Ukom

Menu

Patient safety for children and young people with gender incongruence

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People with gender incongruence and gender dysphoria have different wishes and needs for health services. Many people live well with their gender incongruence and manage it without health care, and others want and need health care. (See glossary in chapter 13 for word explanations)

When Ukom enters the topic of gender incongruence, we look at how patient safety is safeguarded in help and treatment services for gender incongruence and gender dysphoria. Our aim with the survey is to ensure safe help and treatment for children and young people with gender incongruence.

There is an ongoing public debate about treatment options for gender incongruence. This is demanding, and many refuse to participate in the debate. It can be challenging and difficult to participate because disagreements are large both between groups and within groups. We see that choice of words and understanding of the complexity is important. The situation of insecurity and disagreement affects the development of healthcare services.

In our report, we have tried to highlight different perspectives. At the same time, it is important for us to be clear about our findings. That is, what challenges patient safety. Many have worked and are working to confirm and build a good health service for people with gender incongruity and gender dysphoria, both nationally and internationally. Ukom's report builds on this work. We point out that this field now needs a boost to improve patient safety, especially for the health care that is to be provided to children and young people in Norway.

Summary

Ukom has carried out a survey of the treatment offered to children and young people with gender incongruence. The background was notifications directly to Ukom from relatives who question several matters related to patient safety. Several actors, both from the authority side, healthcare personnel and patient and relative organisations, are questioning the soundness and organization of the treatment offer.

The report deals with children and young people in general. There has been a large increase in inquiries to the health service from people with gender incongruity in recent years. In particular, the number of children and young people in their teens who apply to, or are referred for assessment and treatment in the specialist health service, has increased significantly. The biggest increase is among adolescents and young adults who are registered as girls at birth, but identify as boys. Our attention has therefore been particularly directed at teenagers and young people with gender incongruence and gender dysphoria who seek health care.

Children and young people are not fully developed physically, mentally, sexually or socially. This requires special vigilance with regard to patient safety. Our findings and recommendations will also be relevant for the offer for adults.

In the report, we have divided our findings into six main areas:

Insufficient knowledge

The knowledge base, especially research-based knowledge for gender-affirming treatment (hormonal and surgical), is deficient and the long-term effects are little known. This is particularly true for the teenage population where the stability of their gender incongruence is also not known. There is a lack of research-based knowledge about the treatment of patients with non-binary gender incongruence. In order to safeguard patient safety, Ukom considers it necessary that the knowledge base on gender incongruity and gender dysphoria be strengthened, and that the health service offer be arranged in line with the knowledge base.

General management - a guideline with a different background

The Norwegian Directorate of Health's national professional guidelines for gender incongruity lay down guidelines for the health service offer. It concentrates on organisation, equality and rights. This may have been important at the time the guideline was drawn up, because it was necessary to confirm the health service offer to people who experience gender incongruity. At the same time, we consider that deviating from the requirement for the development of knowledge-based guidelines has created room for uncertainty and diverging expectations. Health personnel have been given great opportunities for interpretation within a relatively narrow subject area that lacks a systematic summary of knowledge in Norway. The guideline gives rights without clarifying questions related to prioritization and soundness. This is demanding for the health personnel who manage the services on a daily basis.

Requirements for soundness - particularly related to children and young people

The national professional guideline for gender incongruence is not normative. It does not set specific requirements for investigation or requirements for a medical indication for starting treatment. The mention of children's competence to consent and parents' right to information leaves room for interpretation. The guideline does not establish a sufficient standard for the health service offer, and we believe that for some patients it may pose a patient safety risk. This may go beyond the soundness requirement, which has broad roots in health legislation, and may also be demanding for the supervisory authorities.

Right to healthcare – a gap in expectations

Our investigation suggests that there is a gap between what the guideline outlines and what is possible, given today's available offer and knowledge base. The national professional guideline creates expectations in patients that the health service can only fulfill to a small extent. This applies, among other things, to the right to specialist healthcare services. It is difficult for the service to meet expectations without the knowledge base being well documented, and without a good overview of any negative and harmful aspects of the various treatments. If there is a requirement to use principles for experimental treatment, it will provide a framework that ensures information, thorough follow-up and contributes to more knowledge.

The help and treatment offer - variation in practice and expertise

There is great variation in what offers and what expertise is offered in different parts of the country. There is a risk of both under-, over- and incorrect treatment of children and young people with gender incongruence and gender dysphoria. In addition, we see that there are challenges in establishing a decentralized offer in a narrow and complex specialist field. In order to strengthen the offer, Ukom believes that it is important to strengthen the health service offer in the primary healthcare

service, to build increased interdisciplinary expertise in the specialist healthcare service at regional level and to ensure that the national treatment service has sufficient capacity to meet today's demands.

