a doctor. He's there at the public hearing. He's asserting a position that apparently is taken into account. They give him, seemingly, unlimited time to respond to the speakers -- each time was limited. So he has unlimited time to respond; he apparently takes notes, and you claim those are privileged.

How are those notes protected?

MR. JAZIL: Your Honor, Mr. Van -- Dr. Van Mol was hired, as I understand it, early in the process to go through the scientific literature and help the agency just ferret through some issues. He is not an author of one of the GAPMS

expert reports. He was there at the hearing and he -- during that hearing, there were also materials submitted, as Your Honor notes, through a public portal. There was the document that was called the Yale document, for instance. And there are notes from both Dr. Van Mol and others just debating a response to some of those points.

And those we thought would be properly protected by the work product because they were helping us anticipate how best to respond to arguments that would come up in future litigation.

THE COURT: All right. I overrule the privilege and work product objection on all of that.

You are going to turn it all over.

MR. JAZIL: Understood, Your Honor.

THE COURT: When we get to the litigation, the work product is essentially governed by Rule 26(b)(4)(C), I suppose it is, and that deals with the communications between you and the doctor or the doctors, the various experts. And so there are very limited areas in which communications between the lawyer and the expert get produced.

And I guess I should make sure with the other side before I say it that way. So tell me who is going to speak for the plaintiff and then tell me whether you disagree with the proposition that communications between Mr. Jazil and the other lawyers, on the one hand, and the experts, on the other -- the

experts that are assisting with this litigation and may testify in this litigation, whether those communications are subject to disclosure only as set out in 26(b)(4)(C).

MS. DUNN: Yes, Your Honor, this is Chelsea Dunn on behalf of the plaintiffs.

We would agree the -- the communications with these outside consultants that we are seeking, you know, to remove the assertions of privilege from are those that are prelitigation, the ones that Your Honor is speaking of. We would agree that the postlitigation communications with anyone retained for the purposes of litigation would be covered by Rule 26(b).

THE COURT: All right. So where am I going to set that date?

Because it does seem clear to me that at some point it becomes clear there is going to be litigation and they -- I don't know that the date the complaint is filed is the date. What would the plaintiff have the date be that we shift? I guess part of it may be why doesn't he answer once the rule comes out, we're finished promulgating the rule, and from that point forward it's a litigation issue?

MS. DUNN: Your Honor, I think that would make sense, and we would propose that date as being August 21st, which is the day that it was fully implemented and became effective.

THE COURT: Mr. Jazil, does that date work?

MR. JAZIL: Your Honor, in my mind -- perhaps the rule

hearing date would be more appropriate when it was noted that litigation will follow.

And I apologize, Your Honor. I don't remember the rule hearing date off the top of my head. I believe it was in July.

THE COURT: I think it was -- yeah, I think it was July the 8th.

But you told people at the hearing that they could submit written material. You cut off speakers and said, If you got anything else to say, you can put it in writing. Surely you planned to read that stuff and take it into account before you made your final rule decision, or at least you were obligated to.

So at that point aren't you still in the rule promulgation phase?

MR. JAZIL: Yes, Your Honor, we are. And we are obligated to review and consider the comments.

THE COURT: All right. So August 21st sounds like it works. That's the date when that will shift over.

MR. JAZIL: Yes, sir.

THE COURT: Then the other -- or the second overriding issue I wanted to address, the defense says just 2022 -- here's my understanding of the factual background. And, again, straighten me out -- both sides know a whole lot more about this case than I do at this point.

If I understand it, when this came up in 2022, the Secretary -- and I think maybe at that point it was Ms. Marstiller; I'm not sure I remember correctly -- said, Well, we don't have a policy on this, and it turns out that was wrong. There was a policy promulgated back in, I believe, 2016, maybe in the works in 2015 and promulgated in 2016, somewhere along in there. And so I understand the idea that this came back up in 2022, and so that's when we ought to be talking about, but it also seems to me to be relevant to know what happened back in 2015 and 2016.

And so I have a question for each side. And the question for the defense is going to be: Why isn't it relevant what happened in 2015 and 2016? And then my question for the plaintiff is going to be: What about 2017 through 2021? What do we really need during that period, and probably not the extensive searches that the plaintiffs have asked for.

So let me start on the defense side. What do you do with the prior policy and what was done back in 2015 and 2016?

MR. JAZIL: Your Honor, I go back to what the Court said is a controlling issue here: It's whether, based on current medical knowledge, the State's determination that these treatments are experimental is reasonable. What happened in 2015 and '16 and '17 and '18 and '19 and '20 does not go to the current medical knowledge.

As we discussed at the preliminary injunction hearing,

when I asked the question of is this akin to an administrative review case, Your Honor said based on our discussion of *Rush* that it wasn't and that the Court would consider new evidence, expert testimony presented, perhaps, for the first time at trial to show whether or not based on current medical knowledge the State's exclusions make sense.

And if that's the polestar that's guiding the Court, the parties, and this accelerated schedule, then I respectfully submit, Your Honor, that those prior GAPMS reports are available to the plaintiffs; they can make whatever arguments they'd like about how the State, perhaps, changed its position, but that's not the central issue in the case. And given the central issue in the case, going that far back simply adds burden to the State as it's trying to prepare its defense on an accelerated timeline.

THE COURT: Well, it seems to me that confuses the difference between evidence that's controlling and evidence that's relevant. If you want to know why the apple falls to the ground, you might start with Newton. You might not need Newton, but it's not irrelevant.

And so -- and, also, while it's possible for something to get more experimental than it used to be, usually the progression works the other way around. So the science that was known in 2016 usually doesn't become unknown in 2022. New science comes out and it may turn out that the 2016 science is

wrong, but that doesn't mean it's irrelevant if you are trying to understand this stuff.

On the other side, tell me why you need anything from 2017 to 2021? You may want to know what they were paying for in that period and there may be an easier way to find that out or whether the same policy was in effect, but you are really asking for some pretty broad searches that turn up a lot of gigabytes of information.

Can't we narrow it some?

MS. DUNN: Yes, Your Honor.

Just to provide the Court with some additional information, in recent discovery we have learned that in addition to the 2016 GAPMS memo that we submitted as an exhibit to this motion, the defendants have also engaged in the GAPMS process with regard to two of the other treatments at issue, including cross-sex hormones and gender-confirming surgeries.

We have received drafts of memos that were written by someone in AHCA, but -- or by someone employed by the defendants. We don't have discovery -- the discovery that we received from defendants doesn't give us enough information around these draft reports to understand who wrote them, what the GAPMS process related to these looked like, and, you know, the information that we need to determine how the agency was able to reach such differing results.

So I don't think I mentioned this, but all those draft

memos came out the opposite side of this 2022 GAPMS memo on the treatment of gender dysphoria that's at issue in this case. So, you know, the sources that were relied on, the process that was undertaken, whether or not there were outside consultants used, any documents and communications that are related to the processes, you know, that were employed in those GAPMS reports are incredibly relevant and proportional to the needs of the case.

We understand, you know, as Your Honor mentioned, that some of our requests, including, you know, our search terms for the defendants' email communications database, do return large quantities of information. But I would point out to the Court that since we received the defendants' written responses to our discovery request on December 19th of 2022, we have been actively asking defendants to give us more information about these searches so that we can properly narrow them in order to be manageable.

Not only have we offered a list of custodians without receiving any information from defendants about the size and, you know, breadth of these searches, we've offered a list of custodians and the defendants have ignored, you know, that list.

(Indiscernible crosstalk.)

MS. DUNN: -- with those parameters.

THE COURT: Yeah, let's come back to that in a little bit.

On the time frame, these other analyses that you are talking about weren't just in 2015, '16. There had been some more recent than that but prior to the shift in direction in 2022?

MS. DUNN: We believe that these occurred in 2016 or 2017, but we don't have definitive dates, which is one of the reasons we don't think the limitation can be any later than 2016, unless defendants are able to give us more information about these processes so that we can, you know, better define a narrow -- what we are looking for at this point. 2016 is probably as -- you know, as close to today as we would be able to limit that because of those documents that we've uncovered.

THE COURT: All right.

MS. DUNN: And, Your Honor, I'm sorry. If I could point out one more thing?

We are not totally certain what requests we made that prompted the defendants to produce those documents because defendants haven't provided discovery in a manner where we can tell what is being, you know, produced in response to what inquiry. But we believe that the only reason those memos were overturned -- or turned over is because they were circulated by email during the 2022 GAPMS process for the memo at issue in this case.

And so we don't know what other relevant documents might be in their files from earlier years if those documents

weren't actually, you know, reviewed and circulated by email this year. And so that is, I think, one of the issues that demonstrates how unreasonable this time limitation is.

THE COURT: All right. The other overriding issue I had a question about -- I don't know how much difference it makes, but apparently the plaintiffs' position is that communication from an employee in the Department of Health with the lawyer at AHCA or vice versa can't be privileged.

And my question is why can't they have essentially the equivalent of a -- what in a criminal context would be called a joint defense privilege?

MS. DUNN: Your Honor, you're referencing the emails they have -- that are exchanged with the Governor's offices and the Department of Health, the other state agencies?

THE COURT: Yeah, I don't -- I thought you were talking about the exchanges between AHCA and Health, but the same thing I guess would apply with the Governor's office.

I'm not getting into the question of whether any particular documents are or are not privileged, but, for example, a communication between the Secretary or Assistant Secretary, some manager at the Department of Health with the General Counsel to the Governor, seems to me that could be privileged. And it seems to me that if Mr. Jazil just represents one of those agencies and not the other, it still could be that communications between him and somebody at the

other agency could be privileged. Certainly AHCA and the Department of Health have corresponding interests.

MS. DUNN: Your Honor, we -- with regard to those communications, I think the common interest doctrine would -- requires them to have a common legal interest. And we would suggest that these emails are involving what is maybe more -- probably more described as a joint policy strategy. And the fact that --

THE COURT: Let me stop you for just a minute. It's getting harder sometimes to hear you.

MS. DUNN: Okay.

THE COURT: I don't know what kind of speaker you are on, but if you can get closer and pick up the phone -- you know how those things go -- anything that can improve the quality will make it easier for me.

MS. DUNN: Absolutely. Is this better, Your Honor? I'm holding the phone now. I'm no longer on speaker.

THE COURT: Much better.

MS. DUNN: Okay. So we -- excuse me.

So with regard to the communications with the other state agencies, we believe that these communications would more properly represent a joint policy strategy rather than a common legal interest. Just because communications happen or a strategy between two entities happens to include a concern over litigation doesn't necessarily mean that it rises to a level of

a common legal interest. And I -- at least from the information that we have in this privileged log, defendants have not demonstrated that these communications were in furtherance of litigation or rose to that level of a common legal interest.

There is no, I guess, threat that either the Governor's office or the Department of Health would have been subject to any sort of litigation over the promulgation of the challenged exclusion.

THE COURT: Well, you don't have an attorney-client privilege just because there's litigation. You have an attorney-client privilege even when there is not litigation, so I get it.

Look, conversation between the Secretary and the Governor is not within the attorney-client privilege, period. But a communication between the Secretary and the General Counsel to the Governor, if the Secretary is asking for legal advice and the General Counsel is providing it, that seems to me to be privileged.

And setting aside the question about the Governor's General Counsel -- the Governor outranks the Secretary. But even with two parallel entities, it does seem to me that if, for example, a lawyer for the Department of Health is the expert on some question and somebody at AHCA asks that person for legal advice, that could well be privileged.

So I don't know that that answers any specific

question as we go through this, but I guess what I'm telling you is I reject the plaintiffs' blanket assertion that a communication between a state employee and a state lawyer cannot be privileged just because the agency that employs the employee is different from the agency that employs the lawyer.

MS. DUNN: Understood, Your Honor.

And I think we would not disagree that if those communications were for the purposes of giving or receiving legal advice that they could be shielded from the attorney-client privilege. But in many of the instances where those types of communications are being described in the privileged log, that -- the fact that that is, perhaps, the underlying substance of the communication is not clear and so --

THE COURT: Got it. Got it. Fair enough.

And if we have to go through all the individual privileged items, we'll get to that down the road. But let's get to -- to whether these items may affect more documents.

I think what I propose to do at this point is just go through the list. And I'm working off of the motion itself, which is ECF No. 81. The plaintiffs have broken it down into groupings, and we're -- so the first was Request 3: *Communications between the defendants and the Department of Health about the guideline titled "Treatment of Gender Dysphoria for Children and Adolescents" released on April 20, 2022.*

Mr. Jazil, I kind of scratch my head and say, What's

wrong with that?

MR. JAZIL: Pardon me, Your Honor. I'm pulling those up.

THE COURT: I'm working out of ECF 81 and starting on page 7.

MR. JAZIL: Yes, Your Honor.

Your Honor, our response -- or our amended response to the request for production of documents notes that some of that communication could be covered by the attorney-client privilege because it's all communications between defendants and the Department of Health. I'll represent to the Court that lawyers for AHCA and lawyers for the Department of Health have been talking about these issues. And that's the first objection that was listed there.

Secondly, Your Honor, we made the point that, given the instructions, this was a pretty broad request. It went all the way back from January to -- January of 2015 to the present.

THE COURT: Wait. Wait. Wait. This is about a document that was released on April 20, 2022. If you've got people that were communicating in writing about this in 2015, you've got some of the great forecasters in the history of the world. This is communications about a specific document.

Look, this is not hard. There should have been no objection to this other than privilege, if there are indeed privileged documents that that would capture.

So, look, this one is granted and you are going to pay fees. I mean, this was -- this was not hard.

The next one is *Communications between the defendants and the Governor's office about the same document.*

If anything is privileged, it's privileged. But I don't get how communication about that could otherwise be objectionable.

MR. JAZIL: And, Your Honor, just to clarify, anything that wasn't privileged, we have turned over. We are not withholding documents related to this.

(Indiscernible crosstalk.)

THE COURT: Let me -- let me tell you how this goes. And you may have heard this before. Other people have.

When a lawyer says, I object to this request; it's overly broad, blah, blah, blah; subject to and without waiving the foregoing objection, we are turning over documents -- and that's -- and that's similar -- that's the gist of what you've just said and what you've said in these papers.

Now, let me tell you how an unscrupulous lawyer could use that kind of response and the reason why generally I overrule that kind of objection and compel the production unless there is something else about it that calls for a different result. Suppose you have an ordinary car crash case. The question is who -- it's an intersection collision. The question is who had the green light and whose light was red.

And the plaintiff says, Turn over all documents about the crash.

And the defense lawyer, the unscrupulous defense lawyer, says, Overbroad. Vague, blah, blah, blah; subject to and without waiving the objection, we are turning over documents.

Well, it turns out the defense wrote -- defendant wrote a letter to his brother and said, I ran the red light, but I think I'm going to get away with it. And so the defense lawyer doesn't turn it over because the defense lawyer made an objection that it was ambiguous and overly broad.

And then if the defense lawyer gets caught, the defense lawyer can say, Well, I didn't have to turn it over; I objected.

Now, I'm not suggesting anybody is doing that, but, look, when there's an unobjectionable request for production, and there is a plainly unfounded objection, and then there is a motion to compel, it's no response -- it's no answer for me for the defense to say, Well, we turned over the documents.

I'm going to enter an order compelling you to turn over the documents. If you have already turned them over, you don't have to do it again, but if you haven't turned them over, you have to turn them over.

So I'm going to grant No. 4.

Five, I don't understand why there's an objection to

that. Isn't that pretty clearly discoverable?

MR. JAZIL: Your Honor, again, if there were no lawyers on it who were advising Secretary Marstiller and Tom Wallace, it was turned over.

THE COURT: All right. Well, I'm going to grant the motion to compel.

And let me tell you, the fact that there is a lawyer copied on a communication doesn't make it privileged. It might be privileged, but it's often not.

Two business people can't send business communications to one another and shield them from discovery by copying the lawyer. There are nuances there. The Supreme Court, just yesterday or the day before, dismissed as improvidently granted a case that poked around that issue. I don't know that we've got anything covered where that's the issue here, but when we get to -- if we have to wind up going through the privileged documents, the copying of a lawyer on a document between two business people doesn't make it privileged. If the primary purpose of the document is to get legal advice, then one would expect it to be written to the lawyer as opposed to be written to the other businessperson.

Again, not a hard-and-fast rule, but that's generally what would happen. But if you looked at any particular document, you can usually make a good determination of whether it's privileged or not, and there will be questions around the

edges.

No. 8: *Documents relating to steps the defendant undertook to ensure that recipients continued to receive treatment at the time the challenged exclusion became effective.*

Mr. Jazil, what's wrong with that?

MR. JAZIL: Your Honor, again, nothing is wrong with that request. And, again, we've produced material so long as it wasn't covered by the attorney-client privilege, and we limited the date range to January 1 to the present.

THE COURT: Well, again, that doesn't seem to me that there could be anything before January 1. That one there couldn't be anything, I don't think, until significantly after January 1, 2022, just by the nature of the request.

MR. JAZIL: Yes, Your Honor. I understand that, but I'm going back to the instructions that were provided for the request for production that said, Unless there is a specific time limit placed here, we want you to go back -- almost to '15, I believe.

THE COURT: How could that have anything to do with this request?

MR. JAZIL: Your Honor, it shouldn't and it doesn't, but the instructions that I'm operating under for the request for production say that, Unless I put out a time frame, I want you to go back. So those would be --

THE COURT: If they had --

MR. JAZIL: -- objectionable.

THE COURT: If they had given you an instruction that said, I want you to get all of the documents that you have that are in Ukraine on the battlefield, it wouldn't be burdensome because you would know there are no documents in Ukraine on the battlefield.

On to the next one.

Paragraph 10: *Draft and final correspondence from defendants to Medicaid recipients.*

There's going to be some private information there. I guess let me ask the plaintiffs.

Ms. Dunn, how are we going to -- what do you propose to do about the confidentiality issues here?

MS. DUNN: I believe that would be governed by the protective order that was issued in this case.

THE COURT: It would be, but, look, there's a -- you know, there's one person in Ocala, somewhere in the middle of the state, doesn't have anything to do with this litigation and has gotten treatment from Medicaid. And so, of course, the Medicaid people have those records.

But now you're involved in litigation, and I'm not sure that person necessarily wants the plaintiffs' lawyers to know who he is.

MS. DUNN: Certainly, Your Honor. We would have no objection if the defendants wish to produce documents that were

redacted to protect that kind of -- you know, the identity of the person receiving the communication. Or, you know, we would also accept samples of these communications. So if every, you know, Medicaid recipient on the insurance plan Humana received the same correspondence, one example of that correspondence, either, you know, the form letter or a redacted copy of that letter that went out, I think would suffice.

THE COURT: All right. You don't need the details about some particular treatment or whatever. Got it.

All right. So, Mr. Jazil, if I give you a choice of either providing redacted correspondence on an exemplar of any such correspondence -- your choice -- does that work?

MR. JAZIL: Your Honor, it works for us. I will go back to the agency, but my understanding is any such document that we have, we have produced already.

THE COURT: All right. And what was done about the identities? I guess you produced it; there is a confidentiality order, so presumably it's being maintained as confidential.

MR. JAZIL: Yes, Your Honor. And we have a confidentiality order anytime someone's personal medical information has come up. For example, it came up in the variances that the agencies previously granted. We just redacted that information because we provided it before the entry of the protective order.

So we've done our best to redact that information.

THE COURT: All right. And I've got good lawyers who understand the privacy interest here, so just be careful to protect privacy interests as much as you can.

11, the same thing.

13 --

MR. JAZIL: Your Honor, this --

THE COURT: This goes back to the general issue we discussed at the outset.

MR. JAZIL: Yes, Your Honor.

13 and 14, the only things that we've withheld are things that we've contended were work product. And now, given further guidance from the Court, we know them not to be so, and we'll provide those to the plaintiffs.

THE COURT: Okay. 14 I think is the same thing.

MR. JAZIL: Yes, Your Honor.

THE COURT: 15 I think is the same thing.

MR. JAZIL: Yes, Your Honor.

THE COURT: 17, same thing.

MR. JAZIL: Yes, Your Honor.

THE COURT: 25 is different information, but the same thing. More likely that that also fetches documents that are indeed privileged. For example, if the Secretary sent Mr. Jazil a note and said, How do we do this? then that seems to me to be right in the dead center of the attorney-client privilege.

On the other hand, if two of the businesspeople at the

department send memos back and forth about, How are we going to do this? then that ought to be produced.

MR. JAZIL: Your Honor, for 25 things where someone was not soliciting legal advice from us were produced. Here's one where we limited the time period to January 1 to September 7th. Based on the back and forth that we've just had, there's some discussion about materials from 2015, '16, '17, '18, that could touch on these challenged exclusions where the State may have drafted something saying that it was going to cover them.

We knew of these discussions in prior GAPMS memos. We have turned those over. I don't know whether Your Honor would like for us to do an inquiry beyond the January 1 to the September 7th time frame that we've laid out in our response.

THE COURT: Well, in 25, that doesn't deal with 2015 or 2016. I guess I can go back and read the definition, but I would have thought the challenged exclusion was the new rule saying we are not covering these things.

And so I would understand this request to be for documents related to the new rule, so nothing in 2015 and 2016 could possibly relate to that. Probably the time period that's covered goes from promulgation of the rule forward, although certainly somebody could have been working on policies and procedures before that.

But until this came up in, what, March of 2022, it's

hard to imagine there would be any documents that would be responsive to 25. There are other requests, but we'll get to the things you are talking about.

MR. JAZIL: Yes, Your Honor.

THE COURT: 26, again, same thing; turn them over.

All documents related to the planning, coordination, and content of the July 8th hearing, that's granted. That's the discussion we had before.

And, look, I've read the rather remarkable email exchange between Mr. English and Dr. Cogle. At least according to that email, this rule wasn't handled the way this kind of issue is typically handled. When I say "this rule," this GAPMS memo was not done the same way others were, and the plaintiffs understandably want to know why. And documents related to the planning, coordination and content of that hearing may show why. The critical issue is not whether that hearing was conducted in the usual course, whether it was or wasn't done properly, but those things are relevant.

42, again, that seems proper. I grant that.

43; Mr. Jazil, you want to tell me a reason why that shouldn't be turned over?

MR. JAZIL: Your Honor, if we have the documents, we've turned them over for 43.

THE COURT: Okay. All right.

Then on 52, let me start on this one on the

plaintiffs' side. Here is my issue with this.

This doesn't seem to be related to subject matter. It was just communications between the defendants and a lot of people, and those communications might have something do with this lawsuit; they might not.

MS. DUNN: Yes, Your Honor.

I think -- I don't think we would object to a limitation on this request to relate to the substance of this lawsuit. Although, you know, I will just note that the majority of the individuals identified in defendants' initial disclosures were the same consultants and vendors that they used in the promulgation of the rule, the same individuals that provided the attachments to the GAPMS report, the same individuals who maybe appeared at or testified at that July 8th hearing. And so --

THE COURT: But didn't you capture those communications with one of the other requests?

MS. DUNN: Yes, we did.

THE COURT: Yeah. I'm going to deny 52.

54 -- (audio feed glitch/indiscernible). Read literally, paragraph 54 would ask the defense to provide a copy of the Federal Rules of Civil Procedure; wouldn't it?

What do you think 54 gets that you haven't asked for somewhere else?

MS. DUNN: If there are any documents that defendants have relied upon in answering our -- yes, in providing their

answers to our request for admissions, to the extent that those haven't been provided through our other requests, that's -- that's what we are asking for.

THE COURT: Yeah, this is -- I know you are a careful lawyer; you are trying to make sure you asked for what you wanted. But, again, I think, literally, if they looked at Rule 26 to see what it said, then that was something they considered in deciding what to do or they looked at a few court decisions in deciding whether they could deny an allegation, and you've literally asked them to provide a court decision.

I think that's just too broad, so I'll deny 54.

Same thing on 55.

I understand what you were trying to do. You are trying to make sure you didn't miss anything. I doubt you missed anything.

Then we roll over to the next group, Defendants' -- Plaintiffs' Request No. 6: *The data that was relied on by the defendants in developing and promulgating the GAPMS memo.*

Mr. Jazil, that seems pretty clearly proper. What's wrong with it?

MR. JAZIL: Your Honor, nothing is wrong with it. We have provided everything that we've relied on. We note that the citations are included in the memo itself. And as Mr. Brackett said in his declaration, that's all he relied on as he wrote the report.

THE COURT: Yeah, here's the problem. They don't want to know just what you relied on. They want to know what you got and ignored.

Aren't they entitled to know what information you had and ignored?

MR. JAZIL: And, Your Honor, we've provided that to them. We provided the GAPMS memo with citations. We provided the rulemaking file, which has the other material that they provided, the plaintiffs and other organizations. So we've exhausted the universe of material that we got as part of this rulemaking process and that we've handed over.

THE COURT: All right. So when I compel production, you are not going to have anything to produce. But, again, if you've produced everything they asked for, there shouldn't be an objection.

7 is the same.

And 16, I think, is the same.

That takes us around to No. 19. I've clicked over to page 11 on ECF No. 81. This looks okay to me.

Again, part of the responses may be privileged, and I can't for the life of me understand how communications between the defendants and a Florida Medicaid managed care plan and other utilization review entity could be privileged. It seems to me that ought to be provided.

Mr. Jazil, is this the same thing? Is this something

you have already done?

MR. JAZIL: Yes, Your Honor, we have provided this.

There is one exception. The Humana plan provided us material yesterday that we just haven't had a chance to look at. As you'll note from our meet-and-confer letter, we've been stamping "Confidential/Attorneys Eyes Only" just to expedite the process of providing this material to plaintiffs. This is not attorney-client privilege in some instances. It's just confidential information from companies might be included or confidential information about patients might be included.

MS. DUNN: Your Honor --

THE COURT: All right --

MS. DUNN: -- if I could just -- oh, I'm sorry. I didn't mean to...

THE COURT: That's all right. Go ahead.

MS. DUNN: We believe, based on the response and what we've reviewed thus far in discovery, that these documents have only been provided from the year of January 1st, 2022. So this is something where we think -- this is not the type of request that is limited to, you know, the rule promulgation and beyond.

This request is important to receive -- to search for and locate those communications from earlier than 2022, because it is important to -- when we look to how the defendant was approaching coverage of these relevant treatments prior to the rule promulgation, these communications are important to that.

THE COURT: Yeah, fair enough. That's right.

And, Mr. Jazil, that's the same discussion we had earlier about the time frame.

MR. JAZIL: Your Honor, that's right. I have a concern here where in many instances we are asking these plans to provide us this information and then giving this off to the plaintiffs. I would have to go back to the relevant plans, ask for the information, provide it -- review it, stamp it, provide to it the plaintiffs before the discovery cutoff.

Would it be, perhaps, just simpler --

(Indiscernible crosstalk.)

THE COURT: Well, let me -- hold that thought. Let me come back to it.

But what -- you mean to tell me there are communications between you and, for example, Humana or another managed plan and to get a copy of the communication, you have to ask them for it because you don't have it?

MR. JAZIL: Your Honor, that is what the agency has done to facilitate this. We asked the plans for any communications, any policies that they might have based on Medicaid's coverage for the defendants and --

THE COURT: They all have a contract with the State so they said, Yes, sir, Boss, and they went and looked for it.

MR. JAZIL: Yes, Your Honor. That's exactly what they've done.

And, Your Honor, we are not trying to hide the ball on these issues. You mentioned the Dr. Cogle-Jeff English email exchange, for instance, but we are providing this material. If we have it, we turn it over. So --

THE COURT: Let me tell you one thing that occurred to me with respect to that. I, of course, wasn't involved in the document production, so I don't know. One possibility that occurred to me was that that -- well, not just that, but some of the older stuff -- we got older stuff, I guess, is what I was more concerned about. I thought maybe that the information about the 2016 GAPMS process got turned over because it got attached to things from 2022 that were being produced. And that if there are memos, other materials, from 2016 that did not get attached to 2022 memos, those things haven't been produced.

MR. JAZIL: No, Your Honor, that's not entirely the case. We produced a draft GAPMS memo that dealt with surgeries that someone happened to find in an office, a hard copy that's nowhere on the document management system for the agency. And, you know, in good faith we provided that report. We don't know who the author is.

So we are -- again, Your Honor, if we come across anything that's GAPMS related that deals with these excluded services, we are providing it. We are not, you know, trying to hide the ball here.

THE COURT: All right. You started to suggest a

stipulation with respect to paragraph 19.

MR. JAZIL: Yes, Your Honor.

If the point is that the agency paid for and covered these treatments prior to the rule, we'll stipulate to that fact. And if that's what all these managed care plans were supposedly communicating to the agency, that should then become irrelevant because the agency was paying for and covering these prior to the rule being adopted.

THE COURT: So, yeah, Ms. Dunn, does that take care of the problem? What else are you trying to prove with this stuff?

MS. DUNN: Well, Your Honor, I'm not sure it does fully. And, you know, we are, obviously, willing to consider such compromises and stipulations, and that's something we have raised with defendants.

I think for this particular request -- and this also relates to 21 and 24, which I'm sure we'll talk about in a moment. It's not just the fact that Medicaid was covering these treatments. It's that the coverage of these treatments implemented evidence based -- implemented criteria based on the evidence -- evidence-based clinical practice guidelines that AHCA is required to consider in engaging in the GAPMS process.

And so all of these managed care plans and AHCA itself may have had policies or guidelines that set forth certain criteria for coverage, and those criteria for coverage might then, you know, in turn reference certain clinical practice

guidelines or other sorts of sources which are the same sources that we contend AHCA may have ignored in this -- the GAPMS process, the 2022 GAPMS process, at issue today.

So to the extent that in the past AHCA has determined these are credible sources and/or communicated with their agents about the need to implement criteria based on these sources and this medical evidence, I think that is very relevant and it's probative to the issues -- to the controlling issues in this case.

THE COURT: Mr. Jazil, one other question about it, I guess. One of the things you are required to consider in this process is utilization trends.

Doesn't -- don't these materials show -- or at least aren't they relevant to utilization trends?

MR. JAZIL: Forgive me, Your Honor. I don't -- I don't follow. Utilization trends as in -- pardon me.

I'm sorry, Your Honor. I didn't mean to interrupt you.

THE COURT: You didn't interrupt me.

MR. JAZIL: Oh, sorry, Your Honor.

I didn't follow the question, Your Honor. Utilization trends for how often these treatments --

THE COURT: Well -- and in the GAPMS process, as I understand it from the rule, one of the factors in the (indiscernible/someone coughing) utilization trends the -- and

one of the things some of your experts say is there's a significant increase in the number of people asserting that they are transgender. Some of this historic material may be relevant on issues like those.

I guess it might tell me something if the number of claims for trans treatment went up substantially from 2015 to 2022. It might tell me something else if the request for trans treatments from 2015 to '22 were flat. It might not tell me much, and there are a lot of other things that would go into those trends, but it does seem to me to be potentially relevant.

MR. JAZIL: I understand, Your Honor.

And if I understand it correctly, it's some information detailing how many people are on the cross-sex hormones, the puberty blockers, and are having surgeries would be relevant to information as part of the process.

And, Your Honor, I can represent to the Court I have sought that information from my own client and they don't have a record of how many people are on the puberty blockers, the cross-sex hormones, and the surgery.

So if this is information that's looking to utilization trends, as I've described it, the agency does not have that information, Your Honor. And if we did, we would produce it. And if we somehow manage to create it between now and trial, we will share that with the Court and the plaintiffs.

And forgive me, Your Honor. My voice is fading a

little bit.

THE COURT: Well, I was going to ask you -- you did a pretty remarkable job for somebody that's coming off being ill. And I know you were in a federal proceeding before we started this one. You doing okay? Do you want to take a break? We can break for lunch.

We got a little more to go. We are pretty far along, but you tell me. Mahomes is going to play this weekend, but I'm not looking for that kind of effort out of the lawyers. We can work around your health. How you doing?

MR. JAZIL: I appreciate that, Your Honor. Today is the first day I've had a negative COVID test, so if Your Honor would indulge me with just a five-minute break, perhaps I can just get some hot tea and go from there.

THE COURT: Let's do that. Let's take ten minutes. My computer says 11:44. Let's start back at 11:55.

MR. JAZIL: Thank you, Your Honor.

THE COURT: Stand down until then.

MS. DUNN: Thank you.

(Recess taken at 11:44 AM.)

(Resumed at 11:55 AM.)

THE COURT: This is Judge Hinkle. I'm back. They tell me everybody else is back, so we'll go forward.

I did want to note, I will include in the order that's going to be entered after this hearing a Rule 502 provision so

that -- Mr. Jazil, you said you'd gotten information yesterday. You can turn that over without waiving a privilege under the terms set out in 502(d). We promulgated that rule to allow people to turn things over without trying to put eyes on every document before it was done so that things could move forward without delay and without undermining anybody's substantive interest.

Then I looked ahead. I think what has been said at this point handles most of the rest except for paragraph 33 -- Request 33, and that's the one with all the search terms and we need to talk about custodians and narrowing searches and so forth, so we'll come back to that one.

But before we do that, let me just start with the defense side. Mr. Jazil, tell me why I should not grant the motion for the remaining paragraphs? It's paragraphs 21 and 24, 35 through 39, 40, and 47.

Some of that will be communications with experts that will be governed by what we said earlier in the hearing about Rule 26 and which communications with experts are covered. So I understand that those requests on their face could capture communications between the defense lawyers and the experts in connection with this lawsuit, but those will generally be subject to the work product privilege except in the narrow categories set out in 26(b)(4).

So recognizing that some of that will be work product,

Mr. Jazil, is there any reason that the requests shouldn't be granted for those other paragraphs I listed?

MR. JAZIL: No, Your Honor.

And, again, I note that where we made an objection and withheld a document, it was only on privilege and work product grounds, and we've gotten further guidance from the Court. Everything else that we've had, we have produced. And this goes for all the requests that we've discussed today.

THE COURT: All right. And so then let's double back to 33. The plaintiffs had put forth a number of search terms and the defense has given some information about how many gigabytes of information that those terms might capture. Here's what I'm interested in and I'll get your responses.

It seems to me the burden can be cut down by limiting the number of custodians. I can't tell, from what I've seen, at least, whether you have deduplicated this stuff, whether you've limited emails to threading. I don't have any information on how many unique hits are generated by each of the terms, so at this point it's a little hard to tell.

I guess, Mr. Jazil, the volume you gave me, has it been deduplicated? Have had you threaded the emails? What do these numbers mean?

MR. JAZIL: Your Honor, I'll confess to not being as up to speed on the e-discovery issues as you, but I do not know whether they have been deduplicated or dethreaded. I know that

in some instances there are email domain names such as @eog.myflorida.com and @floridahealth.gov that returned -- I can't tell whether the scan count -- it was scanned down by set -- it suggests that it's three documents or two documents, but we can -- perhaps plaintiffs and the defense are sharing an e-discovery vendor such as DISCO or Relativity, and this may be something where a shared vendor might provide greater insight.

THE COURT: Ms. Dunn, the document, the number of gigabytes they have given is a big number. One of the very good nationally known lawyers who deals in big document cases on a regular basis spoke at the Duke conference, the Advisory Committee on Civil Rules, that the standing committee put on at Duke, gosh, it must be ten years ago now. One of the things they suggested was he made -- tried to make an agreement in every case that they'd have no more than seven custodians, at least to start.

If I told you, Pick seven custodians, wouldn't that be enough?

MR. JAZIL: Your Honor, that was to me?

THE COURT: No, that was to Ms. Dunn. I was hoping we hadn't lost her.

Well --

MR. GONZALEZ-PAGAN: Your Honor, this is Omar --

MS. DUNN: I'm sorry. I'm sorry. I apologize. I was on mute and didn't realize it. Talking to myself.

THE COURT: It has happened to all of us.

MS. DUNN: So I think seven custodians as a starting point is possible. We did, I think, provide a list slightly longer than that to defendants, but not significantly longer.

One of the -- there are a couple of things that we have tried to work with defendants on this issue, one of them being we have been seeking information just like what they filed with the Court for weeks. And it looks like these searches were done in the middle of December and yet defendants never provided us with this information so that we could begin the process of trying to figure out how to narrow down our search terms.

We've also proposed scheduling a meeting between the, you know, the IT representatives for the two different parties to determine if there are ways to make this more manageable, whether or not, as Your Honor noted, things have been deduplicated, if there are either distinct hits or if there are threads that can be, you know, whittled out. Those are all things we would want to be doing to narrow our search, but we have not been able to bring defendants to the table to have these discussions.

The other thing is that we have asked for all these documents in natives, which usually decreases the amount of storage space that they would take up, but defendants have only been producing things to us in PDF. And this list, as you see, is noting a conversion to PDF. So we would be happy to take

these documents in native format if that is something that would make the production more manageable and, in fact, would probably prefer that.

THE COURT: What can you tell me about who is doing the IT function on your side and on the other side and whether getting those people together works? It doesn't sound to me like I can make an intelligent decision right now saying, Here are the terms; here are the searches; produce all those documents. It may be the best I can do today is say, Here's the process; you need to get going, and you need to get it going quickly.

What can you tell me about whether that's the right approach and who's involved in the IT process and what the process ought to be?

MS. DUNN: From our end, Your Honor, I unfortunately -- the IT representatives that we are using are not through my organization. They are through our -- one of our partner -- our co-counsel's firms. If you would just give me a moment.

If Joe Little is on the line, he may be able to speak more specifically.

MR. LITTLE: I'm here, Your Honor. This is Joe Little with Pillsbury.

Basically, as with many larger law firms, we have our own in-house robust IT department. They handle large

e-discovery matters all the time, so they have very, very wide bandwidth to meet with IT representatives from AHCA to figure out what's the easiest way to get these documents produced that wouldn't be too burdensome for AHCA. So we are pretty much ready to roll with that whenever.

THE COURT: So if I said within a week there needs to be a meeting with folks most familiar with the IT issues in the case, work to narrow custodians and limit the burden, that's something you can work with, or you need more guidance out of me than that?

MS. DUNN: Your Honor, I think that's a -- from our perspective, I think that's a very good starting point. I'm hopeful we can resolve -- I'm hopeful we can make significant progress. I feel confident we can make significant progress if we actually had these, you know, respective parties meet.

I would suggest earlier. As Your Honor knows, we are quickly coming up on the end of fact discovery, needing to schedule, you know, some additional fact depositions of agency witnesses, and, in our view, a week may be even a little too long. We could be ready to meet, you know, as soon as -- as soon as the defendants are.

THE COURT: Mr. Jazil, what can you tell me about how quickly you might be ready?

MR. JAZIL: Your Honor, we're happy to meet as soon as the IT staff for the agency is available.

I note that I have a legal team of three, so I'm at a bit of a numerical disadvantage. The seven-custodian limitation coupled with some kind of temporal litigation might also get us a long way to, perhaps, narrowing the scope of things.

I don't know if Your Honor has a perspective on the temporal limitation.

THE COURT: Yeah. I'm inclined to think that 2015 and 2016 may be important years, but it depends some on how much stuff we are capturing.

This is not an easy one to handle because many of these search terms are going to show up in lots of documents that are just not of interest in the litigation. I haven't spent hours thinking about this, but it -- nothing occurs to me immediately where I could say, Oh, if you look at this term, you are going to find everything you need. And so it's going to take some -- probably going to take some trial and error finding out how many unique hits you get for the various terms and which ones produce how much burden. It is the kind of thing that the IT people can look at pretty quickly, and narrowing custodians may help a good bit.

And so there really needs to be some attention to getting it down to the custodians you really need and figuring out what you really need. Nobody wants to -- neither side wants to spend a whole lot of time dealing with documents that don't have anything to do with the case. But you do want to find the

documents that bear on what was done in 2016 and why, and then what was done in 2022 and why, and that probably requires looking at both those dates. It may require looking at dates inbetween; it may not.

If you -- if the people get together and you can do some kind of screening function to figure out what do you get from 2017 through 2021, you may not get anything very valuable at all during that period. And so that may be one where the bang is not worth the buck. On the other hand, I suspect 2016 there may be things. Again, I don't know how much that proves, but it is certainly relevant, what they did when there was a GAPMS process before.

Yeah, arrange a meeting. I hear you saying a week may be too long. It's hard to get busy people. A week is -- a week is prudent. I'm not going to try to tell anybody to do it faster. If they could get together faster, they should. You need to get it started because it's going to be a lot of work for both sides, and the sooner you can get it narrowed down, the better. So I'll require that kind of meeting and then look at it in good faith on both sides, and we'll go from there.

I think that takes care of the motion. Let me look back at my notes about other general issues and make sure there is nothing else.

I can't really tell from the privilege log -- let me make a couple of observations about it. I can't tell, but it

could be that you've got separate items listed. So, for example, if there's an email from client to lawyer, it's privileged. But there may be four more lines on the privilege chart -- on the privilege log listing attachments to the email. Well, the email may be privileged, but the four other documents, just because they are sent to a lawyer doesn't make them privileged. If they would have been -- if you would have had to produce them if they weren't sent to the lawyer, then you'd have to produce them even after they are sent to the lawyer.

Some of those may just be duplications. If somebody sent an email to a lawyer and said, Here are four documents, well, the four documents were probably requested otherwise. So if they've already been produced, then those four attachments may take up a line on the privilege log. But it doesn't matter whether they are produced or not because they are already produced somewhere else. So 543, or however many items it is on the privilege log, may not indicate that that number of documents were withheld as privileged.

A lot of documents are going to be covered by the rulings I made overruling the work product and privilege objections by category. Beyond that, the log has the kind of information one would ordinarily get. Sometimes I can't tell who these people are or who the lawyer was or why it's privileged.

Let me lay out a possible approach and then you can

tell me if this doesn't work. I think what I'm inclined to do is to require the defense to provide an amended privilege log that deletes the stuff from which I've overruled the privilege objection, deletes unprivileged documents that are on that list separately just because they were attachments -- if there are any of them. I'm not sure that's what was going on, but if that's going on, take those off the privilege list so that you just actually have now a good list of items on which you still claim privilege.

And then I'm inclined to say to the -- if the plaintiff is still not -- the plaintiffs are still not satisfied, I'm inclined to say to the parties, Plaintiffs, pick 15 items off the list; Defense, submit them in camera under seal; I'll look at them and decide where we go from there. And if, as sometimes happens this way, they are all privileged, then it's a pretty good indication that everything is okay and that nothing more needs to be done. If it turns out that out of the 15, 5 of them aren't privileged at all, then we've got more work to do.

Mr. Jazil, does that work?

MR. JAZIL: Yes, Your Honor.

One clarification: If there's an attachment to an email that is a case, a case that, you know, perhaps we are concerned about or a case that, you know, we think could be the key to the whole proceeding, is it okay to keep that particular

case, that particular ruling, or a statute that's been attached to a legal analysis on the privilege log or should we disclose the case itself, the statute itself?

THE COURT: I think that's privileged. If you sent a letter to General Counsel and said, Here's the Eleventh Circuit decision that I think is a winner for us, I don't think the other side gets to see that. That's your mental impression and so that's okay.

MS. DUNN: Your Honor, I think what --

THE COURT: There is going to be some other time you have to disclose it. And we've already, you know, had one surprise in this case where at preliminary injunction you are saying, Oh, you know, there is a general exception. I do better when I'm not surprised. So if you've got a case that you think is controlling, it needs to in the trial brief, if not before that.

But I hear you and I don't -- your exchanges with General Counsel on legal strategy, those are protected.

Ms. Dunn, isn't that right?

MS. DUNN: I agree with that, Your Honor. I think the documents we -- the context in which we would be concerned about them claiming privilege is if, for example, one of their third-party consultants who is not an attorney had sent some case to the defendants. I'm not sure that that's -- in my view that would not count, would not qualify under either of the

privileges. And to the extent Mr. Jazil is referencing cases sent by those individuals, I think our position would be that those would not be covered.

But I certainly agree with Your Honor's --

(Indiscernible crosstalk.)

THE COURT: I don't know that that's going to happen and I'd have to spend a little time thinking about that, but that's an expert work product issue that's separate, I think, from what we are talking about here.

MS. DUNN: Well, if they were being exchanged during the rule promulgation process --

THE COURT: Yes, whatever was exchanged during the rule promulgation with those experts needs to be turned over.

MS. DUNN: Okay. Thank you.

THE COURT: All right. So I'll put in some process along those lines.

There was an objection along in there somewhere that I didn't go back over as we got to it, but the plaintiffs are correct that it is no objection that a document is publicly available. It's ordinarily not sufficient to provide a hyperlink, but you can't object and say you can go get that information from the public. If you've got it, you need to turn it over.

Same thing for works -- we may have covered this -- works that were cited in the GAPMS memo. You know, if the GAPMS

memo cites some study, you need to turn the study over. Presumably you have it. And if you don't have it, you can say you don't have it, but that probably has some evidentiary value too.

I think that's all I have. While we are here, Ms. Dunn, is there anything else you think we need to do from your side?

MS. DUNN: I do have two quick things, Your Honor. I just wanted to clarify the Court's ruling on Request Nos. 35 to 39. I wasn't sure that -- I know you mentioned some of these. And I think 40 and 47 would maybe be covered by the normal disclosures, you know, Rule 26 expert disclosure provisions. But I think the responses to Request Nos. 35 to 39 are separate, so I just wondered -- I wanted to clarify the Court's ruling.

THE COURT: You want all of those --

(Indiscernible crosstalk.)

THE COURT: I'm going to grant the motion to compel, but, again, it's subject to the privilege claim and work product.

MS. DUNN: Of course. Thank you.

The other issue we wanted to --

THE COURT: I --

MS. DUNN: Oh, I'm sorry.

THE COURT: No, go ahead.

MS. DUNN: The other issue we wanted to raise

depending on the Court's ruling, as it appears that there will be potentially be additional documents forthcoming from defendants -- we wanted to raise the current scheduling order and the -- you know, the near -- very near-looming fact discovery deadline of February 7th.

We would be comfortable if -- we would ask the Court for an extension on that fact discovery deadline and would be comfortable making fact discovery coextensive with the beginning of expert discovery in order to ensure that we are able to obtain these documents and have some time to review them before scheduling our final agency depositions.

THE COURT: Yeah. Before I get Mr. Jazil's response and find out a particular date, let me give you my usual approach.

Discovery deadlines are really more for the benefit of the lawyers than for my benefit. What I care about is I've got the case set for trial and I plan to try it when it's set. I can give you a long explanation for that, but, look, that's -- it's just better all the way around if we have firm trial dates and keep them.

If you are taking depositions the night before trial, as my mother used to say, No skin off my nose. You can work as hard as you want, but it's just better if you are not doing that. It's better if you have a good clean period before the trial just to prepare for trial.

So if both sides are okay with moving the discovery deadline, it's okay with me. I'm worried about the deadline to move for summary judgment so that I've got time to deal with any summary judgment motion, we've got time to brief it, and I've got time to prepare, and then if we have to have a hearing, I can have a hearing. And sometimes it takes awhile to master all of this and get a ruling out. I need to have time to do all that, but that's just the summary judgment deadline.

There's some depositions that can be taken after summary judgment motions are in. There's a lot of depositions that don't affect the summary judgment issues. So I don't really care if it's something both sides agree to, but you do want to make it easy on yourself. The sooner you can finish, the better you are. I don't want to be doubling back with having to redepose experts because the facts weren't in, that kind of thing.

But as long as we meet those parameters, we can adjust the schedule as needed. And so if you want to say we'll move the fact discovery deadline, that's probably okay. If you want to limit it to matters that need to be done because of the additional document production, we can do that. Sometimes that's more messy than it needs to be.

Mr. Jazil, what says the defense on the fact discovery deadline?

MR. JAZIL: Your Honor, I don't oppose moving the fact

discovery deadline. But like you -- well, not like you, Your Honor -- but just from my perspective, I'd rather we not move it too far because there's a lot of work that needs to be done on the expert side in this case.

And, again, Your Honor, I'm at a numerical disadvantage. If fact discovery is going on contemporaneously with the expert discovery, I just don't have the bandwidth to cover both. And given the accelerated nature of the case, I would suggest a week would be appropriate for now.

THE COURT: Why don't we do this. Why don't we leave the schedule right where it is on the understanding that if there's really a need to alter it because of the additional document production, then we'll do it, and we'll move it as little as we need to, and we'll make it work.

MR. JAZIL: Yes, Your Honor.

And on that note, in the first federal proceeding I had this morning, I note that the District Court in D.C. granted in part our request for discovery from the medical organizations. And that Court was concerned about the discovery deadline in this case because the D.C. District Court has directed the nonparties to make productions to us and has stayed open the potential of depositions of those parties. So I don't want the Court to be blindsided, but that was the resolution of the early proceeding and --

THE COURT: Oh, I didn't realize -- so your earlier

hearing was related to this case?

MR. JAZIL: Yes.

THE COURT: There's a discovery dispute going on in D.C.?

MR. JAZIL: Yes, Your Honor.

And so the Court granted in part and denied in part and held in abeyance the motion to quash that was filed by the parties. So the nonparties in that case, frankly, have asked for, and I don't think unreasonably so, a little bit more time to produce documents to us. The Court has set a deadline of February 2nd for them to make the productions.

So I'd like to just put that on the Court's radar so the Court is aware.

THE COURT: All right. Well, I'm glad to hear that one of my colleagues in D.C. has that under control and I will leave that to the judge there.

And I'll leave this schedule in place and plan to accommodate what we need to.

MS. DUNN: Your Honor, just as a practical matter kind of with the things we know that need to happen, if I can just raise this to the Court? And if your decision is still not to move the discovery deadline, I understand.

So I think one thing is we would want to ask the Court to give defendants as firm deadline by which to produce the outstanding documents that have been ordered today. But kind of

just a bigger note on the timeline from here, plaintiffs have scheduled the agency 30(b)(6) deposition for next week with the goal of having at least a few days after that deposition to ensure that there are no additional documents or additional depositions that need to be scheduled based on what we learn from the 30(b)(6).

But at this point, without a complete production of documents, it doesn't seem likely we'll be able to resolve and wrap up that 30(b)(6) deposition on that timeline. And so having to delay that deposition any further prejudices the plaintiffs' ability to follow up on any information learned in that deposition if we keep the fact discovery timeline where it is.

THE COURT: When is the 30(b)(6) deposition?

MS. DUNN: It's scheduled for February 2nd, a week from today.

THE COURT: If you keep that date on the understanding that if you need to ask additional questions based on any new production, you can do it, does that work?

MS. DUNN: It -- well, Your Honor, I mean, it works to the extent that -- it just seems that it would be very difficult to -- for plaintiffs to receive -- not -- I guess initially it might, in part, depend on what deadline -- or if there is a deadline being set for the defendants to produce.

THE COURT: Yeah, Mr. Jazil, when can you -- a lot of

this stuff you say you've already produced, although I think when you say you have produced it, you produced it for a limited time period, which for many of these requests there won't be anything older because of the nature of the requests. But because you are going to have some searching to do for older things --

(Indiscernible crosstalk.)

THE COURT: What should be the date for production?

MR. JAZIL: Your Honor, with respect to the communications with the experts that predate August 21st, I think that's pretty easy for us to do and we can get that out in a matter of days, by Monday.

As it relates to the custodian searches and emails, I just don't have an answer for how long that Request 33 would take. And I think that's the one that is going to require the bulk of the work. We can commit to having our IT staffs be available as early as tomorrow to get a sense of what that looks like, but it's that Request 33 that I just don't know the answer to.

THE COURT: Right. And that -- knowing that date will require the additional meeting. But if your IT people can be available tomorrow at least for a preliminary meeting, good.

And then we talked earlier about a week. Make sure everything gets finished up within the week, which I think is February 2nd.

MS. DUNN: I think, considering that timeline, you know, plaintiffs would likely prefer to postpone the 30(b)(6) deposition by at least a few days in order to be able to review those documents.

At this point I think expert rebuttal reports are due in early March, and the parties have set aside the dates of March -- I'm sorry; I had my calendar up -- I think March 6th through March 17th for expert depositions. So I do understand that, you know, we don't want to -- that there are reasons to have fact discovery done before really getting into expert discovery, but I think a small amount of overlap under these circumstances doesn't seem very unreasonable considering that those rebuttal reports and the parties kind of agreed reserved dates for expert depositions are still weeks off.

THE COURT: All right. How about this. The expert documents that dealt with the rules, the ones that were the subject of my ruling earlier on the privilege and work product protection, Mr. Jazil says they can produce those by Monday. That's January 30.

The IT staffs are to have at least a preliminary meeting by tomorrow and then finish meeting -- make sure they have a comprehensive meeting by February 2nd. Hopefully, they can get it all done tomorrow, but that may be optimistic.

Produce all the documents I've ordered to be produced, other than the paragraph 33 documents by February 2nd. That's a

week from today.

Extend the fact discovery deadline to February 14.

Extend the 26(a)(2) deadline to February 19. That makes it after the fact discovery deadline. And I haven't looked at further 26(a)(2) deadlines. I didn't look back at the order to see if this is simultaneous or plaintiffs, defense, plaintiffs, how that's set up, but --

MS. DUNN: Your Honor --

THE COURT: -- looking at it and figuring it out, the idea would be to leave the rest of the schedule as is.

MR. GONZALEZ-PAGAN: Your Honor, this is Omar Gonzalez-Pagan.

Just to briefly provide some information, the first 26(a)(2) deadline is not until February 28th.

THE COURT: All right. I looked at an old order.

MR. GONZALEZ-PAGAN: We had corrected --

(Indiscernible crosstalk.)

THE COURT: Oh, yeah. Okay. That was the one I messed up and now I messed it up again. Fair enough.

So that takes -- so that doesn't need to be moved. So if we just move fact discovery to February 14, the 26(a)(2) deadline can stay where it is.

All right. Does that work?

MS. DUNN: I believe so.

THE COURT: All right. Mr. Jazil, that seem to work

on your side?

MR. JAZIL: Yes, Your Honor, everything works on our side. We are going to do our absolute best to get any additional documents we come across to the plaintiffs within a week.

THE COURT: Don't just do your best; do it.

MR. JAZIL: I understand, Your Honor. Yes.

THE COURT: Because we all know your best is good enough.

Very good. All right. I'll get an order out confirming all this. It might not go today. I've got more about to be going on, but I'll get something out as promptly as I can confirming all of this.

MR. JAZIL: Your Honor -- Your Honor, if I may?

Your Honor, earlier in the proceeding Your Honor mentioned that you'd be imposing fees. I would respectfully ask for reconsideration of that.

Your Honor, the only 583 documents we withheld were the ones in our privilege log, and we've been working in good faith over the holiday, et cetera, to produce these materials. And we -- as the Jeff English email suggested, we have not been trying to hide the ball.

So I'll stop there, Your Honor, and just beg the Court's indulgence.

THE COURT: Fair enough. I'll think about it.

I take the rule seriously. And ordinarily it provides that the party's conduct that necessitated the motion pays the fees. So I'll give it some thought, and you'll know what I think when I get the order out.

MR. JAZIL: Thank you.

THE COURT: Anything else on the defense side?

MR. JAZIL: No, Your Honor. Thank you.

THE COURT: Ms. Dunn, anything else on the plaintiffs' side?

MS. DUNN: No. Thank you, Your Honor.

THE COURT: All right. Thank you all.

We are adjourned.

(Proceedings concluded at 12:37 PM on Thursday, January 26, 2023.)

* * * * * * * * *

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter. Any redaction of personal data identifiers pursuant to the Judicial Conference Policy on Privacy is noted within the transcript.

/s/ Megan A. Hague 2/28/2023

Megan A. Hague, RPR, FCRR, CSR Date
Official U.S. Court Reporter

Doc. 118

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER et al.,

Plaintiffs,

v. CASE NO. 4:22cv325-RH-MAF

JASON WEIDA et al.,

Defendants.

_____/

ORDER ALLOWING MR. WEIDA'S DEPOSITION

The defendant Jason Weida has moved for a protective order blocking his deposition. This order denies the motion, allows the deposition, and sets a three-hour time limit.

The State of Florida Agency for Health Care Administration recently adopted a rule barring Medicaid payment for specific categories of treatment for gender dysphoria: puberty blockers, hormone therapy, and surgeries. The plaintiffs assert the rule is unconstitutional, violates the Affordable Care Act's nondiscrimination provision, and violates the federal Medicaid statute.

When the rule was under consideration and adopted, Mr. Weida was the Agency's Assistant Deputy Secretary for Medicaid Policy and Medicaid Quality. This was two levels removed from the Agency's Secretary. Now, though, Mr. Weida is the Secretary. He asserts his position as a high agency official should preclude the plaintiffs from deposing him. And he asserts the effort to depose him comes too late—the notice of deposition was issued just two days before the discovery deadline.

It is relevant both that Mr. Weida was not the Secretary when the rule was adopted and that he is the Secretary today. Without a showing of a substantial likelihood that he has relevant, indeed significant, information not available from other sources, he would not be required to appear for a deposition. But the process by which this rule was adopted—including whether the required public hearing was just a charade to support a predetermined result—is relevant. Whether the consultants who appeared in support of the rule were hired not for their expertise but for their predetermined viewpoint is relevant. Whether the experts who will testify for the defense at the trial were coached by Mr. Weida is relevant.

The record includes documentary evidence from which one could conclude that some consultants and experts were advocates more than witnesses and that Mr. Weida himself had communications directly with them. *See, e.g.*, ECF No. 117-6, 117-10, 117-11, 117-13, & 117-17. At Mr. Weida's insistence, some of the

communications occurred only by telephone, ensuring that nobody else would know their contents. *See, e.g.*, ECF No. 117-13 at 3 ("Let's discuss your email over the phone."); *id*. at 4 ("Hi Andre, yes let's do over the phone.") One could conclude this casts doubt on the Agency's Federal Rule of Civil Procedure 30(b)(6) deposition testimony that the consultants' viewpoint was irrelevant to their selection—that whether they agreed or disagreed with the proposed rule "really was irrelevant, it really was taking a look and making evidence-based conclusions." ECF No. 117-4 at 3.

That one could conclude these things does not make them so. But the plaintiffs are entitled to conduct discovery to fully develop their side of the issue. The test of whether information can properly be discovered is not whether the information, standing alone, will entitle the party to prevail, but only whether the discovery should be allowed as a matter of discretion, taking into account the proper scope of discovery:

> Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Fed. R. Civ. P. 26(b)(1).

Mr. Weida's high rank within the Agency—the so-called apex doctrine—can be seen as a specialized application of this provision. The doctrine weighs heavily against allowing the deposition. But the factors on the other side weigh more heavily. As the only Agency participant in communications that may have substantial probative value both on the merits and in impeaching the Agency's experts, Mr. Weida may properly be required to appear for a deposition, subject to an appropriately reduced time limit.

This ruling would be made anyway but draws further support from the fact that the Agency has not disclaimed an intent to call Mr. Weida as a witness at trial.

The timing of the plaintiffs' effort to depose Mr. Weida does not call for a different result. The Agency was slow to produce important documents, doing so only after entry of an order compelling their production. The late-produced documents showed that Mr. Weida had information others did not. The 30(b)(6) deposition, completed late in the process because of the late document production, did not provide all the discoverable information—and included the assertion noted above that viewpoint had nothing to do with selection of the consultants. The Agency ought not be able to avoid otherwise-proper discovery based on its own delay in providing prior proper discovery.

Under Federal Rule of Civil Procedure 37(a)(5)(B), if a discovery motion is denied, the court "must" order the moving party or attorney or both to pay the

opposing party's expenses, including attorney's fees, unless the motion was "substantially justified" or "other circumstances make an award of expenses unjust." Unless these conditions are met, an award of expenses is "mandatory." *Devaney v. Cont'l Am. Ins. Co.*, 989 F.2d 1154, 1162 (11th Cir. 1993) (citing *Merritt v. Int'l Bhd. of Boilermakers*, 649 F.2d 1013, 1019 (5th Cir. Unit A June 1981)). A position is "substantially justified" if it results from a "genuine dispute, or if reasonable people could differ as to the appropriateness of the contested action." *Pierce v. Underwood*, 487 U.S. 552, 565 (1988) (citations, quotation marks, and brackets omitted); *Devaney*, 989 F.2d at 1163. Here the Agency's position was wrong but substantially justified, so expenses are not awarded.

In sum, as a matter of discretion, under all the circumstances,

IT IS ORDERED:

1. Mr. Weida's motion for a protective order, ECF No. 115, is denied.

2. The plaintiffs may depose Mr. Weida. The plaintiffs' examination must not exceed three hours. Time devoted to the plaintiffs' examination means time spent on questions asked by the plaintiffs' and answers to the questions, including normal delays between questions and answers, but not including time spent on objections.

3. The deadline to conduct the deposition is April 21, 2023. The parties must cooperate in good faith to schedule the deposition by that date. But the deposition

may be conducted on a later date if both sides agree both to the delay and to the specific date on which the deposition will be conducted.

SO ORDERED on April 4, 2023.

s/Robert L. Hinkle
United States District Judge

Doc. 120

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM OF LAW

Defendants Secretary Weida and the Florida Agency for Health Care Administration (individually, "AHCA," and collectively with Secretary Weida, the "State") move for summary judgment under Federal Rule of Civil Procedure 56 and Local Rule 56.1 on all four counts in Plaintiffs' complaint. *See* Doc.1.

For the reasons stated in the memorandum that follows, the State asks this Court to grant its motion. An index to the exhibits that the State references in its motion are included on pages 37 to 39.

Dated: April 7, 2023

Respectfully submitted by:

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CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2023, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

INTRODUCTION

"[B]ased on current medical opinion," Florida's "determination" that certain treatments for gender dysphoria are "experimental is reasonable." *Rush v. Parham*, 625 F.2d 1150, 1157 n.13 (5th Cir. 1980). Since the preliminary-injunction hearing in this case, Norway has joined the growing list of countries that have found the support for "hormonal and surgical" treatments to be "insufficient," and their "long-term effects" to be "little known." Exhibit 1 (Norway Healthcare Investigation Board report). If Florida is wrong, then so too are Norway, Finland, Sweden, the United Kingdom, France, Australia, and New Zealand.

The expert reports appended to this summary judgment further support the State's position that the use of puberty blockers, cross-sex hormones, and surgeries for the treatment of gender dysphoria is experimental. Among others:

- **Dr. Stephen Levine**, a psychiatrist from Case Western Reserve University and an early proponent of gender-affirming care, provides a comprehensive discussion of the literature and the need for caution in administering the excluded treatments. Exhibit 12.
- **Dr. Paul Hruz**, a researcher and clinician at Washington University School of Medicine, does the same from the perspective of an endocrinologist. Exhibit 13.
- **Dr. Sophie Scott**, a neuroscientist from the United Kingdom, explains that the effects of certain chemicals on the human brain simply aren't well known; the first step in the road to surgical transition (the use of puberty blockers) is experimental. Exhibit 18.
- And, of course, the State's rulemaking process included a report from **Dr. Brignardello-Petersen**, a researcher who specializes in conducting systematic reviews of academic literature. Having never published on the issue of gender dysphoria, she took a fresh look

> and found the literature supporting the excluded treatments to be based on low-quality evidence. Doc.49-1 at 59.

By contrast, Plaintiffs and their experts cite WPATH's standards of care and the Endocrine Society's guidelines as the measuring stick for current medical opinion. Though WPATH and the Endocrine Society have resisted the State's discovery efforts to seek information concerning the guidelines and standards, their guidelines and standards acknowledge the problems with the excluded treatments: limited empirical data, lack of long-term studies, likelihood of adverse health effects, and reliance on low-quality evidence. Plaintiffs' experts use sleight of hand to address these problems: Dr. Antommaria, for example, suggests that low-quality evidence means something other than what it says. Plaintiffs' experts also attempt to make WPATH (whose members worked on the Endocrine Society guidelines) into the preeminent medical organization on the issue. WPATH acknowledges, however, that it's an advocacy organization where non-medical experts can work on the standards.

Under the circumstances, there isn't enough to create a genuine issue of material fact concerning the controlling question in this case: the reasonableness of the State's determination. At best, Plaintiffs' experts present their preferred approach to treating gender dysphoria, which includes the use of experimental treatments. Yet that doesn't establish that the State's reticence is unreasonable.

It follows that Plaintiffs can't succeed on their *Rush*-related Medicaid claims (Count III and IV). Section 1983 also doesn't create a mechanism to enforce Medicaid

claims. Nor can Plaintiffs succeed under the Equal Protection Clause (Count I) or the Affordable Care Act's anti-discrimination provision (Count II). That's because the State's health, safety, and welfare enactments are entitled to a "strong presumption of validity." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2282 (2022). Plaintiffs can't overcome the presumption by stacking low-quality scientific evidence on itself. To allow them to do so would confuse impassioned advocacy with dispassionate science and replace State-prescribed caution with private preference.

STATEMENT OF THE CASE & FACTS

Rush explains that it's "a simple matter of logic that the district court's determination should be based on current medical knowledge, regardless of the prevailing knowledge at the time [that the State issued its GAPMS Report or Rule 59G-1.050(7)]." 625 F.2d at 1157 n.13. Still, for the sake of completeness, it's important to trace (1) the steps leading up to the State's decision to exclude reimbursement for certain treatments for one psychiatric condition, (2) the litigation that has ensued, and (3) the state of current medical opinion.

I. The Federal Government's Stance

The State's assessment of the excluded treatments for gender dysphoria was a response to the federal government's actions. On March 2, 2022, the U.S. Department for Health and Human Services issued a notice and guidance on care. Exhibit 2 (HHS notice and guidance). HHS stated that it "stands with transgender and gender nonconforming youth and their families—and 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." *Id.* HHS followed the notice and guidance with a department-issued factsheet that touted the benefits of hormone therapy and surgeries as effective treatments for minors with gender dysphoria. Exhibit 3 (HHS fact sheet). Little scientific support was included. The Department of Justice then threatened states that limited access to such treatments. Exhibit 4 (DOJ letter).

The federal government's 2022 position was an apparent departure from its prior position. In 2016, the Centers for Medicare and Medicaid Services declined to make a determination "on gender reassignment surgery for Medicaid beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population." Exhibit 5 at 1 (CMS memo). It reached that decision "[b]ased on an extensive assessment of the clinical evidence," concluding "there is not enough high-quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." *Id.* at 48. That 2016 determination memorandum has never been superseded by another.

In 2020, HHS declined to "take a definitive view on any of the medical questions raised" "about treatments for gender dysphoria" due to the "lack of high-quality scientific evidence supporting" treatments for gender dysphoria like "sex-reassignment surgeries" and to the reliance on "*advocacy group* (WPATH) rather than on independent

scientific fact-finding." Nondiscrimination in Health & Health Education Programs or Activities, 85 Fed. Reg. 37,160, 37,186-87 (Jun. 19, 2020) (emphasis added). And, as recently as May of 2022, the National Institutes of Health's acting director told the U.S. Senate that the long-term effects of puberty blockers for gender transition are unclear, and that the institutes have only funded *observational* studies in the area. *See* A Review of the President's FY 2023 Funding Request and Budget Justification for the National Institutes of Health, Sen. Comm. on Appropriations (May 17, 2022), https://bit.ly/3QTkaJD (1:12:49–1:14:55).