Speech climate and interaction

We see that in the field of gender incongruence, a demanding climate of expression has developed. The speech climate in the public space affects the information available for children and young people with gender incongruence and gender dysphoria and their families. There is a significant impact on children and young people, also related to treatment and health services. We hear about fear and dread of making mistakes from all quarters. Different opinions about what is the right treatment can create a difficult cross-pressure. Different emphasis and mention of what is necessary at group level can confuse and destroy the patient-therapist relationship and a personalized approach for the person concerned. There is a need to establish a constructive community for everyone who is engaged in good health care for people with gender incongruity.

Ukom recommends

We are concerned that children and young people with gender incongruence have a safe and sound healthcare service. We therefore come up with recommendations that can contribute to this group receiving a better and safer health service offer in the long term. Our recommendations relate to revision of the guidelines, safe frameworks for treatment offered to children and young people and measures to strengthen the knowledge base. The recommendations will also contribute to the systematic collection of data and promote follow-up research. It is important that children and young people with gender incongruence and gender dysphoria, including non-binary ones, are properly looked after while the development of the healthcare service is ongoing.

Ukom recommends:

1. that the Ministry of Health and Care commissions the Directorate of Health to revise the national professional guideline, Gender congruence. The revision must, among other things, be based on a systematic summary of knowledge. We point to several elements that should be included in the audit.
2. that puberty delaying treatment (puberty blockers) and hormonal and surgical gender confirmation treatment for children and young people are defined as experimental treatment. This is particularly important for teenagers with gender dysphoria.
3. that the Ministry of Health and Care is considering whether a national medical quality register should be established for the treatment of children and young people with gender incongruity and gender dysphoria. Necessary measures must be implemented so that such a national quality register can be established, operated and financed in order to contribute to an overview, better quality and reduce unjustified variation in patient treatment.

Continue reading: **Background**

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March 2, 2022

On October 1, 2022, the District Court for the Northern District of Texas issued a judgment vacating the March 2, 2022 document. HHS is evaluating its next steps in light of that judgment but is complying with it.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy

The Department of Health & Human Services (HHS) 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. Attempts to restrict, challenge, or falsely characterize this potentially lifesaving care as abuse is dangerous. Such attempts block parents from making critical health care decisions for their children, create a chilling effect on health care providers who are necessary to provide care for these youth, and ultimately negatively impact the health and well-being of transgender and gender nonconforming youth. The HHS Office for Civil Rights (OCR) will continue working to ensure that transgender and gender nonconforming youth are able to access health care free from the burden of discrimination. HHS understands that many families and health care providers are facing fear and concerns about attempts to portray gender affirming care as abuse. To help these families and providers navigate those concerns, HHS is providing additional information on federal civil rights protections and federal health privacy laws that apply to gender affirming care.

As a law enforcement agency, OCR is investigating and, where appropriate, enforcing Section 1557 of the Affordable Care Act[1] cases involving discrimination on the basis of sexual orientation and gender identity in accordance with all applicable law. This means that if people believe they have been discriminated against in a health program or activity that receives financial assistance from HHS, they can file a complaint.

Federal Civil Rights Laws:

Parents or caregivers who believe their child has been denied health care, including gender affirming care, on the basis of that child's gender identity, may file a complaint with OCR.

Health care providers who believe that they are or have been unlawfully restricted from providing health care to a patient on the basis of that patient's gender identity may file a complaint with OCR.

OCR enforces federal civil rights laws that prohibit discriminatory restrictions on access to health care. Among these laws is Section 1557, which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in covered health programs or activities. OCR

[1] 42 U.S.C. 18116; *see also* 45 C.F.R. part 92.

also enforces Section 504 of the Rehabilitation Act,[2] which prohibits discrimination on the basis of disability in any program or activity receiving federal financial assistance.

Section 1557 protects the right of individuals to access the health programs and activities of recipients of federal financial assistance without facing discrimination on the basis of sex, which includes discrimination on the basis of gender identity. Categorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination. Similarly, federally-funded covered entities restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity likely violates Section 1557. For example, if a parent and their child visit a doctor for a consultation regarding or to receive gender affirming care, and the doctor or other staff at the facility reports the parent to state authorities for seeking such care, that reporting may constitute violation of Section 1557 if the doctor or facility receives federal financial assistance. Restricting a health care provider's ability to provide or prescribe such care may also violate Section 1557.

Section 504 protects qualified individuals with disabilities from discrimination in programs and activities receiving federal financial assistance. Title II of the Americans with Disabilities Act[3] (ADA) protects qualified individuals with disabilities from discrimination in state and local government programs. Gender dysphoria may, in some cases, qualify as a disability under these laws. Restrictions that prevent otherwise qualified individuals from receiving medically necessary care on the basis of their gender dysphoria, gender dysphoria diagnosis, or perception of gender dysphoria may, therefore, also violate Section 504 and Title II of the ADA.

If you believe that you or another party has been discriminated against on the basis of gender identity or disability in seeking to access gender affirming health care, visit the OCR complaint portal to file a complaint online. To read more about Section 1557 and other laws that OCR enforces, please visit our website at https:www.hhs.gov/ocr.

Federal Health Care Privacy Laws - Health Insurance Portability and Accountability Act of 1996 (HIPAA):

HIPAA, the cornerstone patient privacy law, limits the circumstances under which health care providers and other entities may disclose protected health information, such as gender affirming physical or mental health care administered by a licensed provider.

Providers who may be concerned about their obligations to disclose information concerning gender affirming care should seek additional legal guidance regarding their legal responsibilities and other laws.

[2] 29 U.S.C. 794; *see also* 45 C.F.R. part 84.
[3] 42 U.S.C. 12132.

OCR enforces the HIPAA Privacy, Security and Breach Notification Rules,[4] which establish requirements with respect to the use, disclosure, and protection of protected health information (PHI) by covered entities and business associates;[5] provide health information privacy and security protections; and establish rights for individuals with respect to their PHI.[6]

OCR reminds covered entities (health plans, health care providers, health care clearinghouses) and business associates that the HIPAA Privacy Rule permits, **but does not require,** covered entities and business associates to disclose PHI about an individual, without the individual's authorization,[7] when such disclosure is required by another law and the disclosure complies with the requirements of the other law.[8] This "required by law" exception to the authorization requirement is limited to "a mandate contained in law that compels an entity to make a use or disclosure of PHI and that is enforceable in a court of law."[9] Where a disclosure is required by law, the disclosure is limited to the relevant requirements of such law.[10] Disclosures of PHI that do not meet the "required by law definition" or exceed what is required by such law do not qualify as permissible disclosures under this exception.

HIPAA prohibits disclosure of gender affirming care that is PHI without an individuals' consent[11] except in limited circumstances.

If you believe that your (or someone else's) health privacy rights have been violated, visit the OCR complaint portal to file a complaint online.

DISCLAIMER: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or the Departments' policies.

To obtain this information in an alternate format, contact the HHS Office for Civil Rights at (800) 368-1019, TDD toll-free: (800) 537-7697, or by emailing OCRMail@hhs.gov. Language assistance services for OCR matters are available and provided free of charge.

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[4] 45 C.F.R. Parts 160 and 164, Subparts A, C, D, and E.
[5] *See* 45 C.F.R. 160.103 ("covered entity" and 'business associate" definitions).
[6] *See* 45 C.F.R. 160.103 ("protected health information" and "individually identifiable health information" definitions).
[7] *See* 45 C.F.R. 164.508(c) (HIPAA authorization required elements).
[8] 45 C.F.R. 164.512(a)(1).
[9] 45 C.F.R. 164.103 ("required by law" definition). Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
[10] 45 C.F.R. 164.512(a)(1).
[11] For purposes of this guidance, "consent" refers to a valid HIPAA authorization. *See 45 C.F.R. 164.508.*

OASH | Office of Population Affairs

Gender-Affirming Care and Young People

What is gender-affirming care?

Gender-affirming care is a supportive form of healthcare. It consists of an array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people.

For transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being as it allows the child or adolescent to focus on social transitions and can increase their confidence while navigating the healthcare system.

Why does it matter?

Research demonstrates that gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents.[1] Because gender-affirming care encompasses many facets of healthcare needs and support, it has been shown to increase positive outcomes for transgender and nonbinary children and adolescents. Gender-affirming care is patient-centered and treats individuals holistically, aligning their outward, physical traits with their gender identity.