II. The State's Need to Assess the Science

Against this backdrop, the State decided to assess for itself whether the federal government's new position, which contradicts the still-operative 2016 CMS determination, was "actually[,] sufficiently supported" by quality science. Exhibit 6 (91:20–92:4) (Brackett February 8 deposition). The Florida Department of Health and AHCA were tasked with conducting an independent, evidence-based review of the treatments for gender dysphoria. *Id.* (90:5-11–91:1) (AHCA was tasked to "take a" "detailed look at the available medical evidence, or at least the peer-reviewed literature, and to see what it says.").

The Florida DOH acted first. On April 20, 2022, it released a factsheet in response to HHS's factsheet. Notably, the Florida DOH concluded that minors "should not be prescribed puberty blockers or hormone therapy" and that "reassignment surgery should not be a treatment option for children or adolescents."

Exhibit 7 (FDOH fact sheet). The Florida DOH based this conclusion on the "low-quality evidence" supporting gender-affirming care and the international consensus on this issue. *Id.*; *see also* Exhibit 6 (91:2-11).

Referencing the Florida DOH factsheet, AHCA's then-Secretary Marstiller directed Deputy Secretary Wallace to begin the GAPMS process to assess whether the State should reimburse under Medicaid certain treatments for gender dysphoria. *See* Exhibit 8. No one "instruct[ed] AHCA to ensure that Florida Medicaid would not cover treatment for gender dysphoria." Exhibit 6 (90:12-16). This was to be an independent review, and it was to be a GAPMS review, which "provides the best opportunity to go through" medical "literature on a large scale and to make a conclusion" on whether a treatment is clinically unproven or experimental. *Id.* (93:3-12); *see also* Fla. R. Admin. 59G-1.035 (GAPMS Rule adopted in 2015); Fla. Stat. § 409.905(9) (barring payment for services that are "clinically unproven" or "experimental").

Ann Dalton, the AHCA Bureau Chief of Medicaid Policy, recommended that Matt Brackett draft the GAPMS Report. Exhibit 9 (84:2-4, 85:22-15, 86:8-25) (Dalton deposition). She also recommended that two other employees, Devona Pickle, an AHCA program director, and Nai Chen, a pharmacist, assist Mr. Brackett. *Id.* (84:2-4, 86:8-25); Exhibit 6 (96:11-15).

According to Ms. Dalton, Mr. Brackett would be a good drafter, because he "worked with the bureau a long time and previously had the position" "primarily responsible for GAPMS." Exhibit 9 (84:11-23). She called his GAPMS-related

knowledge "extensive." *Id.* (86:15-25). Ms. Dalton also stated that Ms. Pickle had "been with the bureau and agency a very long time," *id.* (84:12-23), and that she previously worked "very closely" with Mr. Brackett and Ms. Pickle, *id.* (86:15-25). Ms. Dalton admitted that she hadn't worked with Mr. Chen as much as other members of the team, but she knew all three to have been part of the Canadian Prescription Drug Importation Program, a multifaceted and important policy initiative. *Id.* (25:6–26:2, 27:18–28:6, 83:19–85:15); *see also* Exhibit 10 (program press release). While the three were busy with this drug-importation program in 2021, by 2022, they had more "bandwidth" to devote to another important policy like the gender dysphoria GAPMS. Exhibit 9 (84:11–85:6).

III. Drafting the GAPMS Report

Ms. Dalton's staffing recommendations were approved, and work began on the GAPMS Report on April 20, 2022. *Id.* (157:22-24). Mr. Brackett drafted the GAPMS Report, with Ms. Pickle and Mr. Chen providing secondary assistance. *Id.* (96:11-15).

"When" Mr. Brackett "started working on [the GAPMS Report]," he "did not know where the evidence would take" him. *Id.* (115:13-17). He read and assessed all eighty-eight articles ultimately cited in the GAPMS Report. *Id.* (158:8-13). "[T]he more and more" he "read the articles that focused on the mental health benefits, the methods and so forth" of hormone therapies and surgeries, "the more" he "realized that all those articles left way too many unanswered questions." *Id.* (115:18–116:3).

Among the questions was a lack of available material on the "long-term" consequences of the excluded treatments. *Id.* (117:1-20). Another was the reliance on

"anonymous surveys" and "whether or not these responses [on the surveys] are credible," especially without "longitudinal history of the[] individuals." *Id.* Even if studies weren't anonymous, Mr. Brackett noted that they often had "sample sizes" that "were very, very small" or made observations over only a "one- or two-year period[]." *Id.* There were still more questions about the "potential causes and associations with gender dysphoria" like "autism, trauma, neglect, abuse, abandonment," and other comorbidities. *Id.*

Mr. Brackett also read materials from organizations, such as WPATH and various medical organizations. *Id.* (117:21–120:7). He gave this material due weight: "their conclusions required thoughtful analysis and probing of the evidence" because AHCA "take[s] the recommendations of clinical organizations very seriously." *Id.* (118:12-19). "[B]ut," Mr. Brackett added, "we also do reserve the right to question those recommendations and we did review those and we did analyze them." *Id.* After reviewing the organizations' recommendations, Mr. Brackett concluded that "very weak evidence" backed their support for gender-affirming care. *Id.* (118:20–120:7).

In addition, AHCA hired Dr. Grossman and Dr. Van Mol to assist Mr. Brackett. Outside consultants aren't usually hired for GAPMS reports, but AHCA hires them for other tasks. *Id.* (104:6-10, 137:10-17) (providing examples). The doctors didn't write or draft any section of the GAPMS Report; that task was Mr. Brackett's alone. *Id.* (98:10-21). They provided Mr. Brackett verbal feedback and research leads as he worked through the materials recommended by organizations such as WPATH. *Id.* (98:3-21,

104:6-20, 109:3-23, 145:17–146:5). Mr. Brackett spoke with the doctors approximately four or five times for a handful of hours. *Id.* (158:17–159:5).

At the same time Mr. Brackett was drafting the GAPMS Report, AHCA asked medical professionals to provide additional perspective, such as a review of the evidence supporting the excluded treatments. *Id.* (131:1–132:19). The experts were Dr. Romina Brignardello-Petersen, Dr. James Cantor, Dr. Quentin Van Meter, Dr. Patrick Lappert, and Dr. G. Kevin Donovan. *See* Doc.49-1 at 5-245.

AHCA didn't make substantive edits to the experts' reports; at most, style and grammar edits were made. Exhibit 6 (145:4-16). There was a possibility that the experts "disagreed with one another" or disagreed with the GAPMS Report, especially if Mr. Brackett had reached "a different conclusion." *Id.* (165:8-21).

This was especially true of Dr. Brignardello-Petersen's work. She's a Canadian researcher with a Ph.D. in clinical epidemiology and health care research, who conducted a systematic review of relevant medical studies through April 2022. Doc.49-1 at 59. That review could have cut against Mr. Brackett's review of the literature. But after reviewing "the best available evidence regarding the effects of" gender-dysphoria treatments, she "found low and very low certainty evidence suggesting improvements in gender dysphoria, depression, anxiety, and quality of life." Doc.49-1 at 62.

With a near-final draft ready in mid-May, AHCA finalized the GAPMS Report on June 2, 2022. Exhibit 6 (84:19-21, 146:20-25). Expert reports from Dr. Brignardello-Petersen and others were attached. Doc.49-1 at 5-245.

IV. Adopting Rule 59G-1.050(7) for the Exclusions

Florida's Administrative Procedures Act requires that "each agency statement of general applicability that implements, interprets, or prescribes law or policy" be "adopted pursuant to the requirements of s. 120.54." Fla. Stat. § 120.52(16), (20). AHCA thus initiated the rulemaking process to exclude puberty blockers, cross-sex hormones, and gender-reassignment surgeries as treatments for gender dysphoria. *See* Exhibit 6 (164:23–165:7).

AHCA issued a notice of proposed rulemaking on June 2. *Id.* (165:22–166:4). Rulemaking can "move very quickly," and because the GAPMS Report was completed (and DOJ had threatened litigation), the process moved along. *Id.* (170:4–171:5).

AHCA solicited public comments as part of the process. It received around 600 comments, and the agency read every one. *Id.* (189:12-16). Many attacked the agency rather than its position, *id.* (192:14-21), but the agency thoroughly considered comments from medical organizations and clinicians who took issue with the substance of the agency's position, *id.* (192:22–193:12). Cases and studies identified in the comments were also reviewed. *Id.* (194:1-16). In particular, the agency searched for new evidence that could "mortal[ly] wound" the GAPMS Report, and therefore the proposed rule, and looked for "contradictory evidence" or "modern, high-quality evidence" that supported the use of the excluded treatments. *Id.* (197:20–198:17). As Mr. Brackett put it, "we want[ed] to make sure that we had not left any stones unturned." *Id.*

AHCA also held a public rulemaking hearing on July 8, 2022. There the agency heard impassioned public testimony from all sides of the issue, Doc.49-2 at 82 ¶¶ 24-25, and AHCA employees Jason Weida, Shena Grantham, and Mr. Brackett, served as panelists. Exhibit 6 (176:13-25). Dr. Van Mol, Dr. Grossman, and Dr. Van Meter also served as panelists for good measure, *id.* (128:18-25), because at this point, the State's position on the excluded treatments expressly conflicted with the federal government's position. The State finalized Rule 59G-1.050(7), and it became effective August 21.

Of course, as with all rules, case-by-case variances and waivers are available. *See* Fla. Stat. § 120.542; Fla. Admin. Rules 28-104.001 – 28-104.006. "Variances and waivers *shall* be granted when the person subject to [a] rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person" and when "substantial hardship" or violation of "principles of fairness" are shown. Fla. Stat. § 120.542(2) (emphasis added). "The agency's decision to grant or deny the petition shall be supported by competent substantial evidence," and that decision is subject to a de novo hearing before an administrative law judge, who is then responsible for the fact-finding in the matter. *Id.* § 120.542(8) (referencing hearings under §§ 120.569 and 120.57). To date, AHCA has yet to receive a request for a variance or waiver from its generally applicable rule excluding certain treatments for gender dysphoria; no one has yet said that the excluded treatments are *not* experimental as to a particular set of circumstances unique to the requestor.

V. The Litigation Begins (and Continues in Other Courts)

Plaintiffs filed their complaint on September 7, 2022. Doc.1. They moved for a preliminary injunction on September 12, 2022. Doc.11. This Court held a hearing on the motion on October 12, 2022, Doc.61, and then denied the motion. Doc.64.

In the order denying the preliminary injunction motion, based on *Rush*, this Court stated that the "controlling" "question" in this case is "whether, based on current medical knowledge, the state's determination that [the excluded] treatments are experimental is reasonable." Doc.64 at 4. In its colloquy with counsel during the preliminary injunction hearing, and again consistent with *Rush*, this Court said that the *Rush*-related review is "not an administrative review of what the State knew at the time" about current medical opinion. Exhibit 11 (hearing transcript).

To assess the current state of medical opinion, on November 8, 2022, the State served subpoenas for depositions and documents on WPATH, the Endocrine Society, and the American Academy of Pediatrics. *E.g.*, *In re Subpoenas Served on Am. Acad. of Pediatrics, et al.*, No. 23-MC-00004 (D.D.C. 2023) (herein "D.C.Doc.") D.C.Doc.1-4. Days later, the State served document subpoenas on fifteen medical organizations that track WPATH and Endocrine Society's perspective. D.C.Doc.1-19.

The eighteen organizations moved the D.C. District Court to quash the subpoenas on First Amendment grounds. D.C.Doc.1. On January 26, 2023, the district court agreed that the State should be entitled to assess whether these organizations represent the so-called medical consensus. Among other things, the court required the

production of documents "sufficient to show how" each organization established its position on treatments for gender dysphoria. D.C.Doc.18. The court held the deposition requests in abeyance.

On February 9, 2023, the eighteen organizations produced a total of 387 documents. Six produced less than five documents each. None adequately responded to the question of *how* they established their guidelines or policy positions.

This response prompted another hearing. After the February 27, 2023 hearing, the court held that the *how* included "the process" used to adopt any "guidelines or policy positions" and "the substantive materials and opinions" "considered." D.C.Doc.26. The latter category covered documents "sufficient to show" "why a particular study was relied upon or rejected," and "whether any dissenting views" were "acknowledged," "considered," and "why such views were rejected." *Id.* The court also ordered WPATH, the Endocrine Society, and the American Academy of Pediatrics to sit for limited depositions. *Id.*

The D.C. Circuit stayed the district court's order on the evening of March 8, 2023. *See In re Subpoenas Served on Am. Acad. of Pediatrics, et al.*, No. 23-7025 (D.C. Cir. Mar. 8, 2023). It did so without explanation and hours before the depositions were to begin. The medical organizations' appeal remains pending. And this discovery dispute serves as the basis of the separate motion in limine filed before this Court.

VI. The Experimental Nature of the Excluded Treatments

The continued reluctance of the organizations to share how they crafted their

preferred treatment protocols is significant, especially when Plaintiffs and their experts rely extensively on the WPATH standards of care and the Endocrine Society's guidelines. That said, the experimental nature of the excluded treatments is clear from the material that's available. Before discussing the material, however, a brief discussion of gender dysphoria is provided.

A. Gender dysphoria and the State's Choices

Gender dysphoria is the distressing incongruence between an individual's *biological sex* and *gender identity*. Exhibit 12 ¶ 28 (Levine report); Exhibit 13 ¶ 54 (Hruz report). Biological sex is "determined at conception" at the chromosomal level, and it "structures [an] individual's biological reproductive capabilities." Exhibit 12 ¶¶ 20-21; *see also* Exhibit 13 ¶¶ 13-18. While sex is biologically based, gender "is a human phenomenon." Exhibit 12 ¶ 22 (quoting Endocrine Society). Gender is the traits society associates with biological males and biological females. *Id.* ¶¶ 19-27 (quoting Endocrine Society); Exhibit 13 ¶ 19. Gender identity is an individual's subjective sense of his or her gender. Exhibit 12 ¶¶ 24-27; Exhibit 13 ¶ 20. Unlike sex, gender identity is mutable. *See* Exhibit 13 ¶ 58; Exhibit 14 at 43 (WPATH standards of care) ("[P]eople may spend some time in a gender identity or presentation before they discover it does not feel comfortable and later adapt it or shift to an earlier identity or representation.").

Gender dysphoria is a psychiatric diagnosis. Exhibit 12 ¶ 36. There are no laboratory tests, imaging, or biopsies that can help establish a diagnosis. Exhibit 13 ¶¶ 57-58; *see also* Exhibit 15 ¶ 24 (Laidlaw redacted report).

For those with gender dysphoria, however, behavioral health services can help. *See, e.g.*, Exhibit 12 ¶¶ 42-49; Exhibit 16 ¶ 136 (Kaliebe report). Florida continues reimbursing for these services. Doc.49-2 at 84 ¶ 28 (providing list). But, unlike behavioral services, surgeries, puberty blockers, and cross-sex hormones alter primary and secondary sex characteristics. They come with risks and their efficacy is suspect.

Drs. Hruz, Laidlaw, and Van Meter all discuss the concerns associated with puberty blockers and cross-sex hormones. Exhibit 13 ¶¶ 67-87; Exhibit 15 ¶¶ 66-40, ¶¶ 149-58; Exhibit 17 ¶ 20 (Van Meter rebuttal report). Dr. Hruz explains that puberty blockers suppress natural puberty. Exhibit 13 ¶¶ 67-68. But he cautions that after "an extended period of pubertal suppression," you can't "turn back the clock" and "reverse changes in the normal coordinated pattern of adolescent psychological development and puberty." *Id.* ¶ 75. Evidence to the contrary is "very weak." *Id.* ¶ 78. Puberty blockers and cross-sex hormones also come with a laundry list of potential health consequences, including issues with bone density, fertility, cancer, and brain maturation. *Id.* ¶¶67-87.

Dr. Scott provides a neuroscientist's perspective on puberty blockers, which are the first step on the road to physical transition. She explains that the current science doesn't support puberty-blocking treatments for minors and that such science is needed, given the "considerable changes" that are happening to brain development during and after puberty. Exhibit 18 ¶¶ 12-13 (Scott report). She states that "more research" is needed to justify this treatment. *Id.* ¶ 16. Current studies suggest that

puberty blockers could lead to negative (and perhaps "irreversible") effects: lower IQ scores, lower heart rates, greater emotional reactivity, higher anxiety, greater avoidance behavior, and more risk-taking behavior. *Id.* ¶ 15.

Dr. Lappert, a plastic surgeon, worries that surgical treatments to cut healthy tissue are firmly in the realm of cosmetic surgeries. Exhibit 19 ¶¶ 47-50 (Lappert report). These treatments introduce the prospect of complications and pose ethical concerns because, unlike other cosmetic procedures, the goal is to induce "functional loss" of the breasts and genitalia. *Id.* ¶¶ 47-50.

There are also mental-health consequences to hormone therapies and surgeries. Dr. Levine, a psychiatrist, comments that "[g]ender transition routinely leads to isolation from at least a significant portion of one's family in adulthood" and can impact future romantic relationships. Exhibit 12 ¶¶ 198-99. That can negatively affect mental health. Dr. Levine also responds to claims of *positive* mental health outcomes and *lower* suicidality after hormone therapies: many of those claims are simply backed by low-quality evidence. *Id.* ¶¶ 134-73. And Dr. Levine notes that those with gender dysphoria likely have mental health comorbidities—anxiety disorders, ADHD, autism spectrum disorder, OCD, for example. *Id.* ¶¶ 43, 134. As such, it remains unclear whether hormone therapies and surgeries will resolve underlying mental-health concerns.

B. Plaintiffs' Reliance on WPATH and the Endocrine Society

1. In disagreeing with the State, Plaintiffs and their experts rely almost exclusively on WPATH's standards of care, Exhibit 14, and the Endocrine Society's clinical

practice guideline, Exhibit 20 (Endocrine Society guidelines). Dr. Olson-Kennedy claims that the WPATH standards of care are "the best available science and expert professional consensus" on treatments for gender dysphoria. Exhibit 21 ¶¶ 10-11, 47 (Olson-Kennedy report). Dr. Shumer states that as "a board-certified pediatric endocrinologist, [he] follow[s] the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care when treating [his] patients." Exhibit 22 ¶¶ 38, 48-56 (Shumer report). Plaintiffs' other experts also rely on WPATH and the Endocrine Society. *E.g.*, Exhibit 23 ¶¶ 9, 31 (Baker report); Exhibit 24 ¶¶ 17-23 (Antommaria report); Exhibit 25 ¶¶ 27, 34 (Karasic report); Exhibit 26 ¶¶ 8, 24, 26, 50-51 (Schechter report). That's not surprising because most of the Plaintiffs' experts are members of or are linked to WPATH. Exhibit 26 ¶ 7 (co-lead author of standards-of-care chapter); Exhibit 25 ¶¶ 8-9 (lead author of standards-of-care chapter and former board member); Exhibit 21 ¶ 11 (member); Exhibit 27 ¶ 13 (Edmiston rebuttal report) (contributing author of standards-of-care chapter and former member); Exhibit 28 ¶ 11 (Janssen rebuttal report) ("member of revision committees" for standards-of-care chapters).

The feedback loop between medical professionals and these two organizations is problematic. That's especially so when other organizations (like the American Medical Association) simply adopt WPATH and the Endocrine Society's perspective as their own, *e.g.*, Exhibit 22 ¶ 55, and when those organizations refuse to reveal the bases of their standards in response to discovery requests.

2. Specifically, WPATH acknowledges that it's an *advocacy* organization focused on transgender health care. Exhibit 14 at 7. Its method of revising the standards of care exacerbates the potential for bias. *First*, both medical professionals *and* non-medical professionals are responsible for revisions. *Id.* at 250; Exhibit 29 (WPATH standards-of-care-revision team criteria). *Second*, for medical professionals to contribute, they must be "[l]ongstanding WPATH Full Member[s] in good standing," "[w]ell recognized advocate[s] for WPATH and the [standards of care]," and "[w]ell known expert[s] in transgender health." Exhibit 29.

In other words, the "best available science and expert professional consensus" on medical treatments for gender dysphoria, Exhibit 21 ¶ 10, comes from a self-selecting group of members of one organization, who are noted advocates for the organization, who all strive to preserve the conclusions reached in previous standards of care, and who may not be medical professionals. Exhibit 14 at 7; Exhibit 29. Dr. Levine calls this an "echo-chamber" that can't "claim[] to speak for the medical profession." Exhibit 12 ¶¶ 53, 71. And Dr. Levine is no transgender-skeptic. He's a medical professional who has "recommended or supported social transition, cross-sex hormones, and surgery for particular patients" with gender dysphoria and was himself a former high-ranking member of WPATH's predecessor organization, the Harry Benjamin International Gender Dysphoria Association. *Id.* ¶¶ 5, 6, 66.

Federal courts also recognize that WPATH's standards don't reflect the medical consensus on the issue. *See, e.g.*, *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019) (The

"WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate over sex reassignment surgery"); *Kosilek v. Spencer*, 774 F.3d 63, 88 (1st Cir. 2014) (en banc) ("Prudent medical professionals" "reasonably differ in their opinions regarding [WPATH's] requirements.").

WPATH is clearly critical of Florida's decision to exclude reimbursement for certain gender dysphoria treatments. It has also been critical of the federal government and other countries like Japan and the United Kingdom. And WPATH took issue with the *New York Times*'s coverage of the treatments for gender dysphoria. *See* Exhibit 31 (WPATH press release); Exhibit 32 (same); Exhibit 33 (WPATH letter to Japanese officials); Exhibit 34 (WPATH press release); Exhibit 35 (same).

3. Bias and advocacy aside, WPATH's standards must concede that the excluded treatments don't rest on a solid scientific foundation *and* that the treatments pose the potential for negative and irreversible consequences. For instance, Chapter 5's Assessment for Adults states:

- The "empirical evidence base for the assessment of" transgender and gender diverse adults "is limited." Exhibit 14 at 34-35.
- "Each gender-affirming surgical intervention has specific risks and potentially unfavorable consequences," including "loss of fertility." *Id.* at 40, 43.
- "Gender-affirming hormone treatments have been shown to impact reproductive functions and fertility, although the consequences are heterogenous for people of all birth-assigned sexes." *Id.* at 41.

4. Like WPATH's standards of care, the Endocrine Society can't speak for the medical community either. In 2017, an Endocrine-Society-appointed panel created its clinical practice guidelines for treating gender dysphoria. Exhibit 20. The guidelines were co-sponsored by WPATH. *Id.* at 1. The panelists responsible for the guidelines had ties to WPATH. Exhibit 13 ¶ 95.

The guidelines themselves used the Grading of Recommendations Assessment, Development and Evaluation or GRADE approach—the same methodology utilized by Dr. Brignardello-Petersen. Exhibit 30 at 12-13 (GRADE handbook); 49-1 at 60. GRADE rates the evidence quality for a treatment recommendation: evidence is either high, moderate, low, or very-low quality. Exhibit 30 at 12-13; Exhibit 24 ¶ 19. With higher-quality evidence comes more confidence that treatments will produce the intended result. Exhibit 30 at 13. With low-quality evidence, or even very-low-quality evidence, such confidence is either "limited" or "little." *Id.* Evidence can be of lower quality based on an underlying study's risk of bias, limitations in study design, inconsistency of results, or imprecision and indirectness of evidence. *Id.*

Plaintiffs' expert, Dr. Antommaria, concedes that of the twenty-eight recommendations in the Endocrine Society's guideline, three are backed by moderate-quality evidence, fourteen are backed by low-quality evidence, five are backed by very-low-quality evidence, and six are backed by no evidence at all. Exhibit 24 ¶ 23; Exhibit 20 at 2-8; Exhibit 30 at 40. Notably:

- Low-quality evidence backs the following: "[w]e suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty." Exhibit 20 at 3.
- Very-low-quality evidence backs the recommendation that "there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years," "*even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years*." *Id.* (emphasis added).
- And the recommendation that "clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment" is backed by no evidence at all. *Id.* at 4 (ungraded good practice statement).

These recommendations thus support the State's conclusion concerning the quality of the evidence supporting the excluded treatments.

Dr. Antommaria responds that treatment recommendations, especially for children, are "infrequently based" on high-quality evidence. Exhibit 24 ¶ 23. Among other things, he cites obesity recommendations for children. *Id.* But recommendations for obesity and other ailments are qualitatively different from those for gender dysphoria; the latter includes treatments with permanent, potentially negative consequences while the former advises that kids eat better and exercise.

C. Policy Choices Concerning Acceptable Risk

To be sure, there's agreement among the experts that the excluded treatments can have permanent, potentially negative, health consequences. Dr. Olson-Kennedy admits, for example, that "deepening of the voice" and "breast tissue development" are "irreversible" consequences of hormone therapy. Exhibit 21 ¶ 32**.** Dr. Shumer mentions potential fertility issues with hormone therapy. Exhibit 22 ¶ 81. Dr. Edmiston

agrees with Dr. Scott that "[t]here is not a large literature on the effects of GnRHa treatment on the brain in humans," and that "[t]here is a small body of literature on the effects of gender-affirming hormone care on the brain in transgender adolescents." Exhibit 27 ¶¶ 29, 31. And some of WPATH's concessions are noted above.

What's left then is a dispute about the magnitude of potential harm and tolerable risk limits. On these policy issues, the State of Florida remains firmly tethered to the international consensus.

Finland's National Science Review concluded that "[i]n light of available evidence, gender reassignment of minors is an experimental practice." Exhibit 13 ¶ 124. Finland reached this conclusion after noting that "there are no medical treatments (for transitioning) that can be considered evidence-based" and that the "reliability of the existing studies with no control groups is highly uncertain," especially considering the potential "risks" of such treatments, such as bone-growth and neurological issues. *Id.*

Sweden reached a similar conclusion. Its board of health said that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatment[s]" in minors, and that such treatments should be provided only in rare cases and ideally as part of experimental trials. *Id.* ¶ 125.

The United Kingdom went further still. Its National Institute of Health and Care Excellence reviewed studies that support hormone therapy for gender-dysphoric minors. *Id.* ¶ 126. The institute concluded that "all small, uncontrolled observational studies" for puberty blockers "are of very low certainty using modified GRADE" and

CERTIFICATE OF SERVICE

I certify that I e-filed this appendix on ECF, which will email everyone requiring notice.

Dated: October 13, 2023 /s/ Mohammad O. Jazil

No. 23-12155

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

August Dekker et al.,
Plaintiffs-Appellees,

v.

Secretary, Florida Agency for Health Care Administration et al.,
Defendants-Appellants.

U.S. District Court for the Northern District of Florida, No. 4:22-cv-325
(Hinkle, J.)

APPELLANTS' APPENDIX – VOLUME IX OF XXI

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they "reported physical and mental health comorbidities and concomitant treatments very poorly." *Id.* As for cross-sex hormones, the institute stated that evidence of their effectiveness was also of a "very low" quality. *Id.* The United Kingdom's Cass Report, which reviewed gender-identity services in the country, stated that there's a "lack of consensus and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response." *Id.*

Others agree. France's Académie Nationale de Médecine says that "great medical caution" must be taken "given the vulnerability, particularly psychological, of this population [gender-dysphoric minors] and the many undesirable effects, and even serious complications, that some of the available therapies can cause." Doc.53 at 11. The Royal Australian and New Zealand College of Psychiatrists has said that there's a "paucity of quality evidence on the outcomes of those presenting with gender dysphoria." Doc.53 at 11. And, as noted above, Norway has also found the support for the excluded treatments to be "insufficient," and their "long-term effects" to be "little known." Exhibit 1.

Under the circumstances, the State's choices are reasonable.

LEGAL STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Disputes are "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty*

Lobby, Inc., 477 U.S. 242, 248 (1986). Facts are "material" if they "might affect the outcome of the suit under the governing law." *Id.*

ARGUMENT

The State is entitled to summary judgment under *Rush* and, separately, Plaintiffs cannot use § 1983 as the vehicle for their Medicaid claims. The State is also entitled to summary judgment on the constitutional and Affordable Care Act claims.

I. The State's Decision Is Reasonable Under *Rush v. Parham*

A. Plaintiffs assert that the State violated two of Medicaid's reimbursement requirements: the early and periodic screening, diagnostic, and treatment service (EPSDT) requirement, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r)(5), and the comparability requirement. 42 U.S.C. § 1396a(a)(10)(B)(i); *see* Doc.1, Counts III & IV**.** But the State need not reimburse payments for experimental treatments. *Rush*, 625 F.2d at 1150. Whether the State's determination concerning the excluded treatments is "reasonable" is governed by "current medical opinion, regardless of the prevailing knowledge at the time" the State adopted the exclusions. *Id.* at 1157 n.13. *Rush*'s standard is thus closer to a rational-basis standard than a mean-ends tailoring standard, which makes sense, because courts aren't medical policymakers.

The State meets *Rush*'s deferential standard. As detailed above, the weight of the scientific literature does not support the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria. Caution is instead the watchword. There's no certainty that the excluded treatments are reversible. *E.g.*, Exhibit 13 ¶¶67-87; Exhibit

19 ¶ 49. The chances are great that those prescribed the treatments suffer from other comorbidities. Exhibit 12 ¶¶ 43, 134. For most, behavioral therapies will help them through this psychiatric condition. *Id.* ¶¶ 42-49; Exhibit 16 ¶ 136. For the exceptional few who can establish that their circumstances warrant it, variances and waivers are available under § 120.542. This approach aligns with the growing global consensus.

And it aligns with CMS's guidance that States "are not required to provide any items or services" the State determines "are not safe and effective or which are considered experimental." *See* CMS, U.S. Dep't of Health & Human Servs., State Medicaid Manual, ch.5, § 5122, //www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.

True, Plaintiffs' experts provide an alternative approach to treatment. At best, however, it's just that: an alternative perspective that can't supersede the State's decision to take a more cautious approach. *See, e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905). At worst, it's the product of an untested and flawed approach sanctioned only by WPATH and the Endocrine Society. Either way, this alternative approach falls short of creating a genuine issue of material fact under *Rush*. The State's conclusion concerning the excluded treatments is reasonable.

B. Nor can Plaintiffs establish comparability. Medicaid requires that services "made available" to an eligible person "shall not be less in amount, duration, or scope" than services "made available to any other" eligible person." 42 U.S.C. § 1396a(a)(10)(B)(i). Thus, there must be some "equivalence between" "Florida-

Medicaid-eligible service[s] and" the excluded treatments for gender dysphoria. Doc.64 at 4-5. For example, a mastectomy is an effective and appropriate treatment for breast cancer, where diseased breast tissue is removed from the body. Exhibit 19 ¶¶ 49, 52, 54. The efficacy of mastectomies for breast cancer treatment says nothing about their efficacy for gender-dysphoria treatment. More broadly, accepting a false equivalency between a treatment approved for a specific malady and gender dysphoria is inappropriate. Plaintiffs' expert reports contain little to no information on this front. Plaintiffs can't show an equivalence.

II. There's No Medicaid Cause of Action Under 42 U.S.C. § 1983

A. Nor can Plaintiffs enforce their Medicaid-related EPSDT or comparability claims through § 1983. *See* Doc.1 at ¶¶ 277, 280. Section 1983 allows for vindication of federally protected *rights* guaranteed by the *requirements* of federal law. *See Collins v. City of Harker Heights*, 503 U.S. 115, 119 (1992).

Broadly speaking, Medicaid dangles a carrot in front of the States. States that meet the criteria in 42 U.S.C. § 1396a receive federal funds. If State plans fall short of Medicaid's requirements after accepting funds, then the HHS Secretary "in his discretion" can "limit payments" to unaffected categories of a Medicaid plan until he is "satisfied" that the State has come back into compliance. 42 U.S.C. § 1396c. While HHS is partially funding a non-compliant Medicaid plan, the affected State can decide whether to accept partial reductions or change its policy. *NFIB v. Sebelius*, 132 S. Ct. 2566, 2607 (2012); *see also id.* at 2642 n.27 (Ginsburg, J., concurring in part, concurring

in judgment in part, and dissenting in part). Notably, HHS has taken no action to defund the State's Medicaid program based on the conduct at issue here.

Neither the Supreme Court nor the Eleventh Circuit has specifically addressed whether the EPSDT or comparability provisions create federally enforceable rights. Though other courts have allowed the use of § 1983 to enforce these provisions, they did so based on the erroneous assumption that "obligations on participating states" are enough. *Smith v. Benson*, 703 F. Supp. 2d 1262, 1273 (S.D. Fla. 2010) (quoting *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 605 (5th Cir. 2004)); *see also Cruz v. Zucker*, 116 F. Supp. 3d 334, 345 (S.D.N.Y. 2015). They aren't. Only an "unambiguously conferred right," not an obligation, can "support a cause of action brought under § 1983." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283 (2002).[1]

In sum, Counts III and IV present no rights to enforce under federal law. Because § 1983 "does not provide a remedy for abuses that do not violate federal law," *Collins*, 503 U.S. at 119, Plaintiffs can't use it as a vehicle to pursue their Medicaid claims.

B. Relatedly, equity doesn't permit Plaintiffs' Medicaid claims. To be sure, courts of equity have "long" granted injunctions to prevent "illegal executive action." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015). But that power is "subject to express and implied statutory limitations." *Id.* A "[c]ourt[] of equity can no

[1] The question of whether statutes like Medicaid can ever give rise to privately enforceable rights under § 1983 is currently before the U.S. Supreme Court in *Health and Hospital Corporation of Marion County v. Talevski*, No.21-806, which was argued November 8, 2022.

more disregard statutory and constitutional requirements and provisions than can courts of law." *I.N.S. v. Pangilinan*, 486 U.S. 875, 883 (1988) (quotation omitted).

In *Armstrong*, the Supreme Court concluded that in enacting another section of the Medicaid Act—§ 1396a(30)(A)—Congress had impliedly foreclosed equitable remedies for two reasons. *First*, "the sole remedy Congress provided for a State's failure to comply with Medicaid's requirements—for the State's 'breach' of the Spending Clause contract—is the withholding of Medicaid funds by the Secretary of Health and Human Services." *Armstrong*, 575 U.S. at 328. *Second*, the clause at issue, which "mandate[d] that state plans provide for payments that are 'consistent with efficiency, economy, and quality of care,' all the while 'safeguard[ing] against unnecessary utilization of' "care and services[,]' was "judicially unadministrable" because it was "broad[]" and lacked "specific[s]." *Id.* As the Court explained, that vague duty evinced Congressional intent for an "exclusive" agency remedy that could bring to bear administrative "expertise" and "uniformity." *Id.*

That rationale fits Plaintiffs' theory hand in glove. For one, no one doubts that the Medicaid Act provisions Plaintiffs hope to enforce are only textually enforceable by the Secretary. 42 U.S.C. § 1396c. And Plaintiffs' chosen statutes are just as broad and non-specific as the one in *Armstrong*; they tell States, for example, in Plaintiffs' own words, to provide "all services necessary to 'correct or ameliorate' a physical or mental health condition," Doc.1 ¶ 276, without defining necessity.

III. The State's Decision Is Constitutional Under the Equal Protection Clause

A. Plaintiffs' equal-protection claim fails as well. The State's health, safety, and welfare actions are subject to a "strong presumption of validity." *Dobbs*, 142 S. Ct. at 2284 (cleaned up). They "must be sustained if there is a rational basis on which" the State "could have thought that it would serve legitimate state interests." *Id.*

Rule 59G-1.050(7) is a health, safety, and welfare regulation that makes a distinction based on a medical diagnosis: the excluded treatments are generally unavailable to those with gender dysphoria but are available to those with other diagnoses (like breast cancer or precocious puberty). The distinction furthers the State's interest in protecting its citizens from unnecessary and experimental treatments that are grounded in low-quality evidence and that threaten to cause permanent harm like sterilization and infertility. Rational-basis review is easily met. *Dobbs*, 142 S. Ct. at 2268; *Otto v. City of Boca Raton*, 981 F.3d 854, 868 (11th Cir. 2020); *Jacobson*, 197 U.S. at 25.

B. Plaintiffs ask for some heightened level of scrutiny to apply because, in their estimation, Rule 59G-1.050(7) makes facially discriminatory distinctions based on sex or transgender status. The problems with this argument are threefold.

First, the en banc Eleventh Circuit in *Adams v. School Board of St. Johns County* foreclosures the sex-based discrimination argument. In that case, the court held that a school board's sex-based bathroom-assignment policy doesn't violate the Equal Protection Clause. 57 F.4th 791, 796 (11th Cir. 2022) (en banc). The court elaborated

that sex-based discrimination is discrimination based on biological sex. *Id.* at 807-08. After all, the Equal Protection Clause protects immutable characteristics, like biological sex. *Id.* (citing *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973)). Exhibit 12 ¶¶ 19-27; Exhibit 13 ¶ 19. That stands in strong contrast to gender identity, which is mutable and isn't afforded heightened constitutional protection. 57 F.4th at 807-08.

The *Adams* school-board policy made a distinction on the basis of biological sex: mainly, biologically male students use one bathroom, biologically female students use another bathroom, or a sex-neutral bathroom is available. *Id.* at 802. "This is a sex-based classification," the Eleventh Circuit held. *Id.* at 801.

That's different from Rule 59G-1.050(7). The rule doesn't make a distinction based on biological sex. The State's rule makes a distinction based on a medical diagnosis—gender dysphoria—which applies to biological males and biological females. *See Lange v. Houston County*, 608 F. Supp. 3d 1340, 1354 (M.D. Ga. 2022); *see also Geduldig v. Aiello*, 417 U.S. 484, 497 n.20 (1974).

Regardless of biological sex, the State will not reimburse gender-affirming care: puberty blockers, hormones or hormone antagonists, sex reassignment surgeries, or any procedures that alter primary or secondary sexual characteristics. Therefore, rational basis—and not heighted scrutiny—applies, and rational basis is still satisfied.

Second, the *Adams* court explained what constitutes unconstitutional discrimination based on transgender status. Notably, the court didn't hold that transgender status is a quasi-suspect class. It said that "we have grave 'doubt' that

transgender persons constitute a quasi-suspect class" and that "the Supreme Court has rarely deemed a group a quasi-suspect class." 57 F.4th at 803 n.5 (citing *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 442-46 (1985)). Transgender individuals thus aren't entitled to heightened constitutional review per se. *Id.*

Whether to apply heightened review then turns on a *Geduldig v. Aiello* "identity" analysis. In *Adams*, the Eleventh Circuit asked if there was either an "identity" or "lack of identity" between the school-board bathroom policy and transgender status; an "identity" between the two would demonstrate unconstitutional discrimination, but a "lack of identity" would demonstrate a lack of unconstitutional discrimination. *Id.* at 809 (quoting 417 U.S. at 497).

In conducting the analysis, the *Adams* court observed what "group" was affected by the bathroom policy and what "group" wasn't affected. The court found that the affected group consisted of transgender students who wanted to use a bathroom that didn't align with their biological sex. The unaffected group consisted of non-transgender students and transgender students who wanted to use bathrooms that aligned with their biological sex. *Id.* at 809. Because transgender students were in both groups, there was a "lack of identity" between the policy and transgender status. Thus, the policy didn't discriminate based on transgender status. *Id.*

So too here. Rule 59G-1.050(7) creates two groups. The group affected by the rule is comprised of transgender individuals who suffer from gender dysphoria. The group unaffected by the rule is comprised of non-transgender individuals and

transgender individuals *who don't* suffer from gender dysphoria. Under *Adams* and *Geduldig*, there's a "lack of identity" between the rule and transgender status.

Third, Plaintiffs can't prove that the State engaged in purposeful discrimination that violates the Equal Protection Clause. "[A] disparate impact alone does not violate the Constitution. Instead, a disparate impact on a group offends the Constitution when an otherwise neutral policy is motivated by 'purposeful discrimination.'" *Id.* at 810 (citing *Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979)). In their facial challenge, Plaintiffs can't prove that the State promulgated its rule "because of" and not "in spite of" its allegedly adverse effect on transgender individuals. *Feeney*, 442 U.S. at 274.

In sum, rational basis applies. That test is met.

III. The State's Decision Complies with the Affordable Care Act

Finally, the State's actions comply with the ACA. Under Section 1557 of the ACA, "an individual shall not, on the ground prohibited under" "title IX of the Education Amendments of 1972," "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity." 42 U.S.C. § 18116. Title IX prohibits discrimination "on the basis of sex." 20 U.S.C. § 1681.

As in the constitutional context, the en banc Eleventh Circuit recently held that, as a statutory matter, "sex" in Title IX means biological sex. 57 F.4th at 812-14 (disavowing reliance on *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020)). For the reasons

discussed above, the State didn't discriminate on the basis of sex. The State thus complied with the ACA.

CONCLUSION

The State asks this Court to grant its motion for summary judgment.

Dated: April 7, 2023

Respectfully submitted by:

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CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F) and 56.1(E), I certify that this motion contains 7,951 words.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2023, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

INDEX TO EXHIBITS

The State provides this index to assist this Court with identifying and finding exhibits in their summary-judgment motion.

Exhibit Number	Exhibit Description[2]
Exhibit 1	Norway Healthcare Investigation Board Report
Exhibit 2	U.S. Health and Human Services Notice and Guidance on Care
Exhibit 3	U.S. Health and Human Services Fact Sheet on Gender-Affirming Care
Exhibit 4	U.S. Department of Justice Letter to State Attorneys General
Exhibit 5	Centers for Medicare and Medicaid Services Decision Memo for Gender Dysphoria and Gender Reassignment Surgery
Exhibit 6	Deposition of Matt Brackett (February 8, 2022) (Combined Volumes)

[2] An unredacted version of Exhibit 15 will be submitted to the court clerk; Plaintiffs are already in position of the unredacted version. And though Exhibit 36 is marked confidential, the parties conferred and agreed that it should not be marked confidential.

Exhibit 7	Florida Department of Health Fact Sheet on Treatments for Gender Dysphoria
Exhibit 8	Letter from then-Secretary Marstiller to Deputy Secretary Wallace
Exhibit 9	Deposition of Ann Dalton
Exhibit 10	Press Release, Governor Ron DeSantis Urges Swift Approval of Florida's Canadian Prescription Drug Importation Program
Exhibit 11	Preliminary Injunction Hearing Transcript (Excerpt)
Exhibit 12	Expert Report of Dr. Levine
Exhibit 13	Expert Report of Dr. Hruz
Exhibit 14	WPATH Standards of Care, Version 8
Exhibit 15	Redacted Expert Report of Dr. Laidlaw
Exhibit 16	Expert Report of Dr. Kaliebe
Exhibit 17	Rebuttal Expert Report of Dr. Van Meter
Exhibit 18	Expert Report of Dr. Scott
Exhibit 19	Expert Report of Dr. Lappert
Exhibit 20	Endocrine Society Guidelines on Treatments for Gender Dysphoria
Exhibit 21	Expert Report of Dr. Olson-Kennedy
Exhibit 22	Expert Report of Dr. Shumer
Exhibit 23	Expert Report of Dr. Baker
Exhibit 24	Expert Report of Dr. Antommaria
Exhibit 25	Expert Report of Dr. Karasic
Exhibit 26	Expert Report of Dr. Schechter
Exhibit 27	Rebuttal Expert Report of Dr. Edmiston
Exhibit 28	Rebuttal Expert Report of Dr. Janssen
Exhibit 29	WPATH Standards-of-Care-Revision Team Criteria
Exhibit 30	Grading of Recommendations Assessment, Development and Evaluation Handbook
Exhibit 31	WPATH's Press Release Regarding Florida Department of Health
Exhibit 32	WPATH's Press Release on National and International Issues
Exhibit 33	WPATH's Letter to Japanese Officials
Exhibit 34	WPATH's Press Release Regarding *New York Times* Article

Exhibit 35	WPATH Press Release on United Kingdom Matter
Exhibit 36	Deposition of Dr. Edmiston

Doc. 120-27

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

CORRECTED EXPERT REBUTTAL REPORT OF E. KALE EDMISTON, PH.D.

I, E. Kale Edmiston, Ph.D., hereby declare and state as follows:

1. I am over the age of eighteen and submit this expert rebuttal report based on my expert opinion.

2. I have been retained by counsel for plaintiffs as an expert in connection with the above referenced litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.

3. I have actual knowledge of the matters stated herein. If called to testify, I would testify truthfully based on my expert opinion.

Background and Qualifications

4. I am an Associate Professor of Psychiatry at the University of Massachusetts Chan Medical School. Prior to this appointment, I was an Assistant

Professor of Psychiatry at the University of Pittsburgh from 2019 to 2022. I have more than 15 years of experience conducting psychiatric neuroimaging research, with a focus on adolescence and young adulthood, mood and anxiety disorders, and impulsivity and emotional regulation. My methodological expertise lies in neuropsychological assessment, multimodal neuroimaging, psychophysiological measures such as heart rate variability, and measures of neuroendocrine function across adolescent development.

5. I completed a bachelor's degree from Hampshire College in 2007, where I studied cognitive science. I received postbaccalaureate training in psychiatric neuroimaging at the Yale School of Medicine. I earned a PhD in neuroscience from Vanderbilt University in 2015, as well as a graduate certificate in medical humanities, with a focus on bioethics and medical decision-making. I then completed post-doctoral training at China Medical University and the University of Pittsburgh.

6. In 2014, I co-founded the Trans Buddy Program at Vanderbilt University Medical Center, a peer navigator and support program for transgender people seeking healthcare. As a part of this program, my work primarily focused on supporting transgender adolescents experiencing mental health crisis. At this time, I also served as the Co-Director for the Vanderbilt University Program for LGBTI

Health. I later replicated the Trans Buddy Program at the University of Pittsburgh Department of Adolescent Medicine.

7. From 2018-2022, I served as a chapter author for the Assessment chapter of the World Professional Association for Transgender Health's *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*.

8. I have authored over 100 peer-reviewed manuscripts, book chapters, and conference proceedings in psychiatric neuroscience and transgender health.

9. Further information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as **Exhibit A** to this report.

Prior Testimony

10. I have not testified as an expert at trial or by deposition within the last four years.

Compensation

11. I am being compensated for my time at a rate of $175/hour. My compensation is in no way contingent on the conclusions reached as a part of my testimony or on the outcome of this case.

Basis for Opinions

12. In preparing this report, I have reviewed: the Complaint in this case; Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the document titled "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria," published by the Florida Agency for Health Care Administration in June 2022, and its attachments; the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-Kennedy, Loren Schechter, and Dr. Daniel Shumer, submitted by plaintiffs; and the expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and Joseph Zanga, submitted by defendants.

13. My opinions are based on my years of research and academic experience, as well as my professional knowledge, as set out in my curriculum vitae (**Exhibit A**) and the materials listed therein; my knowledge of the peer-reviewed literature relating to neuropsychological assessment and brain development; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8; and my review of any of the materials cited herein.

14. I have also reviewed the materials listed in the bibliography attached as **Exhibit B**. I may rely on those documents as additional support for my opinions.

15. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

Adolescent Brain Development

16. Dr. Scott's report stating that adolescents are more likely to engage in risky behaviors relative to adults fails to include the specific context in which this is true. That is, the literature indicates that there are *highly specific circumstances* in which adolescents are more likely to engage in risky or impulsive behavior. Indeed, Dr. Scott lists some of these circumstances in her testimony: driving, drinking alcohol, getting a tattoo. However, none of these examples are relevant to the issue at hand: protracted medical decision-making made in the context of adult guidance and consultation with a medical professional.

17. Dr. Scott fails to cite the large body of evidence indicating that adolescents are capable of deliberative decision making in the presence of adults (i.e., healthcare providers and caregivers) and when decision making occurs over a protracted period. This is the exact context in question: decisions about accessing gender-affirming medical care, such as gonadotropin releasing hormone agonists

(GnRHa) and hormone treatment, are made jointly among the adolescent patient, their caregiver(s), and medical professionals. These decisions are also made over time; data show that the typical time between an adolescent realizing they are transgender and coming out to an adult is three years (Bauer et al., 2022). Furthermore, once an adolescent discloses their identity to a supportive adult, they will then have to schedule a healthcare appointment and undergo assessment prior to accessing treatment. This process typically takes months and for some, even years.

18. Dr. Scott misrepresents the literature on adolescent decision making by generalizing findings made in "hot" contexts to those made in "cold" contexts. Indeed, the Blakemore and Robbins review from 2012 that she cites explicitly states that the literature concludes that adolescents demonstrate adult-typical decision-making abilities in cold contexts. It is not that adolescence is associated with a failure to engage cognitive control networks, but rather, that cognitive control networks are engaged with greater variability during this time than during adulthood. Decision-making is a multifactorial process that includes valuation of both risk and reward. While adolescents are more likely to overvalue reward and underestimate risk when peers are present or when decisions must be made quickly, they demonstrate deliberative and appropriate consideration of reward and risk valuation in the absence of peers, in the presence of adults, and when decisions are made over time.

This important difference in the contextual nature of decision-making in adolescence is an established finding that has been replicated across multiple studies (Chein et al., 2011; O'Brien et al., 2011; Simons-Morton et al., 2011; Smith et al., 2014; Weigard et al., 2014; Hartley & Somerville, 2015; Guassi Moreira & Telzer, 2018). Indeed, deliberative decision making in contexts without pressure to decide quickly has been repeatedly shown in adolescents (Byrnes, 2002; Figner et al., 2009; Wolff & Crockett, 2011; Icenogle & Cauffman, 2021).

19. Dr. Scott also states that "at 18yrs old, the connections to the frontal lobes are not myelinated[1] like a mature adult brain, and this is likely to affect frontal lobe functions." This is an oversimplification of an extremely complex literature. A study of over 10,000 participants has shown quite the opposite: that by the age of 18, adult-level cognition is established (Tervo-Clemmens et al., 2022), while other studies have shown mature integration of functional networks by late adolescence (Marek et al., 2015) and fractional anisotropy of prefrontal white matter (Lebel & Beaulieu, 2011, fractional anisotropy is an indirect measure of myelination). Even though, on average, there are developmental differences in prefrontal myelination,

[1] Myelin is a protein sheath that covers the axons of neurons. The axons comprise white matter in the brain, and bundles of these fibers transmit signals from region to region in the brain. When an axon is myelinated, the signal can travel faster down the axon.

there is not strong evidence that these differences are associated with an inability to make deliberative decisions with the support of caregivers and expert clinical guidance.

20. Furthermore, there is a great deal of variation in the timing of development between different prefrontal white matter tracts, as well as a great deal of variation between individuals. Indeed, in Lebel & Beaulieu's longitudinal study of over 100 individuals from childhood to young adulthood, many individuals showed decreases or no changes in fractional anisotropy (FA) during adolescence, and these differences also varied by prefrontal white matter tract (2011). This literature represents differences in group averages and should not be used to predict the behavior or development of an individual adolescent; we cannot draw conclusions about all 18-year-olds from these studies. This is why the WPATH SOC 8 recommends an individualized approach to joint decision-making regarding healthcare.

There is Little Evidence to Support Defendants' Designated Experts' Speculation about Negative Effects of GnRHas on Cognition

21. Dr. Scott cites a 2016 study by Wojniusz and colleagues as evidence of the negative effects of GnRHas on emotional reactivity in a sample of girls with central precocious puberty. This is puzzling because the authors of this paper explicitly state the opposite interpretation: "Overall, our findings do not provide firm

conclusions with regard to differences in emotional processing between the GnRHa treated CPP girls and age-matched controls." (pp13).

22. Perhaps Dr. Scott has misinterpreted the nature of the emotional flanker task. This task asks participants to determine if two simultaneously presented houses are the same or different. The houses are presented at the center of a screen, and emotional or neutral face distractors flank them. The outcome of interest is the reaction time for the determination of whether the houses are the same or different. The idea here is that people with poor emotional regulation will be more distracted during the emotional face condition and therefore take longer to respond. This interpretation can only be made when reaction times are increased in both the emotional face conditions. In this study, the CPP girls showed longer reaction time than controls during the emotional face condition only when the houses were different, but not when the houses were the same. Thus, the findings do not indicate an issue with emotional regulation. More likely, the results are incidental and due to statistical issues regarding false discovery rate correction, an argument that the authors of the paper themselves make.

23. The authors do find reduced heart rate and elevated heart rate variability (HRV) during the emotional task. HRV is distinct from heart rate and is a measure of cardiac vagal tone. HRV is a proxy for parasympathetic system or "rest and

digest" function. Thus, elevated HRV is associated with increased regulatory capacity and is a marker of health. Thus, these findings are a sign of *optimal* emotional regulation. Indeed, the authors state, "…the lower HR and higher HRV could suggest that treated CPP girls have better emotion regulation capacity and higher adaptability to changing contexts than controls" (pp13).

24. Dr. Scott then points out that, in a separate commentary on the article, Dr. Hayes states that there were "notably" lower scores on IQ measures in the CPP group relative to controls. However, Dr. Hayes's comment, and Dr. Scott's reliance on it, is not supported by the findings of the study. Specifically, none of the differences in IQ were statistically significant, and the mean IQ scores for both groups were within the normal range. Furthermore, the mean difference between groups in this study is within the realm of variation that may occur from repeated administration of the WISC-III, i.e., although scores for an individual tend to remain relatively stable over time, there is fluctuation that occurs even within an individual and small differences in IQ (Watkins & Smith, 2013), as reported in this study, are not only not statistically significant, they are not clinically significant. Dr. Scott has, again, offered a misrepresentation of the literature.

25. Dr. Levine cites a single case study as evidence for an effect of GnRHa treatment on IQ. Case studies are the lowest quality of evidence. Case studies can

provide important evidence for future areas of study or to provide an illustrative example of a common clinical phenomenon, but they should not be used to make general conclusions or policy positions. Putting aside the low quality of evidence typical of case studies in general, this case study does not even provide sufficient support for Dr. Levine's opinion as it describes a transgender girl who, prior to initiation of treatment, already had below average IQ. While Dr. Levine highlights the lack of change in fractional anisotropy values over the course of the study in this case, this could be due to developmental delays that are independent of treatment and are instead related to her low IQ. Therefore, the findings of this case study are simply not generalizable to the broader population.

26. Dr. Michael Biggs, a sociologist, also offers speculation regarding cognitive effects of GnRHa treatment as well, describing it as "…stopping normal sexual and cognitive development…" This statement regarding cognitive development appears to be pure speculation as he offers no citation regarding evidence for deleterious effects of GnRHa treatment on cognition. In reviewing the literature, including through specific searches, I have been unable to find compelling evidence of this. I was able to identify two studies that showed no effect of GnRHa treatment on executive function (Soleman et al., 2016; Staphorsius et al., 2015). The

lack of evidence for these effects is itself compelling, given that these medications have been used in adolescents with central precocious puberty for decades.

Evidence for Effects of GnRHa treatment on the Brain

27. Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa treatment on the brain are both "unknown" and "likely negative." They do not cite any original research that supports this conclusion and thus it is unclear to me how they concluded that the effects are likely negative in the absence of evidence. Dr. Laidlaw even goes so far as to speculate on the individual brain maturation of three specific transgender individuals. Both Levine and Laidlaw admit that there is no evidence from the neuroimaging literature on negative effects of these treatments on brain development, but even if there was, any neuroimaging study that compares group averages would not support an inference about the brains of individual people. There is a great deal of variation between and within individuals in many commonly used neuroimaging measures. For this reason, neuroimaging methods commonly used in research, such as fMRI, cannot be used diagnostically for individual people in the absence of organic brain disease (Schleim & Roise, 2019).

28. Dr. Hruz also speculates in his testimony that there are negative effects of GnRHa treatment on the brain: "A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation". Dr. Hruz then cites a

2013 review paper that describes typical adolescent brain maturation but does not mention or describe any effects of blocking or delaying puberty on the brain (Arain et al., 2013). Dr. Hruz therefore has not cited any support for his conclusion, and I have not identified any studies relating to the evidence of negative longitudinal effects on brain development related to GnRHa treatment in central precocious puberty or in transgender adolescents, even after targeted searches for it.

29. There is not a large literature on the effects of GnRHa treatment on the brain in humans, but this does not render such care experimental. GnRHa treatments have been in used for decades, including for the treatment of gender dysphoria. That said, there are a few cross-sectional studies on this issue, and it is significant that none of the experts (nor the GAPMS memo) cited this literature in their testimonies. In a study that compared transgender adolescent boys and girls taking GnRH agonists to cisgender boys and girls, there were differences in brain function in some brain regions that would indicate congruence with gender identity and other differences that would indicate congruence with sex assigned at birth. However, there were no between-group differences in network function on the basis of GnRHa treatment. Furthermore, the authors searched for relationships between duration of GnRHa treatment in the transgender adolescents and brain function and *were unable to find any effects*. In a diffusion tensor imaging study of fractional anisotropy

values, an index of white matter myelination, *again there was no significant association between fractional anisotropy values and GnRHa treatment* (van Heesewijk et al., 2022). Similarly, in an fMRI study comparing cisgender boys and girls to transgender boys and girls, there were no significant differences in brain activity between transgender and cisgender adolescents during a verbal fluency task, and no deficits in verbal ability in transgender youth (Soleman et al., 2013). In a study of transgender individuals receiving GnRHa treatment and cisgender people, there were differences in brain activity between groups, but these differences were not associated with hormone levels, leading the authors to conclude that these differences are associated with group differences that predate GnRHa treatment (Soleman et al., 2016). In summary, to my knowledge, there have been three studies of brain structure and function of transgender adolescents receiving GnRHa treatment, and none of them have found any significant effects of treatment on the brain.

30. A recent primate study provides evidence for some regional neuroprotective effects of GnRHa treatment, although the results are complex (Godfrey et al., 2023). In this study, the authors compared dominant and subordinate adolescent rhesus monkeys. These monkeys form social hierarchies much like human adolescents, and subordinate monkeys are subjected to aggression from the

more dominant monkeys. Both dominant and subordinate monkeys were randomly assigned to a GnRHa treatment or control group and then followed longitudinally. In the primates exposed to chronic social subordination stress, GnRHa treatment rescued the negative effect of stress on regional brain volume over time. These differences were seen in brain regions such as the amygdala that are well-established in the pathophysiology of depression and anxiety. There were also effects of GnRHa treatment in general; treatment in both social groups was associated with smaller hippocampal volume than control animals. Regarding the prefrontal cortex, a critical region during adolescent development, GnRHa treatment was associated with greater prefrontal grey matter volume prepubertally but this difference decreased by adolescence. There was an effect of GnRHa treatment early in puberty on prefrontal white matter volume; however, this difference was no longer present by the end of the study. Importantly, there are species-specific differences in prefrontal volume changes across puberty; the generalizability of the prefrontal findings to humans should be made with caution. Finally, the authors also assessed social behavior in both submissive and dominant primates over time and were able to determine that, at prepuberty, submissive primates were more socially isolated, but that GnRHa-treated subordinate animals had normalized social behavior (reduced time spent alone) and normalized cortisol response to threat (cortisol is a stress hormone

associated with the hypothalamic pituitary adrenal axis). The authors conclude that "…delayed puberty and estrogen suppression may be protective against the impact of social stress" (pp12). This study provides strong evidence that GnRHa treatment normalizes brain structure, physiological stress reactivity, and social behavior in adolescent primates subjected to social subordination, an ecologically valid non-human primate model of the psychosocial environment for transgender youth.

31. There is a small body of literature on the effects of gender affirming hormone care on the brain in transgender adolescents. In a study comparing transgender boys receiving testosterone therapy and those who were not, testosterone treatment was associated with reductions in mood and anxiety symptoms, as well as reductions in body image dissatisfaction. Gender affirming hormone care was associated with an increase of functional coupling between the amygdala and prefrontal cortex while research participants viewed threatening emotional faces, likely indicating improved emotional regulation of the amygdala in the boys who were treated with testosterone. Indeed, in the boys who were treated with testosterone, greater coupling between these two regions was associated with lower anxiety symptom severity (Grannis et al., 2021). Another study of transgender boys receiving testosterone found that testosterone caused a shift in amygdala

activation, such that it became more typical of cisgender boys than cisgender girls (Beking et al., 2020).

32. 17. Both Dr. Scott and Dr. Biggs cite studies from the animal literature regarding the "side effects" of GnRHa treatment on the brain and behavior. However, they misinterpret or misrepresent the meaning of the term "side effect" in this context. Pharmacological agents have effects. The determination of what is a side effect and what is a desired effect is contextual. For example, Scott cites a 2021 rodent study of GnRHa treatment as an example of the "side effects" associated with GnRHa treatment (Anacker, et al., 2021). If one were to read the abstract of the study and not the full text, it may lead some to come to such a conclusion. However, what the study shows is that, prior to GnRHa treatment, there are sex differences in rodent behavior. Following GnRHa treatment, those sex differences are no longer present. This is the expected and desired outcome of GnRHa treatment, not a side effect. For example, female mice show greater locomotion behavior than male mice. Following GnRHa treatment, male mice show greater locomotion behavior than untreated male mice. Similarly, in a test of social interaction, GnRHa-treated males showed differences in the time spent with male versus female mice relative to untreated male mice, but not relative to untreated female mice. In both force-swim tests and a test of feeding behavior, female GnRHa-treated mice differed from control female mice,

but not from male mice. This is a consistent pattern across behavioral assays performed in the study, and this pattern was present in biological assays as well. GnRHa-treated male mice showed greater corticosterone stress response to novelty than control male mice but did not differ from female mice. GnRHa treatment increased neural activity in the hippocampus of female mice, but this activity increase did not differ from male mice. This is not a compelling study of the side effects of GnRHa treatment, but rather, a study that shows us exactly what we would expect: that blocking sex hormones decreases sex differences, the intended outcome for transgender youth.

33. Dr. Scott and Dr. Biggs cite a series of studies of GnRHa effects on sheep from a specific laboratory. One study from this group did show sex-specific changes in feeding behavior and HRV following GnRHa treatment. While Dr. Biggs opts to highlight changes in behavior in the female sheep that could be interpreted as an increase in anxiety-like behavior, he fails to mention that GnRHa treatment was associated with *improvements* in these behaviors in the treated male sheep (Wojniusz et al., 2011). They also fail to mention that other studies from this group show no effects of GnRHa treatment on cognition (Nuruddin et al., 2013; Wojniusz et al., 2013), and, like the Anacker study, brain differences are best explained by an expected reduction of sex differences following treatment (Nuruddin et al., 2013).

This issue of inappropriate reference group is a common problem in the GnRHa animal literature and its extrapolation to transgender youth (Edmiston & Juster, 2022). While the literature regarding the effects of GnRHa treatment on sheep behavior from this research group is complex, it by no means offers compelling evidence of negative effects of GnRHa treatment. Furthermore, Dr. Biggs highlights a negative effect from one study- an increase in anxiety-like behavior in female sheep only. However, we know from studies of transgender youth and young adults that anxiety and depression symptoms decrease with treatment (de Vries et al., 2014; Dhejne et al., 2016; Aldridge et al., 2021; Chen et al., 2023). This is more compelling evidence than a single animal study, as sheep do not have the complex psychosocial identities that humans do.

Evidence for Negative Consequences of Depression and Anxiety on the Developing Brain

34. The brain is more plastic during adolescence than during adulthood. This means that adolescents are particularly vulnerable and at increased risk for the onset of mood and anxiety disorders, and, if untreated, that the onset of mood and anxiety symptoms can permanently alter the developmental trajectory of the brain into adulthood (Holder & Blaustein, 2014). Termed the "kindling effect", the concept here is that, as the efficiency of neural circuits is reinforced over time (i.e., "neurons that fire together wire together"), each depressive episode or

environmental stressor increases the risk for later depressive episodes. This effect may be amplified during adolescence because of the greater plasticity of the brain.

35. There are well-documented disparities in mental health outcomes in transgender youth that are caused by minority stress (for review, see White Hughto et al., 2015). This includes evidence that transgender people who live in areas with more accepting political climates show reduced biological stress markers and fewer mental health symptoms than transgender people who live in less accepting areas (DuBois & Juster, 2022). Others have shown an association between decreased social support and biological markers of stress in transgender adolescents (McQuillan et al., 2021). Given that transgender adolescents report high chronic stress and high rates of depression, anxiety, and suicidality, transgender adolescents are particularly vulnerable to the effects of stress on brain development, stress system regulation, and long-term mental health outcomes (DuBois et al., 2021; Potter et al., 2021; Randall et al., 2022).

36. In Dr. Levine's testimony, he quotes the Hippocratic Oath, "Above All Do No Harm". He makes this argument on the assumption that GnRHa treatment must necessarily cause harm because it is an intervention. This assumes that the psychosocial environment and biology of transgender youth is like that of cisgender youth. There is a great deal of evidence that this is not the case. Instead, in my

opinion not offering an intervention to transgender individuals that require treatment actually does harm.

37. In this case, puberty blockers have demonstrated efficacy in reducing symptoms of depression in transgender adolescents (de Vries et al., 2011), and therefore may in fact be neuroprotective to the cumulative effects of stress caused by gender dysphoria.

Conclusion

38. There is little to support the Defendants' designated experts' speculation about the negative effects of GnRHa treatment on the brain. In contrast, there is a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents. Furthermore, it is well-known that transgender adolescents face higher rates of psychosocial stress than their cisgender peers, and there is clear evidence for the negative effects of psychosocial stress and poor mental health on brain development. While the effects of GnRHa treatment on the brain are an important area for future research, this does not render such care experimental. To the contrary, this is treatment that has existed for decades and arguments that a purported lack of evidence is equivalent to known harm are spurious, particularly when there is a large literature indicating benefits of treatment and harm of withholding treatment.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22 day of March 2023.