Gender diverse adolescents, in particular, face significant health disparities compared to their cisgender peers. Transgender and gender nonbinary adolescents are at increased risk for mental health issues, substance use, and suicide.[2],[3] The Trevor Project's 2021 *National Survey on LGBTQ Youth Mental Health* found that 52 percent of LGBTQ youth seriously considered attempting suicide in the past year.[4]

A safe and affirming healthcare environment is critical in fostering better outcomes for transgender, nonbinary, and other gender expansive children and adolescents. Medical and psychosocial gender affirming healthcare practices have been demonstrated to yield lower rates of adverse mental health outcomes, build self-esteem, and improve overall quality of life for transgender and gender diverse youth.[5,6] Familial and peer support is also crucial in fostering similarly positive outcomes for these populations. Presence of affirming support networks is critical for facilitating and arranging gender affirming care for children and adolescents. Lack of such support can result in rejection, depression and suicide, homelessness, and other negative outcomes.[7,8,9]

Common Terms:
(in alphabetical order)

Cisgender: Describes a person whose gender identity aligns with their sex assigned at birth.

Gender diverse or expansive: An umbrella term for a person with a gender identity and/or expression broader than the male or female binary. Gender minority is also used interchangeably with this term.

Gender dysphoria: Clinically significant distress that a person may feel when sex or gender assigned at birth is not the same as their identity.

Gender identity: One's internal sense of self as man, woman, both or neither.

Nonbinary: Describes a person who does not identify with the man or woman gender binary.

Transgender: Describes a person whose gender identity and or expression is different from their sex assigned at birth, and societal and cultural expectations around sex.

Additional Information

- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline
- Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents | American Academy of Pediatrics
- Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People | World Professional Association for Transgender Health

HHS Office of Population Affairs
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Gender-Affirming Care and Young People

Affirming Care	What is it?	When is it used?	Reversible or not
Social Affirmation	Adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms and other facilities	At any age or stage	Reversible
Puberty Blockers	Using certain types of hormones to pause pubertal development	During puberty	Reversible
Hormone Therapy	Testosterone hormones for those who were assigned female at birth Estrogen hormones for those who were assigned male at birth	Early adolescence onward	Partially reversible
Gender-Affirming Surgeries	"Top" surgery – to create male-typical chest shape or enhance breasts "Bottom" surgery – surgery on genitals or reproductive organs Facial feminization or other procedures	Typically used in adulthood or case-by-case in adolescence	Not reversible

Resources

- Discrimination on the Basis of Sex | HHS Office of Civil Rights
- Lesbian, Gay, Bisexual, and Transgender Health | Healthy People 2030
- Lesbian, Gay, Bisexual, and Transgender Health: Health Services | Centers for Disease Control and Prevention
- National Institutes of Health Sexual & Gender Minority Research Office
- Family Support: Resources for Families of Transgender & Gender Diverse Children | Movement Advancement Project
- Five Things to Know About Gender-Affirming Health Care | ACLU
- Gender-Affirming Care is Trauma-Informed Care | The National Child Traumatic Stress Network
- Gender-Affirming Care Saves Lives | Columbia University
- Gender Identity | The Trevor Project
- Genderspectrum.org
- Glossary of Terms | Human Rights Campaign
- Health Care for Transgender and Gender Diverse Individuals | ACOG
- Transgender and Gender Diverse Children and Adolescents | Endocrine Society

[1] Green, A. E., DeChants, J. P., Price, M. N., & Davis, C. K. (2021). Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. *Journal of Adolescent Health*, 70(4). https://doi.org/https://doi.org/10.1016/j.jadohealth.2021.10.036

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[4] Trevor Project. (2021). *National Survey on LGBTQ Youth Mental Health 2021*. Trevor Project. https://www.thetrevorproject.org/survey-2021/.

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[9] Sievert ED, Schweizer K, Barkmann C, Fahrenkrug S, Becker-Hebly I. (2021). Not social transition status, but peer relations and family functioning predict psychological functioning in a German clinical sample of children with Gender Dysphoria. *Clin Child Psychol Psychiatry*, 26(1):79-95. doi: 10.1177/1359104520964530. Epub 2020 Oct 20. PMID: 33081539.

U.S. Department of Justice

Civil Rights Division

Assistant Attorney General
950 Pennsylvania Ave, NW - RFK
Washington, DC 20530

March 31, 2022

Dear State Attorneys General:

The U.S. Department of Justice (the Department) is committed to ensuring that transgender youth, like all youth, are treated fairly and with dignity in accordance with federal law. This includes ensuring that such youth are not subjected to unlawful discrimination based on their gender identity, including when seeking gender-affirming care. We write to remind you of several important federal constitutional and statutory obligations that flow from these fundamental principles.