E. Kale Edmiston, Ph.D.

Exhibit A

Curriculum Vitae

E. Kale Edmiston, PhD
Associate Professor
Department of Psychiatry
University of Massachusetts Chan Medical School
kale.edmiston@umassmed.edu

ACADEMIC APPOINTMENTS

Associate Professor of Psychiatry University of Massachusetts Chan Medical School	2022-present Worcester, MA
Assistant Professor of Psychiatry University of Pittsburgh School of Medicine	2019-2022 Pittsburgh, PA
Postdoctoral Scholar University of Pittsburgh Medical Center PI: Mary L. Phillips, MD, MD (CANTAB)	2016-2019 Pittsburgh, PA
Postdoctoral Fellow China Medical University PI: Fei Wang, MD, PhD	2016 Shenyang, China
Research Assistant Yale University School of Medicine PI: Hilary P. Blumberg, MD	2007-2010 New Haven, CT

EDUCATION

PhD, Neuroscience Vanderbilt University	2010-2015 Nashville, TN
Graduate Certificate Medicine, Health and Society Vanderbilt University	2015 Nashville, TN
BA, Cognitive Science Hampshire College	2005-2007 Amherst, MA

RESEARCH

CITATION METRICS (03/23):
Citations: 2087 H-Index: 25 i10 Index: 34

RESEARCH INTERESTS:
social and affective neuroscience, visual processing, anxiety disorders, multimodal MRI, neuromodulation

AWARDED GRANTS:
American Foundation for Suicide Prevention Award 2022

Title: *Real-time study of psychotherapy, suicide risk, and resilience in transgender and non-binary adults*
PI: Sarah Victor
Co-I: **E. Kale Edmiston**
Award amount: $90,000.00

K01 MH117290 Mentored Scientist Career Development Award 2019-2024
Title: *Feed forward visual system function in high trait anxiety*
PI: **E. Kale Edmiston**
Award amount: $868,978.00

Brain and Behavior Research Foundation Early Career Award 2019-2021
Title: *Neuromodulation of visual cortex BOLD in high trait anxiety*
PI: **E. Kale Edmiston**
Award amount: $69,401.00

The Opportunity Fund 2019
Title: *Trans Buddy PGH: Peer healthcare support program*
PI: Gerald Montano
Co-I: **E. Kale Edmiston**
Award amount: $15,000

Center for Interventional Psychiatry 2018
Title: *Neuromodulation of visual cortex and threat sensitivity in high anxiety*
PI: **E. Kale Edmiston**
Award amount: $9,900.00

Campaign for Southern Equality 2017
Title: *The Trans Buddy Program: Mental health advocacy for trans communities*
PI: **E. Kale Edmiston**
Award amount: $1,000.00

University of Pittsburgh Office of Diversity and Inclusion Mini-Grant 2017
Title: *Developing health promotion materials for the transgender community*
PI: **E. Kale Edmiston**
Award amount: $1,000.00

Trans Justice Funding Project 2017
Title: *The Trans Buddy Program: Peer advocacy solutions for mental health care access*
PI: **E. Kale Edmiston**
Award amount: $2,500.00

The Pollination Project 2016
Title: *The Trans Buddy Program: An innovative solution to transgender mental health disparity*
PI: **E. Kale Edmiston**
Award Amount: $1,500.00

Culture, Brain, and Development Grant 2006

Title: *Brain sex differences in mood disorders*
PI: **E. Kale Edmiston**
Award amount: $3,000.00

PEER-REVIEWED PUBLICATIONS (https://orcid.org/0000-0002-3548-6026):
2023:
48. Hoelscher EC, Victor SE, **Edmiston EK**. Gender minority resilience and suicidal ideation: a longitudinal and daily examination of transgender and non-binary adults. Behavior Therapist. (In Press).
47. Schroth-Erickson L, Levin R, Mak K, **Edmiston EK**. A review of the neurobiobehavioral literature of transgender identity. J Gay and Lesbian Mental Health. (In Press).
2022:
46. Coleman E, Radix AE, Bouman WP…**Edmiston EK**…Arcelus J. Standards of care for the health of transgender and gender diverse people, version 8. International Journal of Transgender Health. 2022; 23:1-258.
45. Juster RP, **Edmiston EK**. Refining research and representation of sexual and gender diversity in neuroscience. Biological Psychiatry: CNNI. 2022; 7(21):1251-7.
44. Colic L, Clark A, Sankar A, Rathi D, Goldman D, Kim JA, Villa LM, **Edmiston EK**, Lippard ETC, Mazure CM, Blumberg HP. Gender-related associations among childhood maltreatment on brain circuitry and clinical features of bipolar disorder. European Neuropsychopharmacology. 2022; 63:35-46.
43. **Edmiston EK**, Fournier JC, Chase HW, Aslam H, Lockovich J, Graur S, Bebko G, Bertocci M, Rozovsky R, Mak K, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortical activity during reward expectancy predicts mania risk up to one year post scan. J Affective Disorders. 2022; 319:325-8.
2021:
42. Bertocci MA, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman B, Greenberg T, Phillips ML. Reward circuitry-targeted cathodal transcranial direct current stimulation impacts reward circuitry and affect in bipolar disorder. Molecular Psychiatry. 2021; 26(8):4137-45.
2020:
41. Feng R, Womer FY, **Edmiston EK**, Chen Y, Wang Y, Chang M, Yin Z, Wei Y, Duan J, Ren S, Li C, Liu Z, Jiang X, Wei S, Li S, Zhang X, Nuo X, Tang Y, Wang F. Antipsychotic effects on cortical morphology in schizophrenia and bipolar disorders. Frontiers Neuroscience. 2020; 14:579139.
40. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S, Wang F. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2020; 10:923.
39. Wang Y, Wei Y, **Edmiston EK**, Womer FY, Zhang X, Duan J, Zhu Y, Zhang R, Zhang Y, Jiang X, Wei S, Liu Z, Zhang Y, Tang Y, Wang F. Altered structural connectivity and cytokines levels in schizophrenia and genetically high-risk individuals: associations with disease state and vulnerability. Schizophrenia Research. 2020; 223:158-165.
38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships

among impulsive sensation-seeking, reward circuitry activity, and risk for psychopathology: an fMRI replication and extension study. Biological Psychiatry: CNNI. 2020; 5(7):660-68.

37. Sha Z, Versace A, **Edmiston EK**, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler R, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Quirk G, Haber S, Phillips ML. Functional disruption in prefrontal-striatal network in obsessive compulsive disorder. Psychiatry Research: Neuroimaging. 2020; 300:111081.

36. **Edmiston EK,** Song Y, Chang M, Yin Z, Zhou Q, Zhou Y, Jiang X, Wei S, Xu K, Tang Y, Wang F. Hippocampal functional connectivity in patients with schizophrenia and unaffected family members. Frontiers in Psychiatry. 2020; 11:278.

35. Wei S, Womer F, **Edmiston EK**, Zhang R, Jiang X, Wu F, Kong L, Zhou Y, Tang Y. Structural alterations associated with suicide attempts in major depressive disorder and bipolar disorder: a diffusion tensor imaging study. Progress in Neuropsychopharmacology & Biological Psychiatry. 2020; 98.

34. Beach L, Eckstrand K, Ehrenfeld J, **Edmiston EK**, Ding J. A model for improving transgender healthcare quality. The Joint Commission Journal on Quality and Patient Safety. 2020; 46:37-43.

2019:

33. Sha Z*, **Edmiston EK***, Versace A, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler RS, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Buckner R, Quick G, Haber S, Phillips ML. Multimodal disruption of cerbello-thalamo-motor circuit in obsessive compulsive disorder. Biological Psychiatry: CNNI. 2019; 5(4):438-47. *co-first authors

32. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2019; 10:923.

30. Chang M, **Edmiston EK**, Womer F, Zhou Q, Shengnan W, Jiang X, Zhou Y, Ye Y, Huang H, Zui X, Xu K, Tang Y, Wang F. Spontaneous low-frequency fluctuations in the neural system for emotional perception in major psychiatric disorders: amplitude similarities and differences across frequency bands. Journal of Psychiatry and Neuroscience. 2019; 44:132-41.

29. Xia M, Womer FY, Chang M, Zhu Y, **Edmiston EK**, Jiang X, Wei S, Duan J, Xu K, Tang Y, He Y, Wang F. Shared and distinct functional architecture of brain networks across psychiatric disorders. Schizophr Bulletin. 2019; 47:450-63.

2018:

28. Li J, **Edmiston EK**, Tang Y, Fan G, Xu K, Wang F, Xu J. Shared facial emotion processing in medication-naive major depressive disorder and healthy individuals: detection by sICA. BMC Psychiatry, 2018; 18:96.

27. Chang M, Womer FY, **Edmiston EK**, Bai C, Zhou Q, Jiang X, Wei S, Wei Y, Ye Y, Huang H, He Y, Xu K, Tang Y, Wang F. Neurobiological commonalities among three major psychiatric diagnostic categories: a structural MRI study. Schizophrenia Bulletin. 2018; 44:65-74.

2017:

26. Wang N, **Edmiston EK**, Luo X, Yang H, Chang M, Wang F, Fan G. Comparing amplitude of low-frequency fluctuations in multiple system atrophy and idiopathic Parkinson's disease. Psychiatry Research Neuroimaging, 2017; 269:73-81.

25. Jiang X, **Edmiston EK**, Zhou Q, Xu K, Zhou Y, Wu F, Kong L, Wei S, Zhou Y, Chang M, Geng H, Wang D, Wang Y, Cui W, Tang Y, Wang F. Alteration of a cortico-striatal-limbic neural system in major depressive disorder and bipolar disorder. Journal of Affective Disorders, 2017; 221:297-303.

24. Corbett BA, Blain S, **Edmiston EK**. The role of context in psychosocial stress among adolescents with Autism Spectrum Disorder: piloting a semi-structured, video game-based paradigm. Journal of Intellectual & Developmental Disability. 2017; 43:20-8.

23. **Edmiston EK**, Muscatello RA, Corbett BA. Altered pre-ejection period response to social evaluative threat in adolescents with autism spectrum disorder. Research in Autism Spectrum Disorders. 2017; 36:57-65.

2016:

22. **Edmiston EK**, Donald CA, Sattler AR, Peebles JK, Ehrenfeld JM, Eckstrand KL. Opportunities and gaps in transgender primary healthcare: a systematic review. Transgender Health. 2016; 1(1):216-30.

21. **Edmiston EK**, Jones RM, Corbett BA. Physiological response to social evaluative threat in adolescents with autism spectrum disorder. Journal of Autism Developmental Disorders. 2016; 46(9):2992-3005.

20. **Edmiston EK**, Blain S, Corbett BA. Salivary cortisol and behavioral response to social evaluative threat in adolescents with autism spectrum disorder. Autism Research. 2016; Epub ahead of print.

2015:

19. Tang Y, Chen K, Zhou Y, Wang Y, Driesen N, **Edmiston EK**, Chen X, Jiang X, Kong L, Zhou Q, Li H, Wu F, Xu K, Wang Z, Tang Y, Wang F. Neural activity changes in unaffected children of patients with schizophrenia: a resting-state fMRI study. Schizophrenia Research. 2015; 168(1-2):360-5.

18. **Edmiston EK**, Merkle K, Corbett BA. Neural and cortisol responses during play with human and computer partners in children with autism. Social Cognitive Affective Neuroscience. 2015; 10(8):1074-83.

2014:

17. Corbett BA, Newsom C, Key AP, Qualls L, **Edmiston EK**. Examining the relationship between face processing and social interaction behavior in children with and without autism spectrum disorder. J Neurodevelopmental Disorders, 2014; 6(1):35.

16. Li J*, **Edmiston EK**,* Chen B, Tang Y, Ouyang X, Jiang Y, Fan G, Ren L, Liu J, Zhou Y, Jiang W, Liu Z, Xu K, Wang F. A comparative diffusion tensor imaging study of corpus callosum subregion integrity in bipolar disorder and schizophrenia. Psychiatry Res. 2014; 221(1):58-62.*co-first authors

2013:

15. **Edmiston EK***, McHugo M*, Dukic MS, Smith SD, Abou-Khalil B, Zald DH. Enhanced visual cortical activation for emotional stimuli is preserved in patients with unilateral amygdala resection. J Neuroscience, 2013; 33(27):11023-11031. *co-first authors

14. Liu H, **Edmiston EK**, Fan G, Ku X, Zhao B, Shang X, Wang F. Altered resting-state functional connectivity of the dentate nucleus in Parkinson's disease. Psychiatry Research: Neuroimaging. 2013; 211(1):64-71.

13. **Edmiston EK**, Blackford JU. Childhood maltreatment and response to novel face stimuli presented during functional magnetic resonance imaging in adults. Psychiatry Research: Neuroimaging. 2013; 212(1):36-42.

2012:

12. Fengrong O, Kai L, Qian G, Dan L, Jinghai L, Liwen H, Xian W, **Edmiston EK**; Yang L. An urban neo-poverty population-based quality of life and related social characteristics investigation from northeast china. PLoS One. 2012; 7(6):e38861.

11. Chepenik LG, Wang F, Spencer L, Spann MN, Kalmar JH, Womer F, **Edmiston EK**, Pittman B, Blumberg HP. Structure-function associations in hippocampus in bipolar disorder. Biological Psychiatry. 2012; 90(1):18-22.

2011:

10. Wang F, Kalmar JH, Womer FY, **Edmiston EK**, Chepenik LG, Chen R, Spencer L, Blumberg HP. Olfactocentric paralimbic cortex morphology in adolescents with bipolar disorder. Brain. 2011; 134(7):2005-12.

9. **Edmiston E**, Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. Archives of Pediatric and Adolescent Med. 2011; 165(12):1069-77.

8. **Edmiston E**, Wang F, Kalmar JH, Womer FY, Chepenik LG, Pittman B, Gueorguieva R, Hur E, Spencer L, Staib LH, Constable RT, Fulbright RK, Papademetris X, Blumberg HP. Lateral ventricle volume and psychotic features in adolescents and adults with bipolar disorder. Psychiatry Research. 2011; 194(3):400-2.

2009:

7. Womer FY, Wang F, Chepenik LG, Kalmar JH, Spencer L, **Edmiston E**, Constable RT, Papademetris X, Blumberg HP. Sexually dimorphic features of vermis morphology in bipolar disorder. Bipolar Disord 2009; 11(7):753-8.

6. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Papademetris X, Staib, LH. Improving the reliability of shape comparison by perturbation. IEEE Biomedical Imaging 2009; 1:686-9.

5. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Staib LH and Papademetris X. Shape comparison using perturbing shape registration. IEEE Computer Vision Pattern Recognition 2009;683-90.

4. Wang F, Kalmar JH, He Y, Jackowski M, Chepenik LG, **Edmiston E**, Tie K, Gong G, Shah MP, Jones M, Uderman J, Constable RT, Blumberg HP. Functional and structural connectivity between the perigenual anterior cingulate and amygdala in bipolar disorder. Biological Psychiatry 2009; 66(5):516-21.

3. Kalmar JH, Wang F, Spencer L, **Edmiston E**, Lacadie CM, Martin A, Constable RT, Duncan JS, Staib LH, Papademetris X, Blumberg HP. Preliminary evidence for progressive prefrontal abnormalities in adolescents and young adults with bipolar disorder. J Int Neuropsychol Soc. 2009; 15(3):476-81.

2008:

2. Blumberg HP, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Duman RS, Gelernter J. Influence of vascular endothelial growth factor variation on human hippocampus morphology. Biological Psychiatry 2008; 64(10):901-3.

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Bhagwagar Z, Spencer L, Pittman B, Jackowski M, Papademetris X, Constable RT, Blumberg HP. Abnormal corpus callosum

integrity in bipolar disorder: A diffusion tensor imaging study. Biological Psychiatry 2008; 64(8):730-3.

MANUSCRIPTS (IN PROGRESS):

Ravindranath O, Perica MI, Parr AC, Pjha A, McKeon SD, Montano G, Ullendorf N, Luna B, **Edmiston EK**. Adolescent neurocognitive development and decision-making regarding gender affirming care. (Submitted).

Soehner AM, **Edmiston EK**, Wallace M, Chase HW, Lockovich J, Aslam H, Stiffler R, Graur S, Skeba A, Bebko G, Benjamin OE, Wang Y, Phillips ML. Neurobehavioral reward and sleep-circadian phenotypes predict present and next-year mania/hypomania risk. (Submitted).

Sequiera S, Tervo-Clemmens B, Carmel T, **Edmiston EK.** Towards a biopsychosocial model for neurodevelopment in transgender and gender diverse adolescents: understanding risk and resilience for mood disorders. (Submitted).

POSTERS, ABSTRACTS, AND CONFERENCE PROCEEDINGS:

53. Victor SE, **Edmiston EK**. Ecological momentary assessment of gender-relevant versus other interpersonal stressors predicting self-injurious thoughts and behaviors among transgender and non-binary adults. *Association for Behavioral and Cognitive Therapy Annual Convention. Submitted.*

52. **Edmiston EK**, Fournier JC, Chase HW, Phillips ML. Ventral visual stream functional coupling during implicit emotional face perception is associated with internalizing symptoms: a double dissociation by face valence at baseline and six months post-scan. *American College of Neuropsychopharmacology.* 2023.

51. Victor SE, Hoelscher E, Sandel D, Trieu T, **Edmiston EK.** Interpersonal and intrapersonal gender minority stressors as contribution to suicidal ideation among transgender and non-binary adults. *Suicide Research Symposium.* 2022.

50. Aslam MA, Mak K, **Edmiston EK.** Piloting transcranial direct current stimulation to reduce threat sensitivity in high trait anxiety. *University of Pittsburgh Department of Psychology Undergraduate Directed Experiences in Research Poster Day*. 2022.

49. **Edmiston EK** & Strakowski S. Understanding diagnosis and assessment disparities in transgender populations. *Society of Biological Psychiatry Annual Meeting.* 2022. Discussant, Lunchtime “Fireside Chat” Series.

48. Bertocci M, Afriyie-Agyemang Y, Rosovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Network interference during emotion regulation in distressed adults consistently predicts depression symptoms. *Society of Biological Psychiatry Annual Meeting.* 2022.

47. Afriyie-Agyemang Y, Bertocci M, Rozovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Overcompensation of the central executive network during working memory may be a neural marker for youth at risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

46. Schumer MC, Bertocci MA, Bebko G, Stiffler RS, Lockovich JC, Aslam HA, Graur S, **Edmiston EK**, Chase HW, Johnson SL, Phillips ML. Trait urgency mediates associations between neural emotion-processing markers of emotion-triggered impulsivity and mania in young adults at-risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

45. Young J, Roepke T, Anacker C, Ehrensaft D, **Edmiston EK**, Guthman EM, Eshel N, Marrocco J. Challenges and opportunities for translational research and clinical strategies within the LGBTQIA2S+ community. *American College of Neuropsychopharmacology Annual Meeting.* 2021. Discussant, Study Group.

44. Phillips ML, Bertocci M, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman BA. Targeted non-invasive neuromodulation impacts reward expectancy-related reward circuitry activity and affect in bipolar disorder and healthy adults. *Society of Biological Psychiatry Annual Meeting.* 2021.

43. **Edmiston EK,** Fournier JC, Rozovsky R, Chase HW, Bertocci MA, Aslam HA, Lockovich J, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortex structure and reward-expectancy related activity predict manic symptom changes one year later. *American College of Neuropsychopharmacology Annual Meeting.* 2021.

42. **Edmiston EK**, Phillips ML, Mak K, Chase HW, Fournier JC. Visual cortex coupling and childhood maltreatment: associations with major depression and a compensatory mechanism. *Society of Biological Psychiatry Annual Meeting.* 2021.

41. Marrocco J, **Edmiston EK**, Anacker C, Bangasser D. The study of sex differences and gender bias, and trans inclusive research practices. *American College of Neuropsychopharmacology Annual Meeting.* 2020. Panelist, Networking Session.

40. Chase HW, Fournier JC, Bertocci MA, **Edmiston EK**, Lockovich JC, Aslam H, Stiffler RS, Graur S, Bebko G, Phillips ML. Decision-making variability in mood disorders: new insights for a replication attempt. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

39. **Edmiston EK,** Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. A double dissociation between anxiety and depression symptom improvement and fusiform coupling and positive and negative emotional face processing. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships among impulsive sensation-seeking, reward circuitry activity, and predisposition to bipolar disorder: an fMRI replication and extension study. *American College of Neuropsychopharmacology Annual Meeting. 2019.*

37. Paglisotti T, Montano G, Simpson A, **Edmiston EK**. Preliminary implementation of Trans Buddy PGH: establishing trust among transgender patients and healthcare providers. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day.* 2019.

36. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Phillips ML. Left ventrolateral prefrontal cortical BOLD signal during reward expectancy and impulsive sensation seeking: a replication study. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day. 2019.*

35. Chase HW, **Edmiston EK**, Bertocci M, Fournier JC, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Forbes EE, Phillips ML. Similar neural representation of appetitive and loss avoidance prediction errors across distressed and healthy individuals. *Society of Biological Psychiatry Annual Meeting.* 2019.

34. **Edmiston EK**, Simpson A. Progress report: Quality improvement programming for transgender mental health. Symposium. *TransPride PGH Professional Conference.* 2018.

33. Schroth-Erickson L, Levin R, **Edmiston EK**. Talking to your patients about the biological basis of transgender identity. *Philadelphia Trans Wellness Conference Professional Track. 2018*.

32. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Fusiform gyrus-salience network coupling during emotion processing predicts anxiety and depression symptom change. *University of Pittsburgh Medical Center Department of Psychiatry 18th Annual Research Day*. 2018.

31. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Salience network BOLD response to emotional faces predicts anxiety and depression symptom outcomes. *Society of Biological Psychiatry Annual Meeting.* 2018.

30. Chase HW, Qiu H, Kerestes R, Shah N, Alkhar H, **Edmiston EK**, Soehner A, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Pan L, Eickhoff SB, Phillips ML. Implication of the visual cortex in resting state fMRI studies of mood and anxiety disorders may relate to the propensity for within-scanner sleep. *Society of Biological Psychiatry Annual Meeting.* 2018.

29. Ding J, Ehrenfeld J, Raynor L, **Edmiston EK**, Eckstrand K, Beach L. A proposed systems level quality improvement model for transgender healthcare delivery. *The National Transgender Health Summit*. 2017.

28. **Edmiston EK.** Setting the agenda for transgender neuroimaging: a critical review and future directions. Symposium. *The National Transgender Health Summit.* 2017.

27. **Edmiston EK,** Fournier J, Greenberg T, Bertocci M, Stiffler R, Aslam H, Lockovich J, Phillips ML. Trait anxiety predicts visual system response to emotional faces. *Developmental Affective Neuroscience Symposium*. 2017.

26. **Edmiston EK.** The Trans Buddy Program: an innovative intervention for increasing health care utilization. Symposium. *TransPride PGH Professional Conference.* 2017.

25. Buchanan K, Richmond M, Sattler AR, **Edmiston EK**. Red state solutions for transgender health care access: provision in low resource areas. Symposium. *Philadelphia Transgender Health Conference.* 2017.

24. **Edmiston EK,** Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Predicting quality of life in distressed youth: Cortico-thalamic BOLD signal and reward processing. *University of Pittsburgh Medical Center Department of Psychiatry 17th Annual Research Day*. 2017.

23. **Edmiston EK**, Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Cortico-thalamic BOLD signal during reward processing predicts quality of life at follow up in distressed young adults. *Society of Biological Psychiatry Annual Meeting.* 2017.

22. Eckstrand KL, Mitchell L, **Edmiston EK.** The Trans Buddy Program: Transgender Leadership and peer advocacy for reducing health disparities. *University of Pittsburgh Health Sciences Health Disparity Poster Competition.* 2017.

21. **Edmiston EK.** Reframing the search for transgender neuroimaging biomarkers. *New Materialisms Annual Meeting* Warsaw, Poland. 2016.

20. Corbett BA, Muscatello R, **Edmiston EK**, Muse I. Examining the Diurnal Profile of Children and Adolescents with Autism Spectrum Disorder (ASD) and Typical Development between 8 to 17 years of age. *International Society for Psychoneuroendocrinology.* 2016.

19. Corbett BA, Muse I, **Edmiston EK**, Muscatello R. Diurnal and Stress Hormonal Profiles of Testosterone and Cortisol in Adolescents with Autism Spectrum Disorder (ASD) and Typical Development (TD). *International Society for Psychoneuroendocrinology.* 2016.

18. **Edmiston EK**. Psychophysiological characterization of adolescents with Autism Spectrum Disorder. Presentation, *Chinese Psychiatric Association Annual Meeting.* 2016.

17. **Edmiston EK**, Jones RM, Blain S, Corbett BA. Neuroendocrine and physiological responsivity during social stress in adolescents with and without autism spectrum disorder. *Vanderbilt Kennedy Center Science Day.* 2015.

16. **Edmiston EK**, Valencia B, Corbett BA. Autonomic nervous system function in response to social judgment in adolescents with and without autism spectrum disorder. *International Meeting for Autism Research.* 2015.

15. Corbett BA, Newsom C, Key S, Qualls L, **Edmiston EK**. A randomized wait-list control trial of a peer-mediated, theatre-based intervention to improve social ability in children with autism spectrum disorder. *International Meeting for Autism Research.* 2015.

14. Singer B, Eckstrand K, Ehrenfeld J, **Edmiston EK**. Transgender health and advocacy in academic medicine: an empowerment model. Workshop; *Gay and Lesbian Medical Association Annual Meeting.* 2014.

13. **Edmiston EK**, Corbett BA. Behavioral and endocrine alterations in adolescents with autism spectrum disorder. Selected presentation; *Vanderbilt Kennedy Center Science Day*. 2014.

12. **Edmiston EK.** Effects of a neurobiological explanation of sexual orientation on student attitudes towards lesbian, gay and transgender people. *Society for Neuroscience.* 2013.

11. Corbett BA, **Edmiston EK**, Zald DH. Neural and physiological responses during play with human and computer partners in children with autism. *Society for Neuroscience.* 2013.

10. **Edmiston EK,** McHugo M, Dukic MS, Eggers E, Zald DH. Visuocortical BOLD response to emotional stimuli in the absence of a functional amygdala. *Society for Neuroscience.* 2012.

9. **Edmiston EK.** Pelvic and chest exams in transgender men. Workshop; *Philadelphia Trans Health.* 2011.

8. **Edmiston EK**, Blackford JU. Childhood maltreatment affects face processing. *Biology of Prosocial Behavior.* 2011.

7. **Edmiston E,** Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. *Vanderbilt Kennedy Center Science Day.* 2011.

6. Wang F, **Edmiston E**, Hur E, Kalmar JH, Womer FY, Chepenik LG, Blumberg HP. An Altered Developmental Trajectory of Frontotemporal Connectivity in Bipolar Disorder. *Biological Psychiatry* 2010; 67 (Supplement 9): 107.

5. Wang F, Chepenik LG, Shah MP, Kalmar JH**, Edmiston E**, Spencer L, Duman R, Gelernter J, Blumberg HP. Genes Regulating Neurotrophic Factors that Influence the Corticolimbic Connectivity in Mood Disorders: Treatment Implications. *Biological Psychiatry* 2009; 65 (Supplement 1): 174.

4. Kalmar JH, Wang F, Chepenik LG, Shah MP, McDonough A, **Edmiston E**, Blumberg HP. Amygdala functioning during emotional processing in adolescents with bipolar disorder or ADHD. *Biological Psychiatry* 2008; 63 (Supplement 1): 184.

3. Womer F, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Spencer L, Constable RT, Papademetris X, Blumberg HP. Structural abnormalities of the cerebellar vermis in bipolar disorder. *Biological Psychiatry* 2008; 63 (Supplement 1): 141.

2. Wang F, Kalmar JK, Womer F, He Y, Chepenik L, **Edmiston E**, Blumberg HP. Abnormal morphological correlations within a cortico-limbic neural system in adolescents with bipolar disorder. *American Academy of Childhood and Adolescent Psychiatry.*

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Tie K, Spencer L, Jackowski M, Papademetris X, Constable RT & Blumberg HP. Abnormal callosal integrity in bipolar disorder determined from diffusion tensor imaging. *Biological Psychiatry* 2008; 63 (Supplement 1): 43.

BOOK CHAPTERS:

Edmiston EK, Bertocci M, Phillips ML. Neuroimaging and Circuit Mechanisms of Bipolar Disorder. In *Neurobiology of Mental Illness*. 6th Ed. Eds: Eric Nestler & Alexander Charney. Oxford University Press. (In Press).

Tomson A & **Edmiston EK**. Understanding the basis of gender identity development: biological and psychosocial models. In *Trans Bodies, Trans Selves*. 2nd Ed. Ed: Sand Chang. Oxford University Press. 2022.

Edmiston EK. Community-led peer advocacy for transgender health care access in the southeastern United States: The Trans Buddy Program. In *Healthcare in Motion: Mobility forms in health service delivery and accessibility.* Berghahn Books. 2017.

Robles RJ & **Edmiston EK**. Community Responses to Trauma. In *Trauma, Resilience, and Health Promotion for LGBT Patients.* Springer Press. 2017.

Edmiston EK & Mitchell L. Trans Buddy: Innovation Profile. In *The Remedy: Queer and Trans Voices on Health and Health Care.** Arsenal Press. 2016. *Lambda Literary Award Winner, Non-Fiction Anthology

Eckstrand KL, **Edmiston EK**, Potter J. Obstetric and Gynecologic Care to LGBT Individuals. In *Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care*. Springer Press. 2015.

ADDITIONAL SCHOLARSHIP:

Edmiston EK. Letter to the Editor: The legacy of transgender surgery access is complex. *Annals of Plastic Surgery.* 2019.

Edmiston EK. Invited Commentary: Transgender health research must serve transgender people. *BJOG.* 2018.

Edmiston EK. Feminist bioethics and intersex medical interventions: A review of *Making Sense of Intersex*. *Catalyst: Feminism, Theory, Technoscience*. 2016; 2(1).

Jann JT, **Edmiston EK**, Ehrenfeld J. Letter to the Editor: Important considerations for addressing LGBT health care competency. *American J of Public Health* 2015; e1.

HONORS, AWARDS, AND FELLOWSHIPS:

American College of Neuropsychopharmacology Travel Award	2021
Society of Biological Psychiatry Early Career Investigator Travel Award	2019
NYC tDCS Fellowship City University of New York, New York, NY	2018
Trainee, T32 MH018951 Child and Adolescent Mental Health Research University of PIttsburgh, Pittsburgh, PA	2018-2019
Research Day Department of Psychiatry Outstanding Poster Award	2018
PLOS One Travel Award	2017
Fellow, Winter School in the Neuroscience of Consciousness Canadian Institute For Advanced Research	2017
Trainee, T32 MH16804 Transformative Discovery in Psychiatry	2016-2018

University of Pittsburgh, Pittsburgh, PA

WPATH Outstanding Student Award 2015
International honor for contributions to transgender health research

The Trans 100 2015
National honor for excellence in the transgender community

Point Foundation Scholar 2014-2015
One of 20 selected nationally for program that funds education of LGBT students

Vanderbilt Brain Institute Student Leadership and Service Award 2014

Graduate Student Travel Grant, Vanderbilt University 2013

Fellow, Summer Program in Neuroscience Ethics and Success 2013
Marine Biology Laboratory, Woods Hole, MA

Clinical Neuroscience Scholar for Translational Research 2012-2015
Dan Marino Foundation

Neurobiology of Social Behavior Travel Award 2011
Emory University, Atlanta, GA

President's Scholarship 2003-2005
Case Western Reserve University, Cleveland, OH

TEACHING AND MENTORSHIP

SELECTED TALKS:

Invited Speaker: *Neuroscience in Service of Our Community:* 2023
How Research Rooted in Empathy and Humility Makes Us Better Scientists
Neuroscience Diversity Seminar
University of Maryland School of Medicine

Invited Speaker: *Visual Cortex Distinguishes Anxiety and Depression* 2023
Fournier Group Lab Meeting
The Ohio State Medical School

Presenter: *Assessing Visual Perception in Depression and Anxiety* 2023
Department of Psychiatry Faculty Meeting
UMass Chan Medical School

Invited Speaker: *Neuroimaging Studies of Transgender People* 2022
The Friedman Brain Institute and oSTEM
The Icahn School of Medicine at Mount Sinai

Invited Speaker: *Impulsivity and Reward-related Activity:* 2022
A Stable Marker for Bipolar Disorder risk
STEP Seminar
Truman State University

Invited Speaker: *Assessing Relationships Among impulsivity, Reward Circuitry, and Risk for Psychopathology* Magnetic Resonance Research Center Forum Yale School of Medicine	2019
Presenter: *Fusiform Gyrus Alterations During Emotion Processing: Predicting the Future in Anxiety Disorders* Center for the Neural Basis of Cognition Seminar University of Pittsburgh and Carnegie Mellon University	2018
Panelist: *Setting the Research Agenda in Transgender Health* 27th Annual Issues in Medical Ethics Conference The Icahn School of Medicine at Mount Sinai	2017
Panelist: *Neuroimaging in Child and Adolescent Mental Disorders* Chinese Society of Psychiatry 14th Annual Meeting	2016
The Trans Buddy Program: An Innovative Model for Healthcare Access Medicine Health and Society Colloquium Series Vanderbilt University	2015
Panel Organizer: *Intra-community Stigma in LGBT Populations* 615Thrive Conference Tennessee Department of Health	2015
Transgender Health: Provider Considerations Department of Hearing and Speech Sciences Grand Rounds Vanderbilt University	2014
Sexual and Reproductive Health in LGBT Populations Sarah Fogel, PhD Department of Nurse Midwifery Vanderbilt University School of Nursing	2014, 2015
Panelist: *(Im)Possible Politics: Intersectional Trans Organizing* Ben Singer, PhD; Dean Spade, JD; Lisa Guenther PhD Department of Women and Gender Studies Vanderbilt University	2014
Plenary Speaker: *Creating Change for LGBTI Health* Gay and Lesbian Medical Association Annual Meeting	2013
Invited Speaker: *Threat Detection, Visual Cortex, and Anxiety* Department of Radiology Beijing Normal University	2013
Invited Speaker: *Threat Detection, Visual Cortex, and Anxiety* Department of Psychiatry China Medical University	2013

MEDICAL STUDENT TEACHING EXPERIENCE:

Guest Lecturer: *Neuromodulatory Interventions in Mood Disorders* 2022
Neuroscience Area of Concentration Seminar Series
University of Pittsburgh School of Medicine

Guest Lecturer: *Building Trust with your Transgender Patients* 2021,2022
Texas Christian University School of Medicine

Instructor of Record: *Introduction to Scientific Writing* 2016
China Medical University

Guest Lecturer: *Clinical and Biobehavioral Features of Autism* 2016
Clinical Medicine 400
China Medical University

Guest Lecturer: *Building an Inclusive Practice for LGB and T Patients* 2015
First Year Seminar
Meharry Medical College

Guest Lecturer: *Community Models for Improving Trans Healthcare* 2015
Intercession Course
Meharry Medical College

Guest Lecturer: *Providing Excellent Care for LGBT People* 2015
Capstone Series
Meharry Medical College

GRADUATE AND UNDERGRADUATE TEACHING EXPERIENCE:

Guest Lecturer: *Neuromodulation interventions for threat sensitivity* 2022
Biomedical Sciences First Year Seminar
Graduate School of Biomedical Sciences
UMass Chan Medical School

Guest Lecturer: *Impulsivity and reward-related activity: Predicting mania* 2021
Undergraduate Research Methods
Department of Psychology
University of California San Diego

Guest Lecturer: *Transgender people and neuroimaging: a critical review* 2021
Department of Psychology
Mount Holyoke College

Instructor of Record: PSY0205 Psychopathology 2021
Department of Psychology
University of Pittsburgh

Guest Lecturer: *Transgender People and Healthcare Systems* 2015
MHS 2110: American Medicine and the World

Laura Stark, PhD, Vanderbilt University

Guest Lecturer: *Transgender People and Healthcare Systems* 2015
MHS 3890: Documenting the Body
Odie Lindsey, PhD, Vanderbilt University

Guest Lecturer: *Introduction to Social Neuroscience* 2014
PSY3609: Educational Cognitive Neuroscience
Sasha Key, PhD, Vanderbilt University

Guest Lecturer: *Imagining Transgender Bodies in Healthcare* 2013
WGS 290: Theories of the Body
Aimi Hamraie, PhD, Vanderbilt University

Introduction to Cognitive Neuroscience 2013-2014
Vanderbilt Neuroscience Graduate Program Boot Camp

The Center for Teaching, Vanderbilt University 2013
Scholarship of Teaching and Learning Certificate

Teaching Assistant: NSC201 Introduction to Neuroscience 2011
Department of Neuroscience, Vanderbilt University

TRAINEE MENTORSHIP, CERTIFICATION, AND SUPERVISION:

Culturally Aware Mentorship Workshop 2022
University of Wisconsin Madison School of Medicine

Tiffany Nhan (post bac lab assistant) 2022-present

M. Ali Aslam (undergraduate lab assistant) 2022

Paloma Rueda (undergraduate lab assistant) 2020-2021

Shelby Gardner (undergraduate lab assistant) 2020

Kristie Mak (undergraduate lab assistant) 2019-2020

Taylor Pagliosotti, BA (graduate student, Department of Public Health) 2018-2019

Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips) 2019

Alicyn Simpson, BA (research assistant, Adolescent Medicine) 2018-2019

Hana Choi, BA (intern, The Trans Buddy Program) 2016

William Horn, BA (intern, The Trans Buddy Program) 2015

RJ Robles, BA (student worker, Program for LGBTI Health) 2015-2016

Keanan Gottlieb, BA (summer intern, The Trans Buddy Program) 2014

Cameron Donald, BA (summer intern, Program for LGBTI Health) 2014

Jamieson Jann, BA (summer intern, Program for LGBTI Health) 2014

SERVICE

CURRENT MEMBERSHIPS:
Society of Biological Psychiatry

DEPARTMENTAL, INSTITUTIONAL, AND DISCIPLINARY SERVICE:

Editorial Board, *Journal of Mood and Anxiety Disorders* 2023-present

Member, Grand Rounds Committee 2023-present
Department of Psychiatry, UMass Chan Medical School

Interviewer, Graduate School of Biomedical Sciences 2023-present
UMass Chan Medical School

Co-Director, NeuroNexus Institute 2022-present
UMass Chan Medical School

Co-chair, Diversity, Equity and Inclusion Committee 2021-present
Society of Biological Psychiatry

Member, LGBTQIA+ Task Force 2021-present
American College of Neuropsychopharmacology

Editorial Board, *Bulletin of Applied Transgender Studies* 2021-present

Grant Reviewer, Lesbian Health Fund, GLMA 2021

Member, Diversity, Equity, and Inclusion Committee 2019-2021
Department of Psychiatry University of Pittsburgh School of Medicine

Chapter Author, Assessment of Adults with Gender Dysphoria 2018-2022
WPATH Standards of Care 8 Committee

Member, Diversity and Inclusion Committee 2018-2021
Society of Biological Psychiatry

Ad Hoc Member, Diversity and Inclusion Task Force 2020-2021
American College of Neuropsychopharmacology

Member, Cross-Network Transgender Working Group, 2017-2019
NIH Office of HIV/AIDS Network Coordination

Co-Founder, Trans Buddy Pittsburgh 2016-2018

Student Representative, Vanderbilt Brain Institute Diversity Committee 2015-2016

Founding Director, The Trans Buddy Program Nashville 2014-2016

Co-Director, Vanderbilt School of Medicine Program for LGBTI Health 2014-2015

Assoc. Director, Vanderbilt School of Medicine Program for LGBTI Health 2013-2014

Associate Editor, *Vanderbilt Reviews Neuroscience*	2013-2014
President, Vanderbilt Neuroscience Student Organization	2013-2014
Member, Vanderbilt Neuroscience Organization Academic Committee	2012-2013
Board Member, Vanderbilt School of Medicine Program for LGBTI Health	2012-2013
Affiliate, Vanderbilt Kennedy Center	2011-2016

AD HOC PEER REVIEW:
Acta Psychologica; American Journal of Psychiatry; American Journal of Sexuality Education; Annals of Internal Medicine; Biological Psychiatry: Cognitive Neuroscience Neuroimaging; BJOG: An International Journal of Obstetrics and Gynaecology; Bipolar Disorder; Brain and Behavior; Child Abuse & Neglect; Development and Psychopathology; Developmental Cognitive Neuroscience; Frontiers in Neuroscience; Frontiers in Sociology; Human Brain Mapping; Journal of Affective Disorders; Journal of Autism and Developmental Disorders; Journal of Homosexuality; Journal of Medical Systems; Journal of Neuroscience Research; Journal of Psychiatry, Depression, and Anxiety; LGBT Health; Molecular Autism; NeuroImage; Neuropsychologia; Neuropsychopharmacology; Neuroscience Letters; Psychiatry Research: Neuroimaging; PLOS One; Psychological Medicine; Psychology of Violence; Psychoneuroendocrinology; Scientific Reports; Schizophrenia Research; Transgender Health

REFERENCES

Mary L. Phillips, MD, MD (CANTAB), Pittsburgh Foundation-Emmerling Endowed Chair in Psychotic Disorders, Professor, Department of Psychiatry, University of Pittsburgh School of Medicine. email: phillipsml@upmc.edu

Jay C. Fournier, PhD, Associate Professor, Department of Psychiatry & Behavioral Health, The Ohio State University. email: jay.fournier@osumc.edu

Hilary P. Blumberg, MD, John and Hope Furth Professor of Psychiatric Neuroscience, Professor Departments of Psychiatry and Radiology and Biomedical Imaging, Yale School of Medicine. email: hilary.blumberg@yale.edu

Exhibit B

Bibliography

BIBLIOGRAPHY

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Beking, T., Burke, S. M., Geuze, R. H., Staphorsius, A. S., Bakker, J., Groothuis, A. G. G., & Kreukels, B. P. C. (2020). Testosterone effects on functional amygdala lateralization: A study in adolescent transgender boys and cisgender boys and girls. *Psychoneuroendocrinology*, *111*, 104461. https://doi.org/10.1016/j.psyneuen.2019.104461

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Doc. 120-36

August Dekker

vs.

Jason Weida

CONFIDENTIAL - ATTORNEY'S EYES ONLY

Deposition of:

E. Kale Edmiston, Ph.D

March 23, 2023

Vol 1

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.
_____/

VIDEO-RECORDED DEPOSITION OF E. KALE EDMISTON, Ph.D.

Thursday, March 23, 2023
10:07 a.m. - 11:43 a.m.

VIA ZOOM

Stenographically Reported By:
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ALSO PRESENT:
Zack Bennington, paralegal
Randy Wright, videographer

INDEX OF PROCEEDINGS

Thereupon,
the following proceedings began at 10:07 a.m.:

* * *

THE VIDEOGRAPHER: We are now on the record. The time is 10:07 a.m. This is the video-recorded deposition of Dr. Kale Edmiston in the matter of August Dekker et al. versus Jason Weida, et al.

This deposition is being held remotely via Zoom meetings on March 23rd, 2023. The videographer is Randy Wright, and the stenographer is Barbie Gallo, both in association with Lexitas.

Will counsel please announce their appearance for the record.

MR. BEATO: Good morning. This is Michael Beato on behalf of the defense.

MS. RIVAUX: Good morning. This is Shani Rivaux with Pillsbury, Winthrop, Shaw, Pittman on behalf of the plaintiffs, and with me is Gary Shaw.

MR. GONZALEZ: This is Omar Gonzalez on behalf of the plaintiffs. I'm with Lamda Legal.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

THE STENOGRAPHER: Do we need an appearance from Mr. Bennington?

If you would, Doctor --

MR. BENNINGTON: I'm --

THE STENOGRAPHER: I'm sorry.

MR. BENNINGTON: That's okay.

Good morning. I'm a paralegal appearing here from Holtzman Vogel.

THE STENOGRAPHER: Dr. Edmiston, do you consent to my administering the oath to you remotely this morning since we are not all in person?

THE WITNESS: Yes.

THE STENOGRAPHER: If you would raise your right hand, I'll swear you in. Do you swear the testimony you're about to give in this matter will be the truth, the whole truth and nothing but the truth so help you God.

THE WITNESS: Yes.

THE STENOGRAPHER: Thank you.

THEREUPON,
E. KALE EDMISTON, Ph.D.,
Being by me first duly sworn to tell the whole truth, as hereinafter certified, testified as follows:

DIRECT EXAMINATION

BY MR. BEATO:

Q. All right. Perfect.

Good morning, Doctor. Again, my name is Michael Beato, and I represent the defendants in this case. Before we begin, let me ask you, have you ever been deposed before?

A. No.

Q. Okay. So let me go over some ground rules. So, number one, for the benefit of the court reporter when answering a question, please verbally state "yes" or "no" if the question so desires instead of nodding "yes" or "no."

A. (Nodding head).

Q. Also, a deposition is not an endurance contest. If you need a break at any time, please let me know, and I think we can accommodate that.

Moreover, for the benefit of the court reporter, we can endeavor to limit crosstalk, so I will not speak when you're speaking and vice versa. And if you don't understand any of my questions, please let me know. I'm more than happy to clarify or restate the question.

With that said, let me ask you some preliminary questions. Are there any notes or

documents in front of you right now?

A. I have my -- my report in front of me right now.

Q. Perfect. Any other documents?

A. I have a tablet, but I can put it away.

Q. I'm just curious.

Have you talked to anyone about this deposition?

MS. RIVAUX: I'm going to object to form.

Go ahead, you can answer.

A. I -- my -- my partner is aware that I'm doing it.

BY MR. BEATO:

Q. Okay. What is your current occupation?

A. I am an associate professor.

Q. At what university?

A. UMass Chan School of Medicine.

Q. When did you start this job?

A. September.

Q. And you are a professor of what area?

A. Psychiatry.

Q. What does your job entail?

A. My job entails conducting research and mentoring students.

Q. What specific research?

A. I conduct research in anxiety and depression.

Q. Where do you currently live?

A. I live in Worcester, Massachusetts.

Q. And could you describe to me your educational background.

A. Yeah, I completed a bachelor's degree at Hampshire College, and from there I worked at a neuroscience or psychiatry lab at the Yale School of Medicine.

Then I went on to earn a Ph.D. in neuroscience from Vanderbilt University. And then after that, I did two post docs, one at China Medical University and the other at university of Pittsburgh.

Q. Thank you, Doctor.

And this is a standard deposition question. Are you taking any medications that would affect your memory today?

A. No.

Q. Perfect. So for the purposes of this deposition I'm going to define the firm "gender-affirming care" as puberty blockers, cross-sex hormones, surgeries and treatments to alter primary or secondary sex characteristics for gender dysphoria. Does that work for you, Doctor?

A. I think those are all very different things, so I would actually appreciate specificity.

Q. Okay. Fair enough. But in terms of the blanket term, it's our understanding that it would incorporate those four different treatments. When greater specificity is warranted, I can clarify.

A. Okay.

Q. Are you a psychiatrist?

A. No.

Q. Are you a neurologist?

A. No.

Q. Are you an endocrinologist?

A. No.

Q. Are you a surgeon?

A. No.

Q. In your medical opinion, what is your definition of gender dysphoria?

A. Well, I don't have a medical opinion because I'm trained as a scientist, not a medical provider.

Q. All right. So what is your going definition of gender dysphoria?

A. I would probably -- probably lean on the language that's used in the DSM-5.

Q. And what is your definition of gender identity?

A. A sense of one's self as being a particular gender.

Q. Can one change one's gender identity throughout one's life?

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. You can answer.

A. I don't really feel that it's my place to determine that for another person.

Q. Fair enough.

So based on your previous answers you haven't diagnosed anyone with gender dysphoria?

A. No.

Q. Never prescribed puberty blockers for an individual with gender dysphoria?

A. No. I have a Ph.D., not an M.D.

Q. So cross-sex hormone surgeries, haven't prescribed or performed that for an individual with gender dysphoria?

A. No.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. So now I'm going to pull up a document. Hopefully this works. I am not good with technology, so please bear with me, Doctor.

Tell me if you see this document.

A. Yes.

Q. Okay. Perfect. What is this document?

A. That is my rebuttal report.

MR. BEATO: So, court reporter, I'm going to mark this as Exhibit 1.

(Defendants' Exhibit Number 1 for i.d.)

BY MR. BEATO:

Q. So, Doctor, does this document fairly and accurately state your expert opinions in this case?

A. Yes.

Q. Are all of the studies and evidence you relied on contained in the bibliography in this report?

A. Yes.

Q. So I'm scrolling down on page 1. The title says "corrected." Why is this a corrected copy?

MS. RIVAUX: Objection. You can answer.

A. Can you sort of -- can you restate that?

BY MR. BEATO:

Q. Oh, sure. What does the title of this document say?

A. Corrected Expert Rebuttal Report of E. Kale Edmiston, Ph.D.

Q. Thank you, Doctor. And why does it say "corrected"?

A. Because it was corrected.

Q. Did you submit an earlier version of an expert rebuttal report in this case?

A. Yes.

Q. What is the difference between Exhibit 1, the corrected one, and the previous one?

A. The previous one cited a Soleman 2013 study where I should have cited a Soleman 2016 study, and there are two instances where that's the case.

Q. Thank you, Doctor.

Could you just quickly specify, do you recall which paragraphs?

A. Paragraphs 26 and 29.

Q. Okay. Excellent memory, by the way. It's impressive.

So here's another question. Have you conducted any empirical research on gender dysphoria?

A. Can you define what you mean by "empirical"?

Q. What does empirical research mean to you?

A. All -- if you mean by empirical, original research with data than I've collected, I have. But I have not -- my publications have been reviews of the extant literature.

Q. So to clarify, you have original research with data; is that correct?

A. I'm sorry?

Q. I apologize, Doctor. So am I correct so for empirical research on gender dysphoria you have original research with data?

MS. RIVAUX: Objection. Form.

You can answer.

A. I have done studies related to gender dysphoria, but those studies haven't been published to date.

BY MR. BEATO:

Q. So could you -- oh, I apologize, Doctor.

A. I've also -- but I have published studies that have reviewed the literature on specific topics related to gender dysphoria.

Q. Thank you for the clarification. Could you describe those for us?

MS. RIVAUX: Objection. Form.

You can answer.

A. Yeah. What do you mean by "describe"?

BY MR. BEATO:

Q. Can you explain what you are studying in those studies you referenced?

A. So there is review study that I published some years ago that reviews the primary care literature among transgender people. There is a review paper that

is currently in press that reviews the neuro -- the sort of biological basis for a trans identity. And then I have another paper that has been submitted related to adolescent decision making and brain development as it pertains to gender dysphoria.

Q. Thank you. Are those documents mentioned in your bibliography?

A. They are. There's also another paper that I'm revising that's in the bibliography as well that is about development and mental health in trans adolescents.

Q. In your opinion, what makes a treatment experimental?

MS. RIVAUX: Objection. Form.

A. I would say that that designation is outside of -- that's not my responsibility to determine, but I would say that -- I'll leave it at that.

BY MR. BEATO:

Q. Okay. And you collect research, Professor?

A. Yes.

Q. And you deal with -- do you deal with studies that are high quality and low quality?

A. Yes.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. So what is -- so what makes evidence low quality?

A. There are a lot of different reasons why a study might be low quality. However, all studies have limitations, and so as a scientist my job is to review all of the literature and look at it as a whole because any one study will necessarily have limitations, so you can't look at any one study to sort of draw a definitive conclusion.

Q. So in your answer, Doctor, you mentioned limitations. What are the limitations that you're thinking of?

A. I mean, I think any study can have limitations, and there are so many different sorts of limitations. It can be related to study design or available data. No one study can do everything, so, you know, resources are always finite.

Q. Understood. Could you think of any other limitations besides those two?

A. It -- there are -- I mean, there are numerous possible limitations. That's sort of the nature of science, so I couldn't possibly begin to list every limitation or every possible limitation of a scientific study.

Q. Okay. And, Doctor, how did you learn about this case?

A. I was aware of the law from the news, and I assumed that there would be a challenge to it. And then I was approached by Lambda Legal, and that's how I learned about this specific case.

Q. And in preparing your expert rebuttal report, what defendants' reports did you read?

A. I read Dr. Scott's and Biggs', Dr. Levine's, several others. I don't recall all of them at this time.

Q. So I'm going down on Exhibit 1 to page 3, paragraph 7 which I'm highlighting. Doctor, could you read the highlighting. Don't read the highlight, but can you see the highlighting? It doesn't make the text darker?

A. Yes.

Q. Perfect.

Is that an accurate statement, Doctor?

A. Yes.

Q. Did you rely on the WPATH Standards of Care 8 in making conclusions in your expert report?

MS. RIVAUX: Objection. Form.

A. I relied on my expertise on the topic.

BY MR. BEATO:

Q. Is it your opinion that WPATH sets the professional standards of care for treatments for gender dysphoria?

MS. RIVAUX: Objection. Form.

You can answer.

A. They are one organization. There are other medical organizations that also have standards of care.

BY MR. BEATO:

Q. And what are those medical organizations?

A. Well, the Endocrine Society comes to mind.

Q. Did you review any Endocrine Society documents in making this expert report?

A. No.

Q. In paragraph 7, it states that you were a chapter author for the Assessment chapter; is that correct?

A. Yes.

Q. Does the Assessment chapter involve treatments for adults?

MS. RIVAUX: Objection. Form.

A. The Assessment chapter outlines the assessment process for adults.

BY MR. BEATO:

Q. Does your expert report concern treatment

for adults?
A. No.
MS. RIVAUX: Objection. Form.
BY MR. BEATO:
Q. Do your conclusions reached in the Assessment chapter fairly and accurately describe your opinions and conclusions about gender-affirming care?
MS. RIVAUX: Objection. Form.
A. The Assessment chapter is a consensus document of many experts.
BY MR. BEATO:
Q. Is that a "yes"?
MS. RIVAUX: Objection. Form.
A. I -- you know, my -- I stand by the standards of care as the gold standard for treatment guidelines.
BY MR. BEATO:
Q. Why do you say that?
MS. RIVAUX: Objection. Form.
You can answer.
A. Yeah, because it -- because of the process through which it was created.
BY MR. BEATO:
Q. And what was the process in which it was created?

MS. RIVAUX: Objection. Form.
I'm also going to object to the extent that it would address any issues that are covered by the stay that you -- in this case that you do not go into any of that.
So I'm assuming, Michael, that you're not asking anything that's privileged information as it relates to that.
MR. BEATO: So let me ask you -- let me ask you, Shani, is it plaintiffs' position that I cannot ask any WPATH-specific question to the doctor?
MS. RIVAUX: No, I'm not suggesting you can't ask WPATH questions, but just you can't go into the issues that are currently addressed in the order that stays the discovery relating to internal processes of WPATH. So as long as it's not going into that, it's fine just depending on the question, but I guess that's the concern that I have is just not to violate that court order or to violate any nondisclosure agreement. You can ask anything that's about public information but nothing internal or private to WPATH that would violate that court order or require Dr. Edmiston to violate his

confidentiality agreement.
MR. BEATO: So, for example, asking about how the doctor went about and revised the assessment chapter to Standard of Care 8 I cannot, according to plaintiffs, I cannot ask questions relating to that?
MS. RIVAUX: Ask -- say that again. I'm not sure I understood.
MR. BEATO: Sure. I'll break it down. So in paragraph 7 the doctor states that the doctor was an author for the Assessment chapter for Standards of Care 8. And in revising the standards of care, specifically the Assessment chapter, I cannot ask any questions as to what was the consensus; how did you come up with revisions; what was the process like, I cannot --
MS. RIVAUX: I -- so I think it's going to be tough to -- I'm not giving you any blanket prohibition or objection, so it may be easier just to go question by question.
But I think to the extent it doesn't reveal information that seeks confidential information, then that's fine. So I think the limitation and the instruction is just not to reveal

confidential information.
MR. BEATO: Okay. I'm a little --
MS. RIVAUX: If you want to ask -- ask the question, and then we can, you know -- to the extent it doesn't seek information, my instruction is going to be to the extent it doesn't reveal confidential information or information that would otherwise be barred by the current stay and order, then Dr. -- then Dr. Edmiston can certainly answer the question.
MR. BEATO: Sure. And I'm happy to seek additional court guidance on this particular issue too.
MS. RIVAUX: I'm sorry?
MR. BEATO: I'm happy to seek additional court guidance on this issue too because we believe it goes to credibility.
MS. RIVAUX: Right. Well, I think here really the issue is he's here to take about his expert report, not WPATH. And if there's specific questions that you want to ask about it, you know, we could go about it individually. But, as I mentioned, there's a stay in place as it relates to specific areas relating to WPATH that you're aware of, and, you know, there's a

confidentiality agreement. So to the extent that it doesn't violate those, you can ask the questions. And if we need to seek additional guidance from the court, we certainly can do that.

MR. BEATO: Okay. How about -- okay. How about this? I ask my questions. You can instruct the witness not to answer any questions you believe he should not answer.

MS. RIVAUX: Okay.

MR. BEATO: Okay. Perfect.

BY MR. BEATO:

Q. So, Doctor, how does the -- well, let me take a step back before I take a step forward.

Does WPATH standards of care have a process in which those standards of care are revised?

MS. RIVAUX: Objection. Form.

You can answer.

A. What do you mean by "revised"?

BY MR. BEATO:

Q. So in terms of making a new version.

A. Oh. So the shift -- the drafting of version 8?

Q. Precisely. Perfectly.

A. All right. Yes.

Q. What is that process?

MS. RIVAUX: Objection. Form.

You can answer to the extent it doesn't violate your confidentiality agreement or the stay entered by the Appellate Court relating to the subpoenas to WPATH.

A. I would refer you to the WPATH SOC8 website which outlines that process.

(Defendant's Exhibit Number 2 for i.d.)

BY MR. BEATO:

Q. So I'm going to pull up another document. I'm mark this as Exhibit 2. So I will scroll down. It's six pages. And I will ask if this document looks familiar to you.

A. No, I have not seen it before.

Q. Could you read the title for me?

A. "Establishing the SOC8 Revision Committee and Meet the Chairs and Lead Evidence Team."

Q. And I can represent that this was on the website.

So I'm going to page 3. Doctor, were you a chapter lead when the Assessment chapter was being revised or reviewed?

MS. RIVAUX: Objection. Form.

A. I was a chapter co-author.

BY MR. BEATO:

Q. What's the difference between the two?

A. A chapter lead, I don't believe I can answer a specific question about roles.

Q. Okay. Based on what counsel said?

A. Yes.

Q. Who was the chapter lead during the revision process for the Assessment chapter?

A. Christina. I'm sure she's listed on the website.

(Defendant's Exhibit Number 3 for i.d.)

BY MR. BEATO:

Q. I'm going to pull up another document. This is Exhibit 3. It's a little bit longer than the other one, but I'm going to scroll down. I will also represent that this is from the WPATH website.

Does this document look familiar to you, Doctor?

A. No.

Q. So I'm scrolling down to page 12, and I'll represent that there are individuals under the Assessment Of Adults With Gender Diversity/Dysphoria.

Doctor, do these individuals look familiar to you?

A. Yes.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. How do you know these individuals?

MS. RIVAUX: Objection. Form.

You can answer.

A. I worked with them to write the chapter.

BY MR. BEATO:

Q. Are there any individuals who worked with you who are not listed here?

MS. RIVAUX: Objection. Form. And objection to the extent you can't answer without violating a confidentiality agreement or any stay in this case.

A. The authors list for SOC8 is very long. Many different people were involved in it, and the document was written collaboratively.

BY MR. BEATO:

Q. And earlier in the deposition you said that the standards of care is a consensus document. What does that mean?

A. I would refer you to the process, the consensus process that is outlined on the website.

Q. Can you describe the process just generally?

A. There --

MS. RIVAUX: I'm going to object, again,

only to the extent that you can answer the question -- I mean to the extent the question is asking generalities and not asking specifics into the process or things that would be violated, then that's fine, you can answer.

BY MR. BEATO:

Q. Let me clarify. Generally speaking.

A. Yes, there was a lit review that was conducted externally, and then there were grievance statements, and then the authors all had to build a consensus around the statements.

Q. Understood.

Doctor, are you a member of WPATH?

A. I was. I believe my membership -- I might be overdue on my dues, but, yes, I was at one time.

Q. When did you start being a member of WPATH?

A. I don't recall at this time exactly.

Q. Ballpark range?

A. Probably around probably 2017, I would guess.

Q. And so this is another general question. Looking at Exhibit Number 3 for the individuals listed here -- and, again, you recall working with these individuals?

A. Yes.

Q. Are any of them endocrinologists, to your memory?

MS. RIVAUX: Objection. Form.

A. No.

BY MR. BEATO:

Q. Are any of them surgeons?

MS. RIVAUX: Objection. Form.

A. There are endocrinologists and surgeons involved in SOC8 for the hormone and surgery chapters of SOC8.

BY MR. BEATO:

Q. And how would you describe each of these individual's areas of expertise?

MS. RIVAUX: Objection. Form.

A. I think that the document describes their areas of expertise.

BY MR. BEATO:

Q. Fair enough. So I'm going back to Exhibit Number 2, and I'm scrolling down to page 4, chapter stakeholder members. Again, this is on the public website. Does WPATH when it's revising its standards of care, to your knowledge, employ the help of nonmedical professionals in that process?

MS. RIVAUX: Objection. I'm going to give the same instruction. And also just to the

extent that Dr. Edmiston is also not here, doesn't speak on behalf of WPATH. But to the extent that Dr. Edmiston has personal knowledge that doesn't violate any confidentiality agreement or the order, then you may answer.

A. Can you define "medical professional"?

BY MR. BEATO:

Q. Sure. So, for example, an M.D., an endocrinologist, psychiatrist, someone who's gone to medical school.

A. There are certainly people involved in drafting the standards of care who have expertise who did not go to medical school because obviously there are lots of different manners to become educated and gain expertise on this topic.

Q. And this topic is?

A. Transgender healthcare.

Q. And you mentioned or counsel mentioned a confidentiality agreement.

A. Yes.

Q. As a member of WPATH you signed a confidentiality agreement?

A. No, as a --

MS. RIVAUX: Objection. Form. Sorry.

BY MR. BEATO:

Q. I'm sorry.

MS. RIVAUX: I'm raising an objection only to the extent you're not going to violate any agreement.

BY MR. BEATO:

Q. No, do not violate anything. I'm just asking what's with the confidentiality?

A. The chapter authors all signed it.

Q. I see.

A. We were asked to. I don't know what anyone else did.

Q. Understood. So WPATH asked you to sign that confidentiality agreement?

MS. RIVAUX: Objection to form.

A. I signed a confidentiality statement.

BY MR. BEATO:

Q. Understood. And, again, Doctor, we're just building the record. I don't want you to violate anything or make you feel uncomfortable in answering any questions.

So let me scroll up on Exhibit 2. I know, Doctor, you said you weren't a chapter lead. But looking at the criteria for chapter leads, WPATH full member in good standing. What do you think that means?

MS. RIVAUX: Objection. Form.
A. I assume it means that you're a member of WPATH.
BY MR. BEATO:
Q. A well-recognized advocate for WPATH and the standards of care?
MS. RIVAUX: Objection. Form.
A. I'm not sure what you're asking me. Are you asking me what a -- like what the word "recognized" means? I'm not sure what you're asking.
BY MR. BEATO:
Q. Sure, what does recognize mean in this context, in your opinion?
MS. RIVAUX: Objection to form.
A. That -- that you are known to people in this area.
BY MR. BEATO:
Q. Understood.
So, Doctor, we're going to move away from the process questions.
So now let me see if I can move this.
(Defendant's Exhibit Number 4 for i.d.)
BY MR. BEATO:
Q. I'm now going to introduce this as Exhibit 4. Doctor, does this look familiar?

A. Yes.
Q. What is this document?
A. This is the Standards of Care 8.
Q. Excellent.
So -- well, let me ask you this.
Do you think WPATH is an advocacy organization?
MS. RIVAUX: Objection. Form.
A. No.
BY MR. BEATO:
Q. Why?
MS. RIVAUX: Objection, form.
You can answer.
A. The purpose of WPATH is to gather the scientific evidence and expertise of scientists and clinicians to -- to develop the standards of care and to disseminate research.
BY MR. BEATO:
Q. And what kind of evidence does WPATH collect?
MS. RIVAUX: Objection. Form.
A. So, again, I would refer you to the website which outlines the process for drafting the standards of care.

BY MR. BEATO:
Q. And in terms of the chapter that you assisted with authoring, which chapter is that?
MS. RIVAUX: Objection. Form.
A. I am co-author of the Assessment of Adults chapter.
BY MR. BEATO:
Q. And that is Chapter 5?
A. Yes.
Q. I am now going on Exhibit 4 to page 33. I'm scrolling to the -- now I'm on page 34. I'm scrolling to the bottom of page 34. Doctor, I just have a few questions.
If you look at 5.4, it says, "We suggest..." and 5.5, "We recommend..."
A. Um-hum.
Q. Is there a difference between "suggest" and "recommend" here?
A. Yes.
Q. What is that difference?
A. They are different words.
Q. Okay. Do they convey anything differently? So there is -- strike that.
So they're used synonymously?
A. No.

Q. So what are their differences?
A. The WPATH document has graded evidence, so the language there is specific to the strength of evidence.
Q. And what kind of evidence grading systems does WPATH use?
A. I'm sorry. Can you repeat the question?
Q. Sure. So what kind of evidence grading system does WPATH use?
So, for example, I believe the Endocrine Society uses the GRADE system.
A. I would refer you to the website for that information.
Q. Understood. So now I'm going to go back to page 33, Doctor. One moment, Doctor.
33, I'm highlighting a section. It begins, "For TGD..." and goes all the way to "... required."
So, Doctor, I highlighted this sentence. Just so the record is clear, what does TGD mean in this chapter?
A. I would suggest that you scroll up to the top. It will be defined there.
Q. Right up here (indicating)?
A. Yes.
Q. Transgender and gender diverse?

A. Yes.
Q. So in this highlighted section can you elaborate on that sentence?
MS. RIVAUX: Objection. Form.
A. No.
BY MR. BEATO:
Q. It says what it says?
A. If you have a specific question, I'm happy to, you know -- if you have a specific question. But I -- I don't know what you -- you'll have to ask me a specific question.
BY MR. BEATO:
Q. Sure. So when it says "...less common treatments..." what does less common treatments mean?
MS. RIVAUX: Objection. Form. You can answer.
A. I think if an adult was to ask for an intervention that was nonstandard.
BY MR. BEATO:
Q. As an example, what would that be?
A. I wouldn't really want to speculate.
Q. Can you provide an example, though?
MS. RIVAUX: I'm going to object on the grounds of scope, but you can go ahead and answer.

A. Yeah, I mean, it's a -- it is a bit outside of the scope of, you know, my rebuttal. Sometimes people ask for -- they might ask for a surgical intervention that's nonstandard for as an example.
BY MR. BEATO:
Q. And limited research evidence, what does that mean?
MS. RIVAUX: Objection. I'm going to object on both form and scope here, but you can answer.
A. I mean, somebody -- it's -- there's always a possibility that someone might request an intervention that hasn't been researched before or has been researched very little.
BY MR. BEATO:
Q. Can you provide an example, Doctor?
MS. RIVAUX: Objection. Form and scope. You can answer.
A. I think the same -- the same answer. So if someone were to ask -- if an adult were to ask for a nonstandard surgical intervention, for example.
BY MR. BEATO:
Q. Scrolling to page 34, I'm highlighting another sentence beginning with, "The statements below..." and ending with "...consensus of professional best practice."

Doctor, what does the phrase "consensus of best" -- strike that -- "consensus of professional best practice" mean?
MS. RIVAUX: Objection. Form and scope. You can answer.
A. Yeah, I mean, again, I would refer you to the WPATH website where they outline a lot of sort of the process and the specific terminology that they use in this document.
BY MR. BEATO:
Q. With that in mind, could you today provide me with what your opinion as an author of this section, what consensus of professional best practice means?
MS. RIVAUX: Objection to both form and scope.
You can answer.
A. The consensus of ex -- people with expertise on the topic.
BY MR. BEATO:
Q. And how would you define expertise on the topic?
MS. RIVAUX: Objection. Form and scope. But you can answer.
A. I would, again, refer you to the WPATH website where they talk about the -- they outline the

sort of selection process for authors and how they determine expertise.
BY MR. BEATO:
Q. Okay. So I'm going back to Exhibit -- bear with me. This is now Exhibit 3. Again, we're still on page 12 and 13. Do all of these individuals support gender-affirming care?
MS. RIVAUX: Objection. Form; scope.
And to the extent it doesn't violate your confidentiality agreement or the stay, you can answer and if you know.
A. These individuals support the care that is -- has an evidence -- that -- you know, your question is very broad because gender-affirming care is very broad.
BY MR. BEATO:
Q. It is.
A. And the SOC8 guidelines recommend an individualized approach to care. So I think everyone involved in -- for those individuals they support quality healthcare.
Q. Going back to Exhibit 4, this sentence, Doctor, "The empirical evidence base for the," scrolling to page 35 -- "assessment of TGD adults is limited."

My question is, in the sentence, what does "empirical evidence base" mean?

MS. RIVAUX: Objection. Form and scope. You can answer.

A. So I would have to re-read the chapter in context. I do not want to define what a specific word means in a specific sentence without reading the context in which it occurs.

BY MR. BEATO:

Q. Fair enough. And would that same answer be true for "limited" in this sentence?

A. Yes.

MS. RIVAUX: Objection. Form; scope.

BY MR. BEATO:

Q. Doctor, I apologize. I did not hear an answer.

A. Oh. Yes.

Q. Let's go to the next page. This sentence, Doctor, "Some TGD individuals will have the capacity to grant consent immediately during the assessment."

What does that mean?

MS. RIVAUX: Objection. Form and scope.

A. This is about the assessment of adults and is about the assessment process being individualized.

BY MR. BEATO:

Q. So in an individualized scenario, can an individual be given puberty blockers for gender dysphoria after one medical treatment?

MS. RIVAUX: Objection. Form.

A. I would ask you to restate the question with a little bit more specificity.

BY MR. BEATO:

Q. Fair question, Doctor. Fair question.

Let me -- let me go back to these questions.

Scrolling down to the next page, statement 5.3A, Doctor, what does this sentence mean?

MS. RIVAUX: Objection. Form and scope.

A. So this is a sentence from the adult chapter that says "To access GAMSTs, a TGD person's gender incongruence must be marked and sustained."

So that means that part of the assessment process is to determine sort of the duration of the feelings of gender incongruence and the degree to which they are distracting or upsetting or troubling.

BY MR. BEATO:

Q. Scrolling a little bit further down, while marked and sustained gender incongruence is present, going all the way down to access gender-affirming care, Doctor, what does that sentence mean?

MS. RIVAUX: I'm going to object to form and scope.

A. That if a person -- it just means that -- it's not -- there's not some threshold of suffering that someone -- you know, that someone needs to suffer a certain amount before they're allowed to access healthcare.

BY MR. BEATO:

Q. Okay. Moving to page --

Well, actually, Doctor, we've been going for about an hour. Would you like a five-minute break?

A. No, I'm okay.

Q. Okay. Okay. And, once again, if you'd like a break at any time, please let me know. More than happy to accommodate.

A. Sure.

Q. So this is on Page 38 highlighting the sentence -- oops, no -- I -- I apologize.

Page 39, "in rare cases..." Doctor, in this sentence what does "rare cases" mean?

MS. RIVAUX: Objection. Form and scope.

A. So in rare cases would mean a nontypical instance.

BY MR. BEATO:

Q. And in the context of this sentence what would that nontypical instance be?

MS. RIVAUX: Objection. Form and scope.

A. So I would have to review the Hembree citation there. I mean, one example could be if someone had an estrogen receptor positive cancer.

BY MR. BEATO:

Q. And generally speaking, Doctor, when you were authoring this section, did you read all of these cases that are mentioned in this chapter?

MS. RIVAUX: Objection. Form; scope.

And to the extent it doesn't violate any of the stay order that we discussed or the confidentiality order, you may answer.

A. I have reviewed much of this literature. If you have a specific question about a specific paper, then I would request that you give me a break to review the specific paper.

BY MR. BEATO:

Q. Understood. And perfectly reasonable. I just had a broad general question.

And within the literature that you have reviewed when authoring this chapter, do you know if any of those studies were low evidence?

MS. RIVAUX: Objection. Form; scope.

You can answer.

A. I think that you would have to describe what you mean by "low evidence." I recall you asked me that question before, and I answered that all studies have limitations, and that's why we look at the literature as a whole to draw conclusions.

I'm sure you're aware, there's quite a bit of evidence cited in SOC8. I'm not sure off the top of my head how many citations there are, but it's quite a few.

BY MR. BEATO:

Q. So earlier in the deposition I think you provided examples of low-quality evidence or limitations. Do you recall saying study design could lead to evidence being low quality?

MS. RIVAUX: Objection. Form.

A. I believe I said that that is an example of a limitation. I didn't -- I do not think I said that it was an example of low quality.

BY MR. BEATO:

Q. Okay. And -- okay. And as of right now, you do not recall if any of those citations mentioned in Chapter 5 have low-quality evidence?

MS. RIVAUX: Objection. Form; scope.

A. I -- I take -- I sort of -- I challenge the premise of the idea of low quality. I am instead

talking about the limitations that occur with any scientific study, which is why we do lots of different studies to draw conclusions.

So I sort of -- or not sort of. I object to the premise of the question.

BY MR. BEATO:

Q. So still on page 39, sentence, "Because of the possible harm..." all the way down to "...is important," Doctor, what does this sentence mean?

MS. RIVAUX: Objection. Form and scope.

A. Again, I would ask that if you want me to discuss specific sentences from a very large document that I would be given time to review the document in its entirety to ensure that I am fully representing the context of any particular sentence.

BY MR. BEATO:

Q. Fair enough. And, again, you authored this document, or at least this chapter in the Standards of Care 8?

MS. RIVAUX:

A. I --

MS. RIVAUX: Objection to form; scope and the other restrictions that we've talked about before relating to your confidentiality agreement and the stay order in place.

A. Yes, I was a co-author of SOC8.

BY MR. BEATO:

Q. And this chapter?

A. Yes.

Q. Any other chapters, Doctor?

MS. RIVAUX: Objection. Form; scope; and same objections relating to the confidentiality agreement and the violation of -- and any -- and not to violate the stay in place.

A. I would, again, refer you to the WPATH website which outlines the process by which this document was drafted. It was written via consensus and was drafted collaboratively.

BY MR. BEATO:

Q. Okay. So I don't think you answered my question. Did you -- again, noting the objections, did you contribute in authoring any other chapters in WPATH?

MS. RIVAUX: I'm going to object to form; scope.

Again, do not violate your confidentiality agreement or the stay that's in place.

A. Yeah, that would -- that would -- discussing that would be in violation of the confidentiality agreement.

BY MR. BEATO:

Q. All right. I'll move on.

Doctor, to the best of your knowledge in Chapter 5, does Chapter 5 discuss any negative health risks of gender-affirming care?

MS. RIVAUX: Objection. Form; scope.

You can answer.

A. The Assessment chapter discusses the types of assessments that are necessary to determine eligibility and readiness for gender-affirming care.

BY MR. BEATO:

Q. Does it also talk about risks involved?

MS. RIVAUX: Objection. Form and scope.

You can answer.

A. I would ask what you mean by "talk about." It outlines what assessments need to be or should be done to determine the readiness for care.

BY MR. BEATO:

Q. And if I understand this correctly, part of the assessments involve evaluating benefits and risks?

MS. RIVAUX: Objection. Form and scope.

You can answer.

A. Broadly, yes.

BY MR. BEATO:

Q. And in evaluating the risks, does that

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also -- in evaluating -- sorry.
In evaluating risks, do you also have to weigh irreversible potential medical consequences?
MS. RIVAUX: Objection. Form; scope.
You can answer.
A. This is very standard healthcare. All healthcare interventions have outcomes associated with them, and this is no different from any other type of health intervention.
BY MR. BEATO:
Q. So, Doctor, I would like to take a five-minute break if you don't mind.
A. Sure.
MR. BEATO: Would you mind if we reconvene, just because I like base-five numbers, how about 11:15?
THE WITNESS: Sounds good.
MR. BEATO: Thank you very much.
THE VIDEOGRAPHER: Stand by. We're going off video record. The time is 11:08 a.m.
(A recess was taken from 11:08 a.m. to 11:16 a.m.)
THE VIDEOGRAPHER: We are back on the video record. The time is 11:16 a.m.
BY MR. BEATO:
Q. All right. So, Doctor, let me ask you this.

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And let me pull up Exhibit 1, the expert rebuttal report. Did you base any of your expert opinions on the WPATH Standards of Care Version 8?
MS. RIVAUX: Objection. Form. You can answer.
MR. BEATO: Counsel, can I have the basis for the objection?
MS. RIVAUX: It was confusing the way you worded the question.
MR. BEATO: Okay. I could rephrase.
BY MR. BEATO:
Q. Doctor, did you use WPATH's Standard of Care Version 8 recommendations as a basis for your expert report opinions?
A. I suppose I would ask what you mean by "use." I have expertise and I reviewed the relevant literature.
Q. So I'm scrolling down to page 4, paragraph 13. I highlight, "My opinions are based..." and I go down to "...including my work as a contributing author of WPATH Standards of Care 8."
Doctor, is paragraph 13 a fair and accurate representation of your opinion?
A. Yes.
Q. Is the confidentiality from WPATH, is that

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preventing you from answering some of the WPATH questions in this case?
MS. RIVAUX: Objection. Form; scope; and, again, the same objections relating to the confidentiality agreement and the stay order.
A. I'm adhering to the confidentiality agreement that I signed.
BY MR. BEATO:
Q. Understood.
And, Doctor, again, in your expert report do you opine on adult treatment?
A. In the rebuttal.
Q. Right. Apologies. I can be clear. Let me rephrase.
Doctor, in your expert rebuttal report, do you discuss adult treatment?
A. It -- the primary point or one of the primary points of my report was related to adolescent brain development.
Q. Understood. So where specifically do you mention adults in your expert rebuttal report?
A. I would have to review, but I believe by and large the report is regarding adolescents because that is what is pertinent.
Q. And if you need time to review this report,

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let me know. So, again, your report concerns adolescent treatment; is that correct?
A. Yes.
Q. Now, Doctor, regarding adolescent treatment and gender-affirming care, is there a lot of literature out there on the treatment?
MS. RIVAUX: Objection. Form.
MR. BEATO: Basis for objection?
MS. RIVAUX: It's a really broad, ambiguous question. There's a lot of literature out there. It's just, you know, just a broad, ambiguous question.
BY MR. BEATO:
Q. Okay. Let me rephrase.
Doctor, is there a good, a great deal of evidence on the effects of gender-affirming care on adolescents?
MS. RIVAUX: Objection. Form.
MR. BEATO: Basis, Counsel.
MS. RIVAUX: Same thing. I think it's ambiguous to say whether there's a great deal. I think it's ambiguous. But he may answer.
BY MR. BEATO:
Q. I will scroll down to, we're still on Exhibit 1, page 21.

Doctor, could you read this sentence for me?

A. "In contrast, there is a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents."

Q. Doctor, is "great deal," is that vague?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis?

MS. RIVAUX: What's the relevance?

MR. BEATO: The doctor wrote it.

MS. RIVAUX: Okay. So you can ask him about what he means by it.

BY MR. BEATO:

Q. What do you mean by "a great deal"?

A. So in this instance I'm looking at the literature, the decades of use of GnRHa treatment and the expertise of, my own expertise, the expertise of my colleagues. There's a great deal -- again, there's a great deal of evidence to support this, right. So I'm thinking broadly about evidence from clinical experience of my colleagues as well as the research literature.

Q. Okay. When you say "research literature," what do you mean?

A. Publications like peer-reviewed publications.

Q. Can you provide me examples of those?

A. I would refer to you my bibliography. I think there's quite a few citations.

Q. Can you name one off the top of your head?

A. There's a de Vries paper.

Q. And, again, Doctor, if I'm reading this correctly, "In contrast, there's a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents."

Again, that's accurate?

A. Yeah, so the sentence that that is -- so the sentence begins with the phrase, "In contrast." The sentence prior to it says, "There is little to support the defendants' designated experts' speculation about the negative effects of GnRHa treatment on the brain." So I stand by the sentence as written.

Q. Understood. I will scroll up to page 16, paragraph 31. I highlighted the first sentence. Doctor, could you please read that sentence?

A. Yes, "There is a small body of literature on the effects of gender-affirming hormone care on the brain in transgender adolescents."

So am I correct in assuming that you're trying to suggest that these two sentences are in conflict with each other?

Q. No.

A. Oh, okay. Great.

Q. Let's go to paragraph 5. I'm sorry. I misspoke. Page 5. Bear with me, Doctor. Sorry. So in chapter -- strike that. Sorry.

In paragraph 16, I believe you're responding to one of Dr. Scott's statements; is that correct?

A. Yes.

Q. I'm highlighting one sentence, I believe it's the second sentence, "That is, literature indicates that there are highly specific circumstances in which adolescents are more likely to engage in risky or impulsive behavior."

Doctor, my question is, did you provide a citation for that assertion?

A. I do later on.

Q. Where is that?

A. I believe it's -- yeah, paragraph 18.

Q. And all those cases stand for that proposition?

A. So those are references that describe the context -- the contextual nature of decision making and adolescents.

Q. And I'm scrolling back to page 5. Bear with me. The sentence, "However, none of these examples are

relevant to the issue at hand: Protracted medical decision making made in the context of adult guidance and consultation with a medical professional."

Doctor, my question is, what does protracted mean here?

A. Drawn out.

Q. So in this context, what period of time are we talking about?

A. I'm sorry. They're doing some work outside of my office and it's a little loud. Can you repeat the question?

Q. No problem whatsoever. No problem. And, again, if there's like a -- something going on in the background, more than happy to do that.

So in the final sentence of paragraph 16, "However, none of these treatments are relevant to the issue at hand: Protracted medical decision making made in the context of adult guidance and consultation with a medical professional," what does "protracted" mean? Like what kind of -- here's the question. What kind of period of time are we looking at?

A. So it could be -- you know, I think that it varies, which is why SOC8 recommends an individualized approach. It could be eight months or even years for some people.

Q. Okay. Do you have a citation or a study or some basis for that proposition?

A. I believe in the next paragraph I cite the, I think it's a Bauer study. Yeah, the Bauer 2022 study which outlines the time between an adolescent realizing that they're trans and then them coming out to a healthcare provider.

Q. All right. So the this sentence -- okay. Understood. So that citation for that's -- okay. Thank you, Doctor. That's all I wanted.

A. Um-hum.

Q. Give me one second.

Let's go to Paragraph 25. I think this is on page 10, still on Exhibit 1. I'm highlighting the second sentence in Paragraph 25, "Case studies are the lowest quality of evidence." Could you elaborate on that, Doctor?

A. Yeah, a case study is a study of a single individual, so they are generally not regarded as the type of evidence that we would want to use to make -- to inform, you know, standards of care policy, you know, the -- because it's just regarding a single person, so generally, you know, we don't think of those as being generalizable.

Q. Understood. And what limitations come with

case studies?

A. Well, it's a study of a single person, so we don't know if we can extrapolate the findings to the broader population.

Q. Are there any other limitations inherent with case studies, or it's just the focus of an individual on one person, to your knowledge?

A. I would say that's probably the primary limitation of a case study is just the, you know, questionable generalized ability of them.

Q. Understood.

In your knowledge, do you know if WPATH references any case studies in its standards of care?

A. I don't know off the top of my head, but I do know that WPATH cites a large body of literature that includes empirical studies, longitudinal studies, cross-sectional studies, cohort studies, unlike Dr. Levine who did not cite any valid literature.

Q. And in terms of the literature, does it pertain to adolescent treatments with gender dysphoria?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis?

MS. RIVAUX: I didn't understand the question.

MR. BEATO: Sure, I'll back up. I can take

a step back before taking a step forward.

BY MR. BEATO:

Q. So, Doctor, you said that in the standards of care, in WPATH there's a lot of longitudinal peer-reviewed literature, correct?

A. I said that there is a variety of different types of evidence that are informing recommendations as a whole, so that could include longitudinal cohort, cross-sectional.

Q. Could that also include case studies?

A. It may, yes.

Q. And in terms of the longitudinal cohort literature that you mentioned, does that literature reference or relate to adolescent treatment concerning gender-affirming care?

A. There have been longitudinal adolescent studies. If you're asking me to speak to a specific one, I would want to take a break and review it.

Q. Understood. Without speaking in depth about it, could you identify them for me off the top of your head, or are they mentioned in your bibliography?

A. They are mentioned in my bibliography.

Q. To your mind, does your bibliography reference all of those longitudinal cohort adolescent related studies that you're thinking of right now?

A. I cite the -- so I did a targeted literature review, and I cite the studies that I was -- that I identified that looked at mental health outcomes in transgender youth. I would hesitate to claim that I have cited every longitudinal study of transgender youth, but I did do a thorough literature review.

Q. Fair enough. Fair enough. Are there any additional reports that should be in your bibliography?

A. Not that I'm aware of.

Q. Let me go to paragraph 27 highlighting the first sentence, "Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa treatment on the brain are both 'unknown' and 'likely negative.'"

Does WPATH comment on the effects of GnRH -- I'm going to get it wrong, Doctor. I apologize.

Does WPATH opine on the effects of GnRHa treatment on the brain?

A. Not that I recall, but I would want to review the entire document before making a definitive statement.

Q. Is there a great deal of evidence on the subject?

A. There is --

MS. RIVAUX: Objection.

THE WITNESS: Sorry.

MS. RIVAUX: You can answer.
MR. BEATO: And what's the basis for the objection?
MS. RIVAUX: I'm not sure when you're saying "there's a great deal of evidence on the subject" what the subject in particular you were referring to.
MR. BEATO: The effects of GnRHa treatment on the brain.
MS. RIVAUX: Do you want to rephrase -- the way -- to me, the way it came out was a little -- is a little bit ambiguous. If you want to rephrase it that way, that's fine.
MR. BEATO: No problem whatsoever. I'm just asking for the basis of the objection so I can ask a better question.
MS. RIVAUX: Yeah, that's fine.
MR. BEATO: Perfect.

BY MR. BEATO:

Q. So, Doctor, is there a great deal of evidence on the effects of GnRHa treatment on the brain?

A. There is -- there is evidence. There are studies that look at GnRHa treatment on the brain.

Q. How many studies are you thinking of right now?

A. In humans -- well, also, I guess it would depend. If you mean in humans, in transgender adolescents, I believe there's three neuroimaging studies. There are also animal studies as well.

Q. With, for example, I think, sheep?

A. Yes, there are some studies of sheep.

Q. Sheep and mice?

A. And a primate study also.

Q. And for those -- if I remember this -- please correct me if I'm wrong. For those three human studies, what were the results of those studies?

A. I outlined those in the report. Those studies used different imaging modalities. They found differences in brain structure function that were associated with sex assigned at birth; others that were associated with gender identity.

But when they ran correlations to determine associations between GnRHa treatment and brain structure function, they did not find any -- there were no significant findings.

Q. Okay. So no significant findings of benefits in the treatments?

A. No significant findings of any association.

Q. Understood. And for the animal studies, the sheep, mice and primates, what were the results of those studies?

A. Well, as I outlined in my rebuttal as well as the paper, the review paper that I wrote that I cited, the problem with a lot of the animal literature is that they don't use the correct reference group for comparing. So a lot of those studies report differences with GnRH treatment, but really their difference is between natal sex, so we would expect a medication that delays puberty to have sex-specific effects. That is the desired outcome of the treatment.

Q. And I have no additional questions regarding the report. I do have additional follow-up questions, though.

Earlier in the deposition you stated that you were aware of the law in place in Florida.

A. (Nodding head).

Q. By the way, it's not a law; it's a regulation, but understood, understood.

A. All right.

Q. How did you hear about it, the at-issue regulation?

A. I don't recall.

Q. Understood. If you could think back, was it social media, the news or you don't remember?

A. I don't remember. I don't recall at this time.

Q. And for your expert report, did you review the at-issue regulations?

A. I reviewed, as I believe is stated at the beginning of the report, I reviewed the Florida Medicaid opinion.

Q. The so-called GAPMS report?

A. Yes.

Q. But not the at-issue regulation?

A. No, I did not review the text of it.

Q. But you were aware of the at-issue regulation through something?

A. (Nodding head).

Q. Okay. What is your opinion on the GAPMS report?

MS. RIVAUX: Objection. Scope.

A. I would ask that you just be a little bit more specific.

BY MR. BEATO:

Q. Sure. So in writing this expert report, you reviewed the GAPMS report with the accompanying attachments, correct?

A. Um-hum, yes.

Q. As a professor, as a scientist, what are

your opinions of the GAPMS report?

MS. RIVAUX: Objection. Scope.

You can answer.

A. I was surprised that it didn't seem to cite a lot of relevant literature.

BY MR. BEATO:

Q. What literature would you have cited?

A. All the literature that I cited in my rebuttal.

Q. And in hearing about the at-issue regulation, how do you feel about the regulation?

MS. RIVAUX: Objection.

BY MR. BEATO:

Q. What is your opinion as to the regulation?

MS. RIVAUX: Objection. Scope.

A. I believe that healthcare decisions should be made between patients and providers and their families and based on expert medical evidence and standards of care.

MR. BEATO: Doctor, I have no further questions.

Counsel can ask some follow-up questions.

MS. RIVAUX: I don't have any follow-up questions.

MR. BEATO: All right. Doctor, you're done.

THE WITNESS: All right. Thank you.

MR. BEATO: Thank you, Doctor. I know you're probably busy. And thank you for making yourself available and taking time to answer these questions. It's really appreciated.

MS. RIVAUX: Do you want to give him the instruction about reading or waiving?

MR. BEATO: Could you do that, Counsel?

MS. RIVAUX: Sure. So, Dr. Edmiston, you have the right to read your report and make any changes to the extent that there were any errors in the transcription or you can waive that. Otherwise, you'd get a copy. If you choose to read it, you'll have 30 days when you get it to review it to make any changes. There will be a form in which you can make any correction. And then that gets sent back and a corrected copy will get circulated to everybody.

THE WITNESS: Yeah, I'd like to read it.

MS. RIVAUX: Okay.

MR. BEATO: And, Doctor, just to be super cautious because I know you have a confidentiality agreement, I don't want to violate that at all. If you said something inadvertently that, you know, maybe you probably

shouldn't have said, should this deposition be under seal? We can send the court reporter the protective order. I just want to make sure.

MS. RIVAUX: Yeah, you know what? Why don't we do it that way, and then if there's any reason to unseal it or to seal any specific portion, we can go ahead and do that. And then we can -- you know, if there's anything -- so until Dr. Edmiston has an opportunity to review it, and then we can mark things confidential as appropriate later on. I appreciate that. Thank you.

MR. BEATO: No problem. Doctor, I understand. You're put in a tough position, right. You have -- you got something signed. I respect that. I wasn't trying to make you feel uncomfortable or get around that, so I just want to make sure everything is good.

I will ask, though, for an expedited transcript.

And, Doctor, I want to make sure you have sufficient time to review it, but at the same time we want to get this finalized as soon as possible.

THE WITNESS: I appreciate that.

MR. BEATO: So, Zack, are you on there? We can send over the court reporter the protective order.

THE STENOGRAPHER: I just want to remind you we're still on video record.

MR. BEATO: That's fine. This can all be on the record. That's fine.

Okay. I think we're -- I think we're good. Thank you for your time, Doctor.

THE WITNESS: You're welcome.

THE VIDEOGRAPHER: This is the videographer. Would anyone like to order a copy of the video?

MR. BEATO: A copy of the video, I don't need a copy of the video.

THE VIDEOGRAPHER: And Ms. Rivaux?

MS. RIVAUX: I don't -- I don't think we need a copy of the video at this time. But for the transcript, we'd like it at the same time, please.

MR. BEATO: Yes, expedited.

THE VIDEOGRAPHER: Is there a date for that? Just as soon as possible or --

MS. RIVAUX: As soon as possible.

THE VIDEOGRAPHER: Okay.

MR. BEATO: Thank you very much.

THE VIDEOGRAPHER: And then I'll go ahead and take us off the video record. We're going off the record in the video deposition of Dr. Kale Edmiston. We're going off the record on March 23rd, 2023 at 11:43 a.m.

(Thereupon, the proceedings concluded at 11:43 a.m.)

(The witness did not waive signature.)

CERTIFICATE OF OATH

THE STATE OF FLORIDA)

COUNTY OF PALM BEACH COUNTY)

I, the undersigned authority, certify that E. KALE EDMISTON, Ph.D. remotely appeared before me and was duly sworn on the 23rd day of March 2023.

Signed this 23rd day of March 2023.

Barbara Gallo

BARBIE GALLO, RMR-CRR

Notary Public - State of Florida

My Commission No. GG939757

My Commission Expires: December 15, 2023

CERTIFICATE OF REPORTER

THE STATE OF FLORIDA)

COUNTY OF PALM BEACH)

I, Barbie Gallo, RMR-CRR, Registered Merit Reporter-Certified Realtime Reporter, certify that I was authorized to and did stenographically report the deposition of E. KALE EDMISTON, Ph.D., pages 1 through 69; that a review of the transcript was requested; and that the transcript is a true and complete record of my stenographic notes.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 23rd day of March 2023.

Barbara Gallo

Barbie Gallo, RMR-CRR

Thursday, March 23rd, 2022
E. Kale Edmiston, Ph.D. c/o Shani Rivaux
Pillsbury, Winthrop, Shaw, Pittman, LLP
600 Brickell Avenue
Suite 3100
Miami, Florida 33131
(786) 913-4900
shani.rivaux@pillsbury.com
IN RE: DEKKER vs WEIDA
CASE NO.: CASE NO. 4:22-CV-00325-RH-MAF
Please take notice that on the 23rd day of March 2023, you gave your deposition in the above cause. At that time you did not waive your signature.
The above-addressed attorney has ordered a copy of this transcript and will make arrangements with you to read their copy. Please execute the Errata Sheet, which can be found at the back of the transcript, and have it returned to us for distribution to all parties.
If you do not read and sign the deposition within 30 days, the original, which has already been forwarded to the ordering attorney, may be filed with the Clerk of the Court.
If you wish to waive your signature now, please sign your name in the blank at the bottom of this letter and return it to the address listed below.
Very truly yours,
Barbie Gallo, RMR-CRR
Phipps Reporting, Inc.
1551 Forum Place, Suite 200-E
West Palm Beach, Florida 33401
I do hereby waive my signature.

E. KALE EDMISTON, Ph.D.

ERRATA SHEET

DO NOT WRITE ON TRANSCRIPT - ENTER CHANGES HERE

IN RE: DEKKER vs WEIDA

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

WITNESS: E. KALE EDMISTON, PH.D.

TAKEN: 03/23/2023

PAGE	LINE	CHANGE	REASON FOR CHANGE

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

Date E. KALE EDMISTON, Ph.D.

B

C

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Doc. 233

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

AUGUST DEKKER, legally known as KORI DEKKER; BRIT ROTHSTEIN; SUSAN DOE, a minor, by and through her parents and next friends, JANE DOE and JOHN DOE; and K.F., a minor, by and through his parent and next friend, JADE LADUE, *Plaintiffs*, v. JASON WEIDA, in his official capacity as Secretary of the Florida Agency for Health Care Administration; and FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, *Defendants*.	Case No. 4:22-cv-00325-RH-MAF **FIRST AMENDED COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF**

Plaintiffs AUGUST DEKKER, legally known as KORI DEKKER;[1] BRIT ROTHSTEIN; SUSAN DOE, a minor, by and through her parents and next friends, JANE DOE and JOHN DOE;[2] and K.F., a minor, by and through his parent and next

[1] Although Plaintiff's legal name is Kori Dekker, he is known by and uses the name August Dekker in accordance with his male gender identity. Accordingly, this Amended Complaint refers to Plaintiff as August and uses male pronouns to refer to him.

[2] Pursuant to ECF No. 18, Order Allowing the Doe Plaintiffs to Proceed Under Pseudonyms, Plaintiff Susan Doe, and her parents and next friends, Jane Doe and John Doe, proceed pseudonymously in this action in order to protect Susan Doe's right to

friend JADE LADUE,[3] by and through the undersigned counsel, bring this lawsuit against Defendants JASON WEIDA, in his official capacity as Secretary of the Florida Agency for Health Care Administration, and the FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION ("AHCA") to challenge Florida Administrative Code Rule 59G-1.050(7) and Section 3 of Senate Bill 254 ("SB 254") prohibiting Medicaid coverage of medical services for the treatment of gender dysphoria, and to seek declaratory and injunctive relief. The Challenged Exclusion created by Rule 59G-1.050(7) came into effect on August 21, 2022, and the Challenged Exclusion created by SB 254 came into effect on May 17, 2023 when it was signed into law.

INTRODUCTION

1. A person's access to health care should not be contingent on their sex, gender identity, or whether they are transgender. Yet, that is exactly the situation in Florida. AHCA has made access to medically necessary health care for Medicaid beneficiaries contingent on whether they are transgender.

2. Empirical evidence and decades of clinical experience demonstrate that medical care for the treatment of gender dysphoria, also known as gender-affirming

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privacy given that she is a minor and the disclosure of her identity "would reveal matters of a highly sensitive and personal nature, specifically [Susan Doe]'s transgender status and [her] diagnosed medical condition—gender dysphoria." *Foster v. Andersen*, No. 18-2552-DDC-KGG, 2019 WL 329548, at *2 (D. Kan. Jan. 25, 2019).

[3] Because he is a minor, Plaintiff K.F. is proceeding under his initials pursuant to Federal Rule of Civil Procedure 5.2(a).

care, is medically necessary, safe, and effective for both transgender adolescents and adults with gender dysphoria. Gender-affirming care is neither experimental nor investigational; it is the prevailing standard of care, accepted and supported by every major medical organization in the United States.

3. Under Rule 59G-1.050(7) of the Florida Administrative Code and Section 3 of SB 254 (the "Challenged Exclusions"), transgender Medicaid beneficiaries are denied coverage for gender-affirming care to treat gender dysphoria, without regard to the actual generally accepted professional medical standards that govern such care or the particular medical needs of any Medicaid beneficiary. Specifically, any health care service or procedure that "alter[s] primary or secondary sexual characteristics" or "affirm[s] a person's perception of his or her sex if that perception is inconsistent with the person's sex" is ineligible for Medicaid coverage, though only when that service is being used to treat gender dysphoria. These same health care services, however, are routinely covered by Medicaid when they are for medically necessary purposes other than the treatment of gender dysphoria.

4. The Challenged Exclusions represent dangerous governmental actions that threaten the health and wellbeing of transgender Medicaid beneficiaries.

5. The purpose of Medicaid is to provide health care coverage to individuals who have low income and cannot otherwise afford the costs of necessary medical care. By denying coverage for gender-affirming care, Defendants effectively *categorically*

deny access to medically necessary care to thousands of Floridians who lack other means to pay for such care.

6. Defendants' actions not only come within the context of a series of measures the State has adopted targeting transgender people for discrimination, but they stand in sharp contrast not just to the well-established evidence and widely accepted view of the medical and scientific community in the United States, but also to the policies of the vast majority of states, which provide Medicaid coverage for gender-affirming care.

7. If allowed to remain in effect, the Challenged Exclusions will continue to have immediate dire physical, emotional, and psychological consequences for transgender Medicaid beneficiaries.

8. These consequences need not occur, however, as the Challenged Exclusions are unlawful in multiple respects and therefore should be preliminarily and permanently enjoined.[4]

9. First, the Challenged Exclusions, which Defendant Weida enforces, violate the United States Constitution's guarantee of equal protection of the laws.

[4] Blanket bans like the Challenged Exclusions have been repeatedly found to be unlawful and unconstitutional forms of discrimination. *See, e.g.*, *Fain v. Crouch*, 3:20-cv-00740, Dkt. #271 (S.D.W.V. Aug. 2, 2022) (granting summary judgment in favor of plaintiffs on causes of action also brought in this Complaint); *Flack v. Wis. Dep't. of Health Services*, 3:18-cv-00309-wmc, Dkt. #217 (W.D. Wis. Aug. 16, 2019) (same).

Under the Fourteenth Amendment's Equal Protection Clause, Defendants are prohibited from discriminating against persons based on sex and transgender status.

10. Second, the Challenged Exclusions violate Section 1557 of the Patient Protection and Affordable Care Act (the "ACA"), 42 U.S.C. § 18116, which prohibits discrimination on the basis of sex by health programs or activities, any part of which receives federal funding, such as Medicaid.

11. Third, the Challenged Exclusions violate the Medicaid Act's Early and Periodic Screening, Diagnostic, and Treatment provisions, which require Defendants to affirmatively arrange for services that are necessary to "correct or ameliorate" a health condition for Medicaid beneficiaries under 21 years of age, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r) ("EPSDT Requirements"), as well as the Medicaid Act's requirement for Defendants to ensure comparable coverage to every Medicaid beneficiary, 42 U.S.C. § 1396a(a)(10)(B)(i) ("Comparability Requirements").

12. Accordingly, Plaintiffs seek relief related to Defendants' adoption and enforcement of the Challenged Exclusions, including declaratory and preliminary and permanent injunctive relief, as well as compensatory damages, attorney's fees, and costs.

PARTIES

A. Plaintiffs

Plaintiff August Dekker

13. Plaintiff August Dekker is a 28-year-old transgender man. August, who has been diagnosed with gender dysphoria, is enrolled in and receives his health care coverage through Florida's Medicaid program. At the recommendation of his health care providers, August receives medically necessary hormone therapy to treat his gender dysphoria, which Florida's Medicaid program has covered until now. August has been enrolled in Medicaid at all times relevant to this Amended Complaint. August lives in Hernando County, Florida.

Plaintiff Brit Rothstein

14. Plaintiff Brit Rothstein is a 20-year-old transgender man. Brit, who has been diagnosed with gender dysphoria, is enrolled in and receives his health care coverage through Florida's Medicaid program. At the recommendation of his health care providers, Brit receives medically necessary hormone therapy to treat his gender dysphoria, which Florida's Medicaid program has covered until now. After the promulgation of the Challenged Exclusion, Brit was denied coverage for his chest surgery despite receiving prior authorization for the procedure. Brit has been enrolled in Medicaid at all times relevant to this Amended Complaint. As he is college student, Brit lives in Orange County, Florida while he is in school, and lives in Broward County, Florida, along with his family, when he is out of school.

Plaintiff Susan Doe

15. Plaintiff Susan Doe is a 13-year-old transgender adolescent girl. Susan Doe sues pursuant to Federal Rule of Civil Procedure 17(c) by and through her next friends and parents, Jane Doe and John Doe. Susan, who has been diagnosed with gender dysphoria, is enrolled in and receives her health care coverage through Florida's Medicaid program. At the recommendation of her health care providers, Susan receives medically necessary puberty delaying medication to treat her gender dysphoria, which Florida's Medicaid program has covered until now. Susan has been enrolled in Medicaid at all times relevant to this Amended Complaint. Susan, Jane, and John live in Brevard County, Florida.

Plaintiff K.F.

16. Plaintiff K.F. is a 13-year-old transgender adolescent boy. K.F. sues pursuant to Federal Rule of Civil Procedure 17(c) by and through his next friend and parent, Jade Ladue. K.F., who has been diagnosed with gender dysphoria, is enrolled in and receives his health care coverage through Florida's Medicaid program. At the recommendation of his health care providers, K.F. receives medically necessary puberty delaying medication to treat his gender dysphoria, which Florida's Medicaid program has covered until now. K.F. has been enrolled in Medicaid at all times relevant to this Amended Complaint. Jade and K.F. live in Sarasota County, Florida.

B. Defendants

17. Defendant 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]." Fla. Stat. §§ 409.902, 409.963 (2022); *see also* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10. Defendant Weida is responsible for the enforcement of the Challenged Exclusions. Defendant 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. Defendant Weida's official place of business is located in Tallahassee, Leon County, Florida.

18. Defendant AHCA is 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]." Fla. Stat. §§ 409.902, 409.963 (2022). As such, AHCA receives federal funding to support the Florida Medicaid Program. 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. Moreover, AHCA oversees the promulgation of all Medicaid rules, fee schedules, and coverage policies into the Florida Administrative Code. Fla. Stat. § 409.919 (2022). Defendant AHCA is based and headquartered in Tallahassee, Leon County, Florida.

JURISDICTION AND VENUE

19. The Court has jurisdiction over the claims asserted herein pursuant to 28 U.S.C. §§ 1331, 1343(a)(3)-(4).

20. Plaintiffs' claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201, 2202, 42 U.S.C. § 1983, and Rules 57 and 65 of the Federal Rules of Civil Procedure.

21. Under 28 U.S.C. § 1391(b), venue is proper in the U.S. District Court for the Northern District of Florida because all Defendants reside within this District and a substantial part of the events or omissions giving rise to the claims alleged herein occurred in this District. Venue is proper in the Tallahassee Division of the Northern District of Florida under N.D. Fla. Loc. R. 3.1(B) because it is where the Defendants reside and where a substantial portion of the acts or omissions complained of herein occurred.

22. This Court has personal jurisdiction over Defendants because they are domiciled in Florida and/or have otherwise made and established contacts with Florida sufficient to permit the exercise of personal jurisdiction over them.

FACTUAL BACKGROUND

A. Gender Identity and Gender Dysphoria

23. A person's sex is multifaceted, and comprised of a number of characteristics, including but not limited to chromosomal makeup, hormones, internal

and external reproductive organs, secondary sex characteristics, and most importantly, gender identity.

24. Gender identity is a person's internal sense of their sex. It is an essential element of human identity that everyone possesses, and a well-established concept in medicine. Gender identity is innate; immutable; has significant biological underpinnings, such as the sex differentiation of the brain that takes place during prenatal development; and cannot be altered.

25. Gender identity is the most important determinant of a person's sex. Everyone has a gender identity.

26. A person's sex is generally assigned at birth based solely on a visual assessment of external genitalia. External genitalia, however, are only one of several sex-related characteristics that comprise a person's sex, and as a result, are not always indicative of a person's sex.

27. For most people, their sex-related characteristics are aligned, and the visual assessment performed at birth serves as an accurate proxy for that person's sex.

28. The term "sex assigned at birth" is the most precise terms to use because not all of the physiological aspects of a person's sex are always in alignment with each other as typically male or typically female.

29. For these reasons, the Endocrine Society, an international medical organization of over 18,000 endocrinology researchers and clinicians, warns

practitioners that the terms "biological sex" and "biological male or female" are imprecise and should be avoided.[5]

30. When a person's gender identity does not match that person's sex assigned at birth, gender identity is the critical determinant of that person's sex.

31. Individuals whose sex assigned at birth aligns with their gender identity are referred to as cisgender. Transgender people, on the other hand, have a gender identity that differs from the sex assigned to them at birth. A transgender boy or man is someone who was assigned a female sex at birth but has a male gender identity. A transgender girl or woman is someone who was assigned a male sex at birth but has a female gender identity.

32. The health and wellbeing of all people, including those who are transgender, depends on their ability to live in a manner consistent with their gender identity.

33. Scientific and medical consensus recognizes that attempts to change an individual's gender identity to bring their gender identity into alignment with their sex assigned at birth are ineffective and harmful. Attempts to force transgender people to live in accordance with their sex assigned at birth, a practice often described as

[5] *See* Wylie C. Hembree, *et al*., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869, 3875 (2017), https://perma.cc/FM96-L228 (hereinafter "Endocrine Society Guidelines").

"conversion," or "reparative" therapy, is universally known to cause profound harm and is widely considered unethical and, in some places, unlawful.

34. For transgender people, the incongruence between their gender identity and sex assigned at birth can result in clinically significant stress and discomfort known as gender dysphoria.

35. Gender dysphoria is a serious medical condition recognized in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. The World Health Organization's International Classification of Diseases, which is the diagnostic and coding compendia used by medical professionals, refers to the condition as "gender incongruence." Gender dysphoria is also recognized by the leading medical and mental health professional groups in the United States, including the American Academy of Pediatrics, American Medical Association, the American Psychological Association, American Psychiatric Association, and the Endocrine Society, among others.

36. If left untreated, gender dysphoria can result in debilitating anxiety, severe depression, self-harm, and even suicidality. Untreated gender dysphoria often intensifies with time. The longer an individual goes without or is denied adequate treatment for gender dysphoria, the greater the risk of severe harms to the person's health.

37. The World Professional Association for Transgender Health ("WPATH") and the Endocrine Society have published widely accepted guidelines for treating

gender dysphoria.[6] The goal of medical treatment for gender dysphoria is to eliminate clinically significant distress by helping a transgender person live in accordance with their gender identity. This treatment is sometimes referred to as "gender transition," "transition related care," or "gender-affirming care."

38. WPATH is an international and multidisciplinary association whose mission is to promote evidence-based health care protocols for transgender people. WPATH publishes the Standards of Care based on the best available science and expert professional consensus.

39. The WPATH Standards of Care and Endocrine Society Guidelines are widely accepted as best practices guidelines for the treatment of adolescents and adults diagnosed with gender dysphoria and have been recognized as authoritative by the leading medical organizations.

40. The WPATH Standards of Care and Endocrine Society Guidelines recognize that puberty delaying medication, hormone therapy, and surgery to align a person's primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring) with their gender identity are medically necessary services for many people with gender dysphoria.

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[6] Endocrine Society Guidelines; World Prof'l Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People* (7th Version, 2012), https://perma.cc/62K5-N5SX (hereinafter, "WPATH Standards of Care").

41. The precise treatment of gender dysphoria for any individual depends on that person's individualized needs. The guidelines for medical treatment of gender dysphoria differ depending on whether the treatment is for an adolescent (minors who have entered puberty) or an adult. No pharmaceutical or surgical intervention is recommended or necessary prior to the onset of puberty, however. The individualized steps that many transgender people take to live in a manner consistent with their gender identity are known as "a transition" or "transitioning." The precise steps involved in transitioning are particular to the individual but may include social, medical, and legal transition. Determinations regarding medically necessary care are made on an individualized basis between by the medical professional and the patient.

42. Social transition entails a transgender individual living in accordance with their gender identity in all aspects of life. Social transition can include wearing attire, following grooming practices, and using pronouns consistent with that person's gender identity. The steps a transgender person can take as part of their social transition help align their gender identity with all aspects of everyday life.

43. Many transgender individuals also pursue legal transition, which involves taking steps to formally amend their legal identification documents to align with their gender identity, such as changing one's name through a court ordered legal name change and updating the name and gender marker on their driver's license, birth certificate, and other identification documents.

44. Medical transition, a critical part of transitioning for many transgender people, includes gender-affirming care that brings the sex-specific characteristics of a transgender person's body into alignment with their identity.

45. Gender-affirming care can involve counseling, hormone therapy, surgery, or other medically necessary treatments for gender dysphoria.

46. The most effective treatment for transgender adolescents and adults with gender dysphoria, in terms of both their mental and medical health, contemplates an individualized approach. Medical and surgical treatment interventions are determined by the health care team (usually involving medical and mental health professionals) in collaboration with the patient, and the patient's parents/guardians, if the patient is an adolescent.

47. Under the WPATH Standards of Care, medical interventions may become medically necessary and appropriate after transgender youth reach puberty. In providing medical treatments to adolescents, pediatric physicians and endocrinologists work in close consultation with qualified mental health professionals experienced in diagnosing and treating gender dysphoria.

48. For many transgender adolescents, going through puberty as the sex assigned to them at birth can cause extreme distress. Puberty delaying medication allows transgender adolescents to pause puberty, thus minimizing and potentially preventing the heightened gender dysphoria and permanent physical changes that puberty would cause.

49. Puberty delaying treatment is reversible. When the adolescent discontinues treatment, puberty will resume. Puberty delaying treatment does not cause infertility.

50. For some transgender adolescents and adults, it is necessary to undergo hormone therapy, which involves taking hormones for the purpose of bringing their secondary sex characteristics into alignment with their gender identity (testosterone for transgender males, and estrogen and testosterone suppression for transgender females). Secondary sex characteristics are bodily features not associated with external and internal reproductive genitalia (primary sex characteristics). Secondary sex characteristics include, for example, hair growth patterns, body fat distribution, and muscle mass development. Hormone therapy can have significant masculinizing or feminizing effects and can assist in bringing transgender people's secondary sex characteristics into alignment with their gender identity, and therefore is medically necessary care for transgender people who need it to treat their gender dysphoria.

51. Gender-affirming surgery might be sought by transgender people after puberty to treat symptoms of gender dysphoria by better aligning their primary or secondary sex characteristics with their gender identity. Though not all transgender people require or seek gender-affirming surgical care, such care can be medically necessary when determined to be in the best interests of the patient and supported by empirical evidence.

52. Gender-affirming medical care can be lifesaving treatment and has been shown to positively impact the short and long-term health outcomes for transgender people of all ages.

53. All of the treatments used to treat gender dysphoria are also used to treat other diagnoses or conditions. These treatments are not excluded from Medicaid coverage under the Challenged Exclusion when used to treat any diagnosis or condition other than gender dysphoria, yet they carry comparable risks and side effects to those that can be present when treating gender dysphoria. Thus, the use of these treatments for gender dysphoria are not any more risky than for other conditions and diagnoses for which the same treatments are regularly used.

54. The consequences of untreated, or inadequately treated, gender dysphoria, however, are dire, as untreated gender dysphoria is associated with both clinically significant anxiety, depression, self-harm, and suicidality and higher levels of stigmatization, discrimination, and victimization, contributing to negative self-image and the inability to function effectively in daily life.

55. When transgender people are provided with access to appropriate and individualized gender-affirming care in connection with treatment of gender dysphoria, its symptoms can be alleviated and even prevented.

56. As such, the American Medical Association, American Psychological Association, American Psychiatric Association, Endocrine Society, American College of Obstetricians and Gynecologists, American Academy of Pediatrics, American

Academy of Family Physicians, and other major medical organizations have recognized that gender-affirming care is medically necessary, safe, and effective treatment for gender dysphoria, and that access to such treatment improves the health and well-being of transgender people. These groups and others have explicitly advocated against blanket bans on gender-affirming care like the Challenged Exclusions.

57. The medical procedures for the treatment of gender dysphoria are not "cosmetic" or "elective" or for the mere convenience of the patient, but instead are medically necessary for the treatment of the diagnosed medical condition. They are not experimental or investigational, because decades of both clinical experience and medical research show that they are essential to achieving well-being for transgender patients with gender dysphoria.

B. The Medicaid Act and Florida's Medicaid Program

i. Medicaid Coverage

58. The Medicaid Act, Title XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396-1396w-6, creates a joint federal-state program that provides health care services to specified categories of low-income individuals.

59. 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.

60. 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. In return, the federal government reimburses each participating state for a substantial portion of the cost of providing medical assistance. *See id.* §§ 1396b(a), 1396d(b), 1396(c).

61. 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). While a state may delegate certain responsibilities to other entities, such as local agencies or Medicaid managed care plans, the single state agency is ultimately responsible for ensuring compliance with all aspects of the Medicaid Act. *See, e.g.*, 42 C.F.R. §§ 438.100(a)(2), 438.100(d).

62. Each participating state must maintain a comprehensive state plan for medical assistance, approved by the Secretary of the U.S. Department of Health and Human Services. 42 U.S.C. § 1396a.

63. The state plan must describe how the state will administer its Medicaid program and affirm the state’s commitment to comply with the Medicaid Act and its implementing regulations. *Id.*

64. Under the Medicaid Act, a participating state must provide medical assistance to certain eligibility groups. *Id.* § 1396a(a)(10)(A)(i). One such group is

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).

65. States must administer Medicaid in "the best interests of recipients." 42 U.S.C. § 1396a(a)(19).

ii. The Medicaid EPSDT Requirements

66. The Medicaid Act requires each participating state to cover certain health care services, including inpatient and out-patient hospital services and physician services, when medically necessary. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d. States have the option to cover additional services, including prescription drugs, when medically necessary. *Id*.

67. One mandatory benefit under Medicaid is Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services for beneficiaries under age 21. *Id.* §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r).

68. The fundamental purpose of the EPSDT Requirements is to "[a]ssure that health problems are diagnosed and treated early, before they become more complex and their treatment more costly." Ctrs. for Medicare & Medicaid Servs., State Medicaid Manual § 5010.B.

69. Pursuant to the EPSDT requirements, states must cover four specific, separate categories of screening services: medical, vision, dental, and hearing. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r)(1)-(4).

70. States also must cover "[s]uch other necessary health care, diagnostic services, treatment, and other measures described in [1396d(a)] to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan." *Id.* § 1396d(r)(5). In other words, states participating in Medicaid must cover all medically necessary services for beneficiaries under age 21, even when those services are not covered for adults.

71. Services that fall under 42 U.S.C. § 1396d(a) include inpatient and outpatient hospital services, physician services, and prescription drugs. *Id.* § 1396d(a)(1), (2), (5)(A), (12).

72. Gender-affirming medical treatments, including puberty delaying medication, hormone therapy, and surgery come within the services described in section § 1396d(a) and, thus, are EPSDT services when they are necessary to correct or ameliorate gender dysphoria. *Id.* § 1396d(r)(5) (incorporating services listed in § 1396d(a)).

73. States must "arrang[e] for (directly or through referral to appropriate agencies, organizations, or individuals) corrective treatment the need for which is disclosed by" screening services. *Id.* § 1396a(a)(43)(C).

74. States must initiate EPSDT services in a timely manner, as appropriate to the individual needs of the beneficiary, and absolutely no later than 6 months from the date of the request. 42 C.F.R. § 441.56(e).

iii. The Medicaid Comparability Requirements

75. Under the Medicaid Act, "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).

76. "Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b).

77. A state "Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service ... to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c).

iv. Florida's Medicaid Program

78. The State of Florida participates in the federal Medicaid program. Fla. Stat. §§ 409.901-409.9205. 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. *See* Fla. Stat. § 409.902; 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10.

79. AHCA contracts with private managed care plans to provide health care services to most Medicaid beneficiaries. Fla. Stat. § 409.964.

80. The federal government reimburses Florida for approximately 60% of the cost of providing medical assistance through its Medicaid program. *See* U.S. Dep't of Health & Hum. Servs., Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2022 Through September 30, 2023, 86 Fed. Reg. 67479, 67481 (Nov. 26, 2021).

81. Florida regulations require AHCA to cover health care services that are medically necessary within the scope of Fla. Admin. Code R. 59G-1.035(6), 59G-1.010. To qualify as medically necessary, a service must meet several conditions. *See* Fla. Admin. Code R. 59G-1.010, incorporating by reference AHCA, Definitions Policy at 2.83 (2017) (defining medically necessary care).

82. 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. 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).

83. 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).

84. Until August 21, 2022, Florida Medicaid covered the full range of gender-affirming treatments, including puberty delaying medication, hormone therapy, and surgical care.

85. Effective August 21, 2022, Florida excluded the coverage without any intervening change in federal Medicaid laws or the standard of care for gender dysphoria, as recognized by the medical community.

86. Effective May 17, 2023, Florida codified the exclusion of coverage into statute by enacting SB 254, specifically, Section 3, without any intervening change in federal Medicaid laws or the standard of care for gender dysphoria, as recognized by the medical community.

C. Defendants Adopt the Challenged Exclusions and Target Transgender Medicaid Beneficiaries for Discrimination.

The Challenged Exclusion Created by Rule 59G-1.050(7)

87. On April 20, 2022, Florida's Department of Health ("FDOH") issued a misleading and factually inaccurate set of guidelines titled "Treatment of Gender

Dysphoria for Children and Adults" (hereinafter "FDOH Guidelines").[7] FDOH issued the FDOH Guidelines in direct response to the fact sheet from the U.S. Department of Health & Human Services regarding "Gender-Affirming Care and Young People."[8]

88. The FDOH Guidelines, which are non-binding in nature, directly contradicted the guidance from HHS, as well as the established medical guidelines supported by the country's largest and leading medical organizations.

89. The FDOH Guidelines stated that:

- Social gender transition should not be a treatment option for children or adolescents.
- Anyone under 18 should not be prescribed puberty delaying medication or hormone therapy.
- Gender reassignment surgery should not be a treatment option for children or adolescents.

90. Under the WPATH Standards of Care and Endocrine Society Guidelines, no one is provided pharmaceutical treatment for gender dysphoria until *after* the onset of puberty. No surgical interventions are recommended for transgender adolescents prior to the age of 18, *except* for limited reconstructive surgery for adolescents who

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[7] *See Treatment of Gender Dysphoria for Children and Adults*, FLORIDA DEP'T OF HEALTH (April 20, 2022), https://perma.cc/W33H-6P5Q.

[8] *See Gender-Affirming Care and Young People*, U.S. Dep't of Health & Human Servs. (March 2022), https://perma.cc/399W-T6AC.

have reached Tanner Stage 5 and for whom it is deemed medically necessary by qualified mental and medical health care professionals.

91. The FDOH Guidelines were criticized by, among others, a group of more than 300 Florida health care professionals who care for transgender and gender diverse youth. This group denounced the FDOH Guidelines for citing "a selective and non-representative sample of small studies and reviews, editorials, opinion pieces and commentary to support several of their substantial claims" and misrepresenting "high-quality studies" by making "conclusions that are not supported by the authors of the articles."[9]

92. The 300 Florida health care professionals further stated that the FDOH Guidelines "contradict[] existing guidelines from the American Academy of Pediatrics, the Endocrine Society, the American Academy of Child and Adolescent Psychiatry and the World Professional Association for Transgender Health," and that "[t]hese national and international guidelines are the result of careful deliberation and examination of the evidence by experts including pediatricians, endocrinologists, psychologists and psychiatrists."

93. On April 20, 2022, based on the publication of the FDOH Guidelines, Secretary Marstiller sent a letter to Tom Wallace, AHCA's Deputy Secretary for

[9] Brittany S. Bruggeman, *et al.*, *Opinion: We 300 Florida health care professionals say the state gets transgender guidance wrong | Open letter*, TAMPA BAY TIMES (Apr. 27, 2022), https://perma.cc/5UWE-LURH.

Medicaid, requesting that AHCA determine if the treatments addressed in the FDOH Guidelines "are consistent with generally accepted professional medical standards and not experimental or investigational."[10]

94. The request from Secretary Marstiller to Deputy Secretary Wallace was highly unusual, as AHCA does not generally draft a GAPMS report for services that it is already covering.

95. While AHCA purported to go through its required rule-making process, it was clear the outcome was predetermined: to restrict access to medically necessary gender-affirming care for transgender people in Florida.

96. On June 2, 2022, Defendants published their report, "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" (hereinafter "GAPMS Memo").[11] The publication of the GAPMS Memo was accompanied by the publication of a political webpage within AHCA's website titled "Let Kids Be Kids" (https://ahca.myflorida.com/letkidsbekids/) that included graphics, misleading "fact-checking" of HHS's guidance, and false assertions about social media's alleged influence on experiences of gender dysphoria.

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[10] *Letter from AHCA Secretary Marstiller to Deputy Secretary Wallace* (April 20, 2022), https://perma.cc/YS7S-DFAX.

[11] AHCA, *Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria* (June 2, 2022), https://perma.cc/SUB9-V7DW.

97. The GAPMS Memo wrongly concluded that gender-affirming medical treatments, including puberty blockers, hormone therapy, and surgery, "do not conform to GAPMS [("generally accepted professional medical standards")] and are experimental and investigational." Deputy Secretary Wallace signed the GAPMS Memo and noted his concurrence.

98. To support this conclusion, the GAPMS Memo cited to, and relied upon, five non-peer-reviewed, unpublished "assessments" that Defendants commissioned. The "assessments" are the following:

- Romina Brignardello-Petersen, DDS, MSc, PhD and Wojtek Wiercioch, MSc, PhD: Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence. 16 May 2022.
- James Cantor, PhD: Science of Gender Dysphoria and Transsexualism. 17 May 2022.
- Quentin Van Meter, MD: Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent. 17 May 2022.
- Patrick Lappert, MD: Surgical Procedures and Gender Dysphoria. 17 May 2022.
- Kevin Donovan, MD: Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children. 16 May 2022.

99. These "assessments" illustrate how the GAPMS Memo is the product of bias and was engineered to achieve a particular result.

100. For example, although the GAPMS Memo presents Dr. Quentin van Meter as an expert in medical treatment for gender dysphoria, at least one court in Texas barred him from providing expert testimony on the on the "question of whether an adolescent transgender child should be administered puberty blockers and whether affirmation of an incongruent gender in a child is harmful or not."[12] Dr. Van Meter is the president of the American College of Pediatricians (not to be confused with the American Academy of Pediatrics). The American College of Pediatricians is not a professional association but instead a political group that, among other things, opposes marriage equality for same-sex couples, supports the provision of conversion therapy, and describes childhood gender dysphoria as "confusion."

101. The GAPMS Memo also cites to Dr. James Cantor as an expert on gender dysphoria. However, Dr. Cantor admitted in court to having no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving medical or surgical treatments for gender dysphoria.[13]

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[12] Stephen Caruso, *A Texas judge ruled this doctor was not an expert. A Pennsylvania Republican invited him to testify on trans health care*, PENNSYLVANIA CAPITOL-STAR (Sept. 15, 2020), https://perma.cc/P8AU-3RFC.

[13] In *Eknes-Tucker v. Marshall*, No. 2:22-CV-184-LCB, 2022 WL 1521889, at *5 (M.D. Ala. May 13, 2022), based on Dr. Cantor's lack of experience in providing this type of care, "the Court gave his testimony regarding the treatment of gender dysphoria in minors very little weight."

102. AHCA's GAPMS Memo also cites to an "assessment" authored by Dr. Romina Brignardello-Petersen and a post-doctoral fellow purporting to review the scientific literature regarding gender dysphoria and its treatment. Dr. Brignardello-Petersen has no particular expertise regarding gender dysphoria and is a member of the Society for Evidence Based Gender Medicine ("SEGM"), a group that opposes standard medical care for gender dysphoria, has no publications or conferences, and, upon information and belief, consists solely of a website created by a small group of people.

103. AHCA cites to an "assessment" by Dr. Patrick Lappert, a non-board-certified plastic surgeon. A federal court recently noted that there is evidence that calls Dr. Lappert's "bias and reliability [to testify regarding gender dysphoria] into serious question" and that Dr. Lappert "is not qualified to render opinions about the diagnosis of gender dysphoria, its possible causes, … the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on [] non-surgical treatments," and that his views "do not justify the exclusion" of gender-affirming medical care.[14]

104. On June 17, 2022, AHCA issued a Notice of Proposed Rule seeking to amend Florida Administrative Code 59G-1.050 to prohibit Florida Medicaid from

[14] *Kadel v. Folwell*, No. 1:19CV272, 2022 WL 3226731, at *12-13, 32 (M.D.N.C. Aug. 10, 2022).

covering "services for the treatment of gender dysphoria," including: "1. Puberty blockers; 2. Hormones and hormone antagonists; 3. Sex reassignment surgeries; and 4. Any other procedures that alter primary or secondary sexual characteristics." The Proposed Rule also stated that, "For the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)," the aforementioned services "do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C."[15]

105. The Proposed Rule sought to prohibit Medicaid coverage of medical treatment for gender dysphoria for both transgender adolescents and adults, going beyond the FDOH Guidance.

106. During the 21 days following the issuance of the Proposed Rule, from June 17, 2022 to July 8, 2022, thousands of comments were submitted by individuals, organizations, and medical professionals across Florida in opposition to the rule.

107. On July 8, 2022, AHCA held a public hearing on the proposed rule.

108. The hearing, which was set for 3:00pm on a Friday afternoon, featured a "panel of doctors," none of whom had any clinical experience treating gender dysphoria, to respond to any substantive comments from the audience. The panel of doctors included: Dr. Andre Van Mol; Dr. Quentin Van Meter; and Dr. Miriam Grossman.

[15] https://www.flrules.org/gateway/View_Notice.asp?id=25979915.

109. The panel highlighted AHCA's singular focus on prohibiting coverage of and access to medically necessary gender-affirming care.

110. Dr. Andre Van Mol is a board member of Moral Revolution (https://www.moralrevolution.com/), an organization that believes that "[t]he multitude of possible gender identities and the normalization of same-sex sexual behavior points to a society that has abandoned the desire to accurately define and socialize humanity as a reflection of God's image," and that "[s]ome people experience same-sex attraction and gender dysphoria … not because they were 'born that way,' but because they were born human into a fallen world, and because society has disrupted and confused how we teach children who they are."

111. In reference to transgender youth, Dr. Miriam Grossman has stated that "conditioning children into believing that a lifetime of impersonating someone of the opposite sex, achievable only through chemical and surgical interventions, is harmful to youths."

112. The public hearing was also characterized by participants who were flown in from out of state, who did not profess to be Florida Medicaid participants, or who were opponents of transgender rights bussed in to testify in support of the rule. Many of them were carrying signs and shirts reflecting the "Let Kids Be Kids" slogan that appears on AHCA's webpage regarding the GAPMS Memo. AHCA allowed stickers containing their slogan to be passed out at the front door and at the sign-in table as attendees entered.

113. Notwithstanding the seemingly biased nature of the proceedings, thousands of commenters submitted written comments and many testified at the hearing in opposition to the Proposed Rule. The range of comments highlighted, among other things: the significant and immediate harms that transgender Medicaid beneficiaries in Florida would suffer; the flaws of the GAPMS Memo; the well-documented evidence base for gender-affirming care, including that it is safe and effective for the treatment of gender dysphoria; and that the Proposed Rule was unlawful.

114. Among the comments submitted to Defendants in opposition to the Proposed Rule was a comment by a team of legal and medical experts from Yale Law School, the Yale School of Medicine's Child Study Center and Departments of Psychiatry and Pediatrics, University of Texas Southwestern, and University of Alabama at Birmingham that identifies and refutes the many unscientific claims behind the GAPMS Memo.[16]

115. The comment by the team of experts indicated that:

- **The GAPMS Memo falsely claims that the scientific evidence does not support medical treatment for gender dysphoria.** In fact, medical care for gender dysphoria is supported by a robust scientific consensus. The specific medical services at issue have been used worldwide for

[16] *Letter from Anne L. Alstott et al. to AHCA Secretary Marstiller* (July 8, 2022), https://perma.cc/E432-YUQ7.

decades, meet generally accepted medical standards, and are not experimental.

- **The GAPMS Memo urges a discriminatory policy that violates the federal and state constitutions and federal and state law.** AHCA offered the report to justify the denial of Medicaid coverage for medical care for gender dysphoria. But this discriminatory policy illegally targets transgender people. Neither the June 2 GAPMS Memo nor the AHCA proposal would apply to similar treatments routinely offered to cisgender people.
- **The GAPMS Memo repeatedly and erroneously dismisses solid medical research studies as "low quality," demonstrating a faulty understanding of statistics, medical regulation, and scientific research.** The GAPMS Memo makes unfounded criticisms of robust and well-regarded clinical research, while disregarding other relevant studies altogether. If Florida's Medicaid program applied the June 2 GAPMS Memo's approach to all medical procedures equally, it would have to deny coverage for widely used medications like statins (cholesterol-lowering drugs taken by millions of older Americans) and common medical procedures like mammograms and routine surgeries.
- **The GAPMS Memo cites sources that have no scientific merit.** The GAPMS Memo relies on pseudo-science, particularly purported expert

"assessments" that are biased and full of errors. The "assessments" are written by authors whose testimony has been disqualified in court and who have known ties to anti-LGBTQ advocacy groups. The GAPMS Memo's unfounded claims come from unqualified sources, which include a blog entry, letters to the editor, and opinion pieces.

116. The comment by the team of experts was accompanied by the publication of a report, "A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria," that represents the first comprehensive examination of Florida's GAPMS Memo. The authors of this report contend that the GAPMS Memo is a misleading document intended to justify denying Florida Medicaid coverage for gender dysphoria treatment.[17]

117. In its comment, the American Academy of Pediatrics noted: "[T]he mental and physical health and well-being of transgender children and adolescents often rely on their abilities to access much needed mental and physical health care—care that is in keeping with the widely recognized evidence-based standards of care for gender dysphoria. In proposing this rule, Florida ignores broad consensus among the medical community as to what those evidence-based standards of care are, and instead seeks, for its own discriminatory reasons, to impose alternate standards and an

[17] *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria* (July 8, 2022), https://perma.cc/XZV3-PBEA.

outright ban of specific treatments for transgender adolescents in the state's Medicaid program."[18]

118. Similarly, the Endocrine Society submitted a comment stating: "The proposed rule would deny Medicaid beneficiaries with gender dysphoria access to medical interventions that alleviate suffering, are grounded in science, and are endorsed by the medical community. The medical treatments prohibited by the proposed rule can be a crucial part of treatment for people with gender dysphoria and necessary to preserve their health. … [R]esearch shows that people with gender dysphoria who receive puberty blockers and/or hormone therapy experience less depression, anxiety, and suicidal ideation. Several studies have found that hormone therapy is associated with reductions in the rate of suicide attempts and significant improvement in quality of life. In light of this evidence supporting the connection between lack of access to gender-affirming care and lifetime suicide risk, banning such care can put patients' lives at risk."[19]

119. In addition, interviews with researchers whose studies were cited within the FDOH Guidelines and GAPMS Memo have expressed alarm at how Defendants

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[18] *Letter from the American Academy of Pediatrics and the Florida Chapter of the AAP to AHCA Deputy Secretary Tom Wallace* (July 7, 2022), https://perma.cc/ND5M-TGYJ.