People who are transgender are frequently vulnerable to discrimination in many aspects of their lives, and are often victims of targeted threats, legal restrictions, and anti-transgender violence.[1] The Department and the federal government more generally have a strong interest in protecting the constitutional rights of individuals who are lesbian, gay, bisexual, transgender, queer, intersex, nonbinary, or otherwise gender-nonconforming,[2] and in ensuring compliance with federal civil rights statutes. The Department is also charged with the coordination and enforcement of federal laws that protect individuals from discrimination in a wide range of federally-funded programs and activities.[3]

Intentionally erecting discriminatory barriers to prevent individuals from receiving gender-affirming care implicates a number of federal legal guarantees. State laws and policies that prevent parents or guardians from following the advice of a healthcare professional regarding what may be medically necessary or otherwise appropriate care for transgender minors may infringe on rights protected by both the Equal Protection and the Due Process Clauses of the Fourteenth Amendment. The Equal Protection Clause requires heightened scrutiny of laws that discriminate on the basis of sex[4] and prohibits such discrimination absent an "exceedingly

[1] *See, e.g.*, Michelle M. Johns et al., Ctrs. for Disease Control and Prevention, *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017*, Morbidity and Mortality Weekly Report 68: 67-71 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6803a3.htm?s_cid=mm6803a3_w (finding that transgender youth reported higher levels of violence victimization compared to their cisgender peers).

[2] *See, e.g.*, Exec. Order No. 13,988, § 1, 86 Fed. Reg. 7023 (Jan. 20, 2021); Pamela S. Karlan, Principal Deputy Assistant Attorney General, Civ. Rts. Div., U.S. Dep't of Justice, Memorandum, *Application of Bostock v. Clayton County to Title IX of the Education Amendments of 1972* (Mar. 26, 2021), https://www.justice.gov/crt/page/file/1383026/download.

[3] Exec. Order No. 12,250, § 1-201, 45 Fed. Reg. 72,995 (Nov. 2, 1980).

[4] *See*, *e.g.*, *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 610-13 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *reh'g en banc denied*, 976 F.3d 399 (4th Cir. 2020), *cert. denied*, 2021 WL 2637992 (June 28, 2021); *Whitaker* v.

persuasive" justification.[5] Because a government cannot discriminate against a person for being transgender "without discriminating against that individual based on sex,"[6] state laws or policies that discriminate against transgender people must be "substantially related to a sufficiently important governmental interest."[7]

A law or policy need not specifically single out persons who are transgender to be subject to heightened scrutiny. When a state or recipient of federal funds criminalizes or even restricts a type of medical care predominantly sought by transgender persons, an intent to disfavor that class can "readily be presumed."[8] For instance, a ban on gender-affirming procedures, therapy, or medication may be a form of discrimination against transgender persons, which is impermissible unless it is "substantially related" to a sufficiently important governmental interest.[9] This burden of justification is "demanding."[10] Such a law or policy will not withstand heightened scrutiny when "the alleged objective" differs from the "actual purpose" underlying the classification.[11] In addition, the Due Process Clause protects the right of parents "to seek and follow medical advice" to safeguard the health of their children.[12] A state or local government must meet the heavy burden of justifying interference with that right since it is well established within the medical community that gender-affirming care for transgender youth is not only appropriate but often necessary for their physical and mental health.[13]

In addition to these constitutional guarantees, many federal statutes require recipients of federal financial assistance to comply with nondiscrimination requirements as a condition of receiving those funds. Relevant statutes include:

- **Section 1557 of the Affordable Care Act**[14] protects the civil rights of people—including transgender youth—seeking nondiscriminatory access to healthcare in a range of health

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Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034, 1051 (7th Cir. 2017), *cert. dismissed*, 138 S. Ct. 1260 (2018); *see also* Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellees, *Brandt v. Rutledge*, No. 21-2875 (8th Cir. Jan. 21, 2022); En Banc Brief for the United States as Amicus Curiae Supporting Plaintiff-Appellee, *Adams v. School Board of St. John's County*, No. 18-13592 (11th Cir. Nov. 26, 2021); Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellees, *Corbitt v. Taylor*, No. 21-10486 (11th Cir. Aug. 2, 2021).

[5] *United States v. Virginia*, 518 U.S. 515, 531 (1996) ("Parties who seek to defend gender-based government action must demonstrate an 'exceedingly persuasive justification' for that action.") (quoting *Mississippi Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982)).

[6] *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1741 (2020).