[19] *Letter from the Endocrine Society to AHCA* (July 8, 2022), https://perma.cc/F5TX-J3JY.

have misinterpreted and misrepresented their studies to justify the Challenged Exclusion.[20]

120. Notwithstanding the thousands of comments submitted to AHCA in opposition to the Proposed Rule, as well as the substantive evidence and extensive commentary submitted by leading medical and legal experts and organizations, Defendants filed the Challenged Exclusion as a final rule for adoption on August 1, 2022, a mere three weeks after the close of the public comment period and without having responded in writing to material or timely written comments, as required by Fla. Stat. § 120.54(3)(e)(4).

121. Notice of the Final Adopted Version of the Challenged Exclusion was published on FLRules.com on August 10, 2022 and stated that the Challenged Exclusion would become effective on August 21, 2022.[21]

122. The Challenged Exclusion, in its final adopted form within Florida Administrative Code 59G-1.050, states as follows:

> (7) Gender Dysphoria.
>
> (a) Florida Medicaid does not cover the following services for the treatment of gender dysphoria:
>
> 1. Puberty blockers;

[20] Sam Greenspan, *How Florida Twisted Science to Deny Healthcare to Trans Kids*, VICE NEWS (Aug. 3, 2022), https://perma.cc/GZ6P-W2WN.

[21] https://www.flrules.org/gateway/View_Notice.asp?id=26157328.

2. Hormones and hormone antagonists;

3. Sex reassignment surgeries; and

4. Any other procedures that alter primary or secondary sexual characteristics.

(b) For the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), the services listed in subparagraph (7)(a) do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C.

123. Coverage for the four services listed within the Challenged Exclusion is still available when those services are medically necessary for the treatment of conditions other than gender dysphoria.

124. The Challenged Exclusion ignores the established scientific and medical consensus that the four specified services are frequently medically necessary, safe, and effective for treating gender dysphoria.

125. The Challenged Exclusion results in AHCA refusing to cover medically necessary treatments for gender dysphoria.

126. In addition, the Challenged Exclusion is one of a series of measures the State has taken targeting transgender people, and LGBTQ people more broadly, for discrimination.

127. For example, surrounding the GAPMS Memo's release and the adoption of the Challenged Exclusion:

a. The FDOH issued its factually inaccurate April 2022 guidelines titled "Treatment of Gender Dysphoria for Children and Adults";[22]

b. Florida enacted its infamous "Don't Say Gay" law, Fla. Stat. § 1001.42(8)(c) (2022);[23]

c. Governor DeSantis removed a state attorney from office for, in part, saying he would refuse to enforce any laws criminalizing gender-affirming care;[24]

d. The FDOH sent the Florida Board of Medicine ("FBOM") a "Petition to Initiate Rulemaking," asking it to, among other things, adopt a categorical ban on the provision of gender-affirming medical care to people under 18 years of age and, with respect to adults, to adopt a 24-hour waiting period;[25]

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[22] *Treatment of Gender Dysphoria for Children and Adults*, FLORIDA DEP'T OF HEALTH (April 20, 2022), https://perma.cc/W33H-6P5Q.

[23] Enacted July 1, 2022, the law seeks to erase LGBTQ people and related content from Florida public schools. The widely used "Don't Say Gay" moniker fails to recognize the harms this law intentionally inflicts upon transgender people and others who identify as members of the LGBTQ community.

[24] Florida Executive Order No. 22-176 (Aug. 4, 2022), https://perma.cc/VSG9-2SUJ.

[25] *Petition to Initiate Rulemaking Setting the Standard of Care for Treatment of Gender Dysphoria* (July 28, 2022), https://perma.cc/3PP7-N6WW.

e. The FBOM initiated a rulemaking process for a proposed rule to, among other things, ban gender-affirming care for people under the age of 18;[26]

f. The Florida Department of Business and Professional Regulation lodged a public nuisance complaint against a bar catering to transgender people when that bar had a drag queen reading event;[27] and

g. Florida officials and their spokespersons made a litany of statements denigrating transgender people.[28]

128. Indeed, documents obtained from the Executive Office of Governor Ron DeSantis outline the coordinated nature of these actions and that they are all part of a singular plan. Take for example the following document produced by the Executive Office of the Governor:

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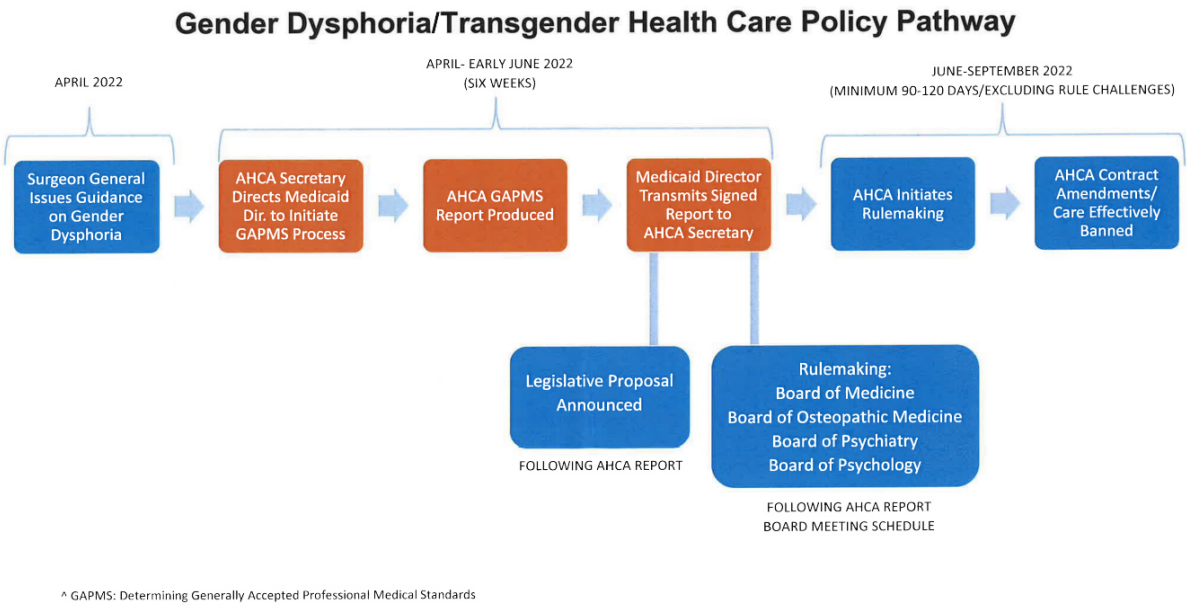
[26] *Meeting Minutes*, FLORIDA BOARD OF MED. (Aug. 5, 2022), https://perma.cc/52A3-2E5V; subsequently, the Florida Boards of Medicine and Osteopathic Medicine adopted rules prohibiting physicians from prescribing gender-affirming care to minors (effective March 16, 2023 and March 28, 2023).

[27] *Fla. Dep't of Bus. and Prof. Reg., Div. of Alcoholic Beverages and Tobacco v. R House, Inc.*, Case No. 2022-035976, Admin. Complaint (July 26, 2022), https://perma.cc/8DRL-KVWY.

[28] Jeremy Redfern (@JeremyRedfernFL), Twitter (Aug. 14, 2022), https://tinyurl.com/2p8vajvw; Governor Ron DeSantis (@GovRonDeSantis), Twitter (Aug. 16, 2022), https://tinyurl.com/yckkuh32; Christina Pushaw (@ChristinaPushaw), Twitter (Aug. 19, 2022), https://tinyurl.com/2p8r5r6c.



129. The discriminatory animus by Defendants toward transgender people is clearly evident by their actions, as the adoption of the Challenged Exclusion deliberately targets transgender people for discrimination in Florida.

The Challenged Exclusion Created by SB 254

130. On May 4, 2023, the Florida Legislature voted to pass SB 254.

131. On May 17, 2023, Florida Governor Ron DeSantis signed into law SB 254, which includes Section 3, "Prohibited use of state funds." Section 3 prohibits "a governmental entity . . . [or] a managed care plan providing services under part IV of chapter 409" from expending state funds on "sex-reassignment prescriptions or procedures" as defined in Section 4.

132. Section 4 defines the prohibited care as (1) the "prescription or administration of puberty blockers for the purpose of attempting to stop or delay normal puberty in order to affirm a person's perception of his or her sex if that

perception is inconsistent with the person's sex" assigned at birth; (2) the "prescription or administration of hormones or hormone antagonists to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex" assigned at birth; and (3) any "medical procedure, including a surgical procedure, to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex" assigned at birth.

133. Coverage for the treatments listed within SB 254 is still available when those services are medically necessary for the treatment of conditions other than gender dysphoria.

134. SB 254 ignores the established scientific and medical consensus that the excluded services are frequently medically necessary, safe, and effective for treating gender dysphoria.

135. Section 3 of SB 254 results in AHCA refusing to cover medically necessary treatments for gender dysphoria.

136. SB 254 deliberately and exclusively singles out transgender people in Florida for unequal treatment and discrimination. The discriminatory animus toward transgender people is evident by the legislative history leading to the enactment of SB 254.

D. The Plaintiffs

Plaintiff August Dekker

137. August Dekker is a 28-year-old transgender man.

138. August is unemployed and receives Supplemental Security Income due to disability, as he lives with debilitating rheumatoid arthritis. He has been a Medicaid beneficiary in Florida since 2014.

139. August experiences and has been diagnosed with gender dysphoria.

140. As a child, even as early as 5 years of age, August felt uncomfortable being perceived as a girl. For example, he would always choose to play a male character when he was roleplaying with his brothers and would also play male characters when he would play "house."

141. Around the age of 13, August was extremely distraught when he got his first period. He ran to his mom crying and wondering what was happening because he did not feel that he was a girl.

142. However, because of his family's religious beliefs, August felt forced to suppress his gender identity as a child and adolescent, which caused him great distress and anxiety.

143. Once he graduated high school, August felt freer to explore his gender expression and come to terms with his gender identity as a man. By 2015, August began to socially transition and live openly as the man that he is.

144. Not long after, August decided to seek out medical care. It took him a while to find a provider who would be qualified and with whom he felt comfortable. Once he found a provider at Metro Inclusive Health in Tampa, August began working

with a therapist before starting hormone therapy. The therapist diagnosed August with gender dysphoria in 2017.

145. Following the diagnosis of gender dysphoria and working with and under the care of his medical and mental health providers, August began undergoing hormone therapy as medically necessary treatment for his gender dysphoria in 2017.

146. August has since worked with different medical and mental health providers, who continue to recommend hormone therapy as medically necessary treatment for his gender dysphoria. He now sees a therapist at Solace Behavioral Health in Tampa and receives his hormone therapy through Planned Parenthood in Tampa.

147. At present, at the recommendation of his medical and mental health providers, August is being prescribed testosterone hormone therapy as treatment for his gender dysphoria. The prescription must be written every month.

148. In addition, in consultation with and under the care of his medical and mental health providers, August obtained chest surgery as treatment for his gender dysphoria in April 2022. This surgical treatment, which was covered by Medicaid, was recommended by his providers as medically necessary treatment for August's gender dysphoria. And it was covered by Medicaid.

149. Medicaid has always covered August's medically necessary gender-affirming medical care as recommended by his medical and mental health providers to treat his gender dysphoria.

150. Being able to receive hormone therapy in the form of testosterone injections and to have chest surgery has allowed August to bring his body into alignment with who he is, provided a great deal of relief to August, and relieved some of the clinically significant distress underlying his gender dysphoria. It has given August the ability to not hate himself or his body and has brought great comfort to his life.

151. Having access to this medically necessary care has allowed August to be the version of himself that he pictured growing up. For August, it feels natural and normal to be able to live as the man that he is.

152. Following his chest surgery, August was able to celebrate his birthday with some friends outdoors in a state park. Having a more masculine chest that conformed with his identity allowed August to be shirtless in public for the first time ever, just like any other man. It was an afternoon full of joy and laughter for August, and he had never felt more euphoric about his body than he did in that moment.

153. The adoption of the Challenged Exclusions have caused August a great deal of distress and anxiety. When August first learned of the new regulations, he felt a great sense of dread. August is now fearful of the future.

154. August's only source of income is his monthly Supplemental Security Income payments of $841. He uses this limited income to pay for rent, food, and necessities, and simply cannot afford his medically necessary hormone therapy without Medicaid, which would cost $60-65 per month.

155. While August could ask some family and friends for money in order to afford his medically necessary care, that is neither guaranteed nor sustainable. It also feels dehumanizing and shameful to August to have to ask for help all the time, especially when his hormone therapy is medically necessary health care recommended by his doctors and which Medicaid has covered previously.

156. August also has experienced the physical effects of having to stop hormone therapy for a period of time. That experience caused him to lose muscle mass, have a higher pitched voice, and lose some of his body and facial hair such that it caused him distress and to a degree that people started perceiving him as a woman instead of the man that he is. It caused August great discomfort and anguish to be perceived as such, and he does not want to ever have to experience that again.

157. The adoption of the Challenged Exclusions, along with other actions taken by Florida's current administration targeting transgender people, have shaken August and caused him to lose hope. August no longer feels safe to be an out transgender person in Florida. Because of the discrimination he sees stoked by Florida's policy decisions to target transgender people, August often worries that someone will perceive him as transgender and decide they want to hurt him. He is frightened about the possibility that losing access to his medically necessary gender-affirming care will cause physical changes that will make it more likely for someone to perceive him as transgender or more feminine. If someone perceives him as

transgender or more feminine, August is afraid that they will verbally or physically assault him.

158. It is incredibly stressful and debilitating for August to have to worry about whether he will be able to get the medical care that he needs, or whether in its absence, he will be incorrectly perceived as female.

159. The Challenged Exclusions threaten the health and wellbeing of transgender Medicaid beneficiaries like August.

Plaintiff Brit Rothstein

160. Brit Rothstein is a 20-year-old transgender man.

161. Brit is a junior in at the University of Central Florida (UCF), where he is studying digital media and minoring in information technology. Brit has a full scholarship to attend UCF, which is the only way that he is able to go to college as his family is low-income and could not otherwise afford tuition and living expenses. Brit worked hard to obtain a Florida Bright Futures scholarship so that he would be able to attend college. He also received a Top Ten Knights Scholarship from the UCF. In addition, Brit participates in a federal work study program, which provides part-time jobs for students with financial need.

162. Given his and his family's very limited income, as well as his age, Brit receives his health care coverage through Florida's Medicaid program, as administered through Sunshine Health.

163. A transgender man, Brit was incorrectly assigned the sex female at birth, but his gender identity is male.

164. Brit experiences gender dysphoria in relation to the disconnect between his sex assigned at birth and his gender identity.

165. Since the third grade, Brit has been aware of his male gender identity. When he was younger, Brit's mom would try to force him to wear dresses to church but he hated dresses and would only want to wear slacks. He also did not understand why he could not have short hair. Even as a child, stereotypical assumptions and expectations regarding his sex assigned at birth did not make sense to him.

166. In the sixth grade, as he approached puberty, Brit's anxiety and depression surrounding his sex assigned at birth was exacerbated, and he would become physically ill when he had to go into the girls' locker room for P.E. Fortunately, there was a guidance counselor who understood the discomfort that Brit experienced in the locker room and the manifesting anxiety and distress it caused him, so she helped him transfer out of P.E.

167. While he was in the seventh grade, Brit was seeing a therapist due to unrelated issues. His therapist saw how much Brit was struggling with not being able to live his life as a boy and, through his sessions with his therapist, Brit became more comfortable with how he was feeling and came to understand that he was a boy. Brit's therapist also helped Brit navigate how to talk to others about his gender identity.

168. After a lot of research about how to explain to his family how he felt and that he was transgender, Brit came out to his dad in 2015, at age 13, and asked that he be treated in accordance with his male gender identity. Brit's parents are divorced, and he came out only to his dad at first. Brit's dad was very supportive and allowed Brit to wear a binder (a garment that helps to give the appearance of a flatter chest) at his house and live as his true authentic self when he was there.

169. Unfortunately, Brit was not able to do the same at his mother's house because she disapproved of him. For example, when Brit came out to his mother as transgender in 2016, she called him an "abomination" and disowned him. Brit has had infrequent contact with his mother or her side of the family since then.

170. Around July 2015, when Brit was 14 years old, Brit began seeing a psychologist, and continued therapy with her until he went to college. Brit's psychologist diagnosed him with gender dysphoria and, after a couple of years of counseling, the psychologist referred Brit to Joe DiMaggio Children's Hospital to meet with a pediatric endocrinologist.

171. Because Brit's mother objected to the medical care for Brit's gender dysphoria recommended by Brit's mental health and medical providers, Brit's dad had to go to court, where he was granted by the court sole decision-making authority as it related to issues involving Brit's gender identity.

172. Thereafter, when Brit was 17 years old, he began to see a pediatric endocrinologist at Joe DiMaggio. By then, Brit had been diagnosed with gender

dysphoria approximately four years prior and had been in consistent and regular counseling since that time. Brit was also living in accordance with his male gender identity to the maximum extent possible, given his family situation.

173. Brit's pediatric endocrinologist determined that it was medically necessary for Brit to begin hormone blockers, which she prescribed for him, and oversaw his treatment. Months later, Brit also began testosterone hormone therapy as medically necessary treatment for his gender dysphoria at his pediatric endocrinologist's recommendation. Medicaid has covered Brit's gender-affirming health care needs, including therapy, blood tests, office visits, and his prescriptions for hormone blockers and testosterone.

174. Hormone therapy, in the form of testosterone, has impacted Brit's life in many positive ways, including the changes to his physical body, his mental and emotional health, and even the self-confidence he has gained through existing in a body that feels more like his own.

175. When he was 18, Brit was able to obtain a court order for legal name change, changing his legal name to Brit Andrew Rothstein, which aligned with his gender identity and who he knows himself to be. Brit also amended his legal government-issued identification documents to reflect his new legal name and correct gender marker as male.

176. Still, however, Brit continued to experience significant dysphoria related to his chest. Ever since his chest developed, Brit had hated the way it looks and feels,

and has long known that he needed to have chest surgery to bring his body into alignment with who he is.

177. Brit wore a binder almost every day, usually for 10-12 hours per day, depending on his schedule. His binder caused him discomfort, left skin indentations, and sometimes caused bruising on his ribcage. In 2018, Brit had to go to the emergency room for chest contusions caused by wearing his binder for too long. Having top surgery was necessary to allow Brit to no longer wear a restrictive binder just to navigate his daily life. Unfortunately, there are very few medical providers in Florida who are both competent in performing gender-affirming chest surgery, and even fewer who also take Medicaid.

178. Brit finally found a surgeon at the University of Miami who accepted Medicaid for chest surgeries in January of 2022. Brit had his consultation with the surgeon in May of 2022 and the surgeon recommended that Brit undergo gender-affirming chest surgery, which was pre-authorized by Medicaid. When Brit received his pre-authorization on August 11, 2022, he felt blessed to finally have the chance to obtain the gender-affirming care he needed.

179. Brit was elated to learn that he would finally be getting the surgery that he needed and had long awaited, and he even had a date scheduled: December 22, 2022. Brit was looking forward to the surgery that would allow him to bring his body into alignment with who he is and eliminate the need for Brit to wear a restrictive and painful binder to hide that part of his body.

180. However, the very next day after Brit learned his surgery had been pre-authorized, Brit learned that AHCA adopted a rule that prohibited Medicaid coverage for Brit's medically necessary gender-affirming chest surgery. To Brit, it was a punch to the gut to learn that the state of Florida had decided to strip coverage for medically necessary medical care from him and other transgender Floridians on Medicaid. It was the highest of highs followed by the lowest of lows.

181. Because of the Challenged Exclusion, Brit's surgery was not covered by Florida Medicaid, despite having been authorized as medically necessary treatment.

182. Without Medicaid, Brit cannot afford to pay for his testosterone prescription and ongoing needs for the treatment of his gender dysphoria. Because of the Challenged Exclusions, Brit is unable to access to the medical care for his gender dysphoria that his medical providers have determined is medically necessary for his health and wellbeing.

183. Brit's family is also of very limited income, and he does not have family members who can pay for his care. Brit's dad is a single parent, who has arranged his entire life around being the sole-caretaker for Brit's twin sister, who lives with cerebral palsy and other disabilities. Brit's dad needs to have the same schedule as his sister because she requires around the clock care and attention. As such, Brit's dad has worked as a teachers' assistant for students with special education needs in the Broward County School District, a job which pays approximately $21,000 per year.

Brit's dad is thus barely able to make ends meet and cannot afford to financially help Brit access the medical care he needs.

184. Brit has spent a long time fighting to become the man that he knows himself to be. He has overcome obstacles and worked hard to get an education and have access to the medical care his providers have deemed medically necessary to treat his gender dysphoria, yet Defendants have created unnecessary additional barriers blocking Brit from the medical care that he needs.

185. Even though Brit is legally male in the eyes of the state and federal government, has testosterone circulating through his body, and has grown facial hair, Brit still lives in fear every day that he will be misperceived as female or perceived as transgender.

186. In high school, Brit recognized how fortunate he was to have a supportive parent who loved him for who he is. Not everyone has that. There were multiple students at Brit's high school who attempted or died by suicide, so Brit decided that he needed to advocate for those who did not have the support that he had from his dad. As a result, Brit was invited to join the Broward County Superintendent's LGBTQ+ Advisory Council, and Brit was the President of his school's Gay/Straight Alliance (GSA) Club. Brit supported his fellow transgender classmates the best that he could, because Brit believes that everyone deserves to feel accepted for who they are.

187. For Brit, the State's decision to deny transgender people, like himself, of access to medically necessary health care and being treated differently than others solely for being transgender is unthinkable and wrong.

Plaintiff Susan Doe

188. Susan Doe is the daughter of Jane and John Doe.

189. Jane Doe is a full-time mom and homemaker. John Doe works for the federal government. He has worked there for 19 years.

190. Along with their two children, Jane and John live in Brevard County, Florida.

191. Jane and John adopted Susan, their 13-year-old daughter, out of medical foster care in Florida when she was 2 years old.

192. Susan is transgender.

193. When Jane and John adopted Susan out of foster care, Susan had several medical issues. She was originally placed in regular foster care and was then moved into the medical foster care program after an incident where she stopped breathing as an infant. At the time she came into the Does' care, she had severe acid reflux that needed treatment and was barely meeting developmental milestones.

194. Because Jane and John adopted Susan out of foster care, she is eligible for Medicaid coverage until she turns 18. Susan has thus been eligible for and enrolled in Florida's Medicaid program since she entered Florida's foster care system as an

infant. Jane and John have kept Susan on Medicaid in order to ensure continuity of care with her existing providers and to ensure that her medical needs are properly met.

195. Although Susan was assigned male at birth, she has known that she is a girl from a very young age. When she was 3 years old, Susan first told her parents that she was a girl. Jane and John allowed Susan to explore her gender expression in deliberate and gradual steps. For example, Susan liked to wear ribbons in her hair and pink bracelets to school, even when she still wore typical boy clothes and had not yet grown out her hair. Jane and John kept princess dresses for Susan at home, and she would often change into a dress as soon as she came home from school.

196. When Susan was in first grade, she became extremely unhappy with her assigned gender. Before that time, she had mostly been a very happy-go-lucky child, but starting in first grade she began getting angry and frustrated easily, and then would become incredibly sad, often crying for 20 minutes or more.

197. Jane and John consulted resources online and researched gender dysphoria in children, and as Susan's parents, had to acknowledge that the discrepancy between Susan's sex assigned at birth and how she felt inside was causing her to suffer.

198. The Does looked for a therapist for Susan. Ultimately, Susan and Jane were able to go to one session with a therapist when Susan was 6, and the therapist advised Jane on how to best support Susan. The therapist told Jane to keep listening to Susan and to allow her to express herself, as Jane and John had been doing. The therapist also suggested buying clothes from the girls' department that were gender

neutral so Susan could wear them to school without attracting attention about her gender presentation.

199. Susan had her last short haircut when she was 6 years old, and when she saw how it looked, she started crying because she felt like the short haircut did not reflect her identity. After that, she started growing out her hair.

200. Around the same time, Jane found out that Susan had started to introduce herself to people with her chosen name, which has since become her legal name, and is more typically feminine.

201. During the summer of 2017, which was the summer before Susan started second grade, Susan told Jane and John unequivocally: "I need to be a girl." To ensure that they were properly supporting Susan, Jane and John took Susan to see a therapist as a family. The therapist diagnosed Susan with gender dysphoria. The therapist also made clear to the Does that Susan knows exactly who she is and that any problems stemmed from when people question Susan's identity. The therapist thus recommended Jane and John continue to support Susan in her social transition.

202. Following the therapist's advice, Jane and John followed Susan's lead and bought her more traditionally feminine clothes, including dresses and skirts to wear to school. Jane and John also worked with the principal and teachers at Susan's school to try to make sure that they used the appropriate name and pronouns for Susan. In addition, the therapist shared with Jane and John, and the Does in turn shared with

Susan's school, the latest research on helping children with gender dysphoria adjust well at school, in addition to in the home.

203. After Susan was able to socially transition and live in accordance with her firmly asserted female gender identity, Jane and John observed Susan feeling a sense of joy. Susan was happy and comfortable in her own skin.

204. In addition, the therapist further recommended that Susan see a pediatric endocrinologist, who could monitor her hormone levels for the onset of puberty and assist with any future medical needs.

205. Jane and John looked for a pediatric endocrinologist that was close to them, but ultimately began working with a pediatric endocrinologist at Joe DiMaggio Children's Hospital in south Florida. Susan has been seeing her pediatric endocrinologist since 2019. The Does drive three hours there and three hours back for every appointment. Initially, the pediatric endocrinologist closely monitored Susan's hormone levels to determine the onset of puberty. Susan had visits approximately every three months.

206. Jane and John have been very deliberate in their approach to supporting Susan. Their goal has always been to support their daughter while following the advice and recommendations of medical and health professionals experienced in dealing with gender identity and gender dysphoria.

207. In July 2020, after Susan began the onset of puberty, the pediatric endocrinologist started Susan on a puberty delaying medication called Lupron as

medically necessary treatment for Susan's gender dysphoria. The medication, which Medicaid has been covering, prevents Susan from developing secondary sex characteristics consistent with male puberty. According to the pediatric endocrinologist, it is medically necessary for Susan to receive a Lupron injection every three months in order for her to live authentically in a manner consistent with her gender identity and to treat her gender dysphoria. By preventing the physical manifestations that accompany male puberty, Susan is also able to avoid negative social and emotional consequences associated with her being forced to develop the characteristics aligned with a gender with which she does not identify.

208. When Susan learned that the puberty delaying medication was necessary to suppress male puberty, she was happy at the prospect. There is nothing worse in Susan's mind than male puberty; she describes it as a "nightmare."

209. Susan's pediatric endocrinologist has been monitoring Susan to determine when it would be medically appropriate for her to begin hormone therapy, and at her last appointment she informed the Doe's that Susan is in fact ready to begin hormone therapy. Susan is very eager to go through female puberty, and is devastated that she is being left behind while her peers go through the experience that she is being denied due to the Challenged Exclusions.

210. In August 2021, the Does' therapist retired from her practice. In November 2021, Susan began seeing another therapist, who is a Licensed Clinical Social Worker. Like the first therapist, the second therapist diagnosed Susan with

gender dysphoria. The second therapist has further supported Susan in managing the symptoms of her dysphoria.

211. In light of Defendants' adoption of the Challenged Exclusions, the Does understand that Florida's Medicaid program will no longer cover Lupron for Susan as treatment for her gender dysphoria. The Challenged Exclusions will also prohibit Medicaid from covering hormone therapy as treatment for Susan's gender dysphoria, which Susan's pediatric endocrinologist has determined she is ready to begin.

212. Jane and John worry about the potential physical and mental health consequences of depriving Susan of the medically necessary treatment recommended by her doctors. Not providing such treatment is not an option for them. For Jane and John, providing Susan with the medical treatment for gender dysphoria that she requires is necessary to ensure her health and well-being.

213. If Susan had to stop taking Lupron and go through male puberty as a result of the Challenged Exclusions, she would be devastated. Susan has been living as a girl in every aspect of her life since 2017. Her legal name was changed to her current affirmed name in 2018, and in 2020, her birth certificate was amended to reflect that she is female.

214. If Susan were no longer able to access the medical care that she needs to align her body with her gender identity, Susan's mental health would suffer tremendously. Susan would not want to leave the house, and Jane and John fear that she might engage in self-harm. Going through male puberty would be torture for

Susan. It would also be agony for Jane and John to watch Susan suffer needlessly when this could be easily eliminated with what they understand to be effective medical care for treating their daughter's gender dysphoria.

215. Through their experience with Susan's medical treatment and extensive conversations with her medical providers over the past five years, Jane and John understand that gender-affirming treatment is medically necessary, safe, and effective treatment for Susan's gender dysphoria.

216. Unlike Susan, Jane and John receive their health coverage through John's employer-provided health plan.

217. While the Does can add Susan to John's health plan, they cannot do so until the open enrollment period near the end of the year, and Susan's coverage would not start before January 1, 2024. Thus, given her ongoing need for gender-affirming care, this is not a feasible solution.

218. In any event, as a child adopted out of foster care, Susan is entitled to have her medical needs covered by Medicaid and Jane and John should not have to move Susan to John's employer-provided health plan in order for her to continue receiving medically necessary care.

219. With Medicaid no longer covering Susan's Lupron treatment, Jane and John will have no choice but to try to pay for her Lupron injections out of pocket. Based on their research, the retail price for a single Lupron shot is roughly $11,000. They will also have to pay out of pocket for her hormone therapy. As the parents of

two children with only one income, Jane and John do not have sufficient resources to provide this care without sacrifice. Jane and John would have to take on debt to pay for Susan's puberty delaying medication and hormone therapy and it would be a hardship for them.

220. Even if the Does are able to add Susan to John's health plan, Susan's health care would be more expensive for them, as they would have a $300 annual deductible for Susan and higher cost-sharing for Susan's gender-affirming care. These are costs they did not have prior to the Challenged Exclusions due to Medicaid's coverage of the medical treatment for Susan's gender dysphoria.

221. Jane and John not only worry about the multitude of harms that would be imposed on their family by the Challenged Exclusions, but also about the effect that Defendants' actions will have on other transgender people and their families.

222. The Does have begun considering moving out of state in order to protect their daughter from state-sponsored discrimination. Jane and John do not wish to move if it can be avoided, as, among other things, it could mean John having to switch jobs and separating Susan and their son from their long-term health care providers, friends, and family. That said, the health and wellbeing of their adolescent children are paramount to them.

223. The Does consider Defendants' decision to stop covering medically necessary gender-affirming medical care through Medicaid to be tragic and dehumanizing. They are concerned about the message the State of Florida is sending

by excluding transgender people from Medicaid coverage to which they otherwise would be entitled simply because they are transgender.

224. Jane and John keep in touch with other families in the LGBTQ+ affirming foster care community and are concerned for the ability of some children to find foster and adoptive families because of the state's hostility toward LGBTQ+ people and concerns about being able to meet the health care needs of those children through Medicaid.

Plaintiff K.F.

225. K.F. is the 13-year-old son of Jade Ladue and stepson of Joshua Ladue.

226. Joshua has raised K.F. since he was three years old and K.F. considers and calls Joshua "dad."

227. Jade is a patient coordinator at a dental office, while Joshua receives Social Security Disability Insurance because he is diagnosed with venous malformation, a type of vascular condition that results from the veins in his leg having developed abnormally.

228. K.F., Jade, and Joshua all live in Sarasota County along with K.F.'s four siblings, ranging in age from five to sixteen years old. They moved to Florida from Massachusetts as a family in August 2020.

229. K.F. is transgender.

230. Because of K.F.'s age and the Ladue family's income, he is eligible for Medicaid. He has been eligible for and enrolled in the program since he and his family moved to Florida. Prior to the Ladue family's move, K.F. was enrolled in Massachusetts's Medicaid program.

231. Although K.F. was assigned female at birth, he has known he was a boy from a very young age. When he was 7 years old, he came out to his grandparents during a camping trip, telling them that he has known since he was four years old that he is a boy and was born in the wrong body. In looking back on K.F.'s childhood, both Jade and Joshua see that K.F. was showing them that he was a boy well before that conversation K.F. had with his grandparents. K.F. always wanted to wear traditional boy clothes (no dresses or skirts), insisted on his hair being kept short, and loved to play shirtless with other boys in their neighborhood.

232. K.F. has never wavered about his gender identity.

233. As with all of their children before their pre-teen years, Joshua and Jade established strict limitations on K.F.'s consumption of television, movies, videos, and video games. At the age of seven, when K.F. came out as transgender, he had never heard of the concept of gender dysphoria, or transgender people, beyond his own experience, which he described first to his grandparents, and then to Jade and Joshua, as simply "being a boy."

234. After K.F. confided in his parents, Jade decided the next best step would be to locate a therapist who specializes in gender dysphoria. Soon after, K.F. had his

first appointment with a Licensed Mental Health Counselor. After thorough evaluation, the therapist was the first to diagnose K.F. with gender dysphoria and made sure that Jade and Joshua understood K.F.'s diagnosis and walked them carefully through what they should expect as K.F. got older.

235. After K.F. began therapy, Jade joined a local PFLAG group, an organization which is dedicated to supporting, educating, and advocating for LGBTQ+ people and their families. She joined the group because it was important to her and Joshua that they demonstrate to K.F. their commitment to supporting him.

236. K.F. was living fully in accordance with his male gender identity in every aspect of his home life and he wanted to be treated accordingly at school. Thus, when K.F. entered the second grade, K.F.'s therapist helped facilitate a meeting between Jade and his school administrators and teachers to talk about K.F.'s gender identity and what actions the school should take to ensure he was fully affirmed and supported as a boy with his classmates in the school environment.

237. Once K.F.'s licensed mental health provider gave her professional recommendation that it was appropriate for K.F. to begin seeing a pediatric endocrinologist, she referred K.F. to the Gender Multispecialty Service (GeMS) Program at Boston Children's Hospital, the first pediatric and adolescent transgender health program in the United States. K.F. had his first appointment with the GeMS Program on September 13, 2015. That first appointment was incredibly thorough, lasting over two hours, and was overall a very happy occasion. It was clear to Jade that

K.F. would be receiving the best possible care and the team of providers confirmed everything that K.F.'s therapist had told them: that K.F. is a transgender boy and that his parents and extended family supporting him in his affirmation of his male gender identity was the best decision for his health and well-being.

238. GeMS continued K.F.'s therapy and started him with pediatric nurse practitioner. The nurse practitioner's role was to monitor K.F.'s hormone levels for the onset of puberty and assist with any future gender-affirming health care needs. K.F.'s care with GeMS continued until the family moved to Florida in August 2020.

239. Before the Ladue family moved, in the summer of 2020, K.F.'s medical providers determined that based on the onset of K.F.'s puberty, it was medically necessary for K.F. to receive his first puberty delaying medication. At the recommendation of K.F.'s medical providers, K.F. received a Supprelin implant, a form of puberty delaying medication which would prevent the onset of secondary sex characteristics typical of girls and women. K.F. received the implant on August 8, 2020, and it was fully covered by Massachusetts' Medicaid program.

240. According to K.F.'s former and current medical providers, it is medically necessary for K.F. to receive puberty delaying medication so that K.F. can live authentically in a manner consistent with his gender identity and to treat his gender dysphoria. By preventing the physical manifestations that would accompany the puberty of his sex assigned at birth, K.F. is also able to avoid negative social and

emotional consequences associated with his being forced to develop secondary sex characteristics that do not align with his male gender identity.

241. As his parent, it is also important to Jade and Joshua that K.F. be able to choose with whom to disclose this deeply personal, private information about himself. Because of the puberty delaying medication, K.F. has that option, and the inherent protection and privacy that it provides.

242. When Jade and Joshua decided to move their family to Florida, Jade researched programs in the state that offered the same or similar level of care afforded by GeMS. Finding a program that offers high quality gender-affirming care and that accepts Medicaid can be challenging. Fortunately, through that research, Jade found the Emerge Gender & Sexuality Clinic for Children, Adolescents and Young Adults based at Johns Hopkins All Children's Hospital (Johns Hopkins Gender Clinic) located in St. Petersburg, Florida.

243. Once they moved, K.F. initiated care with a doctoral-level pediatric nurse practitioner specializing in endocrinology at the Johns Hopkins Gender Clinic. In April 2022, K.F. received his second Supprelin implant which was fully covered by his Florida Medicaid plan.

244. Given how his puberty delaying implant has interacted with his body, which has meant that past implants have only lasted approximately 18 months, it is likely K.F. may need additional puberty delaying medications. In addition, K.F. and his parents have been informed by K.F.'s medical providers that K.F. is ready for

beginning hormone therapy, which K.F.'s medical providers have deemed medically necessary for him.

245. K.F. is adamant that he does not want breasts and would eventually like to have facial hair and muscles. The idea of developing typically female secondary sex characteristics makes K.F. extremely anxious; he prays every night that his puberty delaying medication will be successful. Since K.F. came to understand and express the dysphoria he experienced resulting from his sex assigned at birth at an early age, Jade and Joshua were able to get him the mental health and medical treatment that was necessary, and as a result K.F. is perceived as and accepted by other people as male and very few people know he is transgender. Developing secondary sex characteristics typically associated with girls and women, instead of those aligned with his male gender identity, would be tremendously emotionally and physically painful for K.F.

246. Because Florida Medicaid now excludes coverage of puberty delaying medication when used to treat gender dysphoria, the Ladues worry they will have to pay out of pocket for K.F.'s puberty blocking medication, the treatment K.F.'s medical provider has indicated is medically necessary treatment for his gender dysphoria. The Ladue family has limited income, and they are very worried because they would not be able to afford these costly treatments without Medicaid coverage.

247. K.F.'s medical providers have also told the Ladues that likely within the next year, when K.F. is fourteen years old, that it will be medically indicated for him to begin hormone therapy (testosterone) at a dose appropriate to his age and body

composition. K.F. is very excited about starting testosterone therapy. K.F. usually hates receiving shots but he told Jade he would be happy to take a monthly shot if it meant that he would experience the male puberty that is aligned with his gender identity, such as his voice deepening and growing facial hair.

248. Jade and Joshua are so grateful that K.F. was confident enough and felt safe to come out to them at such a young age. His identifying his gender dysphoria at a young age combined with a loving and supportive immediate and extended family means that they were able to ensure that K.F. received the health care appropriate for him as soon as possible. As a result, his gender dysphoria has been well managed.

249. While K.F. has always dealt with anxiety, before he came out, it was much worse. He experienced what Jade would describe as "night terrors" and had a persistent stomachache. The Ladues would get calls from K.F.'s school that he was not doing well and was often in the nurse's office. The Ladues went to doctors to determine the source of K.F.'s distress, but no one could identify what was causing the problem. After he had firmly established gender-affirming care with GeMS, K.F. became a completely different child; it was like night and day. He had a smile on his face, a light in his eye, and even a glow about him. His performance and attendance in school improved, as did his peer relationships. Like any parent, Jade and Joshua were relieved to see their child happy and thriving.

250. K.F. has also begun the process of legal transition. He has legally changed his name, and has amended his legal name and gender marker on his birth certificate and records with the Social Security Administration.

251. Under the Challenged Exclusions, Medicaid will no longer cover puberty delaying medications for K.F. as treatment for his gender dysphoria. The Challenged Exclusions will also prohibit Medicaid from covering hormone therapy as a medically necessary treatment for K.F.'s gender dysphoria when K.F., pursuant to the medical expertise and recommendations of his physicians, is ready to begin that treatment.

252. Jade and Joshua are incredibly worried about the potential physical and mental health consequences of depriving K.F. the medically necessary treatment recommended by his health care providers. K.F. has been living as a boy in every aspect of his life--medically, legally, and socially--since 2016.

253. If he were no longer able to access the medication that aligns his body with his gender identity, K.F.'s mental health would suffer tremendously, and he would be devastated. Jade and Joshua fear that K.F., and the whole family with him, would go down a dark and scary road fast. For example, they fear that K.F. would not leave his bedroom and he would refuse to go to school, or that he would cut off his communications with his friends, teammates, and teachers. Given how much his gender-affirming care has improved his life and mental health, Jade and Joshua can only assume that reversing that course of treatment would result in the unthinkable happening.

254. Because of these concerns, K.F. going without treatment is simply not an option for the Ladue family. They believe providing K.F. with the medical treatment for gender dysphoria that he requires is necessary to ensure his health and well-being.

255. The Ladue family is under 138% of the federal poverty limit; that is why their children, including K.F., qualify for Florida's Medicaid program. Whether it be paying for a different puberty delaying medication if K.F.'s provider determines the current implant is not working or beginning K.F.'s course of hormone therapy in the next year, the Ladue family simply does not have sufficient resources to provide K.F. the gender-affirming care he requires. They simply could not pay out of pocket for the cost of K.F.'s care.

256. Joshua receives his health insurance through Medicare. He cannot add K.F. to his health insurance. Jade has access to health care coverage for family members because of her job, but the cost of adding K.F. is unaffordable for their family.

257. While Florida is their home, ultimately, the Ladue family will be forced to move if necessary to protect their son's access to medication that is necessary for his health and well-being. Doing so would mean Jade would have to find a new job, Joshua would have to establish his Social Security payment through a new field office, and the kids would be uprooted and forced to start at new schools and make new friends.

258. In addition, the Ladues are Christian and just joined a church that they attend every Sunday. So far, they have felt very welcome and would be sad to break a tie with this faith community and the other communities and relationships they have established in South Florida.

259. For K.F., this would be a particularly difficult and painful transition. K.F. is doing well academically, socially, and athletically. It is awful for Jade and Joshua to even think that K.F. would have to end this participation and leave his teammates friends and teammates because Florida refuses to provide him with coverage for the medical treatment that he needs to live and thrive, medical treatment that is available to many other cisgender young people, simply because K.F. is transgender.

CLAIMS FOR RELIEF

COUNT I
Deprivation of Equal Protection in Violation of the Fourteenth Amendment of the U.S. Constitution

(All Plaintiffs Against Defendant Jason Weida)

260. Plaintiffs reallege and incorporate by reference paragraphs 1 to 259 of this Amended Complaint as though fully set forth herein.

261. The Fourteenth Amendment to the United States Constitution, enforceable pursuant to 42 U.S.C. § 1983, provides that no state shall "deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. Amend. XIV, § 1.

262. Plaintiffs state this cause of action against Defendant Weida, in his official capacity, for purposes of seeking declaratory and injunctive relief, and to challenge his adoption and enforcement of the discriminatory Challenged Exclusions both facially and as applied to Plaintiffs.

263. Defendant Weida is a person acting under color of state law for purposes of 42 U.S.C. § 1983 and has acted intentionally in denying Plaintiffs equal protection of the law.

264. Under the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, discrimination based on sex is presumptively unconstitutional and subject to heightened scrutiny.

265. Discrimination on the basis of nonconformity with sex stereotypes, transgender status, gender, gender identity, gender transition, and sex characteristics are all forms of discrimination on the basis of sex.

266. A person is defined as transgender precisely because of the perception that they contradict gender stereotypes associated with the sex they were assigned at birth. When a transgender person affirms their authentic gender, it inherently contradicts standard gender stereotypes expected of the individual based on their sex assigned at birth.

267. In addition, under the Equal Protection Clause of the Fourteenth Amendment, discrimination based on transgender status is presumptively unconstitutional and subject to strict, or at least heightened, scrutiny. Indeed,

transgender people have suffered a long history of discrimination in Florida and across the country and continue to suffer such discrimination to this day; they are a discrete and insular group and lack the political power to protect their rights through the legislative process; they have largely been unable to secure explicit state and federal protections to protect them against discrimination; their transgender status bears no relation to their ability to contribute to society; and gender identity is a core, defining trait so fundamental to one's identity and conscience that a person cannot be required to abandon it as a condition of equal treatment.

268. By adopting and enforcing Rule 59G-1.050(7), which categorically prohibits coverage for "services for the treatment of *gender* dysphoria," including "*[s]ex* reassignment surgeries" and any "procedures that alter primary or secondary *sexual* characteristics," Defendant Weida is engaging in constitutionally impermissible discrimination based on sex, including, *inter alia*, discrimination based on nonconformity with sex stereotypes and transgender status.

269. Similarly, by enforcing SB 254, Section 3, which categorically prohibits coverage of "*sex-reassignment* prescriptions or procedures," defined as the prescription or administration of puberty blockers, hormones or hormone antagonists, or any medical procedure, including surgical procedure, to "affirm a person's perception of his or her *sex* if that perception is inconsistent with the person's *sex*" assigned at birth, Defendant Weida is engaging in constitutionally impermissible

discrimination based on sex, including, *inter alia,* discrimination based on nonconformity with sex stereotypes and transgender status.

270. Through his duties and actions to design, administer, and implement the Challenged Exclusions, Defendant Weida has unlawfully discriminated—and continues to unlawfully discriminate—against Plaintiffs based on sex-related considerations.

271. The Challenged Exclusions treat Plaintiffs differently from other persons who are similarly situated.

272. Under the Challenged Exclusions, transgender Medicaid beneficiaries who require gender-affirming care are denied coverage for that medically necessary care, while other Medicaid participants can access the same care as long as it is not required for the treatment of gender dysphoria, i.e., gender transition.

273. The Challenged Exclusions on their face and as applied to Plaintiffs deprive transgender Medicaid beneficiaries of their right to equal protection of the laws and stigmatize them as second-class citizens, in violation of the Equal Protection Clause of the Fourteenth Amendment.

274. Defendants' promulgation and continued enforcement of the Challenged Exclusions did not, and do not, serve any rational, legitimate, important, or compelling state interest. Rather, the Challenged Exclusions serve only to prevent Plaintiffs and other transgender Medicaid beneficiaries from obtaining medically necessary medical

care and services to treat their gender dysphoria, complete their gender transition, and live as their authentic selves.

275. As a direct and proximate result of the discrimination described above, Plaintiffs have suffered injury and damages, including mental pain and suffering and emotional distress. Without injunctive relief from Defendants' discriminatory Challenged Exclusions of coverage for gender-affirming care, Plaintiffs will continue to suffer irreparable harm in the future.

COUNT II
Discrimination on the Basis of Sex in Violation of Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116

(All Plaintiffs Against AHCA)

276. Plaintiffs reallege and incorporate by reference paragraphs 1 to 259 of this Amended Complaint as though fully set forth herein.

277. Section 1557 of the ACA, 42 U.S.C. § 18116, provides, in relevant part that, "an individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. §§ 1681, et seq.)"—which prohibits discrimination "on the basis of sex"—"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."

278. Discrimination on the basis of nonconformity with sex stereotypes, transgender status, gender, gender identity, gender transition, and sex characteristics

are all forms of discrimination encompassed by the prohibition of discrimination on the basis of sex under Section 1557.

279. Defendant AHCA receives federal financial assistance such that it is a "covered entity" for purposes of Section 1557 of the ACA. The Centers for Medicare & Medicaid Services ("CMS"), operating within HHS, provide federal financial assistance to AHCA for the state's participation in the Medicaid program. Indeed, Defendant AHCA has a published Notice of Nondiscrimination Policy on its website, stating that the "This Notice is provided as required by … Section 1557 of the Affordable Care Act and implementing regulations."

280. A covered entity, such as Defendant AHCA, cannot provide or administer health care coverage which contains a categorical exclusion of coverage for gender-affirming health care, or otherwise impose limitations or restrictions on coverage for specific health services related to gender transition if such limitation or restriction results in discrimination on the basis of sex.

281. Plaintiffs have a right under Section 1557 to receive Medicaid coverage through AHCA free from discrimination on the basis of sex, sex characteristics, gender, nonconformity with sex stereotypes, transgender status, or gender transition.

282. By categorically excluding "services for the treatment of *gender* dysphoria," including "*[s]ex* reassignment surgeries" and any "procedures that alter primary or secondary *sexual* characteristics" through Rule 59G-1.050(7), Defendant AHCA has discriminated against Plaintiffs on the basis of sex in violation of Section

1557 and has thereby denied Plaintiffs the full and equal participation in, benefits of, and right to be free from discrimination in a health program or activity.

283. Similarly, by prohibiting coverage of "*sex-reassignment* prescriptions or procedures," defined as the prescription or administration of puberty blockers, hormones or hormone antagonists, or any medical procedure, including surgical procedure, to "affirm a person's perception of his or her *sex* if that perception is inconsistent with the person's *sex*" assigned at birth, through SB 254, Section 3, Defendant Weida has discriminated against Plaintiffs on the basis of sex in violation of Section 1557 and has thereby denied Plaintiffs the full and equal participation in, benefits of, and right to be free from discrimination in a health program or activity.

284. As a result of the Challenged Exclusions, Plaintiffs have and will continue to suffer harm. By knowingly and intentionally offering coverage to Plaintiffs that discriminates on the basis of sex, Defendant AHCA has intentionally violated the ACA, for which Plaintiffs are entitled to injunctive relief, compensatory and consequential damages, and other relief.

285. Without injunctive relief from Defendants' discriminatory Challenged Exclusions of coverage for gender-affirming care, Plaintiffs will continue to suffer irreparable harm in the future.

COUNT III
Violation of the Medicaid Act's EPSDT Requirements,
42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r)(5)

(Plaintiffs Brit Rothstein, Susan Doe, and K.F. Against Defendant Weida)

286. Plaintiffs reallege and incorporate by reference paragraphs 1 to 259 of this Amended Complaint as though fully set forth herein.

287. The Medicaid Act mandates that states provide Early and Periodic Screening, Diagnostic and Treatment ("EPSDT") services, which include all services necessary to "correct or ameliorate" a physical or mental health condition, to Medicaid beneficiaries under age 21. 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), 1396d(r)(5).

288. The Challenged Exclusions, and Defendants' refusal, based on the Challenged Exclusions, to provide coverage for services for the treatment of gender dysphoria to Plaintiffs Brit Rothstein, Susan Doe, and K.F., and transgender Medicaid beneficiaries under age 21, violates the Medicaid Act's EPSDT requirements, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r)(5), which are enforceable by Plaintiffs under 42 U.S.C. § 1983.

COUNT IV
Violation of the Medicaid Act's Comparability Requirements,
42 U.S.C. § 1396a(a)(10)(B)(i)

(All Plaintiffs Against Defendant Weida)

289. Plaintiffs reallege and incorporate by reference paragraphs 1 to 259 of this Amended Complaint as though fully set forth herein.

290. The Medicaid Act's Comparability Requirements, 42 U.S.C. § 1396a(a)(10)(B)(i), require that the "medical assistance made available to [eligible individuals] shall not be less in amount, duration, or scope than the medical assistance made available to" other eligible individuals.

291. The Challenged Exclusions, and Defendants' refusal, based on the Challenged Exclusions, to provide coverage for services for the treatment of gender dysphoria to Plaintiffs and other transgender Medicaid beneficiaries, while covering the same services for other Florida Medicaid beneficiaries with different diagnoses, violate the Medicaid Act's Comparability Requirements, 42 U.S.C. § 1396a(a)(10)(B)(i), which is enforceable by Plaintiffs under 42 U.S.C. § 1983.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants on all claims, as follows:

A. Issue preliminary and permanent injunctions prohibiting Defendants from any further enforcement or application of any policy prohibiting coverage of gender-affirming medical treatment for gender dysphoria, including the Challenged Exclusions, and directing Defendants and their agents to provide Medicaid coverage for the medically necessary care for the treatment of gender dysphoria without regard to the Challenged Exclusions;

B. Enter a declaratory judgment that the Challenged Exclusions, which categorically excludes coverage for medically necessary care for the treatment of gender dysphoria, both on their face and as applied to Plaintiffs:

i. Violate the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution by discriminating against Plaintiffs and all similarly situated individuals on the basis of sex, including transgender status, nonconformity with sex stereotypes, sex characteristics, gender, gender identity, sex assigned at birth, and gender transition;

ii. Violate Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, by discriminating against Plaintiffs and all similarly situated individuals on the basis of sex (including transgender status, nonconformity with sex stereotypes, sex characteristics, gender, gender identity, sex assigned at birth, and gender transition);

iii. Violate the Medicaid Act's EPSDT Requirements, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r)(5); and

iv. Violate the Medicaid Act's Comparability Requirements, 42 U.S.C. § 1396a(a)(10)(B)(i);

C. Waive the requirement for the posting of a bond of security for the entry of temporary and preliminary relief;

D. Award the declaratory and injunctive relief requested in this action against Defendants' officers, agents, servants, employees, and attorneys, as well as any other persons who are in active concert or participation with them;

E. Award nominal, compensatory, and consequential damages to Plaintiffs in an amount that would fully compensate each of them for: (1) the harms to their short- and long-term health and well-being from being denied access to medically necessary health care as a result of the Challenged Exclusions and their application to them; (2) their economic losses; and (3) all other injuries that have been caused by Defendants' acts and omissions alleged in this Amended Complaint;

F. Award Plaintiffs their reasonable attorneys' fees, costs, and expenses under 42 U.S.C. § 1988 or other applicable statutes; and

G. Award such other and further relief as the Court may deem just and proper.

Respectfully submitted this 18th day of May 2023.

/s/ Simone Chriss
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CERTIFICATE OF SERVICE

I hereby certify that, on May 18, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

/s/ Simone Chriss
Simone Chriss
Counsel for Plaintiffs

Doc. 235

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' NOTICE OF RE-FILING
DEPOSITION TRANSCRIPTS

Plaintiffs submit this Notice and re-file the following deposition transcripts, highlighted to reflect the deposition designations identified in Plaintiffs' Rule 26(3)(a) disclosures (ECF No. 162), to include their completed errata sheets.

1. Matthew Brackett, Defendant AHCA's 30(b)(6) representative, February 8, 2023 deposition;
2. G. Kevin Donovan, Author of GAPMS Report Attachment.

Dated: May 21, 2023

Respectfully Submitted,

/s/ Chelsea Dunn

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st 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/ Chelsea Dunn
Attorney for Plaintiffs

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

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

AUGUST DEKKER, et al.,
Plaintiffs,
vs.
JASON WEIDA, et al.,
Defendants
_____/

	Volume 1, Pgs. 1 - 124
VIDEOTAPED DEPOSITION OF:	MATTHEW BRACKETT
AT THE INSTANCE OF:	THE PLAINTIFFS
DATE:	FEBRUARY 8, 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

APPEARANCES:

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ALSO PRESENT:
RL Minnich, Videographer

INDEX TO WITNESS

INDEX TO EXHIBITS

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

D E P O S I T I O N

VIDEOGRAPHER: This is the video-recorded deposition of corporate representative for Agency for Healthcare Administration, in the matter of August Decker, et al. vs. Jason Weida, et al. Case No. 4:22-cv-00325, RH-MAF. This deposition is being held at 2727 Mahan Drive in Tallahassee, Florida. Today's date is February 8th, 2023 and the time is 10:08 a.m. The court reporter is Dana Reeves. My name is RL Minnich. I'm the videographer. Would counsel please introduce themselves and the court reporter please swear in the witness?

MS. DEBRIERE: Yes, Katy DeBriere and I represent the plaintiffs.

MS. CHRISS: Simone Chriss and I also represent the plaintiffs.

MS. DUNN: Chelsea Dunn. I also represent the plaintiffs.

MR. JAZIL: Mohammad Jazil for the defense.

MS. DEBRIERE: And we have a few people on the Zoom link from the plaintiff's side. That would be Catherine McKee and Omar Gonzalez-Pagan.

MR. PERKO: And Gary Perko on behalf of the defendants on the Zoom link.

MS. DEBRIERE: And Shani Rivaux has joined us from the plaintiff's side as well.

COURT REPORTER: All right, sir, if you would raise your right hand, please.

Whereupon,

MATTHEW BRACKETT

was called as a witness, having been first duly sworn to speak the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

THE WITNESS: I do.

COURT REPORTER: Thank you.

EXAMINATION

BY MS. DEBRIERE::

Q All right. So we're just going to mark exhibits as they're discussed, if that's okay with you, Matt.

A That's fine.

Q As we walk through those exhibits, I'm going to read off the Bates numbers on the bottom of each page. So those are just the -- that line of numbers I'm reading out loud as we discuss exhibits, and that should help you track what page I'm on as we're discussing them. So we're going to go ahead and mark the notice of deposition as Exhibit 1. I saw that you brought the copy with you, as well, Mr. Brackett.

(Whereupon, Exhibit No. 1 was marked for identification.)

MR. JAZIL: Is this the court reporter's copy?

MS. CHRISS: The witness' copy that can become the court reporter's copy.

BY MS. DEBRIERE::

Q Okay. So just some preliminary stuff before we go over this notice. I'm going to be using the acronym GAPMS quite a bit. That stands for Generally Accepted Professional Medical Standards, and is the acronym that refers to the process described at Florida Administrative Code Rule 59-G-1.035. When I refer to the GAPMS or GAPMS process, do you understand what I mean?

A Yes.

Q I will also 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. Can we agree that when I say gender dysphoria, that's the definition I'm using?

A Yes.

Q I will also be using a phrase categorical exclusion of treatment for gender dysphoria, which

refers to the exclusion in Florida Administrative Code Rule 59-G-1.050(7). Do you understand that that phrase refers to all the services in that particular portion of the rule when I say categorical exclusion?

A I do.

Q And then I will also be using the term EPSDT services, which stands for Early Periodic -- Early and Periodic Screening Diagnostic and Treatment Services. When I say EPSDT, do you know what I mean?

A Yes.

Q Have you ever been deposed before?

A Yes, I have.

Q Okay. So if there's at any point that you don't understand my question, what I want you to do is I want you to stop and ask me to rephrase it. I don't want you to try to attempt to ask -- answer the question if you don't understand it. Okay?

A Okay.

Q I have a problem sometimes of speaking over someone else, I don't know if you have the same problem, but what we need to try to do is just give each other space to pause in between the questions so we're not speaking over each other. Okay?

A I'm fine with that.

Q Okay. Verbal answers. Sounds like, you know,

you speak very clearly, so we shouldn't have a problem, but obviously -- although we do have a videographer here, it's better to speak your answer out loud.

A I do understand. Articulating hand gestures, the court reporter cannot get those into the transcripts.

Q Exactly. All right, if you need to take a break for any reason, totally fine, just let me know. I do ask that you answer my question before we take a break.

A Okay.

Q And then are you on any medications or other substances that could impact your memory today?

A No.

Q And state your name for the record.

A So my full name is John Matthew Brackett.

Q Okay. And it's your understanding that you're representing the Florida Agency for Health Care Administration in a 30(b)(6) deposition?

A That's correct.

Q Okay. What topics, looking at the notice, which is Exhibit 1, notice of 30(b)(6) deposition, what topics were you designated for? Were they all of them here?

A Yes.

Q And you're prepared to testify on behalf of the Agency on each of these topics?
A Yes.
Q Have you seen the 30(b)(6) deposition topics?
A You mean as those listed in the -- yes, I have seen them.
Q And who provided them to you?
A Those were provided to me by our outside counsel.
Q Okay. And did you consent to acting as the agency representative?
A Yes, I did.
Q What did you do to -- excuse me. What did you do to prepare for today?
A Mostly just familiarize myself with areas and topics that are on the list that are not familiar to my current job role, and that's pretty much it. So pretty much standard operating procedures here at the Agency that are -- that might fall under different divisions or different teams, et cetera. And just kind of, like, reviewed some of our coverage policies, some of our rules and some of our own materials.
Q Okay. Who did you speak to?
A Principally, consulted with Andrew Sheeran and for any questions that involved managed care, I

consulted my supervisor Devona Pickle.

Q Did you gather information from anyone, anyone besides counsel?

A I gathered a little bit of information from Devona Pickle, since one of the questions directly involved her role in the process.

Q Okay. I saw that you brought a document with you today, it looks like maybe you reviewed that to prepare. What is that?

A So that is pertinent to the question. I can provide you the exact one. Yeah, I think -- yeah, question three. It was -- since that asked about the process of how we looked at other states' Medicaid programs, which that spreadsheet was -- Devona Pickle administered that role of the GAPMS process. And since that question was on there, I did ask her to provide me with what she used to -- and the research methods used to go through each state Medicaid program to find out what their coverage criteria is, or if they have a statement prohibiting coverage, or if they just don't have any statement whatsoever.

MS. DEBRIERE: Okay. And, Mo, do you know if that was produced to us in discovery?

MR. JAZIL: I don't believe it was. So we'll make copies and get it to you.

BY MS. DEBRIERE::

Q How long did it take you to prepare for the deposition today?

A Well, given that we received these questions about a week ago, I'd probably say I spent probably off and on -- I mean, in between other projects, probably I'd say three, maybe four working days.

Q Okay. A little bit about you. Describe your educational background.

A So I received a -- my -- started off, I got my AA at Tallahassee Community College. I received my Bachelor of Arts in history at Florida University, 2003. I graduated magna cum laude. Received my Master of Arts in History from Florida University in 2005. During my time in graduate school, I did spend a few extra years working on a PhD, which I decided not to finish, but during my grad school years, I presented research papers on numerous topics at numerous conferences. And I also published scholarly articles in the Florida Historical Quarterly and Southern Studies and Interdisciplinary Journal of the South.

Q The conferences, what were those about?

A The conferences ranged. They could -- they were, I think, either conference on Florida history, conferences on environmental history. I think there

were, like, graduate symposiums. So often they're also, like, regional conferences. The topics I represented on ranged from anything from environmental history to public health history.

Q And your PhD, what -- what were you attempting to get it in?

A So I was actually looking at getting my PhD in the history of medicine and public health. And actually, I was -- my dissertation topic was on tuberculosis, on how during the late 19th century, how kind of the infancy of public health agencies and how public health was actually becoming a common concept and how -- and, of course, with the emerging sciences -- well, pretty much with the discovery of microbiology and discovery of the tuberculosis bacteria, how all that was coming together to affect changes in the south in public health, and looking at also how, since tuberculosis was very common, on how that shapes southern identity.

Q Okay. And what's your current position at the Agency for Health Care Administration?

A So my current position is Program Consultant. I work on the Canadian Drug Importation Program primarily.

MS. DEBRIERE: And, Court Reporter, just to note, we're going to refer to the Agency for Health

Care Administration's throughout as either AHCA or the Agency.

BY MS. DEBRIERE::

Q Prior to your role with the Canadian Drug Importation Program -- did I get that right?

A Yeah, close enough.

Q What was your role at the Agency?

A My role at the Agency, I was the Program Administrator over the Specialized Services and Behavioral Health teams. Of course, we oversaw the development and, of course, updating of policies, such as durable medical equipment, community behavioral health, non-emergency transportation, school-based services, hospice. There's actually quite a lengthy list.

Q And how long did you do that for?

A I was in that position for three and a half years.

Q Okay. And prior to that, were you at the Agency?

A Yes, I was.

Q And what was your role then?

A I was a Government Analyst II. And during that time period, that was from January 2017 to November 2017, I was -- my role specifically tasked with

completing the Generally Accepted Professional Medical Standards reports.

Q And prior to that time, were you at the Agency?

A Yes.

Q And what did you do then?

A I would -- I worked in the Office of the Deputy Secretary for Health Quality Assurance.

Q So your time in the Bureau of Medicaid policy was from December 2017 to --

A January 2017 to November 2017. But my job -- but becoming a program administrator, I was still in the same bureau.

Q So GAPMS -- working on GAPMS was January 2017 to November 2017, and then you shifted to another role in Bureau and Medicaid Policy?

A Yes.

Q And that was in December of 2017 through --

A November 2017 through April of 2021.

Q And so since May of 2021 or April 2021 you've been with the Canadian Drug --

A April 2021.

Q Okay. Let's look at the Florida definition of medical necessity. And that is in the Florida Medicaid Definitions Policy, which I'm sure you're intimately

familiar, at Section 2.83, and it's incorporated by reference into rule by Florida Administrative Code Rule 59-G-1.010.

MR. JAZIL: Simone, would you happen to have an extra copy?

MS. CHRISS: Yes.

MR. JAZIL: I'd rather just not lean over his shoulder.

MS. DEBRIERE: You know what, Mo, you can use mine. I basically have it committed to memory.

MR. JAZIL: Thank you.

MS. DEBRIERE: So we'll go ahead and mark this policy as Exhibit 2.

(Whereupon, Exhibit No. 2 was marked for identification.)

BY MS. DEBRIERE::

Q And, Mr. Brackett, if you want to turn to it, it's 2.83.

A Okay.

Q What's the purpose of the Medical Necessity standard listed here?

A So is -- kind of clarify -- can you clarify what's meant by purpose?

Q What does AHCA use that medical necessity standard for?

A So these prongs for medical necessity, as defined, these are our guidelines for determining whether or not Florida Medicaid should cover a service.

Q Okay. Is it correct to say that the standard is used to determine whether Medicaid service should be prior authorized?

A I don't -- I don't -- I don't think so.

Q Okay. Tell me why.

A Because for medical necessity, being medically necessary, this is generally -- this is a criteria for whether or not Medicaid should cover a service. The prior authorization process is just mostly more clinical review to determine whether or not delivery of that service, coverage of that service corresponds to the definition of medical necessity.

Q Okay. So when you're doing a prior authorization review, you do determine whether or not the service corresponds to the definition of medical necessity?

A So since our subcontractors and our managed care plans do our prior authorizations, they do have to make sure that the -- that with the service they're prior authorizing would, if subjected to the medical necessity guidelines and definition, yeah, they have to make sure it corresponds.

Q Okay. And that's part of the prior authorization process?
A That's part of the prior authorization process, yes.
Q If a Medicaid service is found to be experimental by AHCA, would AHCA or its contractors, subcontractors like a managed care plan, still review whether the service meets any other portion of AHCA's medical necessity rule?
A No.
Q Okay. Why not?
A Because it does have to meet the five prongs of medical necessity, and one of those prongs is it has to be in alignment with GAPMS.
Q Okay. So if it's not in alignment with GAPMS, would you analyze it under any other portion of that definition?
A No, we wouldn't.
Q If a Medicaid service has not been determined experimental, using like GAPMS process, can a Medicaid managed care plan use the portion of the medical necessity standard that reads, be consistent with Generally Accepted Professional Medical Standards?
A Once the Agency deemed that it's not consistent, and often these requests usually come to us

from the plans, the plan is not going to cover it.

Q Okay. Is the plan able to make an independent determination of whether those services are experimental in nature, or must that come from -- decision come from AHCA?

A It does not necessarily have to come from AHCA. We do grant our managed care plans a great deal of flexibility when it comes down to the services they wish to cover, but sometimes when they get a service that they're not sure about, they do often -- sometimes will ask us to do a GAPMS review of it to determine whether or not that -- if they should cover it. So sometimes we're kind of more of a reference point, but the plans function pretty independently in these areas.

Q Okay. So the plan can make an independent determination as to whether or not a service is experimental or investigational?

A No. Whether or not to cover -- we don't allow them to do -- we don't allow them to do independent GAPMS reviews, if that's what you're asking.

Q What I'm asking is looking at the prong about whether this service is consistent with GAPMS, whether the plan can deny coverage of a service on that basis without AHCA's initial determination?

A No, they need to consult with us before

they -- they need to consult with us before they use experimental and investigational as a basis for denial, which they will -- we do get requests from the health plans.

Q Okay. All right. So moving on to what's Bates-stamped as defendant DEF_000126105. This is the GAPMS report on cross-sex hormone therapy, which is dated --

MS. CHRISS: May '22.

BY MS. DEBRIERE::

Q May 20th, 2022.

VIDEOGRAPHER: Counsel, can you put that mic on, please? They placed it right beside you.

MS. DEBRIERE: Yes. Yes.

VIDEOGRAPHER: The one to your right. Thank you.

MS. DEBRIERE: I should have worn my suit jacket tonight.

THE WITNESS: It might get hot here shortly, so I may be taking mine off.

MS. DEBRIERE: Should I mark this as 3?

MS. CHRISS: Yes, the one for him.

MS. DEBRIERE: I think we got it split up. I'm sorry. Mo, do you want to copy?

MR. JAZIL: Sure. Do you really have all these

committed to memory?

MS. DEBRIERE: Well, not this one, no, no, but somewhat.

MR. JAZIL: Here's the last one, Katy.

MS. DEBRIERE: Thanks.

MR. JAZIL: That's pretty impressive if you do.

MS. DEBRIERE: Well, not these, but definitely, you know, you practice Medicaid in Florida for seven years, you know what the medical necessity definition is.

(Whereupon, Exhibit No. 3 was marked for identification.)

MS. DEBRIERE: All right. Not a day past seven years, either.

BY MS. DEBRIERE::

Q Okay. So looking at -- do you have a copy, Mr. Brackett?

A Yes.

Q Okay. Looking at -- if you'll flip to what's marked as DEF_000126112, it's page eight.

A Okay.

Q Starting under coverage policy, there's some discussion about federal regulations, and then moving through to the Florida Medicaid section that ends on the top of page 10, if you could just review that for me.

A Okay.
Q So is this an accurate portrayal of the standard to determine Florida Medicaid coverage for prescription drugs?
A Yes, this is.
Q Do all prescription drugs require prior authorization to be reimbursed by Florida Medicaid?
A I can't speak fully to that one. I don't -- I don't believe so, but often our managed care plans, we grant them a lot more flexibility when it comes down to prior authorizations, so they may require prior authorization for every drug. But as far as, like, every single drug, as far as the fee for service system goes, I'm not a hundred percent certain, but I believe that we do not require prior authorization for every single drug.
Q Okay. Do you know if anybody at the Agency would have a hard answer to that question?
A One of our staff pharmacists probably would.
Q So can you briefly describe the process a Medicaid recipient undertakes in seeking prior authorization for a drug?
A Usually, that's taken by the provider usually, or in the case of pharmacy, I'm not sure who would submit the prior authorization. I don't think that

that's -- process is not initiated by the recipient themselves, it's usually initiated by the provider. Of course, it goes through, like, a one-two level review process. That first level is usually done by, like, a nurse or an RN. They just determine whether or not it's medically necessary. If it is, then that one level stops. If it's a denial, it has to go -- I think it goes to a second-level review.

Q Okay. And what is -- what is involved in that review? What is being reviewed?

A Well, I'm not intimately familiar with it because we used it a long, long time ago, prior to SM's. We did that stuff in-house. That was before my time with the Agency, but now that's outsourced to EQ Health Solutions in the fee-for-service system. But they do review the medical records, et cetera, and then, I think, any other materials that are submitted by the doctor, so --

Q Do they compare it to coverage policies or guidelines?

A Well, for children, I don't -- it wouldn't be necessary to because of EPSDT, but for adults, I don't know. That's information that we would have to ask our vendors. I assume they would, but that's an assumption.

Q Okay. Tell me a bit more about what you mean

by coverage guidelines when it needs to be reviewed for children because of EPSDT.

A Well, because of EPSDT, in which, since you're familiar with all this, of course, even regardless of what something says on the coverage policies -- because our coverage policies and our fee schedules are very prescriptive, they list out what services can be covered, what services can't be covered. Our fee schedules, of course, outline the amount of money that we pay for each service and our perimeter service gaps, most importantly, the service gaps. So for children, if it's deemed medically necessary, and usually it does have to go through the prior authorization process for an EPSDT consideration, if it's determined medically necessary, regardless of whether it's on a fee schedule or not, or in excess of our fee schedule, or if it's not listed in that coverage policies, because of EPSDT requirements from the feds, we do have to cover it.

Q Okay. Okay. And how do you define medical necessity for EPSDT?

A It's the same as listed in definitions policy.

Q Okay. What would be the process for obtaining Medicaid coverage for a drug where prior authorization is not required?

A Well, so the thing about Medicaid coverage for

drugs is that we do cover all drugs that are FDA approved. So if -- unless it has a prior authorization requirement and if that FDA approved covered drug can be covered by Medicaid.

Q Okay. What if it's not FDA approved?

A If it's not FDA approved or if it's -- so are we talking about, like, complete non-FDA approval or are we talking about like our off-label usage?

Q Actually, let's back up. So if it's FDA approved, does that mean it does not need to go through the prior authorization process for Medicaid to authorize it?

A If it's not FDA approved, we -- I mean, we're not going to cover it if it's not FDA approved.

Q Okay. If it is FDA approved, does the Medicaid recipients still have to undertake the prior authorization process to --

A If it's FDA approved, and it's a drug that we've required prior authorization, then, yes.

Q Okay. If it's a drug that does not require prior authorization, what does that process look like for coverage?

A I generally -- I think it just -- the pharmacy fills the prescription, they file a claim, agency pays the claim and the dispensing fee.

Q Okay. So there's no review in medical necessity under that --

A Providing the drug does not -- does not have prior authorization criteria, yes.

Q Okay. So if it's a drug that does not require authorization, AHCA does not determine if it's being prescribed for a medically necessary use; is that correct?

A Can you repeat that?

Q Yep. If a drug does not require prior authorization, AHCA does not -- AHCA or its contractors does not undertake a determination as to whether it's being prescribed for a medically necessary use?

MR. JAZIL: Object to form.

THE WITNESS: We covered -- we cover services that are medically necessary. So if it's -- that would be in violation of policy if drugs are being covered -- if drugs are being prescribed and covered, when for -- when medical records and the documentation -- when medical necessity is not being met, that is that -- no, we would not cover in those circumstances.

BY MS. DEBRIERE::

Q How would you make that determination that you would not cover if you're not doing a prior

authorization review?

A So generally when issues like that, when providers are billing Medicaid for services that are not medically necessary, that's usually when our Medicaid -- Medicaid program Integrity, they start getting involved in looking at -- looking at such claims.

Q How would that rise to the surface of triggering an investigation with Medicaid Integrity?

A Well, there are lots of tip-offs. I mean, we do have a -- we do have a fraud hotline. So somebody could report a provider for fraud. There -- it could be result from an on-site survey. Our Bureau of Recipient Provider Assistance does -- they often do Medicaid surveys on providers. It could also potentially result from a -- one of our health quality assurance surveys, if they're going in and looking at, like, their compliance with licensure rules. So it really depends on where the fraud's detected. So there are multiple avenues for reporting Medicaid fraud.

Q Does AHCA have a pharmacy coverage policy for every prescription drug?

A We do have our outpatient prescribed drugs services coverage policy. And that, of course, is for our covered outpatient drug benefit.

Q Does that policy list every potential

prescription drug prescribed under -- prescribed to a Florida Medicaid recipient?

A No. So -- because Florida Medicaid covers any drug that's FDA approved, when these medical necessity guidelines, that's kind of an encompassing umbrella. And then, of course, we do have the preferred drug list which is assembled by the Pharmaceutical and Therapeutics Committee. We always just call P&T, so -- but because the list is so vast we don't actually reproduce it in any kind of a form. So the prescribed drug services policy, the way it's worded is supposed to be all-encompassing, but there are exclusions in Section 5.2 of non-covered service -- of drugs that we won't cover under certain circumstances.

Q Okay. So it lists some drugs you won't cover, but it doesn't list all the drugs you will potentially cover?

A Right. But it's also -- but it's not -- it doesn't specifically state drugs, it's just -- it's more specific to conditions. Like we don't say we won't cover -- well, let me use it -- Viagra, but we say that we will not cover drugs for ED.

Q Okay. So there's some general descriptions of what you won't -- will and won't cover?

A Yes.

Q Is there a pharmacy -- is there an AHCA pharmacy coverage policy for estradiol? And I'm happy to spell it for you if you need it.

A Oh, are we talking about estradiol.

Q Estradiol. Thank you.

A No, we don't have specific coverage policies for specific drugs. And by estradiol, I mean, that's an -- that's a kind of name brand estrogen.

Q Okay. And how about for medroxyprogesterone acetate, or Provera?

A We don't have specific coverage policies for those.

Q Okay. How about micronized progesterone?

A Those would all be encompassed under the prescribed drug services policy.

Q Okay, but not specifically named?

A We don't specifically name drugs.

Q I'm just going to run down the list. Spiro -- and you're going to correct me when I say it wrong -- Spironolactone.

A Spironolactone. That one, I mean, once again, the previous answer applies. It's enveloped by our prescribed drug services coverage policy. We don't have, like, an individual policy addressing that specific drug.

Q Okay. Finasteride.
A I think that's close enough. Same as before it's covered -- it's enveloped by the prescribed drug services coverage policy. We do not have an individual coverage policy for that drug.
Q Dutasteride.
A We do not have an individual coverage policy for that drug, but it is covered. It is -- it is addressed through the prescribed drug services coverage policy.
Q Okay. Testosterone.
A The same as before, we don't have an individual coverage policy for it, but it is covered through the prescribed drug services coverage policy.
Q Testosterone enanthate.
A Same as before, as in, we don't have a specific coverage policy, but it is covered through the prescribed drug services coverage policy.
Q Okay. Two more. Testosterone undecanoate.
A We do not have an individual coverage policy for that, but it is enveloped by our prescribed drug services policy.
Q Gonadotropin-releasing hormone antagonists.
A Gonadotropin, yeah. So, yeah, we do not have an individual coverage policy for GnRH. And that, of

course, would be covered through the prescribed drug services coverage policy, is how it would be addressed.

Q Okay. You do not have a policy, a pharmacy policy for GnRH antagonists?

A Not promulgated into rule.

Q Okay. Do you have any coverage policies -- I didn't realize that when I asked whether there was a coverage policy that you interpreted that to mean that it had to be promulgated into rule. Do you have any coverage policies regarding these drugs that are not promulgated into rule?

A As far as the policy goes, we don't really have a policy so for it -- so much. There was a guideline produced, I think, in 2016 that was given to Magellan for guidance on the prior authorization process, but as far as a policy goes, no, we don't have -- we don't have a specific policy for these drugs.

Q Okay. So there was some guidance that AHCA provided to Magellan regarding GnRH antagonists.

MS. DEBRIERE: Simone, can I have that coverage guidance?

MS. CHRISS: This one?

MS. DEBRIERE: Yes, please. Thank you. We'll mark that as Exhibit 4. You definitely need a copy of this one.

(Whereupon, Exhibit No. 4 was marked for identification.)

THE WITNESS: I've seen it enough times.

BY MS. DEBRIERE::

Q Well, so is that what you're referring to when you said the guidance provided to Magellan?

A Yes.

Q That's all I needed to know. Okay. So I'm sure we'll come back to that. And so you referenced FDA approval in Medicaid coverage earlier. When making decisions about individual claims for coverage for Medicaid recipients, does AHCA or its contractor determine whether the use the drug is being prescribed for is FDA approved?

A Well, absolutely, yes. I mean -- I mean, if it doesn't have FDA approval, I mean, it's still -- I mean, it's either not FDA-approved, it's still going through clinical trials. It's not FDA-approved, then no, it's not eligible for coverage.

Q Okay. How does AHCA do that on an individualized basis?

A So for an individualized basis, generally this is a prior authorization process, the request is put in. The recipients, or health care plan enrollees, the specific condition is evaluated and determination of

medical necessity is made.

Q Okay. What if the drug does not require prior authorization, then how does AHCA determine whether the use it's being prescribed for is FDA-approved?

A That would normally have to involve a retrospective claims review.

Q Okay. So at the time it'd be covered, but then AHCA would go back and look to see if it should have been covered?

A That's correct.

Q And how do they do that?

A How do they do that?

Q Yeah.

A I don't know the specifics, generally either MPI or another bureau. Often people in the field will often look at review claims, and this has happen frequently, that if claims are found to be paid in error or paid for services that were not necessarily -- not medically necessary, but the Agency does have the ability and frequently does gather recoupments on providers.

Q Okay. MPI stands for --

A Medicaid Program Integrity.

Q So that's like a fraud investigation?

A Yes, there are two fraud investigation teams

of the state. For MPI, they're specifically here for Medicaid. Every Medicaid program in the country is required to have a program integrity team, but we also have Medicaid Fraud Control Unit over at the Attorney General's Office.

Q Okay. Just turning back quickly to Exhibit 4, why is this not considered a coverage policy?

A Because coverage policies are generally -- well, first of all, it's not promulgated in a rule. So all of our coverage policies go through the rulemaking process, which is, of course, allows for public input and everything like that. This is mostly more -- these are guidelines developed in-house and provided to our PBM subcontractor.

Q Okay. For use in determining whether or not to prescribe GN -- strike that.

Are there other coverage guidelines like this not promulgated into rule for other drugs?

A For other -- I am not aware of whether or not we have any other guidelines like this.

Q Okay. What about for cross-sex hormone therapy?

A There was -- to my knowledge, there was no guidance or for cross-sex hormones.

Q Okay. So going back to the MPI post-claim

reviews, how often does that happen? Can you quantify?

A I don't have enough numbers of how often it happens, because obviously we have thousands of Medicaid providers. Then we do hear about cases of recoupment, so I couldn't tell you what the percentage of providers that had to pay back to the Agency money, but I can tell -- I can definitely tell -- like, I know -- well, for instance, I know -- like, I think Miami-Dade or Broward County have -- like, their school district actually they had -- after they had received a Federal Audit from HHS, they ended up having to pay back, I think, a million or so dollars in funds because they were delivering services that weren't properly documented and weren't meeting that medical necessity criteria. So as far as the larger numbers go, I don't have those.

Q Is there somewhere publicly the public can access that information, or where we can access that information?

A So a public records request can always be put in. We don't have that information available on our website, but anyone can put in a public records request and find out, like, how often recoupments do occur.

Q Do you know what a drug compendium is?

A Yes. Yeah, I'm aware of three.

Q Which three are you aware of?
A Drug Index is one. There are two others whose names do not -- whose names I do not recall immediately offhand. I believe they are listed. And, of course, they do usually consist of, like, a very large amount of information on each specific drug, and it talks about, like, appropriate uses and so forth. So, for each of these compendia -- and I -- they are -- we do utilize them when evaluating whether or not we can use an FDA-approved drug for an off-label purpose.
Q Okay. Do you know if those three compendia are Drug Text Information System, United States Pharmacopoeia Drug Information and American Hospital Formulate -- Formulary Service Drug --
A That sounds correct.
Q And those are the three compendia listed in the Federal Medicaid Act?
A Yes.
Q Okay. So when I'm using compendium, or compendia for next set of questions, I'm referring only to those three listed in the Federal Medicaid Act.
A Okay, that's fine.
Q For drugs that do not require prior authorization, when making decisions about individual claims for coverage, does AHCA or its contractors

determine whether the use that drug is being prescribed for is supported by citation in one of the compendia?

A So is this for drugs that do not require prior authorization, or drugs that do require prior authorization?

Q Do not require.

A We really don't because we don't require prior authorization. We're not able to check.

Q So that means where AHCA does not require prior authorization for a Medicaid recipient to obtain coverage of a particular drug, it covers the drug without knowing in advance whether the use it's being prescribed for is supported by citation in one of the compendia?

A If we're not requiring prior authorization, there's no way for us to know in advance.

Q Okay. So I know you mentioned it earlier. I'm just going to reference it on my computer, and that is the prescription drug list. And the website link -- I'll turn it so both you and counsel can see it, without spilling my drinks. That URL is HTTPS://AHCA.myflorida -- Florida is spelled out -- .com//Medicaid/prescribed_drug/pharm -- P-H-A-R-M -- _thera -- T-H-E-R-A -- /PDF/PDL.pdf. So I'm showing you what is AHCA's preferred drug list. Do you recognize

it?

A Yes, I recognize that.

Q What is the PDL?

A So the preferred drug list -- so even though we have everything that's FDA-approved, our Pharmaceutical and Therapeutics Committee, they do place drugs on the preferred drug list. I don't know the -- necessarily all the details. I think often it has to do with the ability for the agency to obtain rebates and so forth, so -- but they do put this together. It is publicly available on our website. And, of course, it does -- it does, of course, have age -- it does have age, minimum age, maximum age, clinical care required.

I would like to clarify, though. I know for our -- in our Medicaid Management Information System, which we often dub as FMMIS, we do program for procedure codes and so forth, corresponding diagnosis codes. So if a claim does not correspond to a diagnosis code, and -- that claim can be denied automatically in the system.

Q Okay. Okay.

A Which, I'm sorry, I forgot --

Q No, no, no. It's helpful. I just want to make a note of it.

A And we do program our system with ICD-10

codes, so we do have a build in our system for claims to deny if they don't necessarily correspond to a specific diagnosis code.

Q And that's regardless of whether the drug requires prior authorization?

A If it's prior authorized, the prior -- there's a different process for entering claims into the system that are prior authorized. So I think if it was prior authorized, that would override the automatic denials, but I would have to confirm that, but I believe that's how the system does work.

Q So FMMIS can be programmed to deny a certain service if it's associated with a particular diagnostic code, and that's done automatically?

A That's automatic. Yeah. Claims can deny automatically in the system, so we do have a fail-safe there.

Q Okay. And that's even if the drug does not require prior authorization?

A That's correct.

Q Okay.

A So I know it's definitely the case for the procedure codes that I administered when I was over -- when I was over specialized services. I'm going to assume that we have the same in place for NDC's,

National Drug Codes.

Q Okay. Because the services you were previously working on were not prescription drugs, is that correct, they were other Medicaid services?

A No, they were a little of everything.

Q Do you have a diagnostic code for every drug in the system?

A I can't speak to that at the moment.

Q Okay. Is there some way we can find that information out?

A Yeah, we can -- we can find that out for you.

MS. DEBRIERE: Okay. Can we flag that as a question, follow-up question?

BY MS. DEBRIERE::

Q If a drug is on the PDL, does it mean it's on the fee schedule?

A So we don't -- so with drugs, and this is one of the things with having worked -- working on the Canadian Drug Importation Program is that drug pricing is not a transparent process, so we don't actually list rates, we just list what we cover, or we list what's on the PDL. We don't actually say what we'll reimburse.

Q Okay, but if it's listed on the PDL, even if the rate's not on the fee schedule, AHCA is going to cover it?

A Yeah.

Q Okay. Does the PDL apply to managed care plan coverage of prescription drugs?

A Yes, that's actually -- well, yes, actually. I think -- I think -- I believe it does. That we wouldn't -- I would need to verify, but as far as -- like, I know that's the way our pharmacy benefit works. So with pharmacy benefit managers, generally the law ensures subcontract, that's the pharmacy benefit managers, who handle both their prior authorization of drugs and also negotiating rebates with manufacturers to help, of course, lower expenses. And so -- but for Medicaid, the SMC health plans, they have PBM's that they're really only there for the prior authorization process of prescription drugs. So their PBM's do not negotiate rebates. All that's done on the Agency side. So the agencies have contracted PBM, which is another branch of Magellan. They're the ones that negotiate all the rebates.

Q Okay. Just for clarity of the record, PBM stands for --

A Pharmacy Benefit Manager.

Q Okay. And then SMC PBM's, they're using the PDL to determine whether or not to authorize coverage for a prescription drug?

A Well, since with Medicaid we'll cover anything that's FDA-approved, they're going to be reviewing primarily medical necessity.

Q Okay. Are they going to match up the request for drug coverage to the PDL?

A I don't know if they do that or not.

Q Okay. So you don't know if Medicaid managed care plans rely on the PDL to authorize coverage?

A I don't. I can't speak to that.

Q All right. Let's look at a few specific drugs. Say this one for me again.

A Estradiol.

Q Estradiol. Thank you. Okay. So the PDL indicates that AHCA covers estradiol in each of these formulations, there's many listed here, for at least one indication, but we don't know what the indication is, or at least the PDL doesn't indicate it, correct?

A That's correct.

Q Okay, but AHCA does not cover estradiol to treat gender dysphoria?

A That's correct.

Q For what uses or indications does AHCA authorize coverage for estradiol?

A So for -- well, when estradiol needs to be covered, generally, as I speak very generally, of

course, usually it's used for hormonal imbalances, but I mean, but still we go back -- we defer back to the medical necessity guidelines.

Q So what does the no -- let's look at the very first list -- listed formulation of estradiol, which is associated with Climara 0.025-milligrams-per-day patch. And looking over at the clinical PA required, it says no. What does that mean?

A That means if the provider wants to prescribe it, that, of course, they can prescribe it without having to have a clinical review process.

Q So that means no prior authorization is ever required?

A Not under fee-for-service. Managed care plans, however, they have the flexibility to make it go through prior authorization.

Q Okay. So in fee-for-service, estradiol will be covered without AHCA or its contractor first determining for what purpose it's being used?

A Right, not until the claim comes in.

Q Okay. So that would mean that Medicaid could cover this drug if it were prescribed for non-FDA-approved uses?

A That's, of course, where our claim system comes in. So our claim -- our claim system was

programmed -- and, of course, I'm speaking generally of our CPT codes, et cetera, that if it doesn't -- if the diagnosis code doesn't align with what's in the system, that can come back as a denial.

Q Okay. So for estradiol, let's use this as an example, but not a hypothetical, in real life.

A Okay.

Q If estradiol is prescribed for treatment of gender dysphoria, is FMMIS programmed to automatically deny that claim?

A I would have to confirm with our -- with our Medicaid fiscal agent operations to make sure -- to know whether or not that the system has been updated for -- to deny that.

Q Is it possible to program a system to do that?

A To program it to deny it?

Q Based on -- based on the diagnostic code --

A From my experience, it's pretty -- it's a pretty simple affair to update the system to -- when we -- because we are uploading new and deleting diagnosis codes or uploading new procedure codes, I mean, it's generally a pretty straightforward process.

Q Okay. Can you provide us a list of those diagnostic codes at some point?

A For estradiol?

Q I think -- well the diagnostic codes would be -- are you using CPT codes? What are you using?
A So we use ICD-10 for --
Q ICD. Okay.
A -- because it's going to be primarily -- those are going to be like your -- well, those are your service codes. Those aren't drug codes.
Q Okay. So you use -- for your diagnostic codes, it's associated with ICD-10?
A That's correct.
Q Okay. So, looking at testosterone, this indicates that -- we've got to get there first, don't we? So this indicates that AHCA covers testosterone, and each of these formulations listed on the PDL for at least one indication, although based on the PDL, we don't know which indications for which it covers; is that correct?
A Yeah. I mean, there's a very large number of FDA-approved clinical indications for testosterone.
Q Okay. Just for clarity, AHCA will never cover testosterone when used to treat gender dysphoria, is that correct?
A Yes.
Q And it looks like, at least some of these formulations, including, for example, Andrew Durham,

four milligrams, 24-hour patch, that there is a clinical prior authorization that's required. Is that correct?

A Yes. Yeah. Based on the PDL? Yes, there would be a PA required.

Q For what uses or indications does AHCA provide prior authorization or approve coverage?

A So that goes back to our definition of medical necessity.

Q Okay. Would it also be governed by AHCA's drug criteria? And I'll just -- I'll pull that up. So when I say AHCA's drug criteria, I'm referring to that criteria listed at https://AHCA -- A-H-C-A --.myflorida.com/Medicaid/prescribed_ drug/drug _criteria.shtml.

And so would the drug criteria -- I'm looking at the screen. It says testosterone criteria updated 6-16-2022. Would the indications for which testosterone will be prior authorized -- prior authorized, would it be contained in this criteria?

A It would be contained in that criteria. That's correct.

Q Okay. Is this list exhaustive of all prescription drugs that AHCA will cover?

A I think -- I mean, I haven't seen the entire list, so -- but, I mean, for any drugs that we deem that

criteria is necessary, I imagine that would be an exhaustive list.

Q Okay. This applies in fee-for-service, correct?

A Those would apply for fee-for-service, yes.

Q How about for managed care?

A Managed care plans would need to be able to -- they would -- they would need to mirror their criteria and align it with the agency's.

Q So it can't -- my understanding is the managed care plan criteria cannot be more restrictive than what AHCA --

A That's correct. So they can be less restrictive, they can't be more restrictive.

Q Okay. Would the drug criteria listed here at the link to testosterone provide all the instances in which testosterone would be covered after prior authorization review?

A On the criteria?

Q Uh-huh?

A After --

Q Yes.

A Well, I would -- I'd have to -- I haven't actually had a chance to physically look at the criteria, so -- but I would assume that what we have the

criteria is accurate, especially given that it was updated in June 2022.

Q Okay. Turning back to EPSDT briefly. If the drug was being prescribed to a child under age 21, when AHCA or its contractor was undertaking the prior authorization process, could AHCA or that contract -- would AHCA or that contractor deviate from this criteria if the drug was otherwise prescribed for a medically necessary use?

A I have trouble following that question.

MR. JAZIL: Object to form.

BY MS. DEBRIERE::

Q So where testosterone was prescribed to a child under 21.

A Okay.

Q And EPSDT applies, then could AHCA or its contractor in its prior authorization review deviate from the criteria listed here? If medically necessary.

A As long as it meets medical necessity criteria, whether or not there's criteria involved and it meets -- if it's for an off-label use and it meets our off-label criteria, I mean, under EPSDT, I mean, yes, Florida Medicaid can cover it, but -- I mean, that would, of course, require significantly in-depth review, et cetera, but, I mean, hypothetically speaking, yes.

Q And one of the requirements -- just to circle back -- one of the requirement under that medical necessity review is that the prescribed drug cannot be for an experimental or investigational use, correct?

A That's correct.

Q All right. Just turning quickly back to FMMIS programming of the ICD-10 codes, what ICD-10 codes are programmed into the system for estradiol?

A What ICD-10 codes?

Q Yes.

A We would have to check the system. I would -- because I know pharmacy codes are set up a little differently than our procedure codes. So I'm kind of using the procedure code as analogous to the drug codes, but we would need to speak with one of our pharmacists.

MS. DEBRIERE: Can we flag that as a follow-up question, too? I had one more. So if you -- can we take a break for two minutes? I just want to confer -- or we can do longer if you need a second to go to the bathroom.

THE WITNESS: If you need a break, you can go ahead and take the break. That's fine.

MS. DEBRIERE: Thank you. Okay.

VIDEOGRAPHER: This concludes video one. The time is 11:05 a.m.

(Brief recess.)
VIDEOGRAPHER: This is the beginning of video two. The time is 11:08 a.m.
BY MS. DEBRIERE::
Q All right. So turning back to the preferred drug list, AHCA's preferred drug list, and looking at the formulation of testosterone cypionate -- did I say that correctly?
A I really don't know.
Q The PDL indicates that AHCA covers testosterone cypionate for at least one indication, although it doesn't say what indication, correct?
A Not on the PDL, no.
Q Does it say it anywhere? Is there anywhere we can find that information?
A Unless there's that criteria, unless we have a criteria listed on the website, generally, no, that's like one of the things -- I mean, we do have our claim system set up, which -- but like all that information is -- I mean, I suppose it could be obtained through public records request. That's usually the process.
Q Okay. So AHCA will never cover testosterone cypionate, or any formulation of testosterone for treatment of gender dysphoria, is that correct?
A That's correct.

Q So looking at the formulation of testosterone cypionate of testosterone CYP 1000 milligrams per 10 milliliters, that indicates there's no clinical prior authorization required, correct?

A That's correct.

Q So that means that AHCA will cover the drug or reimburse for the drug without determining for what use it's being prescribed?

A Well, based on my understanding of how our system works, through my experience is that the claim would deny.

Q Because why?

A Because the diagnosis code that'd be associated with that drug would trigger the system to do a denial.

Q Okay. So you're looking not at the indication of the -- what indication the drug's being prescribed for, but instead you're looking at the diagnostic code?

A So -- that's correct. Part of the process requires the procedure code, diagnostic code and place of service. Of course, those are for our health services, but those three all have to be programmed into the system. So say you're delivering a -- doing a checkup in a other setting, or you're doing like a setting that's not approved by us, it's not in our

policy, that claim would deny.

Q Okay. What if it wasn't for the treatment of gender dysphoria? What if it was for a diagnostic code that was not programmed to automatically deny?

A If it was for -- so if it was for a diagnosis code that was not programmed to deny?

Q Right.

A If it's programmed in the system -- we don't -- so we program the codes that it will approve. So all the other codes, it's not loaded in the system would automatically deny. So each -- so there'll be a set of ICD-10 codes that are -- that would link up with a particular service. As long as the diagnostic code corresponds to that service, the claim will pay.

Q Okay. So with the formulation of testosterone cypionate that we've been discussing that no clinical prior authorization is required, if the diagnostic code is programmed into the system, then it's going to automatically approve without looking at the indication for which the drug is prescribed?

A Provide that the claim form is -- it's a clean claim and all the pertinent information corresponds with the physician requirements, they will pay.

Q What is involved in a clean claim?

A No errors.

Q Errors of what?
A Someone might type in the wrong code by accident. Maybe they -- human error.
Q Okay. But you're -- but in that clean claim, there's no requirement to submit the indication for which it's being prescribed or AHCA undertaking a review of that?
A I mean, we do do retrospective review of claims.
Q At the time the coverage is being requested.
A Okay. Can we go back a little bit?
Q Yeah, yeah. Yeah. So looking at this formulation of testosterone cypionate, where no clinical prior authorization is required, when the claim is submitted and -- when the claim is submitted, AHCA is not doing a review of whether the indication it's being prescribed for -- sorry. Scratch that.
Looking at testosterone cypionate, in the formulation that we've been discussing where no clinical prior authorization was required, when the claim is submitted, AHCA -- neither AHCA nor its contractors does a review to determine for what indication the drug is being prescribed for?
A Right, there'd be no manual clinical review process or prior authorization process, if that's what

you're asking.

Q And when you said AHCA will only cover drugs that are FDA-approved, does that mean that AHCA never covers off-label use of a drug?

A We do have a -- no, we definitely would never -- we have a procedure for covering FDA-approved drugs for non-approved clinical indications, AKA off-label use. We do have a procedure for that. So we wouldn't necessarily -- no, we would never say never. That's --

Q Okay. I thought you said earlier that AHCA will only cover FDA-approved drugs?

A Right. But, I mean, like, let's say there's a drug that -- okay. Let's say it's been manufactured by European pharmaceutical or, you know, it's a pharmaceutical and it hasn't gone through the FDA review process, brand new drug. It's not FDA-approved. It's really not even approved -- it's not even approved for sale on the market. We won't cover those.

Q Okay. Okay. But you will cover drugs that are FDA-approved for uses that in and of themselves are not FDA-approved, for off-label uses?

A Yes, we have a procedure for that.

Q Okay. Do you ever program into the system the use of a drug for a condition for which the drug is not

FDA-approved?

A I can't speak to a hundred percent for that, but it seems it'd be counter to the process we have in place for reviewing off-label use for drugs.

Q Okay. And what is that process?

A So, it's a three-prong process. Step one is that there has to be a trial period for FDA-approved drugs for that clinical indication to have tried to have been used. And, of course, if the FDA-approved drugs for that kind of indication are not successful, then the -- then it moves to the second prong, which, you know, that requires like phase-three clinical trials having had to be completed on that drug. Then the third step is that the peer-review literature and one of the three drug compendia that we mentioned earlier has to pass the list or support it.

Q So you're looking at when determining whether or not you'll authorize coverage for a prescribed drug, you're looking at more than just whether the indication for which it's being prescribed is listed in the compendia?

A Yes, it's a little bit more comprehensive, correct.

Q Yeah. And so first you look at the individual Medicaid recipient and you determine whether or not they

CERTIFICATE OF SERVICE

I certify that I e-filed this appendix on ECF, which will email everyone requiring notice.

Dated: October 13, 2023 /s/ Mohammad O. Jazil

No. 23-12155

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

August Dekker et al.,
Plaintiffs-Appellees,

v.

Secretary, Florida Agency for Health Care Administration et al.,
Defendants-Appellants.

U.S. District Court for the Northern District of Florida, No. 4:22-cv-325
(Hinkle, J.)

APPELLANTS' APPENDIX – VOLUME X OF XXI

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Dated: October 13, 2023

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tried other drugs?
A That's correct, yeah.
Q Okay.
A It would be an individualized basis.
Q Okay. And then the second step was what?
A A phase-three -- the drug had to have completed phase three clinical trials.
Q And then the third step is you look to see if the indication that's being prescribed for is listed in the compendia plus --
A Plus support in the peer-reviewed literature.
Q Okay. Let's look back at Exhibit 3.
MS. DEBRIERE: Simone, do you have that handy? That's the cross-sex hormone therapy GAPMS.
MS. CHRISS: You should still have those two versions.
MS. DEBRIERE: I might have it. I have a notice of deposition and I have a cross-sex hormone therapy. Here it is.
BY MS. DEBRIERE::
Q Is there anywhere on this GAPMS that describes the process for the criteria used?
A It's on page nine, if you're referring to the off-label use.
Q Okay. And that starts with the criteria that

utilized under the Florida Medicaid program and authorization for drugs for off-label purposes are as follows?

A Uh-huh.

Q Okay. And that's what you just described to me?

A Yes.

Q Yeah. Okay. All right. Turning to past GAPMS regarding gender dysphoria.

A Okay.

Q We are aware, plaintiff's counsel is aware of three pre-2022, at least draft GAPMS reports regarding Medicaid coverage of the treatment for gender dysphoria. One we've already marked as Exhibit 3, and that is the May 20th, 2022 version of the GAPMS for cross-sex hormone therapy. We actually know of two other versions, one dated June 23rd, 2017 and one dated April 19th, 2022. So we're going to mark the June 23rd one as Exhibit 5?

MS. DUNN: Yes.

(Whereupon, Exhibit No. 5 was marked for identification.)

THE WITNESS: Yeah. I have to apologize for the auto-dating on those documents, so I can probably give you more accurate dates --

BY MS. DEBRIERE::
Q Yeah, let's get the documents in front of you, and then that's exactly what we were wondering about. It can get confusing.
A I can give you more --
Q That would be -- that's exactly what we're after. We appreciate that.
MR. JAZIL: They're identical except for the date, right?
MS. DEBRIERE: Yes. Yeah -- well, that's not true. Yeah --
THE WITNESS: Well, I have this one. I mean, it's fine. There's one -- there should be one for surgeries.
MS. DEBRIERE: No, no. We're just looking at the versions of cross-sex hormone therapy right now. We have three different versions, at least, that we've found so far.
MR. JAZIL: Thank you.
BY MS. DEBRIERE::
Q Okay. So let's first look at the one with the June 23rd date.
A Okay.
Q June 23rd, 2017. Who authored the version of this report?

A So listed in our assignment writing and tracking page in SharePoint, the author of this was Sarah Craig.
Q Okay. And do we have that routing form?
MR. JAZIL: You should.
THE WITNESS: They should have it. We -- I did produce it for everybody.
BY MS. DEBRIERE::
Q Okay. And then that was back in 2017 when she authored this?
A She authored it in 2016. This is actually -- so to provide a little context.
Q Please.
A So in 2016, this was before I came to the Bureau of Medicaid Policy, there wasn't -- there wasn't a GAPMS position. Because they were accumulating a lot of services, a lot of requests for coverage, they created two GAPMS positions in the fall of 2016. They were filled in January 2017. So GAPMS reports often went to subject matter experts. So that's -- so in 2016 when this one was completed, the person who completed it, their primary job was not GAPMS.
Q Okay. What was Sarah Craig a subject matter expert in?
A She was one of our pharmacists.

Q Okay. And right now, just for clarity of the record, we're looking at June 23rd, 2017. That's labeled Exhibit 6.

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

BY MS. DEBRIERE::

Q Who -- so saying that, let's move on to the April 19th, 2022, which is labeled as Exhibit 5, who authored this report -- or made the revisions, I should say, in the April 19th, 2022 version?

A The only person I'm aware of who worked on this one was Sarah Craig. Since this was done before my entrance into the Bureau, and she's the only author listed in our system.

Q And were any changes made on the April 19th, 2022?

A No. That may have been a day when it was pulled out to be printed.

Q Okay. Why would it have been pulled out to be printed?

A I think -- because there had been some questions about the history of whether the Agency had previously done any work on this subject.

Q Okay. And why did those questions arise?

A Those questions had arisen as part of the

request process for the GAPMS report we did, and that was approved on June 2nd.

Q And that's related to the treatment of gender dysphoria?

A That's correct.

Q Okay. Does Sarah Craig still work at the Agency?

A Sarah Craig, I think, left in 2020.

Q Okay. Do you know where she went?

A I do not.

Q Were there any changes -- looking back at Exhibit 3, which is dated May 20th, 2022, there are some revisions on this one.

A Okay.

Q For example, Beth Kidder is crossed out and Ashley Peterson's name is put in. And the subject line is crossed out and there's just some edits and comments. And it looks like some text was added, for example, on page three.

A I was not privy to any edits or changes being made after -- I was not privy to any changes being made to that document.

Q Okay. Well, just to be clear, you're here as the Agency representative and not in your individual capacity, so you should have some knowledge about any

revisions to these reports, based on your designation as the Agency representative. Can you not speak in that capacity to it?

A As far as the work goes during the time period that we were working on the June 2nd GAPMS?

Q Uh-huh.

A That -- the work for the determination of the transgender dysphoria in relation to consistency with GAPMS, that task was specifically designated to myself, and Nai Chen and Devona Pickle in supporting roles.

Q Okay. Right now, though, I'm just asking about revisions made to the May 20th, 2022 version. You do not know who made these revisions, is that correct?

A I do not know who made those revisions, because -- as the Agency witness. Nobody was requiring revisions to that document.

Q But there were revisions made based on what I'm looking at.

A Whoever did so was doing so on their own accord.

Q Okay. Who had access to this document?

A Well, given that any -- actually, anybody has access to that document because the documents -- it's available on our SharePoint site. It doesn't require a password. Anyone in the bureau, anyone who's

knowledgeable of our repository could go through and pull up that document.

Q Okay. Could it have been Ashley Peterson who made the revisions?

A It's possible. We would have to find out from our IT department.

Q Okay. I think we do need that information. And then who's GS? There's some comments on the side there on the front page, Exhibit 3. It says GS 1.

A Well, GS would be initials. Would usually like last name first, first name second. I might -- might occur to me later on. I can't --

Q Would it be Sheena Grantham?

A It's possible. I don't know.

Q Okay. Can you track who has access to this document?

A Yeah, our IT department can track whoever had made edits to that.

Q Okay. Okay. So we can find out the answer to that question?

A Yes.

MS. DEBRIERE: Let's flag that.

BY MS. DEBRIERE::

Q Was this report ever finalized?

A To my knowledge, and I did actually do some

history -- do historical digging on this one. Since our pharmacy manager at the time, and I do need to add it because I forgot to add, that I did consult Arlene Elliot, who was the pharmacy manager at the time that this report was initially prepared, I did confer with her to determine whether or not it was finalized. And what I mean by finalized, it went through the review process and was signed off by the deputy secretary. She let me know that it had not.

Q Okay. Do you know why or why not? Why was it never finalized?

A Well, generally, and this is often the case with GAPMS reports, is that because it's -- well, Medicaid is a -- it's very busy -- we're a very busy division. We have lots of requests, lots of asks, lots of projects, and often GAPMS reports, usually, for those of us who like to be very detailed and very analytical, we, you know, it's -- it's a craft. It's almost like each one is like a seminar paper or scholarly article. It takes time to read and review. And usually it's -- and sometimes often, because unless somebody's asking for it, or if it's deemed a low priority, often it just -- it just often waits. And that may have been why. That's speculation, though.

Q Okay.

A But it's not surprising that a GAPMS draft is out there and didn't complete the review process. Solely it's because there's just too many other projects going on.

Q And GAPMS is generally low priority?

A It depends.

Q What does it depend on?

A Depends on the situation, because often when the managed care plan requests for the GAPMS, that's usually -- those usually have to be addressed quickly.

Q Okay. Let's set expedited GAPMS aside. Just traditional GAPMS, are they generally low priority?

A A traditional GAPMS? Well, like I said -- like I said, it often depends on the context. It depends on the request. Sometimes it could be -- sometimes it's a stakeholder who made their voice known downtown. Sometimes -- I mean, it really depends on the context.

Q Okay. When you're referencing downtown, what do you mean by that?

A The Capitol.

Q Okay. So sometimes GAPMS will get bumped up if the Capitol is the person who's raising --

A It just depends on the situation/I just don't want to commit to an absolute answer saying that they're

all low priority, because not every single circumstance or every single GAPMS means that it will be.

Q Okay, but with the cross-sex hormone therapy GAPMS, you're guessing that one reason why it was never finalized is because it was low priority?

A That's a guess in relation to my experience when I had the role.

Q Okay. And what was your experience when you had the role?

A When I -- when I had the role, I had it for about 10 months, and I think I drafted ten reports and two of them made through the review process. Those two I reviewed in January. They weren't finalized and signed off on until July of that year. So often, it was more trying to -- you know, reminding supervisors at different levels to review them so they can move forward. And given how busy everything was, especially with legislative session going on or other special projects taking precedence, often if it could be done -- put on hold until the next day or later, it was.

Q Okay. And so for the two of the ten reports that were finalized, it took seven months for the reports to be finalized, reviewed and finalized?

A Yes.

Q Prior to its adoption, prior to AHCA's

adoption of the categorical exclusion of treatment for gender dysphoria, did Florida Medicaid -- were there any instances where Florida Medicaid ever authorized coverage for cross-sex hormone therapy to treat gender dysphoria?

A Were there any circumstances? The Agency didn't have a policy or criteria regarding cross-sex hormones or, like, hormones for that clinical indication.

Q So that wasn't quite my question. My question is prior to the adoption of the categorical exclusion of treatment for gender dysphoria, were there any instances, so --

A Under -- so, well --

Q Did Florida Medicaid ever cover treatment of gender -- use of -- did Florida Medicaid ever authorize coverage for cross-sex hormone therapy to treat gender dysphoria?

A So by Florida Medicaid, are you referring to the Agency?

Q AHCA or any of its contractors, Medicaid managed care plans or EQ Health or --

A Under fee-for-service, that was -- no, it was not an approved clinical indication. Obviously, with managed care plans, since they have the flexibility to

cover services that, you know, that are not necessarily clarified in our coverage policies so -- I mean, it's possible that we could have done that, yes.

Q Okay. So, to be clear, in fee -- under fee-for-service, prior to the adoption of the categorical exclusion for the treatment of gender dysphoria, there was never an instance of Florida Medicaid covering cross-sex hormone therapies to treat gender dysphoria?

A Are you referring to the fee-for-service?

Q Fee-for-service only.

A We don't necessarily have that information available.

Q Why?

A Well, not offhand.

Q Why?

A Well, going -- because we want to go back several years. We're assessing an extensive data pull.

Q Or even just six months prior to August 21st, 2022.

A So I think we did do a data pull for the past year. And that data pull, of course, show the results of what services we were covering, had the number of recipients with the diagnosis for gender dysphoria, and those who received treatment. So I'll defer to that

data.

Q So we don't have that data in front of us. And, again, you were produced as the 30(b)(6) representative, so what did that data show?

A That data did show that some -- that there were a handful of recipients who were receiving the services.

Q In fee-for-service?

A I think fee-for-service. I think managed care.

Q Okay. So there were times, prior to the adoption of the categorical exclusion for the treatment of gender dysphoria, that Florida Medicaid covered cross-sex hormone therapy for treatment of gender dysphoria?

A Cumulatively for the whole program, yes, there were.

Q Okay. So another previous GAPMS regarding gender dysphoria is the GAPMS entitled puberty suppression therapy, and that begins at DEF_ 000288776. Although, for clarity of the record, I do want to say we received multiple versions of this document, as well.

MS. DEBRIERE: Do we have the final one, by any chance? I'm positive it was my mistake in terms of listing exhibits.

MS. DUNN: The one that was signed?
MS. DEBRIERE: Yeah.
MS. DUNN: That's a whole different -- it has a different name.
MS. DEBRIERE: I'm sorry, guys. That's my fault. My fault.
MR. JAZIL: Counsel, do you want him to clarify that date issue? I think he mentioned it as you were --
MS. DEBRIERE: Oh, yeah, I thought he did. I'm sorry if -- please, go ahead and clarify the date issue.
THE WITNESS: So both of these GAPMS were initiated in 2016.
BY MS. DEBRIERE::
Q Okay. When you say both of these GAPMS, you're referring to --
A Referring to the one on the cross-sex hormone therapy.
Q Okay.
A And the one on the puberty suppression.
Q Okay. Let's not talk about the puberty suppression one just yet, because I want to get the right exhibit into the record first.
A Okay, but as far as the date goes, these were

projects from 2016.

Q Okay. Okay.

MR. JAZIL: Counsel, if you'd like me to just make additional copies of that, I'm sure we can.

MS. DEBRIERE: So there are multiple versions that were provided to us of this document. We are looking for another version that has a signature on it, although I'm sure Mr. Brackett can speak to it being finalized. But just to make everyone's life easier in the long run, we are going to try to -- yeah, this is great. Okay.

Chelsea, should we mark it?

MS. DUNN: Yeah. Do you want that Exhibit 7?

MS. DEBRIERE: Are we on 7? Okay.

(Whereupon, Exhibit No. 7 was marked for identification.)

BY MS. DEBRIERE::

Q All right. We have only one copy of this, and it's DEF_000288776, entitled puberty suppression therapy, dated September 14th, 2016. And the reason we were -- and that's going to be marked as Exhibit 7. The reason we wanted that one is because if you turn to the back page, it's signed by Mr. Senior. So we assume then that's the final report?

A This would be the final report if he signed

it.

Q Okay. So it was adopted by the Agency?

A The recommendations in this GAPMS were -- yes, they would be adopted.

Q Who authored this report?

A So in the --in our system, our SharePoint system, that was the individual listed for this report was Monique Johnson.

Q Okay. And who was Ms. Johnson? What was her subject matter expertise?

A So she was a program administrator and she oversaw the primary care services team, which is primarily like surgeries, inpatient -- inpatient services, dental services. Like, I think like surgical procedures, things like that. Of course, child health checkup procedures. Generally be like primary care and preventive, anything that would fall into those categories.

Q Why would she then look at puberty suppression therapy?

A So this was, at the time before we had the defined GAPMS individuals, so I can only speculate as to why she was selected. It may have been she had bandwidth at the time to do it, but since there was no one who actually did GAPMS full time, I don't -- I can't

speak as to -- because I'm not that familiar with her background, I can't -- and, of course, this was 2016, but more or less, there may have been a number of reasons for why she was selected for this.

Q Okay. Why wouldn't it have gone to a pharmacist?

A We don't have the -- an answer for that.

Q Was Ms. Johnson a pharmacist or pharmacy tech or had any --

A I think she was an RN.

Q Okay.

MR. JAZIL: Counsel, just so the record's clear, this copy of Exhibit 7 has highlights on it. Did you --

MS. DEBRIERE: It would have not been -- it would have been highlighted by us. Is that right? Yeah. So my apologies.

MS. DUNN: It's the only copy we have, but we can potentially print a clean copy.

MS. DEBRIERE: And it's Bates-stamped.

MR. JAZIL: It's fine. I just want the record to be clear that it's highlighted and the highlights were added by counsel for plaintiffs, not the witness.

MS. DEBRIERE: Yes. Thank you for that, Mo.

BY MS. DEBRIERE::

Q Okay. So going back to Exhibit 4, pubertal suppression -- yep. This is the special services criteria. This was developed only six days after the puberty suppression therapy GAPMS report. Is that correct?

A You mean the criteria?

Q Yes. Yes. Exhibit 4.

A Based -- I'm going to defer to the dates on this, because it predates my time in the Bureau of Medicaid Policy. So if the dates say 30 days, then that would be --

Q The dates say six days.

A The dates say six days?

Q Yeah.

A I'll defer to that.

Q Okay. Are these two documents related?

A Can you provide some context on what related means?

Q Is one based off another?

A It seems -- it would appear that following the completion and approval of the GAPMS process, that this document was completed, routed and then approved, based on the time stamps.

Q Okay. So was the special services criteria at

Exhibit 3, was it drafted based on the information contained in the GAPMS report related to puberty suppression therapy?

MR. JAZIL: Exhibit 4?

MS. DEBRIERE: Did I say 3? I'm sorry. Exhibit 4. Thank you, Mo.

THE WITNESS: It looks like it's fairly consistent.

MS. DEBRIERE: Okay.

THE WITNESS: Based on the EPSDT consideration portion.

BY MS. DEBRIERE::

Q So based on your understanding of office operations, then it's likely that the special services criteria was drafted in response to the puberty suppression therapy GAPMS?

A Yes.

Q Okay. And this is the -- this policy, Exhibit 4, is the criteria that AHCA used prior to its adoption of the categorical exclusion of treatment for gender dysphoria to determine whether gonadotropin-releasing hormone analog would be prior authorized for pubertal suppression and treating gender dysphoria, correct?

A Yes, correct.

Q Okay. Between the time this policy was

adopted, which was October 6th, 2016, and the time AHCA adopted the categorical exclusion of treatment for gender dysphoria in August of 2022, if an individual's condition met the criteria laid out in this policy, then Florida Medicaid would cover the cost of the drug for pubertal suppression and the treatment of gender dysphoria, is that correct?

A Providing that the criteria, and prior to the challenge exclusion, yes.

Q Okay. Between October 6, 2016, and the time AHCA adopted its categorical exclusion of treatment for gender dysphoria, how many times did AHCA authorize the drug set forth in this policy for the treatment of gender dysphoria?

A We would have to defer at least -- at least prior to the challenge exclusion being implemented, we'd have to defer that data for that time period, but we'd have to go all the way back to 2016 as far as the data goes, at least in fee-for-service, to determine how many recipients actually received the -- actually received authorization for it.

Q Do you have any knowledge of any time period in which fee-for-service covered it, based on the criteria in this policy?

A So this -- so once this policy -- so once this

criteria was released to Magellan, Magellan was our PBM for fee-for-service. So they did the prior authorizations for fee-for-service. So Magellan would review each case individually.

Q Okay. Do you know how many times Magellan authorized it based on the criteria?

A I do not have those numbers.

Q Okay. Can we get those numbers?

A We can try to find them. We can try to get those numbers. It's a very long time period.

Q But it is your understanding that in certain instances, Magellan did authorize it?

A We would have to -- we would have to look at those numbers.

Q Okay. Because previously, when we were discussing cross-sex hormone therapy, you did know that in some instances fee-for-service had covered the drug to treat gender dysphoria, but you don't have that same information for pubertal suppression?

A That's speaking more about Medicaid, cumulatively as far as the differences between fee-for-service and managed care encounters, I would have to take a look at the data to get the exact numbers of what was in the fee-for-service system versus the encounters for the managed care were. But we would --

have we would have to go ahead and get this information from Magellan going back to find out exactly how many times that they get pre-authorization requests versus how many approval/how many denials.

Q Okay. Let's just look quickly at exhibit -- it's going to take me a second to find it.

MS. DEBRIERE: Simone, is the list of Medicaid recipients and discussion of their authorizations -- yeah. I don't know. Yeah, that's it. Not surgery, though. There should be a drug one. Maybe I'm wrong. They probably didn't include it.

BY MS. DEBRIERE::

Q Mr. Brackett, while we're looking for that, let's go back to the notice of deposition. In the deposition topics, we do list the number of Florida Medicaid recipients who -- participants who have sought any form of care for gender dysphoria from January 1st, 2015 until the enactment of the challenged exclusion. And so as we're sitting here today, you're telling me you can't answer whether -- or how many times AHCA or one of its contractors authorized coverage of pubertal suppression therapy for treatment of gender dysphoria, is that correct?

A That's correct, as of now, but we can get that

information.

Q And you will provide us that information?

A We will obtain that information.

Q Okay.

MS. DEBRIERE: So I think that given that there are a few places where we have follow-up questions I do, at this point, just want to say that once those questions are answered, we're going to reserve some time for this deposition so that we can do follow-up questions based on the information that's provided to us, because right now there's some holes that Mr. Brackett is not able to fill, and once that information is provided to us, of course, we will probably have follow-up questions. So we just need to reserve some time for --

MR. JAZIL: Okay. And just so the record's clear, I think I provided objections to the last set of depo topics. There may have been an objection to this particular topic, going back to 2015, but we'll work with you. If we can gather the information, we'll provide it.

MS. DEBRIERE: Okay.

BY MS. DEBRIERE::

Q So looking at the final GAPMS report related to treatment of gender dysphoria, it's entitled gender

confirmation surgery.

MS. DEBRIERE: Oh, gosh. Do we have it from the past deposition? I'm sorry. We had, like, over 50 exhibits and clearly it's completely my fault not putting them in the list. We can always pull back around to them and print it out at lunch, too. There it is. Okay. We're going to mark this one as Exhibit 8, and it's entitled GAPMS gender confirmation surgery, dated July 19th, 2017.

(Whereupon, Exhibit No. 8 was marked for identification.)

BY MS. DEBRIERE::

Q And this one does have markups on it that are not our markups, they're from the Agency. Who authored this report?

A So this report is authored by Rebecca Buceo.

Q Okay. When?

A This was authored in the summer of 2017.

Q How do you know who was authored by?

A I was in the bureau at the time and was present when the project was being assigned out.

Q Okay. Why weren't you assigned the project?

A I was actually being assigned -- I was working on another project related to designated state health programs and getting approval for those through the

Centers for Medicaid -- Medicare and Medicaid Services. So I was actually on a kind of a legislative priority project. And so I was not assigned to this one.

Q It's my understanding that there's only one hard copy of this report, is that correct?

A That's correct.

Q Okay. Whose office was it found in?

A So, I -- this report, I did -- it was in a binder with -- so this report was found in Rebecca Buceo's old office. So she had an office in the bureau. I know she maintained her GAPMS materials there.

Q Okay. And what else was in that binder?

A I think some of the research articles she used.

Q Is that it?

A That was it.

Q Okay. Is Rebecca Buceo still with AHCA?

A No, she's not.

Q When did she leave?

A I believe she left in 2019.

Q Okay. And what was her subject matter expertise?

A She had a behavioral health background. That was her -- that was her subject matter expertise.

Q Did she have any expertise in surgery?

A Not professionally, no.
Q What about not professionally?
A In other words, she's never worked as a surgeon or anything like that. But, I mean -- but I mean -- or in the formal education in that area.
Q Okay. But did she have any experience with surgery that would help her inform the drafting of this GAPMS?
A I couldn't speak to that.
Q Did AHCA ever rely on the conclusions in this report?
A So this report did not get past her immediate supervisor, so, no.
Q Okay. Prior to its adoption of the categorical exclusion of treatment for gender dysphoria, did Florida Medicaid ever cover gender confirmation surgery for the treatment of gender dysphoria?
A Under fee-for-service, to the best of my knowledge, we didn't. In managed care, there were a few instances where the managed care plan did approve the procedure.
MS. DEBRIERE: Okay. Can we look at those exhibits now? The -- I forget what they're called. They're a weird name. ATTB, ATTA. It's a weird name. It wouldn't come to me.

BY MS. DEBRIERE::

Q Okay. So I'm handing you -- these were natives, so they were not Bates-stamped, but I'm handing you documents produced to plaintiffs in discovery. They were also not labeled, and I just want to ask you some questions about what they mean. We'll mark that as exhibit -- actually, I'll take those copies. I'm sorry. Well mark this as Exhibit 9 and 10. And, I'm sorry, because they're natives, they don't have Bates stamps.

(Whereupon, Exhibit Nos. 9 - 10 were marked for identification.)

BY MS. DEBRIERE::

Q So looking at Exhibit 9 first, which is two pages total, front and back.

MS. DEBRIERE: Seems like they -- yeah, it printed out -- I see. Do I put it together? What do we do?

BY MS. DEBRIERE::

Q Let's look at under service type, outpatient surgery. Line item status is approve. Does that mean that Florida Medicaid approved outpatient surgery?

A Yes, that would mean it was approved.

Q Okay. And the product description was mastectomy with a primary diagnosis code of F649?

A Uh-huh.

Q So that means that the outpatient surgery was approved for a mastectomy for a diagnosis code of F649, is that correct?
A That's correct.
Q Okay. And F649, what is that diagnosis code?
A That's gender dysphoria.
Q Do you know if -- can you tell by this document whether -- it appears that it was approved by children's medical services under product roll-up.
A So based on these two -- so based on these two, I can't tell if the recipient is in managed care or if they're in fee-for-service. So in Exhibit 10 --
Q Yeah.
A -- this looks like this would be managed care.
Q Okay. And how do you know that?
A Because it has, like, the member effective category.
Q Okay. If the title of both of these documents had the term CMS on it, would that mean that it's managed care?
A Children's Medical Services is overseen by Sunshine Health. So, yes, it's managed care.
Q And looking at Exhibit 10, the Medicaid ID, does that correspond to individual Medicaid recipients?
A Each Medicaid recipient has a unique Medicaid

ID assigned to them. That's correct.

Q Okay. And these documents are indicating that there were authorizations of surgeries for primary diagnosis codes of F640 and F649, is that correct?

A Yeah, that's correct.

Q Okay. And F640 is a diagnostic code for what?

A So F64, generally, there is a decimal point after the 4. So it was F64. The way ICD-10 codes work, it's kind of like a taxonomy. So F64, categorically, is gender dysphoria. So F64.9 would be like a -- like a subcategory of that general diagnosis.

Q So these documents are showing that, at least in managed care, prior to the categorical exclusion -- prior to AHCA's adoption of the categorical exclusion for the treatment of gender dysphoria, there were times in which Florida Medicaid covered surgery to treat gender dysphoria; is that correct?

A That would be correct.

Q Okay. Let's turn to the June 2022 GAPMS. We have this exhibit. And Exhibit 11 will be the June 2nd, 2022 GAPMS related to the treatment of gender dysphoria.

(Whereupon, Exhibit No. 11 was marked for identification.)

BY MS. DEBRIERE::

Q I'm going to refer to this throughout as the

June 2022 GAPMS.

A That's fine.

Q When was the request to initiate this GAPMS made?

A So the formal request was made on April 20th. That was the date of the Secretary's letter.

Q Were there any informal requests prior to that time?

A There were some informal, I guess, indicators of, you know, trying -- when they were trying to determine whether or not we had bandwidth, you know, and so there was some informal indicators that this project would be coming down the pipeline because they were trying to figure out who to do it. So we were aware of the Secretary's letter it would be coming to us.

Q Okay. When you say they were trying to figure out. Who is they?

A Our Agency leadership.

Q And who is that comprised of?

A So that was primarily for the Bureau of Medicaid Policy, Ann Dalton was our bureau -- is still our bureau chief at the time.

Q So Ann Dalton had knowledge of the potential for this project coming down prior to April 20th, 2022; is that correct?

A Yes.
Q Okay. Who else in leadership was aware that this would be coming to AHCA prior to April 20th, 2022?
A At the time, Secretary Weida was serving as Assistant Deputy Secretary. He did have knowledge.
Q Okay. Anybody else?
A To my --to my knowledge, those two were the ones with the knowledge of this project.
Q Okay. When did you have knowledge of the project?
A Just probably a few days before we were given the letter.
Q Okay. So, like, April 17th?
A Something around there. Yeah, I don't remember the exact date.
Q Okay. Who did you gain the knowledge -- who did AHCA leadership gain the knowledge from?
A As far as the project goes, the decision to do a GAPMS to my -- so that was to do a GAPMS report, that was determined by our legal as the best route to evaluate the medical necessity for treatments for gender dysphoria. It was that -- it was subjected to the GAPMS process.
Q Okay. And which counsel was that?
A Andrew Sheeran, who's now our General Counsel.

Q Okay. And who contacted -- was Mr. Sheeran the first point of contact related to what eventually became the June 2022 GAPMS?
A No, I don't think he would have been the first point of contact.
Q Who would have been the first point of contact?
A Generally, our first point of contact would have been our General Counsel at the time.
Q And that was?
A Josephina Tamayo.
Q Okay. And who contacted Josephina Tamayo about this project?
A So this project, about the GAPMS in particular --
Q No.
A -- or about requesting a Medicaid review?
Q Requesting a Medicaid review.
A So that, of course, that did come down from the Governor's office.
Q Okay. Who in the Governor's office made the request?
A So that is -- so it was a multi-party meeting. So the three staffers from the Governor's office that were involved were, I think, Katie Strickland, Ryan

Newman and Maureen Farino.

Q Okay. What other agencies were involved?

A As far as the decision for Medicaid's review?

Q No, as far as that initial request coming from the Governor's office. You said there was a multi-party meeting.

A Well, between AHCA's staff and Governor's office staff.

Q I see. Okay. What other AHCA staff were present at that meeting besides Ms. Tamayo?

A I think at that meeting, I think Deputy Secretary Weida may have been present, I think the General Counsel, I think, Andrew Sheeran, may have been present as well.

Q Okay. Anybody else present at that meeting, besides those people that you just named?

A I can't name them with any specificity.

Q Okay. Were they from other agencies other than the Governor's office or AHCA?

A So in regards specifically to this project?

Q Are there other projects we should be aware of?

A Well, I -- there were, I think, some people present from the Department of Health.

Q Regarding what project?

A But that was regarding their review of treatments for gender dysphoria.

Q Based on actions related to the Board of Medicine or based on CMS guidance?

A What do you mean -- when you say CMS, are you referring to Children's Medical Services or --

Q No. Centers for Medicare. Great question.

A That guidance was actually not by CMS, it was from HHS.

Q Excuse me, HHS.

A It was in regard to that guidance.

Q Okay. So there was some presence of Department of Health there, as well, but not related to Medicaid?

A Right.

Q Okay. And what was the date of that initial meeting?

A I don't have -- know the date offhand. I think it was like early April.

Q Okay. And at that meeting, it had not yet been determined that AHCA would use the GAPMS process to evaluate whether treatment for gender dysphoria was experimental, is that correct?

A I think that -- yes, I believe that is correct, based on -- based on the information we've

gathered, is that the decision is to route it to the GAPMS process was done after that conversation.

Q Okay. So what was the Governor's office request for the meeting?

A The Governor's office request was to -- in response to the HHS documents, the Department of Justice documents, Department of Education documents regarding gender dysphoria, designing treatments for gender dysphoria, the evidence for gender dysphoria, it was that the Department of Health and AHCA both undertake reviews.

Q Did the Governor's office instruct AHCA to find -- did the Governor's office instruct AHCA to ensure that Florida Medicaid would not cover treatment for gender dysphoria?

A No.

Q Okay. Did the Governor's office make any specific requests about Florida Medicaid coverage as it related to the treatment of gender dysphoria?

A The Governor's office wanted the Agency to undertake the review.

Q But what type of review did it want the Agency to undertake?

A It wanted to take a look at -- a detailed look at the available medical evidence, or at least the

peer-reviewed literature, and to see what it says.

Q Okay. You referenced earlier the Florida Department of Health's investigation on the HHS fact sheet. What did that investigation find?

A So the Department of Health's fact sheet, of course, provide some cursory information, like go into some snapshots of some literature out there, you know, stating that the evidence for support -- that was supporting gender dysphoria treatment was too weak for this to be considered a standard treatment for that condition.

Q Okay. And so at the time of this initial meeting in early April, when there was a discussion of DOH's findings, at that point there was a conclusion that the information or evidence to support treatment of gender dysphoria was weak?

MR. JAZIL: Object to form.

MS. DEBRIERE: I can strike that.

BY MS. DEBRIERE::

Q Why did the Governor's office want AHCA to review Medicaid coverage for treatments of gender dysphoria?

A So in response to these documents, there were questions about whether or not the evidence supported what HHS, DOJ and DOE was -- at least the United States

DOJ, United States DOE, the claims they were making. They wanted to do a review to see whether or not this -- the evidence that's supporting was -- actually sufficiently supported those claims.

Q Did the Governor have a specific position on whether HHS' findings were accurate, prior to AHCA's review?

MR. JAZIL: Object to form.

THE WITNESS: No.

BY MS. DEBRIERE::

Q Did DOH have a position on whether HHS' findings were accurate prior to AHCA's review?

MR. JAZIL: Object to form.

THE WITNESS: Can you rephrase that question?

BY MS. DEBRIERE::

Q Yeah. Did DOH -- at that initial meeting, what conclusions had DOH drawn about the HHS report?

A So DOH, they didn't -- they didn't release their opinions until April 20th, the day we got the letter.

Q Okay. But had they -- at that meeting, had they formulated those opinions?

A To my -- based on the information given to me, they had not yet formulated those.

Q So why did AHCA general counsel decide that

the best process to undertake the review was the GAPMS process?

A Because, well, I'm speaking based on our -- on how policy works is that, of course, the medical necessity definition does have a prong saying that the service has to be consistent with generally accepted professional medical standards. So the best way to do a review to either -- to determine whether or not something is consistent with GAPMS is to do that, undertake that review process, and that really provides the best opportunity to go through the literature on a large scale and to make a conclusion.

Q Okay. To your knowledge, had there ever been a time previous where a GAPMS was used to determine the experimental nature of services previously covered by Florida Medicaid?

A To my knowledge, there was not.

Q So this is the first time the GAPMS process was used to determine whether services that were already being covered by Florida Medicaid were experimental?

A To my knowledge, yes.

Q The folks at the initial early April meeting, did they reach out to HHS to get the info they relied on before conducting their own review?

A Are you talking about the Florida Department

of Health folks?

Q Or the Governor's office, anyone involved in that meeting.

A No, we -- with the releases, the document releases from those -- from those federal agencies was sufficient.

Q So AHCA did not reach out to HHS either?

A No, we had their documents. We didn't -- we didn't have any need to question them on them.

Q In the letter you're referring to from Secretary Marstiller dated April 20th, 2022, is that correct?

A Uh-huh.

Q That's the letter that directed Tom Wallace, the Director -- I'm sorry --

A State Medicaid Director, Deputy Secretary.

Q Thank you. That was the letter directing him to undertake GAPMS related to treatment of gender dysphoria, right?

A Yes.