[7] *Grimm*, 972 F.3d at 608 (quoting *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 441 (1985) (internal quotations omitted)).

[8] *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993) ("Some activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed.").

[9] *Virginia*, 518 U.S. at 533.

[10] *Id.*

[11] *Miss. Univ.*, 458 U.S. at 730.

[12] *Parham v. J.R.*, 442 U.S. 584, 602 (1979).

[13] *See, e.g.*, *Brandt v. Rutledge*, 551 F. Supp. 3d 882, 891, 893 (E.D. Ark. 2021).

[14] 42 U.S.C. § 18116.

programs and activities.[15] Categorically refusing to provide treatment to a person based on their gender identity, for example, may constitute prohibited discrimination under Section 1557. As the U.S. Department of Health and Human Services has stated, restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care providers solely on the basis of their sex assigned at birth or their gender identity may also violate Section 1557.[16]

- **Title IX of the Education Amendments of 1972**[17] prohibits sex discrimination, including sex-based harassment, by recipients of federal financial assistance that operate education programs and activities.[18] Policies and practices that deny, limit, or interfere with access to the recipient's education program or activity because students are transgender minors receiving gender-affirming care may constitute discrimination on the basis of sex in violation of Title IX.

- The **Omnibus Crime Control and Safe Streets Act of 1968**[19] prohibits sex discrimination in certain law enforcement programs and activities receiving federal financial assistance.[20] If a law enforcement agency takes a transgender minor who is receiving gender-affirming care into custody or arrests the child's parents on suspicion of child abuse because the parents permitted such medical care, that agency may be violating the statute's nondiscrimination provision.

- **Section 504 of the Rehabilitation Act of 1973**[21] protects people with disabilities, which can include individuals who experience gender dysphoria.[22] Restrictions that prevent, limit, or interfere with otherwise qualified individuals' access to care due to their gender

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[15] *See, e.g.*, Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, reprinted at 86 Fed. Reg. 27,984 (May 25, 2021).
[16] U.S. Dep't Health & Hum. Servs., *Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy* (Mar. 2, 2022), https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf.
[17] 20 U.S.C. § 1681, *et seq*.
[18] *See* Karlan, *supra* note 2; *see also Doe v. Snyder*, --- F.4th ---, 2022 WL 711420, at *9 (9th Cir. Mar. 10, 2022); *Grimm*, 972 F.3d at 619.
[19] 34 U.S.C. § 10101, *et seq*.
[20] *See* 34 U.S.C. § 10228(c)(1); *see also* Kristen Clarke, Assistant Attorney General, Civ. Rts. Div., U.S. Dep't of Justice, Memorandum, *Interpretation of Bostock v. Clayton County regarding the nondiscrimination provisions of the Safe Streets Act, the Juvenile Justice and Delinquency Prevention Act, the Victims of Crime Act, and the Violence Against Women Act* (Mar. 10, 2022), https://www.justice.gov/crt/page/file/1481776/download.
[21] 29 U.S.C. § 794. Additionally, Title II of the Americans with Disabilities Act extends disability civil rights protections with respect to all programs, services and activities of state and local governments, regardless of the receipt of federal financial assistance. *See* 42 U.S.C. § 12132.
[22] *See, e.g.*, *Doe v. Penn. Dep't of Corrections*, No. 1:20-cv-00023-SPB-RAL, 2021 WL 1583556, at *12 (W.D. Pa. Feb. 19, 2021), report and recommendation adopted in relevant part, 2021 WL 1115373 (W.D. Pa. March 24, 2021); *Lange v. Houston Cnty.*, 499 F. Supp. 3d 1258, 1270 (M.D. Ga. 2020); *Doe v. Mass. Dep't of Correction*, No. 1:17-cv-12255-RGS, 2018 WL 2994403 at *6 (D. Mass. June 14, 2018); *Blatt v. Cabela's Retail, Inc.*, No. 5:14-CV-04822, 2017 WL 2178123 (E.D. Pa. May 18, 2017).

dysphoria, gender dysphoria diagnosis, or perception of gender dysphoria may violate Section 504.

All persons should be free to access the services, programs, and activities supported by federal financial assistance without fear that they might face unlawful discrimination for doing so. Courts have held that many nondiscrimination statutes contain an implied cause of action for retaliation based on the general prohibition against intentional discrimination, and agencies have made this clear in regulations.[23] Thus, any retaliatory conduct may give rise to an independent legal claim under the protections described above.