Q Why did Secretary Marstiller's letter say that she was making the request in response to DOH guidance rather than a request from the Governor?

A Because the DOH guidance had just been published.

Q Okay. But she was asking Mr. Wallace to undertake that GAPMS process because it was a request from the Governor's office, correct?

A A request for the state agencies to look at the existing evidence and making recommendations, that initially came from the Governor's office. Since I wasn't physically -- since I personally was not present for those meetings, I can't exactly speak to the sequence, but DOH would undertake its review. And, of course, once they published their guidance, we undertook ours.

Q Okay. Just to be clear, there's a few times that you said to your knowledge, but, again, you're testifying as an Agency representative?

A Yes.

Q So this is to the knowledge of the Agency, correct?

A To the knowledge of the Agency, yes.

Q When did AHCA begin work on the 2022 GAPMS? What date?

A We started work on April 20th.

Q You didn't do anything prior to that?

A No. I mean, I may have done, like, an article search, just to see what was out there, but as far as any large-scale work goes, no, we didn't do -- we didn't

do anything like that.

Q Okay. And, again, just to be clear, no one at the Agency, because you're in the capacity as an Agency representative. So my question is not just about whether you started anything related to the 2022 GAPMS.

A The Agency did not -- did not start work until April 20th.

Q Who worked on the 2022 GAPMS at the Agency?

A You mean the June 2022 GAPMS?

Q Yes.

A So I was primarily the author. It was myself, Devona Pickle prepared the maps of the United State Medicaid programs. Nai Chen prepared the maps for the internet -- for the European countries to classify who covered what, but that was it. It was the three of us.

Q Okay. And I apologize. Can you just one more time run through what everybody's roles were? You were the primary author. Mr. Chen worked on the maps.

A Worked on the maps for Western Europe.

Q Okay. And what did Dede Pickle do?

A The maps for the State Medicaid programs.

Q Okay. And as primary author -- so you wrote everything else except for the maps in the state Medicaid coverage, then?

A That's correct.

Q Okay. And did you have any assistance?
A It's -- GAPMS are a solitary project, any extensive research project is, because once you immerse yourself in the literature, it's very difficult to have assistance because you're trying to get up to -- you have to transplant knowledge from yourself to them. It's actually just easier to do it, to kind of sail the waters on your own. And this is coming from speaking from experience on, like, a myriad of research projects, from scholarly articles, master's theses for, like, works -- other works for the Agency, previous GAPMS reports. Once you under -- once you reach a certain understanding of that knowledge, it comes a point where you -- it makes sense -- it's more efficient for you to do it in a solitary fashion.
Q Okay. So you were the only one involved in outlining and reviewing the literature that became the June 2022 GAPMS?
A Yes.
Q Okay. Was there anyone else at the Agency -- so you didn't work with Mr. Chen on the literature or --
A Nai, he did -- he occasionally he'd find an article and give it to me, but other than give me the occasional article, that was -- that was it. I went through, reviewed the article, like, broke it down. As

far as any content or analysis, he just gave me copies of articles.

Q Okay. Okay. And so no one else at the Agency -- did anybody else at the Agency take on that role to where they were sending you articles or anything related to that? I guess what I'm trying to determine is whether anyone else assisted you with drafting?

A Nobody assisted me with the drafting.

Q Inside or outside the Agency?

A We did have a few consultations with some of our contracted experts --

Q Were they a verbal consultations?

A They were verbal.

Q Only verbal?

A Yeah, but as far as drafting went, they weren't involved in that process.

Q Okay. So they didn't write any of the main report?

A They did not write any of the main report.

Q Or outline it or anything?

A No.

Q Okay. Looking at -- I have another exhibit, the Van Mol ATF. We're going to mark this as Exhibit -- Exhibit 12. What is wrong with me today? And it's entitled Agency for Health Care Administration

after-the-fact request form under 35k.

(Whereupon, Exhibit No. 12 was marked for identification.)

BY MS. DEBRIERE::

Q So, reason for occurrences, where I'm reading and second sentence to the last, due to the need to start work quickly, all of the purchase order elements were not available until May 6th. Why was there a need to start work quickly?

A Since this is -- since we did have a request, and since we were writing in response to the Department of Health, which had already had published their findings, the Agency, of course, we considered this a priority project, and this was mostly that's -- that's pretty much, it was a priority project.

Q I'm sorry. Why was it a priority project?

A It was priority project because in relation to -- in relation to the Department Health guidelines, which had been released, then, of course, because, you know, as the state of Florida wanted to respond to the HHS documents, which had also been released, because we didn't want a significant amount of time, like, five or six or seven months to elapse before the Agency had gotten its response out.

Q Okay. So you wanted to make sure that there

would be a quick response to the HHS guidance?
A Yes.
Q Okay. When I say a decision tree checklist for GAPMS, do you know what I mean?
A Are you referring to, like, to a checklist?
Q Yes.
A Yes, I do know what you're referring to.
Q Okay. Did AHCA do a decision tree checklist for this report?
A So that decision tree checklist, that was a -- is an internal process, and each person who does GAPMS often kind of brought their own unique perspective or unique approach to them, since these are research projects and there's not really a formula for it, but I believe -- I think Jeffrey English, I think, helped to develop a checklist, which I think he used when making evaluations. I kind of have my own mental checklist when I did them. And also, actually, I actually wanted to kind of help refine, to help cut down the number of GAPMS requests we had. As we started going through requests, we started realizing, well, some of these really aren't GAPMS, these are just coverage determinations.
Q What -- How did you know that?
A Generally -- okay, well, FDA approval for the

clinical indication.

Q Okay.

A If a national coverage determination's been released by Medicare, things like that.

Q Okay. What about if it was already listed on AHCA's fee schedule?

A Not necessarily.

Q Why?

A Because -- just because it's listed on AHCA's fee schedule, it does not necessarily mean that it's -- wouldn't be experimental or investigational for another clinical indication.

Q So based on the checklist, if it was listed on the fee schedule, that one isn't going to determine whether or not it should go through GAPMS?

A It shouldn't, no. And that was -- when I -- when I did GAPMS, that was not part of my criteria.

Q After the checklist was developed, how many GAPMS did you do?

A The checklist was developed well after I had left that role.

Q Okay. So -- but we know you did the June 2022 GAPMS, so at least one right?

A Uh-huh.

Q Okay. After the checklist was developed, for

any other time that AHCA undertook a GAPMS, was a checklist completed?

A I think there were some completed checklists that I was able to find in our PDM, but that was after the fact. When I embarked on this one, I was not aware a checklist even existed. Not that I didn't apply kind of a mental checklist when I was going through it to check to see if there were certain elements in there that would either come to the conclusion that this shouldn't be that way through GAPMS or not.

Q What was your mental checklist?

A FDA approval for a clinical indication, which would mean that there was already substantiating research for it, which had been done by federal agency, which would kind of render GAPMS point moot, or a national coverage determination by Medicare. And the national coverage determination is pretty much -- it's like a Medicare GAPMS, and it's -- there aren't that many NCD's out there because there's a risk involved in getting an NCD, but if -- but Medicare NCD's are backed by substantial amounts of research. So if there's an NCD out there supporting a treatment and mandating coverage for a specific service, and all the research they do behind it, it kind of also -- it renders doing the GAPMS moot.

Q Okay. Any other -- anything else on your checklist?
A No, those were the two items I usually look for.
Q So that's it. And then if they didn't pass those two tests, they went to a GAPMS?
A Went to a GAPMS.
Q Okay. So -- I'm sorry. I just need to find my place in the outline. When was the checklist developed? Remind me. 2017?
A No, the checklist would have been developing in 2019.
Q 2019. Okay. During the 2022 -- the start of the 22 -- 2022 GAPMS, you mentioned that you were having conversations with the Governor -- or there was an initial meeting with the Governor's office when the request was made and DOH was also present?
A Prior to the request being made.
Q After the request was made, was there any communication with the Governor's office?
A No.
Q After the request was made, was there any communication with the Department of Health?
A No.
Q What about HHS?

A No.
Q And what about Alliance Defending Freedom?
A No.
Q Liberty Counsel?
A No.
Q Okay. What consultants were used by AHCA in the development of the GAPMS.
A So during the development, we have a few verbal conversations with Doctors Miriam Grossman and Andre Van Mol.
Q Okay. And what did those conversations entail?
A Well, Dr. Van Mol, he just offered suggestions for articles and research for us to look at. He did provide us with a bibliography for our consideration, as far as -- mostly just leads on research to help save time in finding resources. And Dr. Grossman, of course, she provide us with some history of gender dysphoria treatments, and gave us more reviews of some scientific techniques.
Q How did you get connected with Dr. Van Mol?
A So Dr. Van Mol, like all of our experts, who also provide published reports, so the process for those was that we did get a name at the very outset of the process, which was Michelle Cretella. And by contacting

her, she led us to other providers -- or other practitioners who had expertise in the fields, and that's how AHCA made contact with these individuals.

Q So Michelle was the only person who connected AHCA to the consultants it relied on for the 20 -- June 2022 GAPMS?

A Yeah.

Q Okay. And who Michelle?

A Michelle -- Dr. Michelle Cretella?

Q Uh-huh.

A She's a physician. I think she has some affiliations with, like, a couple of -- I think American College of Pediatrics, I think. I'm not sure what her other affiliations are.

Q How did you find her?

A Well, her name was passed on to us from the Department of Health.

Q Okay. What's her relationship with to the Department of Health?

A I -- the Agency does not know what her relation to the Department of Health is.

Q Okay. So you just accepted this recommendation by the Department of Health as the person who would connect you to the consultants you would use to develop the 2022 GAPMS?

A Yes.
Q You didn't do any outside research on whether you should seek out other consultants?
A Well, we were vouching for our -- for the consultants. I mean and so we did want individuals who had expertise in their respective fields of medicine, and who also were going to take an evidence-based approach.
Q Okay. Who at Department of Health recommended Dr. Cretella?
A Don't -- we don't have the name of the individual.
Q Because it was sent in an anonymous email? Why don't you have the name?
A We can get that information for you.
Q So you don't have the name, but the Agency has the name, correct?
A The Agency might have a name. We need to confirm that.
Q And who at the Agency was this communication sent to? I mean, how was it communicated?
A To my knowledge, it was verbal. It was a verbal exchange.
Q Okay. So who at AHCA was part of that conversation?

A So I think when it came down to, you know, reaching out to experts and determining who the experts we should use were, I think Andrew Sheeran and Jason Weida were involved.

Q Okay. So it was either Andrew Sheeran or Jason Weida who received that information from the Department of Health related to Dr. Cretella?

A Yes.

Q Could it have been anybody else at the Agency?

A I don't think so. I mean --

Q It seems like you have a name in mind.

A Well, I mean, there were other senior leaders. The Secretary may have been given the name, or Chief of Staff may have been given the name, so, but --

Q Who was the chief of staff?

A Cody Farrell.

Q And who was the person who spoke with Dr. Cretella about her recommendations?

A I think -- I think Andrew Sheeran and Jason spoke about that -- spoke to them about the recommendations.

Q And she recommended everyone, is that correct?

A Well, she -- from what I gathered, there was, like, recommendations. She gave some names. And not everyone she recommended, of course, we decided to go

with. So there were some that we did turn down.

Q Who did you turn down?

A We can get that -- we can get that -- we can get those names for you.

Q With Dr. Cretella, was there any consideration given to the associations, the medical associations of which she was a member?

A No.

Q Okay. So you didn't look to see if she was associated with any particular medical association?

A No.

Q You just went off the recommendation of Department of Health?

A Yes.

Q Was Dr. Cretella paid for her assistance with -- to AHCA?

A No.

Q So DOH didn't pay her or anything?

A Well, I don't know at DOH, that's a question for the Department of Health. AHCA did not -- we did not establish a financial arrangement with her.

Q Okay. Are you -- are you personally aware of any financial arrangement between Dr. Cretella and Department of Health?

A No.

Q Okay. I'm sorry. Who did you turn down?
A We would have to get those for you.
Q Okay. And so Dr. Grossman and Dr. Van Mol just gave you some article leads, and that's all?
A Gave some article leads, some background information. Yeah, it was -- I mean, as far as providing us with content to include in the report, they did not.
Q Why not?
A Because it was an independent assessment by the Agency.
Q Okay. Did -- but they didn't write any of the reports that were in the attachments to the June 2022 GAPMS either?
A Right?
Q Why not?
A I think because we had experts. We already had a psych -- one psychologist who was writing one. We already had -- we, of course, we had physicians for, like, plastic surgery. We had a bioethicist, as well. Since those bases were covered, we felt they would best benefit us by helping provide guide -- guidance with research.
Q Were they ever given the option of writing a report for one of the attachments?

A No, we didn't ask them to write a report.
Q Okay. Did they ask if they could write a report?
A No, they did not.
Q How did you identify Dr. Romina Brignardello-Petersen?
A So through the contacts we were making, her name was passed on to us as someone at McMaster University who had some experience in doing evidence evaluation.
Q Did Dr. Cretella pass on that name?
A As far as the actual contact that gave us that name?
Q Uh-huh.
A Dr. Cretella was kind of the head of the tree of the contacts. We would have to go back and get that information on who gave us the exact name for Dr. Brignardello-Petersen.
Q Okay. But Dr. Cretella was the one who -- so what -- if Dr. Cretella didn't recommend Dr. Brignardello-Petersen, who would have?
A We would have to get that information for you.
Q Would it have been another physician?
A Yes, it likely -- yes, it would have probably been another physician.

Q What other physicians provided recommendations for consultants?
A We would have to get that information.
Q What all physicians did you talk to you prior to -- or in the process of drafting the --
A So in the process of drafting the report, we really -- we talked to Doctors Grossman, Van Mol. There were a couple conference calls with the experts who provided the reports, but those weren't about our report, that was just mostly more -- that was talking to them about them doing their reports.
Q Okay. So who recommended Dr. Cantor?
A We -- that may have been Dr. Cretella who had recommended him. We would need to confirm that.
Q Okay. So, again, just pointing to topic 24 in the notice of deposition, we asked for an Agency representative who was knowledgeable as to --
MS. DEBRIERE: No, no. I just don't know what -- I have no idea where it is.
BY MS. DEBRIERE::
Q So looking at topic 24, and we asked very specifically about the identification of Dr. Brignardello-Petersen, Dr. Cantor, Dr. Van Meter, Dr. Lappert, Dr. Donovan, in the inclusion of the written assessment. So I don't know what to say. I mean, it

seems like you're not able to answer the question.

MR. JAZIL: So, counsel, the topic says the process by which AHCA prepared the memo, and I read that to mean the process by which we identify these experts. And so he's detailed the process. It was an initial consultation with one physician, and then it was -- one person recommends another, recommends another. And I think he said that a lot of these were oral. To the extent that we have any written records of who specifically said, hire Dr. Romina Brignardello-Petersen, we'll supplement the production with that.

MS. DEBRIERE: Other than written records, Mo, can you get us -- can you just do an investigation of who spoke with these individuals and collected this?

MR. JAZIL: So who -- so I think he's answered that, it was General Counsel's Office, and it's now Secretary Weida, who spoke to these individuals. If the question is who specifically recommended each expert --

MS. DEBRIERE: Yes.

MR. JAZIL: -- I'll ask. And if there's a written record, it would have been turned over to you already. If there's an oral record, beyond

what he's talked about, well --
MS. DEBRIERE: If someone knows. Because if someone knows at the Agency --
MR. JAZIL: -- you know, Bob talked to Jill, Jill talked to Jane, Jane talked to Jason and said, hey, hire Brignardello-Petersen, I'll get that information for you.
MS. DEBRIERE: Thank you.
BY MS. DEBRIERE::
Q Whose decision was it to engage with Dr. Van Meter? I'm sorry. Who recommended Dr. Van Meter? I apologize.
A That's information we would have to --
Q So you don't know who recommended any of these individuals other than Dr. Cretella?
A Right.
Q Okay. When did AHCA first become aware of the HHS fact sheet on gender-affirming care in young people?
A We became aware of it, since we do follow HHS publications, much of our staff in Medicaid, so forth, they are actually on -- they receive automatic updates, so we became aware of them as they came out.
Q What was AHCA's independent reaction to the fact sheet?
A Well, as the Agency initially didn't -- didn't

have a reaction. There was -- we didn't -- we don't react publicly to HHS documents.

Q Okay. So did AHCA -- you stated in your declaration filed with the court on January 23rd -- are you aware of what I'm talking about? I can get you a copy, if not.

A I should be aware of it. I've reviewed it.

Q Okay. That litigation was highly likely because in drafting the GAPMS report, the GAPMS determination might conflict with federal standards. Do you remember saying that?

A Yeah. If I -- yeah, I mean, it's written and signed off on, then, yes.

Q Okay. With what federal standards, did you think it might conflict?

A Well, it might -- it would probably conflict with that guidance that was released from HHS.

Q Any other federal standards?

A No.

Q Why did you think it would conflict with the guidance from HHS?

A Because the guidance from HHS, the conclusions we made -- that we made following an independent assessment, conflicted with the HHS guidance. The HHS guidance did state that these were, like, medically

necessary treatments, that evidence supporting them, so that they would alleviate mental health systems symptoms, et cetera. Our concluded -- our conclusions and our assessment of literature deemed otherwise, so we knew that there would be a potential conflict.

Q At what point did you realize that there would be a potential conflict?

A When we -- during the drafting process. So we realized that the evidence was inadequate to support the claims that HHS was making, or that -- that's when we realized that there would be -- there would be a conflict.

Q Okay. Did you anticipate that the GAPMS report would conclude that the relevant services were experimental?

A When I started working on it, I did not know where the evidence would take me.

Q At what point did you realize that you were going to conclude that the services were experimental?

A As -- the more and more I read the articles that focused on the mental health benefits, the methods and so forth, the more I realized that all those articles left way too many unanswered questions. This -- there was also -- there wasn't any evidence available to answer those outstanding questions. I

realized that I couldn't -- that there was not going to be -- that the conclusion was going to be, no, it was not consistent.

Q Okay. So your analysis of those services. So I think one of your concerns related to the treatment of services for gender dysphoria that is now excluded under 59-G-1.050(7), was that the services were not supported by randomized controlled trials, is that correct?

A That was one element of many elements.

Q Okay. Does AHCA ever require that -- does every -- does AHCA require that every treatment or procedure it covers be supported by randomized controlled trials?

A So to contextualize that question, every medical service is unique. So we don't apply a uniform set of standards to every single medical service, because every single medical service is for a specific condition, every medical service carries its own pros and cons, risks versus benefits. So we don't necessarily -- we don't have a one-size-fits-all model for evaluating each and every medical service.

Q You mentioned unanswered questions as you were reviewing the literature for treatment of gender dysphoria, or the services you were analyzing. What were those?

A So those are iterated in the GAPMS report, but generally like -- well, number one, long-term. And other unanswered questions, like a lot of these studies were based on anonymous surveys. How are we supposed to know whether or not these responses are credible, if we don't have any longitudinal history of these individuals? I mean, one of the things that we came up with when we were doing the literature review is the etiology. There are lots of potential causes and associations with gender dysphoria, not -- not including but not limited to autism, trauma, neglect, abuse, abandonment, things like that. So because there was so many unanswered questions, I mean, how are we supposed to know whether or not a one-time survey is going to accurately capture all of that, especially if it's done -- being taken by anonymous people, or if the survey -- or for those that weren't anonymous, the sample sizes were very, very small. So and, of course, you're talking about one- or two-year periods. These -- the changes prompted by these treatments are permanent.

Q Did you adopt any of the conclusions about treatment for gender dysphoria relied upon by the American Academy of Child and Adolescent Psychiatry?

A The American College of -- can you repeat that?

Q American Academy of Child and Adolescent Psychiatry. I think it's AACAP.
A No, I don't recall we -- us using their recommendations.
Q What about the American Academy of Family Physicians?
A No, we didn't use theirs.
Q What about the American Academy of Pediatrics?
A We did do an evaluation of theirs.
Q Did you rely on them, their conclusions?
A So what do you mean by --
Q Did you -- did you lend credence to their conclusions?
A Yeah, yeah. It was -- their conclusions required thoughtful analysis and probing of the evidence. We do take the recommendations of clinical organizations very seriously, but we also do reserve the right to question those recommendations and we did review those and we did analyze them.
Q And after you reviewed and analyzed them, did you adopt them?
A No, we found that they were based on very weak evidence.
Q Okay. What about the American College of Obstetricians and Gynecologists?

A No. I mean -- I mean, there -- we didn't -- so, aside from AAP, we did notice, like most of the recommendations, guidelines, were very, very similar, very straightforward, and they usually are based on Endocrine Society and WPATH guidelines.

Q And did you adopt the recommendations from the Endocrine Society and the Pediatric Endocrine Society?

A No, we did not. We did review those in close detail, though, and analyze them.

Q What about -- I'm sorry. The other WPATH?

A Yes. So the World Professional Association for Transgender Health, we did closely review their guidelines. We did -- we did analyze them. And, of course, we do discuss them in lengthy detail in multiple areas of the GAPMS report.

Q And ultimately you disagreed with their standards?

A Ultimately, yes.

Q What about the American Psychiatric Association?

A I think we actually didn't make reference to them in the GAPMS report.

Q Did you adopt their conclusions related to the treatment of gender dysphoria?

A No, we did not.

Q What about the American Psychological Association?
A No, we did not.
Q American Medical Association?
A We did not.
Q When you say we, you mean --
A The Agency.
VIDEOGRAPHER: Excuse me, counsel. Sometime soon, I need to take a short --
MS. DEBRIERE: Oh, yes.
VIDEOGRAPHER: -- to start the next video. Do you want to take a break? We could take a -- do you want to take a 30-minute lunch break or --
THE WITNESS: I'm good with that, yeah.
VIDEOGRAPHER: Okay. This concludes video two. The time is 12:42 p.m.
(Whereupon, the deposition resumes in Volume 2.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF LEON)

I, the undersigned authority, certify that the above-named witness personally appeared before me and was duly sworn.

WITNESS my hand and official seal this 21st day of February, 2023.

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF LEON)

I, DANA W. REEVES, Professional Court Reporter, certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages, numbered 5 through 120, are a true and correct record of the aforesaid proceedings.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 21st day of February, 2023.

_____.

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

Gary V. Perko, Esq.
gperko@holtzmanvogel.com

February 21, 2023

RE: August Dekker, et al. vs. Jason Weida, et al.
February 8, 2023/Matthew Brackett/5696545

The above-referenced transcript is available for review. The witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason on the attached Errata Sheet. The witness 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 fail(s) 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).

August Dekker, et al. vs. Jason Weida, et al.

February 8, 2023/Matthew Brackett

E R R A T A S H E E T

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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.

_____ _____

Matthew Brackett DATE

p

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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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

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

AUGUST DEKKER, et al.,
Plaintiffs,
vs.
JASON WEIDA, et al.,
Defendants
_____/

	Volume 2, Pgs. 125 - 261
VIDEOTAPED DEPOSITION OF:	MATTHEW BRACKETT
AT THE INSTANCE OF:	THE PLAINTIFFS
DATE:	FEBRUARY 8, 2023
TIME:	COMMENCED: 1:30 P.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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Tallahassee, Florida 32301

ALSO PRESENT:
RL Minnich, Videographer

INDEX TO WITNESS

INDEX TO EXHIBITS

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

D E P O S I T I O N

Whereupon,

MATTHEW BRACKETT

was called as a witness, having been previously duly sworn to speak the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

VIDEOGRAPHER: This is beginning of video three. The time is 1:30 p.m. We're on the record.

EXAMINATION

BY MS. DEBRIERE::

Q So prior to break, we were talking a little bit about Dr. Van Mol and Dr. Grossman's involvement in the 2022 GAPMS. How did AHCA identify them to participate in the July 8th rule hearing that was related to?

A So the -- are we talking about the rule hearing?

Q Yes, related to the June 2022 GAPMS.

A So since we had already been working with them in relation to the GAPMS project, because Dr. Grossman is a psychiatrist, and Dr. Van Mol is a family -- family practice practitioner, that's based on their backgrounds and their knowledge of the existing evidence, that was our basis for selecting them to be on the panel for the July 8th hearing.

Q And turning back to the individuals who wrote reports for the June 2022 GAPMS, who made the decision to contract with them to prepare those reports?
A So after establishing each one, we wanted to -- their backgrounds and their suitability to provide reports, that decision was made by, I think, now Secretary Weida.
Q And who was involved in determining whether they had the appropriate backgrounds to write the reports?
A So I think those individuals who were working with the experts, I think that was, of course, now Secretary Weida, I think at our time, General Counsel Josephina Tamayo.
Q Okay. Anybody else?
A I don't --
Q Were you involved?
A I was not.
Q Was Nai Chen involved?
A He was not.
Q Was Dede Pickle involved?
A She was not.
Q Okay. So now Secretary Weida and Josephina Tamayo were the two people who decided whether the consultants who read the reports were qualified to do

so?

MR. JAZIL: Object to form.

THE WITNESS: So are you asking that whether or not those two only assessed their credentials?

BY MS. DEBRIERE::

Q Yes.

A I mean, yeah. I mean, they assessed their credentials and looked at their background and experience and knowledge.

Q Were those the only two people that assessed their credentials before deciding whether to engage them?

A In regarding the Agency, I mean, the -- Andrew Sheeran may have been involved. So it's possible a couple others with the principal decision to rely on those experts was theirs.

Q Okay. And so just to be clear, you were not involved in that decision?

A I was not involved in that decision.

Q And Nai Chen was not involved in that decision?

A That's correct.

Q And Dede Pickle was not involved in that decision?

A Correct.

Q When making that decision, did AHCA investigate whether any of the consultants had a stance related to the treatment of gender dysphoria?

A We, of course, were looking for those that had -- were knowledgeable about the existing literature of gender dysphoria, and those who would, for the supplemental reports, would take an evidence-based approach.

Q Did it -- so those were the only two criteria that you used to determine which consultants you would engage with?

A Correct.

Q And so opposition to gender-affirming care was not a factor in who you chose?

A We were specifically looking -- I think we might be talking semantics on what we consider opposition, but we were looking for individuals who were going to make reports and recommendations based on the existing evidence.

Q Okay. Was whether the vendor had experienced treating -- I'm sorry. Was whether the consultant had experienced treating gender dysphoria a factor?

A Not so much a factor that would outweigh the knowledge of the existing literature and the evidence, since this was going to be a -- the GAPMS process really

takes into account peer-reviewed literature. It takes into account evidence-based clinical guidelines, et cetera, so those are our primary -- our primary factors in evaluating the experts and their ability to contribute to this report.

Q Would people who actually provide treatment in gender dysphoria be most familiar with peer-reviewed literature as it relates to their practice?

A Well, that is a complicated question. They don't necessarily have to be. It's possible to -- I mean, it is possible -- I mean, it is hypothetically speaking, someone could engage in treatment of these individuals and run and follow anecdotes.

Q So it's not important to AHCA that the consultants with whom you engaged had actual experience treating gender dysphoria?

A So based on how the GAPMS rule is written, the needs of the report, we really -- the primary ask was for individuals who were steeped in the evidence.

Q But didn't necessarily have actual real life experience treating gender dysphoria?

A Right, that wasn't a primary consideration.

Q Okay. For -- was AHCA aware that all the consultants with which you engaged took a stance to oppose mainstream medical organizations' stance on

gender-affirming care?

MR. JAZIL: Object to form.

THE WITNESS: So are you talking about in opposition or in contradiction?

BY MS. DEBRIERE::

Q Contradiction.

A We -- whether contradiction or alignment really was irrelevant, it really was taking a look and making evidence-based conclusions.

Q Speaking to Dr. Brignardello-Petersen -- I'm sorry. I'll start here actually. In deciding on whether to use these consultants, was any input provided from the Alliance Defending Freedom?

A No.

Q What about the Heritage Foundation?

A No.

Q Liberty Council?

A No.

Q Society for Evidence-Based Gender Medicine?

A We may have gotten Romina's name from that organization.

Q Okay. And what about the Family Christian Coalition?

A No.

Q Did you get anybody else's name from the

Society for Evidence-Based Gender Medicine?

A Because the -- because it was verbal conversations, so don't -- don't think so, but the kind of details -- because there's a lot of verbal conversations and no written record, so --

Q Maybe?

A It could be a maybe at best.

Q And did the Family Christian Coalition recommend any of -- or play any role in the recommendation of the consultants --

A No.

Q -- with AHCA engaged? What about the Florida Citizens Alliance?

A No.

Q The Florida Department of Health?

A Well, the Florida Department of Health passed along to the name of Dr. Michelle Cretella. So, yes.

Q What about the Governor's office?

A No.

Q The Surgeon General Ladapo?

A Well, he would be acting in his capacity as, of course, the agency head for the Department of Health. So the Department of Health, cumulatively, gave us that name.

Q Did he personally?

A There was a conversation, like, once with our general counsel Tamayo at the time with Dr. Ladapo, but we don't recall whether or not the name was given during that conversation.

Q I think you touched on this a bit earlier, so I apologize for circling back around, but did AHCA consider using any other consultants in the development of the June 2022 GAPMS?

A By any other --

Q Other than those that wrote the reports or Grossman or Dr. Van Mol?

A There were those who were contacted. Of course, there was -- it was all verbal conversations, but not necessarily -- not necessarily considered to write a report either.

Q And do you remember who you were -- who you contacted?

A Since it was all through verbal conversations, it was eight months ago, it wasn't through written correspondence, the -- we're not really aware of all those details.

Q And who was the one who did the contacting?

A The contacting was done, I think -- I think by Andrew Sheeran. He's now our General Counsel. I think Josephina Tamayo -- Tamayo. Sorry. I think she also

was involved in contacting them.

Q Okay. And those were all phone calls?

A These were verbal conversations, yes.

Q So no communication by email?

A No.

Q Did you use the folks who ended up not offering the reports -- aside from Dr. Van Mol and Dr. Grossman and the individuals who authored the reports, did you use the people that you contacted in any other capacity?

A No.

Q And what was the scope of the agreement between AHCA and each consultant?

A So each consultant, of course, they provide us their hourly rate. We wrote up purchase agreements that those amounts cannot exceed $35,000 because of the nature of the procurement.

Q Can you speak a little bit more to that? I'm not -- I'm unfamiliar with the way that -- the regulations that govern that.

A So if it were to exceed $35,000, it would have to be a competitive procurement, and that's why -- so the -- so we, of course, we enter in agreements with each of these experts. The amounts paid to them cannot exceed 35,000.

Q Okay. What was each vendor -- in procurement of consultants, was this the usual procedure? I'm sorry. In contracting.

A Yeah, this is the procedure that we can follow.

Q That you can follow, but is it the usual procedure?

A Well, I mean, what is defined by a usual procedure? I mean --

Q How many times in prior GAPMS have you contracted with a consultant to develop the GAPMS?

A Well, we haven't, but then there are instances -- I know with coverage determinations, et cetera, that sometimes we will actually send stuff for a physician review, like over at EQ Health Solutions. So it's not unusual for us to ask for medical experts or clinical expertise on a prospectus.

Q Had you ever previously contracted and paid the person for that clinical expertise?

A No, we had not.

Q What was the total budget allocated to the development of the GAPMS?

A You know, 35,000 times seven. That'd be 210 -- 245,000.

Q So each consultant is capped at --

A That was the cap of the budget.
Q And is that 34,999, or 35 straight?
A I'm leaning towards 34,999, so we can subtract $7 from that amount.
Q Okay. Has each consultant been paid in full for that work?
A Each consultant has been paid in full for the work they completed.
Q Okay. Some of those consultants now, though, are acting as experts in this case and being reimbursed for that, as well?
A Those would be under separate agreements.
Q Okay. In the example you just gave about using outside physician consultants for the other GAPMS, did AHCA pay those other consultants?
A For other GAPMS? Those consultants are usually salaried or have hourly rates from our subcontractors.
Q Okay. Okay. But you didn't enter into any kind of vendor agreement with them?
A No, they're already employed by one of our subcontractors.
Q Okay. Did all of the $35,000 paid to the vendor -- paid to the consultants come directly from AHCA?

A Yes.
Q Was AHCA reimbursed by anyone else for those consultant payments?
A No.
Q Other than through its subcontractors, has AHCA ever previously retained outside consultants to undertake a review of the evidence-based clinical practice guidelines for GAPMS?
A Well, previously, we did actually have -- of course, we discontinued it, but we did have PAYS, which was back -- and we had it throughout 2017 -- which was a course and evidence review guide program that I had to subscribed to. We did have that and often referenced that in the early days, but after the amount of time, and because it was an expensive subscription, we discontinue it.
Q So that was a subscription service. Do you -- can you recall any time that you engaged with an outside consultant, other than those employed by your subcontractors?
A No.
Q What about to undertake a review of professional literature?
A No.
Q To actively participate by making a

recommendation or assessment as to the experimental or investigational nature of the service?

A No.

Q Why didn't you use the subcontractors -- AHCA subcontractors, why didn't you rely on their expertise in developing the June 2022 GAPMS?

A Because of this GAPMS and because of the nature of the subject. We did anticipate litigation after -- once the report was done and once we were working on it. So because of that anticipation, we needed to have experts that were -- that did have a degree of expertise in this field. Our subcontractors, their practices are more like general practitioners, or may be specialized in other areas, and they wouldn't be able to adapt quickly enough to the learning curve to provide a valuable assessment.

Q So you were concerned about attacks litigation might have on the integrity of that report itself?

A Can you repeat that?

Q Well, you said that because you anticipated litigation, that's why you engaged with consultants who had expertise, in particular --

A The Agency needed as robust a report as possible. So because we needed such a robust report, and because of the HHS guidance, the Department of

Health, so the fact that there were published documents out there, the Agency did need to come up with a response that we needed to disseminate as robust as possible, and that's why we engaged with the outside experts.

Q Why is gender-affirming care different from any other Medicaid service?

A Well, I'm going to defer to GAPMS process and our GAPMS report. For -- for the response to that is that gender-affirming care, of course, we are looking at, like, a treatment model that has very weak and low-quality evidence supporting it. And because we did a review and assessment of the literature, because there are a lot of claims made, especially by HHS, in particular, about its efficacy, because of its nature, because of -- and because of the low-quality evidence, that's how we deemed it. I mean, it is a different sort of care than we can consider traditional.

Q The GAPMS process is used to determine whether a Medicaid service is experimental, right?

A Yes.

Q So then that question is presented in any Medicaid service you're evaluating under GAPMS?

A That's right.

Q So why is gender-affirming care different?

A I'm going to defer to the conclusions we drew in the GAPMS report.

Q Why did you anticipate litigation before you even reached a decision?

A Well, I think that's because, I mean, this is often a very touchy subject. It's something that's frequently seen in the mainstream media. And, of course -- of course, the documents from HHS. It is a high-profile issue. It's considered by many to be controversial. So that should -- that's kind of why we did anticipate potential litigation resulting from whatever determination we made.

Q Why didn't you need gender dysphoria experts from the prior gender dysphoria GAPMS?

A For the prior ones?

Q Uh-huh.

A So for the prior ones, I think at the time -- I mean, we have to take it in context at the time, and, of course, these were done piecemeal, these were all separate reports, not one large one. So in the course -- at the time because this wasn't viewed as far as a potential hot topic, there wasn't the HHS guidance at the time, that's -- I think the best explanation as far as to why we decided not to engage with consultants.

Q HHS releases guidance all the time, though,

about coverage?

A Uh-huh. That's correct. It does.

Q Did you anticipate litigation for the 2016 GAPMS memo on puberty suppression therapy?

A The staff of the Agency who were present for that determination are no longer with the Agency, so we, in our current capacity, can't speak to that.

Q Did you undertake any research to derive an answer for that question?

A No, we didn't.

Q Did you look at any past memos related to whether or not the GAPMS might have litigation initiated?

A It's always a concern with every coverage determination and every GAPMS we do because inevitably, if we do say no to a service, there's going to be disappointed party. So it is a consideration we always have in place that there might be litigation.

Q Well, then that brings me back to the question as to why gender-affirming -- why this GAPMS is different?

A Well, this brings us back to the present circumstances behind how much attention the subject's been drawing in the media. The -- and it goes back also to the HHS guidance, which was making claims based on

evidence that we determined was insufficient.

Q So I only listen to NPR, I'll be honest. I don't watch any news. What media? Where's this a hot topic in the media?

A Oh, I mean, let's see here. I mean, we can name a lot of sources. I also -- I do listen to NPR myself. So NPR actually does periodically have an article on it. Then, of course, let's see here, there's quite a few other sources of things listed here. CNN, MSNBC, ABC, NBC. Your major outlets. New York Times. The Guardian.

Q How long has the media coverage been going on for?

A So as far as media coverage goes, well, the media coverage, there's always been smatterings of it here and there, but I think when -- as far as it becoming a consistent theme probably the past year. But that's not me speaking on behalf of the Agency, that's me speaking from personal observation.

Q Okay. Fair enough. Did AHCA share any of the draft consultant reports with external entities?

A We did not.

Q The Governor's office?

A We did not.

Q Department of Health?

A We did not.
Q No one?
A No, they stayed internal.
Q Did AHCA provide any material to the consultants to review in drafting their reports?
A No, we did not.
Q Did AHCA edit the reports of the consultants?
A There was some copy editing for style and grammar. Other than that, no, we did not make edits to the content.
Q So no substantive edits?
A No substantive edits.
Q And that includes Lappert's report?
A That includes Dr. Lappert's report.
Q And Dr. Donovan's report?
A And that's for Dr. Donovan.
Q And did any of the consultants provide edits to the AHCA GAPMS report?
A So after we finished the draft, we did send drafts to Doctors Grossman and Dr. Van Wol and they provided some feedback, but none of the feedback met -- were made -- resulted in drastic changes. I think -- I think Dr. Van Mol suggested we -- there's one more article we could discuss, and we added some content in there regarding that. They did help us correct some

terminology errors. There are some -- so there are some technical edits that were made. But as far as anything substantive, my first draft, I mean, was largely intact by -- from the first draft process to when we had the final draft.

Q Okay. And you were the only person involved in making the first draft?

A I can articulate a little bit more on how that went. So while the experts -- while the experts were composing their reports, I was composing mine. And once we had their reports, then that was -- then we did add -- we added some snippets from their reports in our report to make it more, I guess you could say, cumulative.

Q Okay. So only after the consultants who wrote a report, those reports were done, then you pulled some of that information into your --

A Correct. So my section was complete when we started receiving their reports.

Q Okay. Okay. What was the date of your first draft?

A I think the date of my first draft -- let's see here -- want to say early to mid May.

Q Okay. So, like, second week of May-ish?

A Somewhere around there, yeah.

Q Going back to the edits that the consultants provided to your report, what terminology had to be corrected?

A What was it? I mean, it was some medical terminology. I don't remember the specifics. I mean, it was very, like, miniscule changes.

Q Where they red lines in, like, a Word document?

A No, the edits were given to me verbally and I made them -- sometimes I made them right there when we were talking to them.

Q Okay. You stated in your declaration filed with the court on January 25th, 2023, that the only sources you relied on for the June 2022 GAPMS, were those cited in the works cited section of the report; is that a correct statement?

A That's correct.

Q So that means that the only sources that you consulted or considered -- or cited in the June 2022 GAPMS report?

A During the -- yeah, during the writing of the GAPMS, those were the sources consulted.

Q Nothing else?

A During the drafting of the report, nothing else.

Q What about after?
A Afterwards, more out of intellectual curiosity, I did want to try to see what else was out there, but that was more for personal intellectual curiosity than it was for professional purposes.
Q Okay. What were those things that you reviewed?
A Articles by Jack Turban.
Q Can you spell his last name?
A T-U-R-B-A-N.
Q I'm not familiar.
A Well, it's -- he is cited in our report, but he also is -- he's frequently quoted a lot, so I was curious to see what other in print articles he had produced.
Q Quoted in what?
A He's often cited in, like, news stories, media.
MS. DEBRIERE: Simone just got a note that folks are having trouble hearing me.
BY MS. DEBRIERE::
Q All right. When you were considering whether the services listed at 59-G-1.050(7) were experimental, did you evaluate whether excluding those services would be budget neutral?

A No, we did not.
Q Did you consider whether private insurance covers the services excluded by 59-G-1.050(7)?
A For this one we didn't, but primarily when we do GAPMS, we really aren't interested in public and private insurers. We're primarily interested in state Medicaid programs and Medicare since, like, Florida Medicaid, they're public payers. So primarily, we really want to know what the public payers say. Usually, our lowest priority for GAPMS is to provide analyses of what private payers pay. And generally, often we need those to supplement if we're unable to get that many policies from Medicaid programs across the nation, but since it's -- for this GAPMS, we actually surveyed all 50 states, then we had adequate information from that. Most GAPMS reports, usually we get maybe 10 or 12 when it comes down to coverage policies, it's -- it's pretty much what we can find in a certain amount of time. But for this one, we've -- since Dede Pickle was working on it independent, she was able to survey all 50.
Q And why is it covered under private insurance informative of whether or not a service is experimental?
A Can you repeat that?
Q Uh-huh. Why don't you rely on -- why don't

you consider private insurance coverage to be something -- I'm having trouble formulating what should be a simple question.

Why don't you look at private insurance coverage when you're determining whether or not a service is experimental?

A Well, private insurance works differently. I mean, Florida Medicaid, like Medicare, is a taxpayer-funded health care system. Private insurers, since they're privately funded, there's a great deal more latitude, what they can cover and what they don't have to cover, and they're more subject to the competition of the market, as opposed to Medicaid programs. So we -- while we do -- some often will look, but often it's -- we often try to find what private payers pay for following what we get from Medicare and Medicaid. So, I mean, when it comes down to it, we can, but it's not an absolute requirement, and we really do want to find out what the Medicaid programs are paying for. That's our first and foremost criteria for looking at the coverage of -- other payers coverage.

Q So it's not apples to apples, because in Medicaid and Medicare, you've got state taxpayer dollars to consider, correct?

A That's correct.

Q Okay. But when you undertook the June 2022 GAPMS, you did not evaluate whether or not excluding those services would be budget neutral?

A No, we didn't for this one, but we -- but that's also not necessarily unique to this, as well.

Q So in other GAPMS, you've not evaluated the budget neutrality of the service, whether or not you're going to cover it?

A That's correct. In the GAPMS I did in 2017, for, I think, like the nitrous oxide of -- pretty much like an adjuvant to this, kind of jumped-up asthma test, we didn't do a cost budget analysis because, like, we weren't going to cover, it's not going to affect anything.

Q So then you did evaluate whether it was budget neutral. You won't be covering it, so, therefore, it was neutral?

A Well, we just -- we just don't -- we just don't do one, because, I mean, we're not covering it. So it comes down to if we were going to make a coverage determination, that's when you do a fiscal analysis. So a coverage determination is definitely turned into a fiscal -- it needs -- it needs a fiscal analysis, because we're -- need to find out whether or not we're going to be able to stay within our budget.

Q I see. I see. So in this instance, because we are talking about the only GAPMS that excluded a service previously covered, did you do anything to determine whether or not that would cost or save the state money?

A No.

Q I think you have -- you brought information with you today about this. How did you collect state Medicaid program coverage data?

A So on that spreadsheet, so Dede Pickle, she went across the -- yeah. So she --

MR. JAZIL: Do you want to mark it as an exhibit?

(Whereupon, Exhibit No. 13 was marked for identification.)

THE WITNESS: She surveyed 50 states and I think territories -- even up in the territories -- and was looking to see what their stances were on gender-affirming care, to see whether or not they had statements saying that they will cover it or policy saying that they wouldn't. And then there -- those that just didn't have a policy available, or had no policy in place.

BY MS. DEBRIERE::

Q So Dede Pickle was the one who put together

the spreadsheet?

A Yes.

Q Okay. And where did she look to find this information in each state?

A Well, she went to their state Medicaid web pages, looked at their -- like, their coverage guides or materials in each state Medicaid -- Medicaid programs. There can likely be idiosyncrasies. I mean, some have -- some are like ours, have a ton of coverage policies, others are like Texas, Texas has one gigantic coverage policy, which actually does -- despite the fact it's huge, it's actually kind of more efficient. It's -- you can get everything from there. But that's -- that's what they do in Texas. Everything's bigger in Texas. But she went and looked at all of the different state -- various state Medicaid programs and saw what their policies were and saw what was available. And, of course, put the findings in the GAPMS report.

Q Did she only do an online search?

A Yeah, it was only an online search.

Q Did she contact any of the Medicaid programs?

A No.

Q Did she look at any of the policy reporters?

A No, we -- no, we didn't use policy reporter for this GAPMS.

Q So just looking at the state's Medicaid Agency websites?

A For the Medicaid, yes. But, generally, without having worked in Medicaid, one of our research criteria for across all kinds of reports and projects is that we do want to see what other states do. And so that gives us a great deal of familiarity of how to navigate other states' programs. And one of our side projects is the statewide Medicaid managed care program. And, of course, we're always looking to see what other states are doing. So we get a great deal familiar with how to navigate the web pages of other states.

Q So at least half the states' Medicaid programs explicitly cover pubertal suppression treatment for gender dysphoria, is that correct?

A Based on -- based on the findings of the map. So what -- so I will defer to the findings on the map.

Q Only ten exclude?

A Defer to the findings as stated in the map.

Q Okay. How about we do this: Based on the findings in the map, only 10 states explicitly exclude pubertal suppression therapy. How did you take that into account when you reached the conclusions that you did about the services being experimental, that particular service being experimental?

A As far as that goes, it's informational, but there was -- there was a divide between states that do cover and states that don't. Primarily when making the determination we focus -- we really focused on the evidence and what the evidence said about treatments for gender dysphoria since the Medicaid program -- since there is -- seems like there's an absence of policies for a lot of states. There are some states that come out and say yes, and then there are some states that say no. There is a -- there's a divide and you can even potentially say like there could be a debate between amongst the 50 states plus territories of whether or not coverage is appropriate.

Q But you did say earlier on that you -- whether a service is covered under the other state Medicaid programs is usually a factor that you weigh heavily in determining whether a service is experimental.

MR. JAZIL: Object to form.

THE WITNESS: So when it comes down to it -- it's like, so often, it's not just other Medicaid programs, but also Medicaid programs are similar to Florida. There are some Medicaid programs -- I'll name two -- New York and California that are -- that cover things very, very liberally, as far as services. Like, these added everything in their

fee schedules, where Florida Medicaid -- and Florida Medicaid prides itself on being a very fiscally responsible Medicaid program. So often we try to see what states that are similar to our Medicaid program, what they do. But we also do see, we see overwhelming amounts of coverage from states like us and states across the union, then that does factor in our decision, but for in this circumstance, because there is a split, if we were going to have to more -- rely more so on the evidence, than the notion that all these states cover services, there -- it's not -- it's not unanimous at all.

BY MS. DEBRIERE::

Q Did you ever contact the states that explicitly exclude and ask them why they explicitly exclude?

A We did not.

Q Did you ever call those states that have no coverage statement one way or another and ask them?

A We didn't reach out to states. I mean, their policy's online. I mean, that -- I mean, their published policy is sufficient to give us the responses we need to look at -- to look at it. Even for other GAPMS, we don't contact other states.

Q Did you analyze how much Florida Medicaid spends on -- spent on treatment for gender dysphoria prior to the categorical exclusion?

A No, we did not.

Q Do you have any plans to reevaluate your findings in the GAPMS report based on the September 2022 release of the WPS standards of care version eight?

A So in the immediate term, well, we don't, so -- but, I mean, we can reopen the GAPMS later on, there is -- there is a process for that. But generally, I mean, these standards of care, I mean, based on the release of one set of new standards of care, I mean, for the time being we don't have any immediate plans, not based on the release of one new update.

Q Okay. How long did you personally work on that initial draft of the June 2022 GAPMS report?

A Oh, I was working on it pretty much until the day it came out.

Q And you started that second week in May?

A Well, no, that was after I had the very first initial draft done.

Q Okay. So tell me when you first started working on it.

A April 20th.

Q Okay. So from April 20th until when it came

out. Published on what -- well, we know that it was first reviewed by your higher-ups on June 1st. So April 20th to June 1st?

A Yeah, that's sufficient.

Q Okay. And you worked with Nai Chen and Dede Pickle.

A Uh-huh.

Q Did you read all of the articles in the work-cited section?

A I read every single document in that works cited section.

Q 88 articles?

A All of them.

Q Okay. Were you able to read everything, understand it, and draft a report in --

A Yes.

Q How often during that time period did you communicate with the consultants?

A Oh, I think between four and five times.

Q And four or five times over that entire time period?

A Yeah, during those time periods, yes, we have -- periodically have, like, a one-hour discussion with them.

Q So you talked to them about five hours total

over that time period?
A I think that's a valid estimate, yes.
Q Okay. Do you think it's more than that, like more like 10 hours?
A No.
Q Okay. Turning back really quickly to the amount of -- the cost of treatment for gender dysphoria. How much was spent on the coverage of gender dysphoria versus how much was spent -- strike that.
Do you know how much, prior to the adoption of the categorical exclusion, how much annually AHCA spent on the coverage of gender dysphoria?
A We did not.
Q Are you able to obtain that information?
A Our data analytics between managed care plans paid per claim, and anything in fee-for-service, our data bureau could probably muster that up.
Q Is there a way that we should ask for that information to make the question clearer?
A You'd want to -- you would -- to put in a request we would need diagnosis code, we'd need NDC, and we would need CPT codes.
Q And what's NDC?
A National Drug Code.
Q Okay. And then for surgery, what would you

need?

A You would need the corresponding CPT code.

Q Okay. So you need the diagnostic code, the NDC for drug coverage, and the CPT code?

A And the time -- the date ranges.

Q And the date ranges. Okay. And then you could tell us how much AHCA -- or the Florida Medicaid program paid in coverage of -- treatment for gender dysphoria over a given period of time. Okay. When you were communicating with the consultants about drafting the June 2022 GAPMS report, what kinds of questions did you ask?

A Generally, questions about -- mostly just questions about, like, articles, like studies, making sure we have our bases covered, things like that. We wanted to make sure we didn't miss anything, or there's anything glaring we -- because it isn't a piece of academic work it is, it is -- mainly it's like a thesis or a dissertation, because we make a case, we have to support that case. So we want to make sure we have our bases covered.

Q What were the consultants' positions on WPATH?

A Their positions were that -- I think they identified -- all they did was identified it as an advocacy group, like a combination of clinical

professionals, plus advocates, community activists can join it. So that -- it's kind of a hybrid organization, that they explained that to us. So that was pretty much all the information they gave.

Q And you felt like that was an adequate explanation of what WPATH was?

A Yes.

Q What about the Endocrine Society? What was their position on?

A Their position was the Endocrine Society. I mean, it is an established clinical organization. They felt like the other guidelines, they had released guidelines, but the Endocrine Society was transparent in releasing their guidelines. They did clarify that their recommendations were based on weak or very weak evidence. They also clarified that their guidelines were not a standard of care, that they were just guidelines.

Q And that's the Endocrine Society. Who does that -- or your consultancy, who did that?

A The Endocrine Society. So the Endocrine Society, in the text of their guidelines, they do identify each line of the treatment model, like the puberty suppression, the cross-sex hormones and surgeries. Primarily the hormones is the Endocrine

Society, but they are very clear that it's either low- or very-low-quality evidence that supports it, and they also do put that disclaimer on there, this is not a standard of care.

Q What was your -- what was the consultants' position on the American Psychiatric Association's recommendations for gender-affirming care?

A It didn't come up in the conversations.

Q Okay. How about the AAP?

A The AAP was that the evidence available to support the AAP's positions wasn't sufficient.

Q Okay. What about the AMA?

A We didn't talk about the AMA.

MS. DEBRIERE: Okay. So I would like to -- do you have the exhibit of the Medicaid policy routing and tracking form for the June 2002 GAPMS?

MR. JAZIL: Can you re-mark on this --

MS. DEBRIERE: Yes, please. I think -- I need a bigger one.

(Whereupon, Exhibit No. 14 was marked for identification.)

THE WITNESS: Yeah, that new formulation makes it taste just like the real thing.

VIDEOGRAPHER: It's pretty good.

MR. JAZIL: See, we're finding common ground.

THE WITNESS: Wasn't, like, Coca-Cola and all their peace commercials, they were holding hands around the world? That was from the '70s, I think.

BY MS. DEBRIERE::

Q Okay. So I'm handing you what's been marked as Plaintiff's Exhibit 14. It's the Medicaid policy Routing and Tracking Form for the June 2022 GAPMS. There's a start date column there. What's that mean?

A That's a start with the routing process. So generally, for this, usually -- usually they try to provide like a window. We always have, like, a window of review. So for this, we enter the dates in the system. The GAPMS is routed to first -- well, actually, since my supervisor Dede was out, I was her delegate, so I did sign on her behalf. Then it went to Ann Dalton who signed. And, of course, Secretary Weida, of course, signed in his role, and then went to Deputy Secretary Wallace.

Q Okay. So start date's when the document hits their desk?

A Yes.

Q Okay. And then end date's when they've reviewed it and passed it on?

A Yes.

Q Okay. Date received is going to measure the

date that it hit their desk, but they didn't necessarily pick it up and start reviewing it? I'm trying to understand what's the difference between --

A Date received should be when they got it.

Q Okay. And the start date's when they start reviewing it? What's the difference there?

A Start date, end date -- yeah, that should be.

Q And the approval column means that the GAPMS was approved by each person that checked the box and initial by it?

A That's correct.

Q Okay. So the June 2022 GAPMS report, which is 46-pages long and contains five separate reports from AHCA consultants, it was reviewed and approved by each person on this list in one day?

A Yes.

Q And all four people on this list reviewed and approved the June 2022 GAPMS report in the span of two days?

A Uh-huh, that's correct.

Q Oh, I see there MB for DVP.

A Yeah.

Q Why choose to adopt the 2022 GAPMS report into rule?

A Because -- so since we had determined it to be

experimental and investigational, so we decided that we didn't need to make the -- based on the evidence, based on what the GAPMS said, the categorical exclusion promulgating the rule is necessary.

Q Okay. So you adopted into rule because it was a categorical exclusion?

A It was going to be, yes.

Q When was that decision made?

A The decision that was made -- the decision to make -- to make a new categorical exclusion, of course, that was not going to be made until after we had completed the GAPMS report and signed off on, because obviously, had either the experts had they disagreed with one another, or if I'd come up with a different conclusion, can't make a categorical exclusion unless everyone was in sync. So it was one of those things where had -- had the expert opinions disagreed with each other, had I come up with a contradictory conclusion, there -- you had -- we had to wait until after the report was done before we'd sign whether or not to proceed with the categorical exclusion.

Q And when was the decision made to adopt it into rule? Was that at the same time that you decided to make it a categorical exclusion?

A That was made after we had had the report

signed and done.

Q Okay. Sorry. I need to be more specific. What date was that decision made?

A Well, I think it was probably made June 2nd.

Q Okay. And who made that decision?

A That would have probably have come down from Secretary Marstiller, that would have come down from now-Secretary Weida, and it would have come from our General Counsel, Josephina Tamayo?

Q Why would it have come from those people?

A So -- because, of course, with our General Counsel, with our Secretary, I mean, they do make the decisions for the Agency. It's not out of the -- I mean, it is typical in their role to make a decision to promulgate something into rule.

Q Would that generally, though, be handled by the Bureau of Medicaid policy?

A Sometimes. It depends on -- depends on the nature of the rule change. Depends on where -- where it's originating from.

Q How often has that decision come from the Medicaid Secretary?

A So let's -- so to talk about the rulemaking process a little bit.

Q Yeah.

A So rule -- proposes for rule changes come from all different directions and --

Q Let's back up. Instead of talking generally about rule changes, let's talk about changes to coverage policies.

A Those can be made by our Deputy Secretary. Those can come from the Secretary. I mean, anyone who --

Q How often does that happen?

A We can't speak to how often it happens. I mean, it does happen.

Q Had it happened more with the Bureau of Medicaid policy?

A You mean, those in Medicaid policy who initiated these changes?

Q More often than not?

A I actually would probably say not.

Q Oh, okay. I'm just -- I'm surprised because we learned from Ms. Dalton that the -- both the rulemaking process and the coverage policy units are housed within the Bureau of Medicaid policy.

A Well, that's correct, they are, but often they're responding to directives given to them from either senior leadership or legislative changes.

Q Okay.

A So, yeah, while they are the ones that implement and write and craft the new policies or update the policies, they're often not the ones that are piloting these new policies.

Q Or initiating the decision as to whether or not --

A Precisely.

Q -- or adopt them into rule?

A Correct.

Q So you said that it was the decision to adopt into rule was made on June 2nd, is that correct?

A That's correct.

Q Okay. And the notice of rule development, that was issued on June 3rd, correct?

A Yeah.

Q I swear.

A Yeah, I'm deferring to the record on that.

Q Sure.

A The rulemaking process is highly documents, so I'm going to be deferring to the documentation for the rulemaking process.

Q Okay. So it took less than 24 hours for AHCA to decide to adopt the conclusion in the 2022 GAPMS report into a rule? And even less than that, because you made it the same day that the report was released,

correct?

A Yes.

Q And at that time, you also knew which section of 59-G it was going to go into?

A Yes, we did.

Q And who had to sign off on that decision?

A So all of our -- so whenever we adopt a rule, it does go through a lengthy routing process. So it does start -- the process starts in the Bureau of Medicaid Policy, starts with the rules -- we have a rules unit. That gets signed off on, then it goes to the AHCA administrator authorities section, they have to sign off. Then after that it goes to the Bureau Chief of Medicaid Policy. Of course, likewise, they have to review and sign off. Then it goes to the Assistant Deputy Secretary of Policy and Quality. They have to sign. Then, of course, the Deputy Secretary for Medicaid has to sign. General Counsel's Office has to sign. And then the Secretary is privy to all the changes. And if Secretary decides like, wait, wait, we can't do this or, no, there's a problem, yeah, that sometimes can result in a frustrating headache, because it takes a lot of work to get something that far.

Q Well, so the decision to adopt a categorical exclusion to rule was made on June 2nd and the Notice of

Proposed Rule was made on June 3rd. So it was routed through that entire process in less than 24 hours?

A Are we talking about the GAPMS or the rule?

Q The rule?

A Yes. And that -- and that's not unusual sometimes for -- for the process to move very quickly.

Q Okay. Because you just made it sound like it was a very lengthy process.

A It is with the number of people, but it's -- the rule content is very -- it's a very small addition. It's not like a brand new coverage policy, because often -- it depends on the nature of the rules. Like one addition, that can move fast. Sometimes with -- like, for instance, in my experience as a program administrator, we completely overhauled the community behavioral health policies. That was five new coverage policies. So that, of course, is going to require a much lengthier review process rather than a quick amendment to a rule. So it really depends on the nature of the rule. If it's a very lengthy coverage policy, yeah, that can take some more time if it's -- but if it's like adding a few bullets or amending a line, that can -- that can move along much faster because the review time's just not -- a lengthy review process is not necessary.

Q Or deciding to eliminate three types of services that were previously covered by Florida Medicaid?

A Correct. And, of course, but -- and, of course, we have the GAPMS memo to substantiate that.

Q Okay. Okay. So speaking to the rule, it bans Medicaid coverage for -- puberty blockers or cross-sex hormone therapy and surgery if done so to treat gender dysphoria, correct?

A That's correct.

Q But not to treat other diagnoses?

A Not to treat other diagnoses. Only for the diagnosis of gender dysphoria.

Q Okay. Is this the only time that GAPMS has been used to categorically eliminate coverage of treatment for a particular diagnosis?

A For the one -- I think pretty much since the institution of the GAPMS process, I think this was a first.

Q Once the decision was made to adopt the conclusions of the 2022 GAPMS report into rule, who was in charge of that process?

A So our rule promulgation process, Cole Gerring, he oversees the rule promulgation process for our coverage policies and administrative rules for

Medicaid.

Q Does he head the Rules Unit under the Bureau of Medicaid policy?

A Yes, he does.

Q Who drafted the actual language for the rule?

A I believe -- I believe he drafted the language.

Q Did anybody revise it or have any input that --

A There was input. So I mean, there were some discussions. I remember we did have a meeting with everyone to -- between, I think, like, Sheena Grantham, myself, I think Dede Pickle, I think Secretary Weida, I think like Sheena Grantham from General Counsel's office, since rules are her area. I think there were there was a -- there was a discussion on making sure this was the finalized content we wanted.

Q And how long did that discussion take?

A About an hour.

Q Okay. And what kinds of topics were discussed during that?

A Just determining how granular we should get, mostly.

Q Okay. Okay. Was there any conversation about whether adopting this categorical exclusion might

violate comparability under the Federal Medicaid Act?

A No.

Q What about EPSDT?

A No, because since we already have the -- we've already had the GAPMS report to substantiate the overriding EPSDT guideline -- guidance and requirements.

Q Because Florida Medicaid does not have to cover a service under EPSDT if it's experimental?

A That's correct.

Q I had another question. Talking about how granular to get with the language, was there any conversation about what the Federal Medicaid Act requires in terms of prescription drug coverage?

A I don't think so. Not during that conversation.

Q Any other conversations had about that?

A As far as the federal requirements for prescription drug coverage? No, I don't think we had any conversations like that.

Q Okay. Any other conversations about comparability under the Federal Medicaid Act?

A No.

Q So comparability under the Federal Medicaid Act was not taken into consideration when adopting the categorical exclusion?

A No.
Q Who planned the public hearing regarding the proposed language in 59G-1.050(7)?
A So for the public hearing, since we did anticipate a larger than normal crowd, we -- so I think that was a joint effort between Cole Gerring I think, Chief -- now Chief of Staff Brock Juarez, then Chief of Staff Cody Farrell, and I think -- I think Secretary Weida also had a little bit of input when it came down to selecting the venue and making sure that we had adequate staff and then also arranging for security as well.
Q Why did you feel a need for security?
A Because of this -- the controversial nature of the change and how those with opinions on it -- those with feelings about it, I mean, they are deep-seated. I mean, there's -- so because of the sensitivities involved, we just felt that it would be best in the event -- and we did think it was unlikely, but in the event that someone might get upset or unruly, to have security.
Q Why did you pick the venue you picked?
A Size and location.
Q What factors did you take into consideration for size and location?

A That we would have adequate seating. That, of course -- of course, location where it was, being downtown, so --

Q Downtown being an easier location to get to?

A Yes.

Q Why did the location need to be easy to get to?

A Because, I mean, since -- I mean, you know, we do government in the Sunshine, we wanted the hearing to be accessible to as many people as possible, so we wanted to be able to fill as many seats as we could. The facilities here at AHCA weren't going to be sufficient for that. The Department of Transportation auditorium was a very, very good venue, not just -- not just to be able to provide those of us who were on the panel visibility to the audience, but also just because of the seating capacity. So it just was an ideal venue compared to what we had available at the Agency.

Q Where do you normally hold rule hearings?

A We usually hold them here.

Q Why were you concerned about adequacy of seating?

A Because we did expect a large turnout.

Q Why did you expect a large turnout?

A Because of the amount of coverage that the

GAPMS report had received, because of everything that we'd been seeing, as far as -- per previous news stories prior to the release, we just knew that this was a sensitive subject. A lot of people have a deep-seated conviction about it one way or the other, and we just anticipated a large turnout.

Q In the planning of the public hearing, did AHCA communicate with the Governor's office at all?

A No.

Q Did AHCA communicate with Department of Health at all?

A No.

Q Who participated in the public hearing from AHCA?

A So the participants from AHCA were myself, Sheena Grantham, whose General Counsel's office, Secretary Weida. Those are the -- those are the three of us who were on the panel for AHCA. And, of course, I think Cole Gerring handled the administrative procedures and then I think to help -- help with crowd control, we had, I think, Brock Juarez and some of the staff from communications also helped arrange in making sure that there's adequate seating, and just kind of serve -- just helping out in any way, or any capacity that was necessary, as needed.

Q Did anybody at AHCA help facilitate the attendance at the hearing?

A There -- I think there's a speaker sign-in sheet at the entrance. I think that -- like, I think one of the Agency staff under Brock at the time was -- was allowing people to sign in.

Q Were there any particular people that were encouraged to be at the hearing?

A No.

Q Are you aware of the Governor's office encouraging anybody to attend the hearing, anybody in particular?

A No. No.

Q Did anybody pay someone to attend the hearing?

A So for our -- for our experts, Dr. Grossman, Dr. Van Meter and Dr. Van Mol, they were compensated for their time spent at the hearing, or their time traveling -- for Dr. Van Mol and Dr. Van Meter, their time traveling and their travel expenses. So we did reimburse them, but that was it.

Q Did that include the same agreement with the $35,000 cap or was that a separate agreement?

A I don't think it was a separate agreement, because the three of them had not come anywhere close to exhausting their caps.

Q Did AHCA provide any materials to those consultants prior to the hearing to review for the hearing?
A On the day of the hearing we gave -- we gave them each bound copies of the report, but those materials were already available online, so -- but we just -- we just gave him paper copies or to reference but nothing -- no other additional materials.
Q You didn't provide them any other materials other than the GAPMS -- the June 2022 GAPMS?
A That's correct.
Q To review prior to the hearing?
A Correct.
Q Did you have any meetings with the consultants prior to the hearing to prepare for the hearing?
A We had a couple -- there were a couple Zoom calls.
Q How long did those last?
A About an hour?
Q What kind of things were discussed during those meetings?
A Mostly the format. You know, we were talking about, like, of course, Dr. Grossman, who was not going to be able to travel. So we were talking about technological arrangements. I think with Doctors Van

Meter and Van Mol, we were mostly talking about travel arrangements and, like, where they'd sit and so forth, so I mean --

Q Did you offer any questions that they might anticipate from the audience and how they should respond?

A To our experts? We didn't.

Q And why was it necessary to have the consultants there?

A So -- well, since -- because we were actually anticipating a crowd that was going to be largely opposed to the challenge exclusion, we wanted to be able to respond promptly and articulately to any comments that were provided.

Q If you wanted to respond promptly and articulately to any comments that were provided, what was the purpose of having a public hearing?

A So the public hearing is to, of course, gather feedback, but we also knew that we were likely going to have either some type maybe medical professionals or advocacy groups, or other advocates, and we did want to be able to provide them with a little bit of engagement to show that we do take their comments into consideration, that we do think about them, that we do engage with them.

Q Did the consultants respond to any comments by a supporter of the rule?
A I don't think they did, actually.
Q How about those that were opposed to the rule?
A There was really -- I think Dr. Van Meter responded once. I think Dr. Van Mol responded once. And Dr. Grossman didn't respond to anything.
Q And that was -- both of those responses were in response to individuals who were speaking in opposition to the rule?
A Yes.
Q Have you ever participated in another rule hearing where there is direct and prompt response to public comment?
A Yes. Yeah, we do. Yeah, I mean, I've participated in numerous rule hearings here at the Agency. We do respond to comments.
Q When you say we, do you mean the office staff?
A Office staff, yes.
Q What about consultants with which AHCA has contracted?
A We -- we generally don't -- we generally don't. It's a -- it was a unique experience for this case, but we generally don't have contracted consultants at our hearings.