* * *

Thank you for your continued commitment to improving the well-being of children and their families. The Department is always available to help ensure that state and local governments, many of which are recipients of federal financial assistance, meet their obligations under federal law. Please feel free to contact the Department's Civil Rights Division for assistance if you have further questions.

Sincerely,

Kristen Clarke
Assistant Attorney General
Civil Rights Division
U.S. Department of Justice

[23] *See, e.g.*, *Jackson v. Birmingham Bd. of Ed.*, 544 U.S. 167, 173 (2005) ("Retaliation against a person because that person has complained of sex discrimination is another form of intentional sex discrimination…"). Examples of agency regulations that prohibit retaliation include 24 C.F.R. § 1.7(e) (Dep't of Housing and Urban Development); 34 C.F.R. § 100.7(e) (Dep't of Education); 38 C.F.R. § 18.7(e) (Dep't of Veterans Affairs); and 45 C.F.R. § 80.7(e) (Dep't of Health and Human Services). Other relevant regulations can be found in the Civil Rights Division's Title VI Legal Manual. Civ. Rts. Div., U.S. Dep't of Justice, *Title VI Legal Manual*, Section VIII, https://www.justice.gov/crt/book/file/1364106/download.

NCA - Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) - Decision Memo

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Decision Summary

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination of whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery is reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination related to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

Decision Memo

To: Administrative File: CAG #00446N

From: Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group

Joseph Chin, MD, MS
Deputy Director, Coverage and Analysis Group

James Rollins, MD, PhD
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Elizabeth Koller, MD
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Analyst

Subject: Final Decision Memorandum on Gender Reassignment Surgery for Medicare Beneficiaries with Gender Dysphoria

Date: August 30, 2016

I. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

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II. Background

Below is a list of acronyms used throughout this document.

AHRQ - Agency for Healthcare Research and Quality
AIDS - Acquired Immune Deficiency Syndrome
ANOVA - Analysis of Variance

APA - American Psychiatric Association
APGAR - Adaptability, Partnership Growth, Affection, and Resolve test
BIQ - Body Image Questionnaire
BSRI - Bem Sex Role Inventory
CCEI - Crown Crips Experimental Index
CDC – Centers for Disease Control
CHIS - California Health Interview Survey
CI - Confidence Interval
CMS - Centers for Medicare & Medicaid Services
DAB - Departmental Appeals Board
DSM - Diagnostic and Statistical Manual of Mental Disorders
EMBASE - Exerpta Medica dataBASE
FBeK - Fragebogen zur Beurteilung des eigenen Korpers
FDA - Food and Drug Administration
FPI-R - Freiburg Personality Inventory
FSFI - Female Sexual Function Index
GAF - Global Assessment of Functioning
GID - Gender Identity Disorder
GIS - Gender Identity Trait Scale
GRS - Gender Reassignment Surgery
GSI - Global Severity Indices
HADS - Hospital Anxiety Depression Scale
HHS - U.S. Department of Health and Human Services
HIV - Human Immunodeficiency Virus
IIP - Inventory of Interpersonal Problems
IOM - Institute of Medicine
KHQ - King's Health Questionnaire
LGB - Lesbian, Gay, and Bisexual
LGBT - Lesbian, Gay, Bisexual, and Transgender
MAC - Medicare Administrative Contractor
MMPI - Minnesota Multiphasic Personality Inventory
NCA - National Coverage Analysis
NCD - National Coverage Determination
NICE - National Institute for Health Care Excellence
NIH - National Institutes of Health
NZHTA - New Zealand Health Technology Assessment
PIT - Psychological Integration of Trans-sexuals
QOL - Quality of Life
S.D. - Standard Deviation
SADS - Social Anxiety Depression Scale
SCL-90R - Symptom Check List 90-Revised
SDPE - Scale for Depersonalization Experiences
SES - Self Esteem Scale
SF - Short Form
SMR - Standardized Mortality Ratio SOC – Standards of Care
STAI-X1 - Spielberger State and Trait Anxiety Questionnaire
STAI-X2 - Spielberger State and Trait Anxiety Questionnaire
TSCS - Tennessee Self-Concept Scale
U.S. - United States
VAS - Visual Analog Scale
WHOQOL-BREF - World Health Organization Quality of Life - Abbreviated version of the WHOQOL-100
WPATH - World Professional Association for Transgender Health

A. Diagnostic Criteria

The criteria for gender dysphoria or spectrum of related conditions as defined by the American Psychiatric Association (APA) in the Diagnostic and Statistical Manual of Mental Disorders (DSM) has changed over time (See Appendix A).