Q And where did the slogan, Let Kids Be Kids come from?

A So that came from within, I think, our own Agency, our Communications Department or the Chief of Staff's office.

Q Was there any input in developing that from outside entities?

A No.

Q So AHCA is wholly responsible for that slogan?

A Yes.

Q Was AHCA responsible for the printing off of the stickers that had the slogan contained on it that were being passed out at the hearing?

A No.

Q Do you know who was responsible for that?

A We do not know where those came from.

Q Is it normal to have slogans of an Agency passed out at a rule hearing? Have you ever seen that before?

A I have not seen that before, so -- but we -- that was not something that the Agency had anticipated, and we certainly were not responsible for the passing out of stickers with a slogan on it.

Q Did outside counsel appear at the public hearing? Did AHCA outside counsel appear at the --

A Yes, they did.
Q Why?
A Because, of course, sensitive nature. I mean, there were -- there were attorneys also -- there was -- because there was counsel that -- you know, who are representing the plaintiffs who were also there. We do anticipate litigation, so it was -- we did see to it that we had outside counsel there to gather information and be able to observe the procedures.
Q So AHCA had -- at the point of the public hearing, AHCA had retained outside counsel to defend against any potential litigation that the rule invited?
A Yes.
Q What was outside counsel's role at the hearing?
A Outside counsel's role, I think -- I think just calling up the speakers as they came. I think they actually -- we had them helping out with the -- with the hearing process and procedures.
Q What kind of -- well, okay. Did AHCA give the consultants any instructions to prepare for the hearing?
A Basic ones. Most of -- I think, you know, like to when responding that, you know, we would prompt them to respond. Basic -- very basic instructions.
Q And so the instruction was that when AHCA

wanted someone to -- one of the consultants to respond, you would prompt them to?

A So, yes. And during the hearing, Secretary Weida would defer either to Dr. Van Meter or he would defer to Dr. Van Mol when he needed -- when a response was needed from one of them.

Q Okay. Just going back to the slogan really quick, who in AHCA came up with that Let Kids Be Kids slogan?

A I think -- I think it was a -- I think it was a team effort. I think, like, it was Cody Farrell and, I think, Brock Juarez. I think they worked on the Let Kids be Kids slogan.

Q Anybody else?

A No, it would have been primarily them.

Q Who directed them to develop the slogan, or was it their idea?

A So the orders would have been given verbally. We don't know, like, exactly how they were told to do that specific slogan.

Q When was the -- when was the slogan developed?

A It was developed, I think, in the days preceding the release of the report.

Q When was the final draft of your report done?

A So the final draft -- so the final draft as

far as -- so the very, very final draft, like the last finishing touches, as much as copy edits, was done that week of the 2nd, but as far as the substantive components of the report, that was done probably a few weeks prior to the release.

Q So when was the slogan developed?

A Slogan was developed -- I think they did -- were working on it, like, the week before the release.

Q Is it normal for AHCA to develop a slogan for the conclusions found in a GAPMS report?

A No, this is -- this was a first.

Q Why develop a slogan?

A Well, we do develop slogans for whenever we do have -- do releases, or whenever we have new programs. For instance, Canadian Prescription Drug Importation, we do have a slogan for that. We do have a web page dedicated to prescription drug transparency pricing. So we do have -- often to correspond with our press releases, we often will do a logo.

Q But you just said it's not normal for a slogan to be developed for GAPMS. So why do it in this instance?

A So because HHS had already -- had made announcements with the publication of their documents, Department of Health had done theirs, we, of course,

likewise, because we were publishing this document, was to, of course, create the website and to, of course, create some graphics along with that website.

Q So was the slogan meant to draw attention to a particular message that the Agency was trying to send?

A No, I mean, other than that, we did the report and we did was evidence-based and concluded these treatments were experimental and investigational.

Q For children and adults, right?

A For children and adults.

Q And why was it Let Kids be Kids?

A Because -- so for adults with -- when it comes to Medicaid, states -- because you don't have the EPSDT consideration, states can be much more -- have much more discretion in denying coverage. They have a lot more latitude to be able to deny coverage, so -- but for services that are intended for pediatrics, or are under EPSDT considerations, that's partially -- partially why not -- like one of the services that we evaluated was puberty suppression, adults aren't going to use that.

Q But the conclusion of the GAPMS report was that all treatment for gender dysphoria was experimental for kids and adults?

A That's correct.

Q The slogan's just targeted at kids?

A Yes, that's correct.
Q Why?
A So it comes back down to the EPSDT considerations. Because like -- well, for starters, I mean, when it comes to adult coverage, that's a totally different category. But for kids, especially with puberty suppression and especially with the cross-sex hormones, because of the experimental and investigational nature, that's probably why we -- why the Agency embarked on a, I guess, child-based kind of graphic for its web page.
Q What does it mean Let Kids be Kids?
A I think, well, as far as semantics go, I think that could mean something different to everybody.
Q What did AHCA by it?
A Let kids be free to explore their own identities and figure out who they are.
Q What are some examples of other slogans AHCA's used for its programs?
A Well, lower prescription drug costs.
Q That's a slogan that we can find?
A Yeah. I mean, that's one we've been using for a while. I was using as -- under my signature on my email, so things -- yeah, but, I mean, there are slogans. I think like prescription drug transparency.

I mean, that's part of, you know, the state's mission is when it's coming up with new programs -- and obviously it's not isolated to AHCA, I mean, every agency's going to have slogans and graphics for their new programs. I mean, if you look at the Department of Children and Families, they're promoting Hope Florida in a big capacity. So for a lot of these -- so for a lot of these programs that they want to have -- they want them to be now such high profile, of course there's going to be graphics and slogans.

Q Prescription Drug Transparency is not very catchy, I'll say. Why create a web page dedicated to supposedly fact-checking Health and Human Services? Is that normal?

A No, it's not, but following -- but the thing is following the review of the evidence and how our findings really did contradict what was in HHS documents, because we really wanted to demonstrate -- because we do understand, it's a GAPMS report, it's 46 pages. Not many people are going to take the time to read it. So we wanted to kind of put it -- we wanted to put the case in more simplistic layman's terms and make it accessible to the audience to show that, hey, yeah, this is a sensitive report. Yeah, if you got an hour and a half and you understand medical terminology and

literature, you might have fun reading it, but for quick information, we wanted to provide a resource, because HHS had made all these claims regarding gender dysphoria treatment, we want to make it accessible to everybody that they could look at it and five minutes later understand the gist of what we were saying in the GAPMS report.

Q Prior to the July 8th public hearing, did AHCA communicate with anyone from the Christian Family Coalition?

A No.

Q Anyone from Florida Citizens Alliance?

A No.

Q Including Pastor Rick Stevens?

A No.

Q Anyone from Warriors of Faith, the Florida Chapter?

A No.

Q Including Troy Peterson?

A No.

Q Anyone from Protect our Children Project?

A No.

Q That includes Pastor Ernie Rivera?

A That's correct.

Q Okay. Anyone from Florida Prayer Network?

A No.
Q And that includes Pam Olsen?
A Correct.
Q Anyone from Partners for Ethical Care?
A No.
Q What about Chloe Cole?
A No.
Q Sophia Galvin.
A No.
Q Anyone from the Rainbow Redemption Project?
A No.
Q How many comments did AHCA receive in response to the proposed changes to 59G-1.050?
A 600 or so.
Q Oh, that's all? Did AHCA read them all?
A We did.
Q Who at AHCA reviewed them?
A It was a combination. So, like, I think Cole Gerring, Nai Chen, myself, I remember we did sit down once and we started going through all the emails. Most of them were very brief, maybe like one or two lines, not substantive whatsoever. For the more substantive ones, those I did careful reviews of.
Q So it's three people. You, Nai Chen and Cole Gerring?

A Uh-huh.
Q Okay. And you split them up amongst each other?
A We read them together.
Q What process did you use to decide whether or not to incorporate the input into the final rule?
A We wanted to look at the -- we looked at the content of every -- of every single comment. A lot of the comments were just saying don't do this, or something -- or something very sensationalist. So a lot of the comments we really couldn't take into consideration because there wasn't -- there wasn't -- there was no substance behind them. So there were some comments that were -- we did receive some feedback from -- I think we got something -- we got -- we got a lengthy comment from American Academy of Pediatrics. We got a very lengthy one from Yale University. We got feedback from the Endocrine Society. I think one of UF's gender clinic physicians wrote us up, not a terribly long comment, but wrote us a comment. So we did want to take a look at the substantive onces. But we did them into -- we did take into consideration every comment submitted to us.
Q Did you receive any comments from the people who had Medicaid coverage for treatment of gender

dysphoria?

A During the comment review, there wasn't any -- we didn't -- we didn't notice any comments from those offhand, but, of course, that was over six months ago. So we -- because of the volume of comments, we did have to read them fairly quickly.

Q Had you received a comment from anyone who was receiving Medicaid coverage for treatment of gender dysphoria, how would you have factored that into your ultimate determination?

A Well, we would -- we would have looked at it. We would look at the content. We were wondering, like, what kind of services they were receiving and so forth, but it depends on what the comment was. If they provided a case for why they were getting it, you know, but we didn't -- we didn't receive anything like that.

Q For those people who lost Medicaid coverage for treatment of gender dysphoria, or were going -- stood to lose based on the categorical exclusion, during any of this process, was there any consideration given to the inability to access that care?

A There was. We did have questions. We wanted to make sure that if we were to discontinue individuals who were receiving, particularly cross-sex hormones, we wanted to -- we did have questions like, would there be

withdrawal? What would -- would they need some -- would they be weaned off the medication? How would -- how would the Agency take that into consideration? And we actually kind of realized that if, say, if they do need to discontinue testosterone because of the categorical exclusion and their doctor deems, well, they're going to need some small doses to wean themselves off, but we also realized that necessarily wouldn't be for gender dysphoria, that would be because of withdrawal symptoms, and that would be a different diagnosis.

Q Did you give that guidance to any treating professionals or Medicaid recipients?

A No, we didn't.

Q Okay. Why was it necessary to review the comments quickly?

A It wasn't necessary to; it was just -- I mean, most of the comments were because the nature, they were -- most of them were sensationalist, a lot of them just hurled insults at us, a lot of them ad hominem attacks, things like that. We just kind of went through a lot of them very fast.

Q So that wasn't quite my question. It sounds like you were able to review them quickly.

A I think I want to rephrase as we were able to. We weren't really in a hurry. Because, obviously, like,

we got a 47-page comment from Yale University. That was not a five-minute skim, obviously. So there were those we deemed to be substantive comments that warranted in-depth attention, and then there were those we deemed non-substantive comments and just read. They're like -- yeah, we received some ones that were using, I will say, the colorful metaphors. And then we don't -- I mean, obviously, not going to pay attention to those, so -- but the substantive ones that where they're putting together, like, an argument or making points, being something that we have to take back and think over, we did invest time in those, yes.

Q Were there any discussions about the comments between you and Cole and Mr. Chen?

A As far as the discussions go, no, most of discussions were like, okay, let's move on to that one, that one's just insulting us or that one's -- that one's expletive-laden, let's move on. So when we got the substantive ones, of course, those were -- those were handled differently.

Q How were they handled differently?

A So those, because they were going to take in-depth review is not something that's going to be a group activity. Of course, we printed those out and started reviewing with a fine-tooth comb.

Q Did AHCA review the underlying cases and studies cited in those substantive comments?

A Yeah.

Q Okay. How did they factor those in to the ultimate determination?

A So we did take a look. So we checked to see what studies that Yale University and the AAP brought into it. And we looked at two responses from the Yale University, not just the response that they made to us, because Yale University frequently cited their response to Texas and Arkansas, we pulled that up as well and did -- and analyzed that. So we looked to see what articles they were citing and we were -- so we checked to see whether our GAPMS report or any of the expert reports also did evaluations of those studies to see that -- make sure that we were in alignment.

Q Okay. Do you remember any particular underlying cases or studies?

A There's -- I think there's one by Jack Turban that they cited. I think there was one that we did cite in GAPMS review. We didn't discuss it at length, this was by Tordoff, et al. And we looked at that. And, of course, but we also captured those in Dr. Brignardello-Petersen's piece that they were evaluated as, like, being very low-quality or in a critical risk

of bias.

Q Okay. How did you determine whether -- okay. Turning to the implementation. Sorry.

A Okay.

Q Hold on. One second. Something breaking is coming in. Did you review any comments that reference court cases?

A We did see some comments that referenced, I think, like Bostock v. Clayton. I mean, there were some cases referenced in the comments, but, of course, I mean, we were primarily interested in -- we were looking for comments that were providing -- that were either providing examples of literature or anything that was going to contradict the GAPMS report. In other words, we were looking -- we were looking for anything that, I guess you could say, delivered, like, a mortal wound or something like that, something that would foreseeably cause us to have to go back and make revisions or cause us to have to retract the rule, or something that -- or a comment that we couldn't just dismiss or a comment that we couldn't explain. So those were what we were looking for.

Q What types of information provided by the public would have mortally wounded your conclusion?

A So a mortal wound would have come from a

quality study, or a number of quality studies.

Q And define a quality study.

A So something that -- well, a quality study, well, I mean, that -- that's a pretty broad definition of what you're asking for, and there are different ways a quality study can come about, but something that, of course, lengthy longitudinal histories on participants, either has adequate control groups. And this is not an all-inclusive list. These are just examples. Also follows participants for a lengthy period.

Q Well, what's the difference between that and a lengthy longitudinal study?

A Long -- when it comes to a longitudinal history, what we mean by longitudinal history, and this is often for behavioral health, is that longitudinal history is necessary to really ascertain the full impacts of somebody's mental health conditions. Because it's -- because mental health, it's not necessarily like an acute illness or a chronic condition diagnosis. So, like there's treatment histories, medications and -- like, in other words, and, of course, like activities of daily living, how that all is affected. So it's usually something that has to be obtained over a number of years.

So, mental health longitudinal histories, but

we also were finding in the studies that we evaluate for the GAPMS process that they lacked participants' longitudinal histories. If they even -- if they even did -- provided any histories or any -- identified the recipients or the participants at all. I mean, there were so many studies where they were -- I think there was one that we came across, and this was during the comment period, that was just a massive survey and they were trying to give gift cards to participants. And, of course, people were just completing it, but it was like a one-time snapshot, and it's subjective self-reports. So I mean, there are a myriad examples that we can say for high-quality evidence, and not to mention RCT's, as well. So --

Q What does that stand for?

A Randomized control trials. So there -- so, yeah, so that was what we were looking for, evidence that -- evidence that would hold up to questioning, and that's not what we were finding.

Q So in undertaking the review of the comments, the only thing you were looking for is anything that would, in your definition, cause a mortal wound to your conclusion in the GAPMS?

A That was among one of the things we were looking for.

Q What else were you looking for?

A I mean, we were looking -- we were looking for -- I mean, we, of course, we were looking to see if there's anything that would directly conflict with the GAPMS report. That was one thing, because the rule's foundation was the GAPMS report. So that's the big reason why we were looking for contradictory evidence or evidence that would be like, well, wait a second, we say it's all -- you know, because our primary argument is it's low-quality evidence and therefore experimental, experimental investigational. That basis doesn't sustain itself if all of a sudden there's modern, high-quality evidence out there. So we want to make sure that we had not left any stones unturned. But we were just -- you know, I mean, we -- this things we weren't -- that was the primary thing we were looking for.

Other things -- I mean, we also, I mean, anything that spoke to the legality of it, but I mean, of course, we wouldn't necessarily evaluate that. We'd turn that over to legal, but anything that was looking -- that was looking at the legality of what we were doing. So I mean -- so, I mean, there were different angles. I think when I was looking at it through my personal lens, that was what I was looking

for.

Q Are you aware that similar exclusions have been found unconstitutional in other federal districts?

A I am aware at the district level that there have been some -- some exclusions that have been tossed, yes.

Q All right. Turning to the implementation --

MR. JAZIL: We've been going for an hour and a half. Could we do a five-minute break?

MS. DEBRIERE: Sure.

VIDEOGRAPHER: This concludes video three. The time is 3:00 p.m.

(Brief recess.)

VIDEOGRAPHER: This is beginning of video four. The time is 3:08 p.m. we're on the record.

BY MS. DEBRIERE::

Q Just after that break, and I should have asked this earlier, just after that break, did you have any conversations with anyone during that break?

A During --

Q Just this recent break? Did you have conversations with anyone?

A I mean, talked about, like, personality types on 16 personalities, just had a conversation, but as far as the case goes, no.

Q Okay. What about at lunch?
A Just a quick touch-base with our attorneys.
Q Okay. How long did you talk?
A 15 minutes.
Q Okay. All right. Turning to implementation of the rule with managed care plans. Did Florida Medicaid managed care plans -- well, we've already answered that. What's the purpose of Inter-Qual?
A Inter-Qual?
Q Uh-huh.
A I don't have the answer to that.
Q Okay. Are you familiar with it at all?
A I'm not familiar with Inter-Qual.
Q Did AHCA develop, or help develop language for notices of adverse benefit determinations in order to incorporate the categorical exclusion of treatment for gender dysphoria?
A No.
Q AHCA didn't assist at all in developing the language for those denials for terminations?
A No, managed care plans were -- handled those themselves.
Q Okay. Did AHCA review any of the language that managed care plans submitted to AHCA for review?
A No.

Q Same question for notices of outcome relied on by EQ Health?

A No, AHCA wasn't directly involved in those.

Q Did they review the notices of outcome language?

A No.

Q Okay. What about Magellan?

A Magellan? No.

Q Did AHCA develop or help develop language for any other types of notices used to notify a Medicaid recipient of a denial or termination of treatment for gender dysphoria?

A No.

Q All right. Can I have the notice of adverse benefit determination, and that's Bates-stamped Defendant_ 000292335, I think. We'll check? Did I get it right? I don't think I did. I'll read the correct Bates-stamp on -- so this is going to be the Molina Health Care Notice of Adverse Benefit Determination. I'm not going to name the Medicaid recipient. And the date stamp appears to be cut off, but it is dated October 26th, 2022, and the initials for the recipient are AS.

(Whereupon, Exhibit No. 15 was marked for identification.)

MR. JAZIL: Counsel, can we agree that this should be confidential, attorney's eyes only?

MS. DEBRIERE: Absolutely.

MR. JAZIL: Do you mind if I write that on top of the --

MS. DEBRIERE: Not at all. Not at all. So the previous Bates stamp I gave was not correct, but the Bates stamp on this exhibit is cut off, so I can't provide the actual number, but I think I've sufficiently described it. And, of course, it will be Exhibit 15.

BY MS. DEBRIERE::

Q All right. This particular notice of adverse benefit determination is from Molina. In that second page there, it runs through AHCA's medical necessity definition, correct?

A Yes, that's consistent.

Q And that's consistent across notices of adverse benefit determinations?

A So each health plan is a little idiosyncratic in how they do NABD's. We'd have -- we'd have to verify with managed care plans. I mean, the contracts does provide specific requirements when it comes down NABD's and sending them.

MS. DEBRIERE: Mo, do you know if you guys have

produced an NABD template to us?
MR. JAZIL: We've never --
MS. DEBRIERE: I know they exist. They should be pretty easy to --
MR. JAZIL: I'll check. What's that stand for, again?
THE WITNESS: Notice of Adverse Benefit Determination. It's a long phrase for a denial.
BY MS. DEBRIERE::
Q Or termination or reduction?
A Or termination, or reduction.
Q Or partial reduction.
A It's --
Q Okay. So this particular notice of adverse benefit determination is to an actual Medicaid recipient, correct?
A Yes.
Q And it looks like it's been it's denying a request for coverage of testosterone cypionate.
A That's correct.
Q Okay. And what is the reason for the denial?
A The box for other authority non-covered benefits is checked off.
Q Why isn't the, request service is not a covered benefit, checked off?

A We would have to ask that question of the plans.

Q Okay. So you don't require some kind of uniform response to not -- that plans must provide when there's a non-covered benefit?

A We're not aware of one. There -- I don't think there's one mentioned in the contract.

Q Okay, but I guess my other question is, would it be equally sufficient, had they checked off, must meet accepted medical standards and not be experimental?

A They could have checked that box. They could have checked, the requested service is not a covered benefit. They could have checked other boxes, as well.

Q Okay, but it is accurate to say that it is not a covered benefit?

A Yeah, that is accurate.

Q Is any plan allowed to currently cover treatment for gender dysphoria of the services listed and 59G-1.050(7)?

A For any plan right now currently?

Q Yes.

A No. No plan can cover them.

Q Since the adoption of the categorical exclusion of treatment for gender dysphoria, how many notices of adverse benefit determination have been sent

to Medicaid beneficiaries that denied coverage for services on the basis of --

A So for MMA plans, so we did a little looking into this -- so for managed medical assistance, which most of these recipients, given their ages, are going to be on MMA, we do not actually require the MMA plans to submit reports regarding how many NABD's that they actually mail out to their enrollees. Long-term care, that process is different. We do require them for long-term care to mail those to report to the Agency how many NABD's they are sending out, but for MMA we currently don't have that as a requirement.

Q Okay. So is that -- does the same hold true for notice of appeal plan -- plan appeal resolutions?

A As far as that goes, I don't think -- I don't think we're collecting information from the plans on those.

Q Okay. So generally, not just as related to treatment of gender dysphoria?

A Generally.

Q What about notice of outcomes?

A Notice of outcomes, I don't think we're collecting them from those informations either.

Q Okay. Just generally, do any of those notices include reference to the variance in waiver process

described at Florida Statute 120.542?

A No. I mean, we definitely -- I mean, so looking at this, this is in compliance with what we do, we require them to have, which is an appeals process. So, no, we don't -- we do not require the plans to include the procedures for variances.

Q Okay. So those procedures are not listed in notices of denial?

A That would be correct.

Q Okay. How many grievances have been submitted to AHCA regarding a claim related to AHCA's adoption of the categorical exclusion of treatment for gender dysphoria?

A So that information, we do have a complaint hub for recipients and providers who'd like to submit complaints, be given the -- when the questions came in, we, of course, have to reach out because our complaint hub is actually down in Fort Myers, so it's not -- it's not here locally, so that's information we're still in the process of obtaining.

Q And once you obtain that, you'll provide it to us?

MR. JAZIL: Yes.

MS. DEBRIERE: Can you put that as a follow-up?

BY MS. DEBRIERE::

Q How many -- how many appeals of Notice of Adverse Benefit Determination denying care on the basis of the exclusion have there been?

A As far as appeals going up to the fair hearing level, I think that's zero.

Q Okay. What about -- yeah, so that would include both notice of plan appeal resolutions as well as notice of outcome?

A Yeah.

Q Okay. Prior to August 21st, 2022, did AHCA ever reverse a decision made by AHCA or by a plan to deny pubertal suppression therapy for the treatment of gender dysphoria?

A We did not.

Q You never reversed a decision to deny?

A To deny?

Q Yeah.

A No, we never did. Sorry. I misunderstood the question.

Q Okay. I just want to make sure you're understanding. So prior to the adoption of the categorical exclusion, did AHCA ever reverse a decision to deny puberty suppression therapy for the treatment of gender dysphoria?

A So if a plan reviewed for medical necessity

criteria decided, no, it didn't meet the criteria and issued denial, no, we never reversed it.

Q What about upon a fair hearing review?

A Are we talking about, like, since 2015?

Q Well, I'm asking ever, but if 2015 is a helpful marker.

A I don't have that information offhand.

Q Is that information you can obtain?

A I think we can.

Q Prior to August 21st, 2022, did AHCA ever reverse a decision to deny cross-sex hormone therapy for the treatment of gender dysphoria? And by reverse I include at the fair hearing level.

A That's information that we would have to obtain.

Q Same question for surgery in furtherance of the treatment for gender dysphoria.

A At the fair hearing level, we would have to obtain that.

Q So you will tell us the number of times, if ever, that AHCA reversed a decision at the fair hearing level to provide treatment in furtherance of -- services and treatment for gender dysphoria?

A We can confirm it. It's probably zero.

Q Okay.

A As far as overturning a decision that was already a denial, it's probably going to be zero, but we just want to confirm.

Q Okay. I'll tell you, we have different information.

A Okay.

Q How many AHCA fair hearings have been provided where the categorical exclusion of treatment for gender dysphoria was an issue?

A Well, can you repeat that?

Q How many AHCA fair hearings have occurred where the subject at issue was the categorical exclusion of treatment for gender dysphoria? So where the rule exclusion --

A We'll have to obtain those numbers.

Q Did any -- do final orders in general reference the variance and waiver process described at Florida Statute 120.542?

A You'll have to slow down and ask the question a little bit --

Q Sure. Sure. The final orders that are issued at the end of any AHCA Medicaid fair hearing, do those written final orders contain any reference to the variance and waiver process at Florida Statute 120.542?

A I don't think the final orders do. I don't

think they do.

Q Okay. Is there any way you can get confirmation of that answer?

A I mean, we could obviously pull up a copy of the final order and see if that information is included.

Q If we had a copy of an AHCA final order, would that be sufficient to determine, and it did not list it, would that --

A I'll defer to our attorneys, if that's sufficient.

MR. JAZIL: That'd be sufficient. If you have one, you can show it to him.

MS. DEBRIERE: Well, we can pull one up, can't we?

MS. CHRISS: Just one?

MS. DEBRIERE: Yeah. Yeah. Why not. Yeah, as long as their name's blocked out, which really shouldn't matter here because we're dealing with an AHCA employee.

THE WITNESS: Yeah. I mean, I'm cleared to review PHI and recipient information. It shouldn't be a problem.

MS. DEBRIERE: Do you want another one? I can send you another one. Bear with me one second.

I'm going to forward you this email. And

it's -- I can tell you what the name of the document is. It's the last document, 23. That should be the last one. Chelsea's copied on that one, too.

THE WITNESS: Okay.

MS. DEBRIERE: Okay. Okay. So feel free to just scroll through it and see if you see any reference -- oh I'm sorry, it isn't a touchscreen?

THE WITNESS: I don't know where the scroll bar.

MS. CHRISS: It's just -- just use two fingers and just go like that.

MS. DEBRIERE: Oh, it's a Mac.

MS. CHRISS: I'm sorry.

THE WITNESS: Okay. There it goes. Yeah. Ipads and iPhones I'm good with, Mac's I never got comfortable with.

MS. DEBRIERE: The next exhibit I'm going to do is emails related to the policy transmittal and the policy transmittal itself, if that helps.

MS. DUNN: Yep.

THE WITNESS: So are we talking about the -- that last paragraph on the final page that's, like, notice of judicial review?

BY MS. DEBRIERE::

Q Yes. So does that relate to the variance waiver process?

A I mean, it doesn't point out the variance processes as described in section -- or Chapter 120. I think that's more if they want to appeal to the next level -- next court level. I don't think that's in response to the variance process. That's a different process.

Q Okay. Thank you. So it does not mention the variance waiver process --

MR. JAZIL: Would it be possible just to read off the --

MS. DEBRIERE: Yes, absolutely. So it says at the bottom: Notice of a right to judicial review. A party who is adversely affected by this final order is entitled to judicial review, shall be instituted by filing the original notice of appeal with the Agency clerk of AHCA, and a copy along with the filing fee prescribed by law with the District Court of Appeal and appellate district where the Agency maintains its headquarters or where a party resides. Review proceedings shall be conducted in accordance with the Florida appellate rules. The Notice of Appeal must be filed within 30 days at the rendition of the order to be

reviewed.

THE WITNESS: Our various processes doesn't involve appellate courts, so it would not be an appellate case, so it's a different affair.

BY MS. DEBRIERE::

Q Thank you. Okay. Did AHCA work with Florida Medicaid managed care plans to implement the exclusion set forth in 59G-1.050(7) in any way?

A No. I mean, the publication's in the Florida Administrative Register, that was to provide ample notice -- public notice that the rule's changing, the managed care plans are responsible for keeping up with changes to manage -- to AHCA's coverage policies and administrative policies.

Q What about plan transmittal? Are you maybe forgetting those?

A We do not do a plan transmittal for this. Are you referring to a policy transmittal?

Q Yes.

A We did not send out a policy transmittal.

Q Okay. Okay. So we have what's marked as Exhibit 16 and Exhibit 17. Exhibit 16 is some emails from Dede Pickle to Jason Weida, cc'ing Ann Dalton. And those are dated August 22, 2022. I believe that's where they start. Also involved are you, Matt, and Ashley

Peterson. Also, I just want to note that Exhibit 17 is an SMMC policy transmittal dated August 22nd, 2022.

(Whereupon, Exhibit Nos. 16 - 17 were marked for identification.)

BY MS. DEBRIERE::

Q Getting back to the list of questions. So did AHCA not send the plan policy transmittal out, Exhibit 17?

A We did not send them out.

Q Why?

A Pretty much because all it's doing is reproducing what was already stated in the rule. The rules -- the rule -- the policy changes already in rule, that was announced through the FAR. Policy transmittal's a little superfluous at this point.

Q Why draft an entire plan transmittal and then not send it out?

A Which this happens frequently. Sometimes we will draft something and later decide not to -- not to use it, or not to utilize that content in favor of different strategy. So, in this case, since the rule -- since the rule change itself was pretty self-explanatory and pretty direct, just we later deemed wasn't necessary.

Q Who made the decision not to send out the

policy transmittal?

A I think that would have been -- that would have been Secretary Weida.

Q Only Secretary Weida? Is it Weida or Weida?

A Weida. I mean, as Assistant Deputy Secretary, he would be within his purview to decide whether or not to send something out -- or to send something out, but given that the rule itself was self-explanatory, and we just decided that a policy transmittal wasn't necessary.

Q All right. In the email exchanges -- I think it's on the second page -- oh, and Jason Weida, at this time that he made this decision, was not the Secretary -- AHCA's Secretary, correct? At the time this was sent, Mr. Weida was not the AHCA Secretary, correct?

A Right, he was Assistant Deputy Secretary for Policy and Quality.

Q On the last page, it looks like you were the person who drafted the first policy transmittal, is that correct?

A Yes. Yeah, I mean, Dede and I, it was a collaborative effort between the two of us. We were, of course, working on each other's language.

Q Why did you think Dede -- why did you and Dede think it was important to draft a policy transmittal?

A We were asked to.
Q By who?
A I think Ann Dalton asked Dede to work on it.
Q Okay. And later -- well, let's look to -- Ashley Peterson says on August 22, 2022 at 10:35 a.m.: I added one thing to help clarify that these drugs will still be provided, just not for gender dysphoria. Please let me know if you think this is unnecessary or adds confusion.

So at least Ashley thought there was some clarity that could be provided to plans on the implementation of the exclusion.

MR. JAZIL: Object to form.

THE WITNESS: Okay. There's several emails. Which one are you --

BY MS. DEBRIERE::

Q This one is from Ashley to Dede, copying you.
A August 22nd, 11:04 a.m. That's Dede --
Q 10:35 a.m.
A Okay.
Q It's DEF_0002587.
A Okay. I think it was just a minor, minor technical catch. I mean, when we worked on this, I mean, we were just fine tuning the drafts.
Q And further up Ann wants to include the 60-day

language in the alert, which has been later included. What is the 60-day language?

A That would be the bottom paragraph of the policy transmittal.

Q Okay. And that you're referring to starts with: To ensure the safe discontinuation of puberty blockers or hormone and hormone antagonists for the treatment of gender dysphoria?

A Uh-huh.

Q Then the managed care plan must notify its subcontractors, providers, enrollees receiving active treatment and changes in coverage, and they must honor any current prior authorization of prescribed outpatient drugs for the treatment of gender dysphoria through 60 days after the date of this policy transmittal. So that means that under the 60-day rule for continuity of care, the managed care plans were to continue coverage of the prescribed outpatient drugs for the treatment of gender dysphoria, correct?

A Only for those existing prior authorizations had already been approved.

Q Okay. So that meant that AHCA was -- or that Florida Medicaid was covering this drugs?

A Yeah, just for the sake of honoring existing PA's.

Q Was it not important that the plans know that they should maintain continuity of care?

A It's actually in the contract. I mean, when you refer to continuity of care, can you clarify what you mean by continuity of care?

Q In this instance, I'm talking about the continued coverage for 60 days of those prescribed outpatient drugs for the treatment of gender dysphoria.

A As far as the continuity of care went, I mean, there -- as far as medically necessary services, enrollees are always going to have access to those. So when it comes to the continuity of care, whether or --

Q They're not going to have access to services that have been previously covered, but now are excluded, correct?

A That'd be correct.

Q Okay. So the 60-day continuity of care ensures that after that categorical exclusion is adopted, those individuals continue to access that care for 60 days?

A This, of course, was a draft. It was never sent out.

Q At some point, AHCA thought that the 60-day period of continuity of care should apply in this situation, correct?

A Since this was a draft and it was not -- not officially sent out, this is not -- since it is draft language, it is not an official transmittal, we sent out to the health plan, so this does not formally represent the views of the Agency. This is a -- this is a draft that we created, deliberated upon and decided not to send out.

Q Who decided?

A That would, of course, been leadership. That would have been -- would have gone to Assistant Deputy Secretary Weida.

Q And he was the only one who was involved in that decision, correct?

A I mean, since he oversees the bureau policy, that's -- which means policy transmittal, yes, he had -- is within his -- is within his job description and his responsibilities and rights to veto sending out a policy transmittal.

Q Okay. Since the policy transmittal was not sent out, then is it AHCA's position that those who had a current prior authorization at the time that categorical exclusion was adopted, was not entitled to the 60-day continuity of care period -- were not entitled?

A So once the rule went into effect, that was,

of course, the notice of the plans that the coverage for these services has to stop.

Q Immediately?

A Well, I mean, that's based on what the rules say, yeah.

Q Okay. So they -- that means that the plans were not to implement this 60-day period of continuity of care as described in this transmittal?

A Right, we didn't provide notice of -- them of this.

Q Okay. And it was AHCA's position that Medicaid beneficiaries were not entitled to that?

A That's correct.

Q Okay. You previously noted how people on hormones may go through withdrawal, there was something as part of your 2022 GAPMS request. Why wasn't that important to communicate to the plans?

A Well, because withdrawal is not gender dysphoria. It's a different -- that's a different -- it'd be a different diagnosis altogether.

Q But in the decision to no longer cover drugs that may cause withdrawal, was it important to communicate to the plans or providers that they may need to help facilitate transition off those drugs that would no longer be covered?

A We were leaving that to the health plans to manage independently, as well as the providers of these services.

MS. DEBRIERE: Do we have a document titled Florida Medicaid health alert? You just -- under DEF_000258815. I feel like I've had the same Bates stamp number. So we're marking as Exhibit 18, the Florida Medicaid health care alert sign-off form.

(Whereupon, Exhibit No. 18 was marked for identification.)

THE WITNESS: I'm familiar with that. I drafted it.

BY MS. DEBRIERE::

Q That would definitely have been one of my questions.

A No, I'm listed on there as the analyst who drafted it.

Q And there's Dede and Ann.

A Yeah.

Q Okay. Did this healthcare alert go out to all providers?

A That provider alert did not go out.

Q And the provider alert on the back, it lists that same language to ensure the safe discontinuation of puberty blockers or hormones and hormone antagonists for

the treatment of gender dysphoria, or allow transition to payment to non-Medicaid funding sources. You incorporated the reference to the 60-day continuity of care period. You drafted that one. Did you include that 60-day language?

A Yeah. I -- yeah, I did include that.

Q Why did you think it was important to include?

A Because at the time we were -- we were creating a provider alert in sync with -- in sync with the policy transmittal, so we wanted to make sure that they used the same language and addressed the same things.

Q And why wasn't this sent out?

A Because -- because, well, we've deemed that the notice of the rule is sufficient, and that once the rule had said that AHCA will no longer cover these services, we could no longer cover those services. I mean, the rule was clear-cut. It's very -- I mean, language is pretty -- pretty straight to the point and direct.

Q Who made the decision not to send this out?

A That would have come from Assistant Deputy Secretary Weida at the time.

Q Did you agree with that decision?

A I thought it was sufficient. I actually

thought given that we put the rule out there, the rule is very straightforward, noticing, like, we had the providers, health plans, adequate notice was given.

Q Did Ms. Dalton agree with the decision not to send any of this out?

A I can't speak to Ms. Dalton. She and I didn't confer on our opinions of whether to -- we didn't confer on how we felt about it.

Q Was there any stated opposition to not sending these out?

A Not that I'm aware of, no.

Q So in managing withdraw, how would a plan or provider know how to navigate that if AHCA wasn't -- if AHCA notified them that they weren't going to cover the service that was needed to help titrate individuals off of their hormones or puberty suppression therapy?

A So it comes back down to practitioners delivering treatment to their -- to their patients. Once again, it comes down to how, like -- you know, when they know that they can't treat for gender dysphoria anymore, and they know that the individual might suffer -- might suffer withdrawal symptoms from testosterone. We, of course, did see some conflicting information on that one, whether they would experience symptoms or not, or estrogen, or if there were

withdrawal symptoms, you'd be treating the withdrawal. And, of course practitioners, we do trust the medical professionals to know what condition they're treating, when the -- because they do so every day when their course -- when they're, of course, diagnoses. And, of course, when the medical coders come in there to do the billing, it's --

Q If transition involved smaller dosages of hormones over time to treat gender dysphoria, how was the provider and the plan to know that they could continue to prescribe that?

A It would be coming through a different diagnosis code. And since we only said that for -- we only said in the rule only for the diagnosis of gender dysphoria. So if they're -- so if they're taking on some small doesn't testosterone because of withdrawal, that's a different -- that's a different diagnosis altogether.

Q How would they know what diagnosis code to use?

A So, practitioners and providers often don't -- aren't that familiar with the coding system. That's where their coders do to figure out. So their coders, of course, review the medical records and, of course, put in the CPT codes, they put in the ICD-10 codes, the

place of service. So usually the claims process is usually done either by often, like, a clearing house or individual coders that sometimes just rotate like a circuit through different physicians offices and so forth.

Q So when we're talking about the safe discontinuation of a medication, wouldn't the prudent thing to do would be to notify providers and plans of the options they had to ensure that individuals who could no longer access this treatment could at least come off of it as safely as possible?

A Given that physicians deal with that kind of situation, for other diagnoses and medical services, we just didn't feel it was necessary. That's one area we were going to, like, leave it. Practitioner discretion was how to withdraw their patients from testosterone or estrogen, if it was even necessary at all.

Q Did any managed care plan ask questions about how to implement the categorical exclusion of gender-affirming care?

A I don't think we received any questions for managed care plans.

Q What about from providers?

A I don't think we received any provider questions either.

Q Did any plan communicate that they will continue coverage in spite of the categorical exclusion?
A Definitely no.
Q Could a plan do that?
A Well, they hypothetically can --
Q Would Florida Medicaid allow them to do that?
A No, we would not.
Q I'm showing you what's marked as -- well, I will be in a second -- what is marked as DEF_ 000169125. It's the template member handbook -- actually, let's skip that one. I'm sorry. I'm sorry.
MS. DUNN: Oh, I'm sorry, we have numbers that aren't lining up with --
MS. DEBRIERE: Yeah, let's actually -- let's move to the emails from Susan Williams between her and Magellan. I'm not sure what the Bates stamp is. Okay. Thank you.
(Whereupon, Exhibit No. 19 was marked for identification.)
BY MS. DEBRIERE::
Q And that's marked as 19 and it's a series of emails between Susan Williams, Jessica Forbes at AHCA, Ashley Peterson, and the first date on the document is June 3rd, 2022. The subject is for treatment of gender dysphoria for children and adolescents.

A Well, this was -- well, we received this prior to the promulgation of the challenge exclusion.

Q You did. So, Stephanie McGriff over at Magellan says, Hi, Ashley and Susan, attached are the internal criteria not publicly posted. CCM that the implemented all meds with the gender code equals B, both in the subsequent updated denial letter that includes the non-discriminatory verbiage. What are the internal criteria she's referring to?

A So it looks like the email chain started on April 20th, following the release of the Department of Health's guidelines. So there were 14 impressions to AHCA at that time. We had just initiated the GAPMS process for these treatments.

Q Yeah. In fact -- so looking at the email from Alicia King Wilson dated April 20th -- so that would be the day that the Florida Department of Health released its guidance, right?

A Yes.

Q And Secretary Marstiller directed Tom Wallace just to start the GAPMS process.

A Yes.

Q It says: Leslie noted MMA does have an internal gender dysphoria criteria, which is attached. This internal document serves for a GnRH analog used to

delay puberty in adolescence with gender dysphoria, but it does not speak to use of hormone therapy. This document was provided by the Agency due to a fear of hearing requests received from Lupron for recipient with this diagnosis. All requests for use of the drug at that time to delay puberty were to be vetted by AHCA before a final determination is made. Can you explain that a little bit more? What does it mean that AHCA had to vet all determinations? What determinations was AHCA vetting?

A I don't -- I mean, it's tough to fully understand the context of this email. I mean, the context level is light throughout the chain, because I mean, Magellan does handle the prior authorization of clinical reviews for drugs in the fee-for-service system.

Q Okay, but it says that this document was provided the Agency due to a fair hearing request received from Lupron first, recipient with this diagnosis, all requests required vetting by AHCA before a final determination was made. So, I mean, I interpret that to mean that anytime Magellan received a request for Lupron to treat gender dysphoria, AHCA had to vet it before a decision as to coverage would be reached. Am I wrong?

A No, that's what it sounds like. The pharmacy -- the pharmacy processes may involve -- as far as like the pharmacist job descriptions go -- I mean, as far as like vetting, that's the kind of the questions like, are they -- because we don't do in-house prior authorizations or clinical determinations anymore. We haven't done those since SMC went into a fact.

Q Was a special exception made for the coverage of hormone therapy to treat gender -- I'm sorry -- for the treatment of puberty suppressant?

A No. No. Yeah.

Q So not to your knowledge --

A I'm just trying to figure out what they mean by vetting. Like, in other words, does this mean -- like, is Magellan sending the determination back to AHCA for yes or no approval?

Q Yeah.

A So they could be doing that.

Q But you don't know?

A Don't know.

Q Can we find that information out?

A We might be able to, because like -- because it's only a few emails, and we're trying to go over the process. I mean, it is possible that we could ask people who do oversee this area. I mean, they might

give us some information, but they may not be able to describe the exact context of the email because, I mean, sometimes things get lost in translation.

Q Does Susan Williams still work here?

A Yes, she does.

Q Does Ashley Peterson still work here?

A Ashley Peterson recently left us.

Q What's recent?

A Last week.

Q Find another opportunity?

A Yeah.

Q How about Kelly Reuben?

A Kelly Reuben's still here.

Q Jessica Forbes.

A Jessica Forbes is still with the Agency.

Q Shantice Green.

A No, she's not here anymore.

Q She find another opportunity?

A I believe so, yes.

Q All right. So, as a reminder, all gender codes were removed from programming as directed by the Agency in 2017. What does that mean?

A I'm not sure because I'm not sure what they mean by CCM. Generally, when we do -- when we make systems updates, it's either done through a file

maintenance or a customer service request to Gainwell Technologies oversees the FMMIS, so --

Q You were familiar with the programming of the ICD-10 codes, but you're not familiar with programming of the gender codes?

A Well, no, I'm familiar with the -- how diagnosis codes are programmed in the system, but this CCM acronym I'm not familiar with.

Q What is a gender code?

A You mean a gender code? Well, what they mean by gender codes, I'm assuming that means the ICD-10 Code F64. That's -- that's assuming that's what that means.

Q What's a B for both?

A Maybe that's written reference to male and female.

Q What is the significance of that? Why does it matter if it's -- what are the options? B for both and then, what, M for male, F for female?

A That could -- I mean, that's what I'm assuming based on -- based on this email chain. I mean, it's a little difficult because -- I mean, there's a lot of extrapolation and it's -- much of it's open to interpretation, so --

Q Sorry, I lost my place. Please prepare a CCM to remove gender code from all the NDC's. What are

NDC's? You said that?

A National drug codes. So that's almost like -- kind of like a procedure code, because each drug has a corresponding NDC. So the system doesn't recognize drug names or recognize national drug codes.

Q Okay. And that was actually -- that instruction was provided to someone -- Arlene Elliot sent that instruction to someone back in 2017, to remove the gender code. Do you have any idea why Magellan and AHCA were talking about this on June 3rd?

A No. We hadn't announced that we were going to do a categorical exclusion yet.

Q Okay. I think this is just a place where we're going to need to reserve some time for deposition after you're able to do some adequate research on what the information this email contains, and then we can do some follow-up questioning. Okay.

You mentioned earlier, were there any communications from the plans about the exclusion prior to its adoption?

A What do you mean? Do the plans have any -- do we discuss with the plans prior? No.

Q All right. Turning to waivers and variances under Chapter 120, are you familiar with that process?

A Oh, yes, I am.

Q Okay. I'm going to hand you a copy of the statute, Section 120.542. We'll mark that as Exhibit 20.

(Whereupon, Exhibit No. 20 was marked for identification.)

BY MS. DEBRIERE::

Q Are you familiar with the statute?

A Yes, I'm familiar with it.

Q Based on your understanding, what is the purpose?

A So the purpose of this is because, of course, agencies are granted rulemaking authority. And because agencies now -- and, of course, the rulemaking process, I mean, it's public, transparent, but there are times that there may be an exception that's required, so it's kind of like the check and balances that if a variance is required on a rule that -- like a party could apply to that agency that administers that rule for consideration of a variance.

Q Does the purpose of the underlying rule have to -- the spirit of it have to be met in granting the variance or waiver?

A What's meant by the spirit?

Q I'm trying to look for the specific language. So under subpart two, variance and waiver shall be

granted when the person subject to this rule demonstrates the purpose of the underlying statute -- I guess in this case it would be a rule -- or what statute will we be referencing?

A Well, in legal terminology, I mean, differences between rule and statute, I mean, statutes, of course, are approved by the legislature, goes to the Governor, and the rules are done under the authority of the statutes. So, I mean, like agencies are authorized to grant variances and waivers to requirements of the rules consistent with the section and with rules adopted under the authority of the section. So, I mean, they do call out rules, specific. Then, of course, this applies to all state agencies, so --

Q Who makes a determination at AHCA whether a petitioner has established a substantial hardship under the statute?

A Those come through our General Counsel's office. So if somebody wants to request a variance, they do so through our agency clerk.

Q And how is the determination itself made?

A So the agency clerk will reach out to individuals to, of course, who have pertinent knowledge about the -- about the circumstances of the request of the variance, will ask for input. And, of course, the

determination's made. It rides up to the Secretary. The Secretary has to do the final approval for a variance.

Q So same question as to determining whether principle -- principles of fairness are violated, who makes that determination?

A So when it comes to waivers and variances, that's same process. Goes to the agency clerk. Then, of course, does an investigation, consults with individuals who are knowledgeable about the pertinent subject, and then it goes up to the Secretary.

Q Has AHCA developed any criteria to guide its determination of whether to grant a variance or waiver from the categorical exclusion of gender-affirming care?

A No. No, we haven't. Variances are determined on a very individualized basis.

Q So, again, turning back to the -- ensuring the purpose of the underlying statute, 120.542 specifically states that variance and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means for the person. So that means the granting of the variance or waiver shows that the purpose of the underlying statute will be or has been achieved by granting it. What statute -- in reviewing

any request for a variance or waiver from 159G-1.050(7), how would you demonstrate that the purpose -- well, what statute will be at issue, first of all?

A Well, for the statute -- I mean, would be Chapter 409. Those are the Florida Medicaid -- that consists of the Florida Medicaid statute, so --

Q What specific -- what specific provision of 409 would you be looking at?

A I mean, we'd be looking at -- well, for the variance, we'd probably be looking at, like, I mean, somewhere under 409.9, probably under covered services or optional services.

Q Okay. So how -- if someone requested a waiver or variance from 59G-1.050(7), under what circumstances would AHCA authorize coverage of the services listed in that rule?

A Well, we can't speak to those because I don't think -- we haven't gotten a request for variances on this yet. So like it says, a highly individualized process. We will be looking at in-depth at the recipient, looking at all the records available, and, of course, discussing things with various experts and so forth. But each request is individualized. So because each request is individualized and focuses on the specific individual, we can't project on what grounds we

would grant a variance under.

Q Well, so the June -- the categorical exclusion of treatment for gender dysphoria was adopted because the certain -- AHCA found that those services were experimental, correct? And Florida Medicaid cannot cover services that are experimental?

A That's correct.

Q So in what situation could AHCA grant a waiver or variance covering services that AHCA has found to be experimental?

A Well, I mean, based on the rule we wouldn't. I mean, based on the rule, we would deny the variance, but because each variance, it's individualized requests, we would have to go through and evaluate each one individually.

Q Would the person have to establish that the service they're requesting is not experimental?

A We will not be placing the burden on the recipient.

Q Who would the burden be on?

A Well, that would be on -- it'd be an individualized process, evaluating all the -- all -- whatever medical records that we can get a hold of. That's -- that's process that we use in the past, but based on the rule, I mean, yeah, we say that these

would -- you have a categorical exclusion. While we -- while the variance process is available, but because we have a categorical exclusion, we do declare the services to be experimental, investigational due to very-low-quality evidence that -- yeah, I mean, we would deny variance, but because variance reviews are individualized, we don't want to speak in absolute terms on the variance process. But for -- because, I mean, there's all kinds of questions that could come up in the review of the medical records. Maybe it was a -- maybe it was a misdiagnosis. Maybe something else could come up. That's pretty much why. So --

Q Okay.

A Everything is different and --

Q If a person sought a waiver of the application of 59G-1.050(7) so they can receive Medicaid coverage for a mastectomy that is specifically to treat their gender dysphoria, under what circumstances would that waiver be granted?

A For -- under what circumstances?

Q Yeah.

A Well, I mean, we did declare this service to be experimental investigational.

Q So they could not get a waiver, correct? The waiver would be denied?

A Based on the very general, hypothetical situation that you provided, straight out just for gender dysphoria, they got denied by their insured so they request a variance.

Q Yeah.

A Based on our rule language, yeah, it'd be denial.

Q And someone is entitled to a fair hearing when Medicaid coverage is denied, correct?

A Yes, they are.

Q Given that the Agency has found the services in 1.057 -- 59G-1.050(7) to be experimental, and therefore never medically necessary, correct?

A Correct.

Q Could someone ever prevail at a fair hearing where they sought coverage of the services for gender dysphoria?

A Well, based on our rule, based on our findings, no.

Q Could someone use the variance or waiver process to get around the final decision issued after the fair hearing?

A Well, I mean, they can request a variance, but then they would go through the process, but based on our rule and our findings, no.

Q How often do Medicaid beneficiaries file variance requests?

A So in the research for this case, we found 10 requests, and that's since going back to about 2015, 2016.

Q Okay. So between 2015, 2016 to present, there has been 10 requests?

A That's correct.

Q Okay. These variances -- and I have copies of all of them, if you'd like to reference them. They request that a service that AHCA affirmatively covers. So there's -- there's a few types of variances we found in our review. There's situations in which AHCA affirmatively covers the service, but the individual wants an amount greater -- in a greater amount or duration.

A Yeah, I'm familiar with that one. It's -- there was a variance request -- and it was actually several various requests, because they were granted for six months at a time. We're talking about our recipient under our I-budget waiver. So, of course, our I-budget waiver -- and no, it isn't, it's codified in rule. So, of course, there was a service limit on these behavior assistance services at the time. They were requesting additional behavior assistance services. So while -- so

because we already covered the service, and they're just looking for additional services, you know, and that that's -- that's flexibility that we can grant because we haven't actually gone through -- the service they are requesting, we have not codified as a categorical exclusion, and we've not deemed that service be experimental investigational.

Q Okay. And that's true for all the services that are contained in the variances --

A Yeah, from what I could tell, they're pretty much all I-budget.

Q Okay. And they -- none of the services that they were requesting some kind of variance on had been categorically excluded, correct?

A Correct.

Q Okay. And none of them have been determined experimental?

A Right.

Q Okay. Do you know of every Medicaid recipient who made a request for a variance, if they were represented by counsel?

A No, we don't know if they were all represented by counsel or not.

Q Because I did notice that the recipients were all listed.

A Yeah, the recipients were listed. The information is referred to the agency clerk. Then the Agency does its internal processes.

Q Do you know what pro se means?

A No.

Q So, in any of the requests for variances to the Medicaid recipient, him or herself, do any of the direct request for the variance, or did they need assistance?

A Given the complexities of request and legalities of it, I would -- I think it's safe to say that they had some assistance, although it's not required.

Q Okay. Between April of 2022 and August 21st of 2022, did anyone at AHCA ever discuss the variance or waiver process for use in challenging a denial based on the categorical exclusion of treatment for gender dysphoria?

A No.

Q All right. Turning to our specific clients, at anytime prior to August 21st, 2022, did Florida Medicaid cover any of the services listed at 59G-1.050(7) for the treatment of gender dysphoria and that actually --

A You're talking about --

Q Everyone.
A You're talking about after the hard date when the ruling took effect?
Q Anytime prior to that, did Florida Medicaid cover any of the services listed at 59G-1.05 --
A Prior to the effective date, yes.
Q Okay. So they covered puberty blockers?
A Yes. Well, for that small handful of recipients we pulled the data on, yes.
Q They cover cross-sex hormone therapy for the treatment of gender dysphoria?
A Yeah. I mean, as far as data showed.
Q Did they cover surgery for the treatment of gender dysphoria?
A From our data revealed, yes.
Q At any time prior to August 21st, 2022, did Florida Medicaid cover any of the services listed at 59G-1.050(7) for August Dekker?
A We did go through our -- we did go through there the recipient's histories, yeah.
Q Did Florida Medicaid cover puberty blockers for August Dekker to treat gender dysphoria?
A For August Dekker?
Q Yes.
A Puberty blockers?

Q Yes.
A I don't believe so, no.
Q Did Florida Medicaid cover hormone therapy for August Dekker in treatment of gender dysphoria?
A For August Dekker, yes. I think -- I think his managed care plan, Humana was providing him those.
Q And he's still currently eligible for Florida Medicaid?
A Last time we checked he was still Medicaid eligible.
Q Okay. And he's still enrolled in Humana, or did he switch to another plan?
A Well, we haven't -- we haven't verified since -- we did have an enrollment period and recipients are eligible to switch plans during that enrollment period.
Q In the coverage of hormones for treatment of August Dekker's gender dysphoria, how long -- for how long did AHCA authorize that treatment? For how long did Florida Medicaid cover that treatment?
A I don't know the exact length. We would have to go back and take a look at the records we received from Humana on the case.
Q More than six months?
A I think it was more than six months.

Q More than a year?
A That's where it gets hazy.
Q Was coverage for hormones to treat gender dysphoria terminated for August Dekker after August 21st?
A According to rule, yes, it would be terminated.
Q Did Florida Medicaid cover surgery for August Dekker and treatment of gender dysphoria?
A Yes.
Q When?
A So that would have been prior to the -- that would have been prior to the challenge exclusion being implemented. Then to clarify, that was -- is -- the managed care plan was covering that outside our state plan benefits.
Q How do you know that?
A Because our state plan does not -- does not specify the service as being -- as being mandated for coverage. In other words, if Humana had denied the service, well, it would have just been a denial because it's not a -- Medicaid doesn't -- we don't have that in our state plan. Managed care plans have to cover all state plan services. Sex change operations are not a state plan covered service.

Q Surgery is a state plan covered service?

A Surgery, yes, but for -- but not for this -- necessarily this condition.

Q Does the state plan specify for what conditions services are provided?

A No, it doesn't break down the diagnosis codes, but this was one -- was the plan's discretion. The plan could have said yes. The plan could have said no. It was up to the plan.

Q Were federal Medicaid match dollars used to pay for August Dekker's surgery?

A So capitation rates that we pay to the plans are per-member per-month rate. That is a combination of federal matching dollars and state revenue.

Q Okay. At any time prior to August 21st, 2022, did Florida Medicaid cover any of the services listed at 59G-1.050(7) for Brit Rothstein?

A Based on the -- based on the records that we pulled, based on the recipient's individual histories that we were -- we were able to locate, looked like, yes, we did.

Q Okay. Did Florida Medicaid ever cover puberty blockers for Mr. Rothstein?

A So for Mr. Rothstein -- so for Mr. Rothstein -- I -- so. Sorry. I think he's one of the

adult plaintiffs?

Q Yes. Yes. And you said that he -- I'm sorry -- pulled in a lot of directions.

A We did cover services that we did determine to be experimental investigational prior to the challenge exclusion.

Q And no longer cover them, correct?

A Yes, because of the challenge exclusion.

Q Same question for KF.

A Since -- with KF, we did have a hard time since for the minors we didn't have, like, their full identification information. Trying to locate their records in the system, I think there were encounters, based on information we had, that did show they were receiving GnRH.

Q Okay. For the treatment of gender dysphoria?

A Yeah.

Q Okay. And that includes Susan Doe, as well?

A Based on what we could find, looked like they -- that there had been some coverage.

Q And they're -- KF is still currently eligible for Florida Medicaid, is that correct?

A We would have -- I think -- I think they would be, because we haven't been doing these determinations because of COVID. So, yes, they would still be

Medicaid-eligible. That would go for all the plaintiffs.

MS. DEBRIERE: Okay. Let's -- can we take a five-minute break?

MR. JAZIL: Sure.

VIDEOGRAPHER: Okay. This concludes video four. The time is 4:15 p.m.

(Brief recess.)

VIDEOGRAPHER: This is the beginning of video five. The time is 4:30 p.m. We're on the record.

BY MS. DEBRIERE::

Q All right. Turning back quickly to plaintiff August Dekker, did Humana violate Florida Medicaid policy by covering his surgery for treatment of gender dysphoria?

A No, they did not at the time.

Q Okay. And then I just want to talk about a few more exhibits. One labeled -- we've marked as Exhibit 21, and that is the GAPMS queue that was provided to us.

(Whereupon, Exhibit No. 21 was marked for identification.)

BY MS. DEBRIERE::

Q And it looks like the most recent date on that queue was maybe an update to one of the GAPMS in 2019.

That's as far as it goes. Are all -- are these the only GAPMS that are currently pending?

A So the requests came in to pull the most recent GAPMS queue.

Q Yeah.

A So at this -- when I went through our -- we have a GAPMS folder that's on our shared drive. I did look through to see what -- we have a folder for the GAPMS queues. I did pull the most recent one. This was the most recent one that had been updated that was in there --

Q I'm sorry. Go ahead.

A This does -- this does consist of a lot of GAPMS reports, which I do remember drafting some of those as well, but this was our most recent one.

Q And have there been GAPMS reports created after 2018?

A Yeah, I think there have been.

Q Why aren't they on this list?

A I'm not -- I'm not sure why they wouldn't be included on this list. This list should be updated on regular basis, so I'm not sure why they wouldn't be included on this, or on the list on the share drive, because the GAPMS queue is really is not so much for the GAPMS analyst, because GAPMS analysts generally have a

pretty good idea of what's outstanding, what's pending, and what's been turned in. It's more for leadership -- or their supervisor to pull and take a look at when necessary, so I'm not sure why this hasn't been listed to update in this current.

Q So whoever's working in GAPMS at the time has a good understanding of which GAPMS are pending.

A When I was -- when I had the role, I could tell you exactly where all my reports were, what their status was and where they stood in the queue. So, yeah, I kind of had all committed to memory.

Q Okay. Would that be true of anyone holding that GAPMS position?

A As far as pulling it from memory, I couldn't vouch for the other employees as to their memories, when it came down to their reports that are outstanding.

Q But they should have a good sense?

A They should have a good sense of what's pending and what's been turned in.

Q Can you provide us a list of what's pending that's not listed on this queue?

A So I think -- so I think the ones that are still pending aren't -- I think there were, like, reopened reports. I think we had gotten requests from the manufacturers of Atheno, was the asthma tests that I

discussed earlier. That was one I had to have finalized. We've gotten a request for them to -- for us to review it, provided that they don't send some more evidence and more studies that have been done after our original report. So I think that one was reopened. That one should still be pending. Then there was specially modified low-protein foods. That was another one that I had written up. We had gotten requests to reopen that one that, and to reevaluate that service. I think there was another one, which was the -- which was a bone growth stimulator called Exigent. I think that one is still outstanding and pending. Now, those are just some examples of ones I can think are still pending.

Q Were there any new requests made after December of 2018?

A Yeah. I mean, there have been some new requests for either, like, expedited GAPMS or full GAPMS. I mean, we do get the service requests in fairly frequently, so --

Q Because it would be odd if any new requests hadn't come in almost five years --

A Correct. Yeah.

Q Okay. But there's no way -- all right. And then I just want to put into the record, because we've

been referring to it quite a bit, we'll Mark it as Exhibit 22, and that is the document from Health and Human Services that we've referenced multiple times during the deposition. Is that the one you're referring to?

A That's correct. This is it.

(Whereupon, Exhibit No. 22 was marked for identification.)

BY MS. DEBRIERE::

Q Thank you. And then the guidance from the Florida Department of Health regarding treatment of gender dysphoria for children and adolescents dated April 20th, 2022. That's Exhibit 23. Is that the document that we've been referring to when we're talking about DOH guidance?

A Yes, it is.

(Whereupon, Exhibit No. 23 was marked for identification.)

MS. DEBRIERE: And then -- I think that's it for my questions. The only thing I wanted to put on the record, Mo, is we are at what time, Videographer?

VIDEOGRAPHER: Do you mean the whole run time or --

MS. DEBRIERE: Just the questioning time.

Yeah, the time that we've been live and active on the record.

VIDEOGRAPHER: Five hours, eight minutes plus five and a half minutes.

MS. DEBRIERE: Okay. So want to just say that we have an hour and 45 minutes of questioning --

MR. JAZIL: Sure.

MS. DEBRIERE: -- to reserve?

MR. JAZIL: And so the depo is open. I'd like to ask questions at the end. So I'll just reserve that until after our second session, is that okay, or would you like for me to --

MS. DEBRIERE: Can I confer with my team quickly? Okay.

VIDEOGRAPHER: We will remain on the record?

MS. DEBRIERE: We'll go off the record.

VIDEOGRAPHER: Okay. Off the record at 4:36 p.m.

(Discussion off the record.)

VIDEOGRAPHER: We're back on the record. The time is 4:37 p.m.

MS. DEBRIERE: And plaintiff's counsel is all finished with their questioning.

EXAMINATION

BY MR. JAZIL::

Q This is Mohammed Jazil for the defense. I'll try to be brief, recognizing we have time limitations here. Mr. Brackett, I'd like to have you look at Exhibit 3 again.

A Okay.

Q Exhibit 3 has a date on it, May 20th, 2022. I want the record to be clear, why is that date not accurate?

A This date isn't accurate because that date is -- automatically sets to the date you print it out.

Q And what sets that date?

A The template is automatically set to enter in this current date that you're viewing the document. So it automatically updates the second you open it.

Q And that's the template in the AHCA document?

A That is our template, yeah.

Q And when was this GAPMS report created?

A This GAPMS was originally created in 2016.

Q Thank you. You discussed with my friend the variance and waiver process. Do you recall that testimony?

A Yes.

Q You testified that the variance and waiver process is individualized. Do you recall that testimony?

A Yes, I do.
Q Once a variance and waiver request comes in, it goes to the clerk is what you testified to, if my understanding is correct?
A Yes.
Q And then the clerk routes it to whom?
A The clerk gathers information and it has to be routed up to the secretary.
Q Is it routed directly to the Secretary or is there any other office that it goes through first?
A I'd have to take a look at the variances again. It might be -- I think it probably have to route through General Counsel before it goes to the Secretary.
Q Okay. And is the General Counsel's office responsible for the formulating the Agency's position on legal issues?
A Yes.
Q Does that include the variance and waiver process?
A Yes.
MR. JAZIL: I have no further questions.

FURTHER EXAMINATION

BY MS. DEBRIERE::
Q Just one redirect. Very brief. On Exhibit 3, which is the GAPMS memo dated May 20th, 2022, that was

the date it was printed out. It also appears changes were made on that date, is that correct?

A Based on the comments in the edits, yeah, it looks like somebody had made changes to that document on that date.

Q But you don't know who that person is?

A SG, I'm -- I can't speak to who SG is.

Q But you will find that information out for us?

A We can -- we can figure out who, but we would -- probably want to verify with IT.

MS. DEBRIERE: Okay. That's all.

MR. JAZIL: So, counsel, while we're still on the record, he's still under oath, so I'm not going to obviously talk to him about any issues that might come up, but with your consent, I'd like to at least work with him to gather the additional information that's being sought. Is that appropriate?

MS. DEBRIERE: I mean, I would assume that would be your process.

MR. JAZIL: He is under oath, and so I'm obviously not going to try to, you know --

MS. DEBRIERE: I see. I see.

MR. JAZIL: -- work with him while -- work with him on his testimony, I say, as I try to gather

additional information, so I'll make that clear on the record.

VIDEOGRAPHER: Anyone else? Anybody by Zoom?

MS. DEBRIERE: No.

VIDEOGRAPHER: Okay. This concludes the February 8th, 2023 portion of the video-recorded deposition of Corporate Representative for Agency for Health Care Administration. The time is 4:40 p.m.

COURT REPORTER: Are you going to be ordering this?

MS. DEBRIERE: Yes.

COURT REPORTER: All right. And Mo has requested a rough draft. I told him I could get it to him tomorrow. Do you guys -- would you guys like one, as well?

MS. DEBRIERE: Yes, please.

(Whereupon, the deposition was concluded at 4:40 p.m., and the witness did not waive reading and signing.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF LEON)

I, the undersigned authority, certify that the above-named witness personally appeared before me and was duly sworn.

WITNESS my hand and official seal this 21st day of February, 2023.

_____.

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF LEON)

I, DANA W. REEVES, Professional Court Reporter, certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages, numbered 128 through 257, are a true and correct record of the aforesaid proceedings.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 21st day of February, 2023.

Dana W. Reeves

_____.

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

Gary V. Perko, Esq.
gperko@holtzmanvogel.com

February 21, 2023

RE: August Dekker, et al. vs. Jason Weida, et al.
February 8, 2023/Matthew Brackett/5696545

The above-referenced transcript is available for review. The witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason on the attached Errata Sheet. The witness 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 fail(s) 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).

CERTIFICATE OF SERVICE

I certify that I e-filed this appendix on ECF, which will email everyone requiring notice.

Dated: October 13, 2023 /s/ Mohammad O. Jazil