Gender dysphoria (previously known as gender identity disorder) is a classification used to describe persons who experience significant discontent with their biological sex and/or gender assigned at birth. Although there are other therapeutic options for gender dysphoria, consistent with the NCA request, this decision only focuses on gender reassignment surgery.

B. Prevalence of Transgender Individuals

For estimates of transgender individuals in the U.S., we looked at several studies.

The Massachusetts Behavior Risk Factor Surveillance Survey (via telephone) (2007 and 2009) identified 0.5% individuals as transgender (Conron et al., 2012).

Derivative data obtained from the 2004 California Lesbian Gay Bisexual and Transgender (LGBT) Tobacco Survey (via telephone) and the 2009 California Health Interview Survey (CHIS) (via telephone) suggested the LGB population constitutes 3.2% of the California population and that transgender subjects constitute approximately 2% of the California LGBT population and 0.06% of the overall California population (Bye et al., 2005; CHIS 2009; Gates, 2011).

Most recently, the Williams Institute published a report that utilized data from the Centers for Disease Control's (CDC) Behavioral Risk Factor Surveillance System (BRFSS). Overall, they found that 0.6% or 1.4 million U.S. adults identify as transgender. The report further estimated 0.7% of adults between the ages of 18-25 identify as transgender, 0.6% of adults between the ages of 25-65 identify as transgender, and 0.5% of adults age 65 or older identify as transgender (Flores et al., 2016).

In a recent review of Medicare claims data, CMS estimated that in calendar year 2013 there were at least 4,098 transgender beneficiaries (less than 1% of the Medicare population) who utilized services paid for by Medicare, of which 90% had confirmatory diagnosis, billing codes, or evidence of a hormone therapy prescription. The Medicare transgender population is racially and ethnically diverse (e.g., 74% White, 15% African American) and spans the entire country. Nearly 80% of transgender beneficiaries are under age 65, including approximately 23% ages 45-54. (CMS Office of Minority Health 2015).

For international comparison purposes, recent estimates of transgender populations in other countries are similar to those in the United States. New Zealand researchers, using passport data, reported a prevalence of 0.0275% for male-to-female adults and 0.0044% female-to-male adults (6:1 ratio) (Veale, 2008). Researchers from a centers of transgender treatment and reassignment surgery in Belgium conducted a survey of regional plastic surgeons and reported a prevalence of 0.008% male-to-female and 0.003% female-to-male (ratio 2.7:1) surgically reassigned transsexuals in Belgium (De Cuypere et al., 2007). Swedish researchers, using national mandatory reporting data on those requesting reassignment surgery, reported secular changes over time in that the number of completed reassignment surgeries per application increased markedly in the 1990s; the male-to- female/female-to-male sex ratio changed from 1:1 to 2:1; the age of male-to-female and female-to-male applicants was initially similar, but increased by eight years for male-to-female applicants; and the proportion of foreign born applicants increased (Olsson and Moller 2003).

III. History of Medicare Coverage

Date	Action
August 1, 1989	CMS published the initial NCD, titled "140.3, Transsexual Surgery" in the Federal Register. (54 Fed. Reg. 34,555, 34,572)
May 30, 2014	The HHS Departmental Appeals Board (DAB) determined that the NCD denying coverage for all transsexual surgery was not valid. As a result, MACs determined coverage on a case-by-case basis.

CMS does not currently have a NCD on gender reassignment surgery.

A. Current Request

On December 3, 2015, CMS accepted a formal complete request from a beneficiary to initiate a NCA for gender reassignment surgery.

CMS opened this National Coverage Analysis (NCA) to thoroughly review the evidence to determine whether or not gender reassignment surgery may be covered nationally under the Medicare program.

B. Benefit Category

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories as outlined in the Act. For gender reassignment surgery, the following are statutes are applicable to coverage:

Under §1812 (Scope of Part A) Under §1832 (Scope of Part B)
Under §1861(s) (Definition of Medical and Other Health Services)
Under §1861(s)(1) (Physicians' Services)

This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

Timeline of Medicare Coverage Policy Actions for Gender Reassignment Surgery

Date	Action
December 3, 2015	CMS accepts an external request to open a NCD. A tracking sheet was posted on the web site and the initial 30 day public comment period commenced.
January 2, 2016	Initial comment period closed. CMS received 103 comments.
June 2, 2016	Proposed Decision Memorandum posted on the web site and the final 30 day public comment period commenced.
July 2, 2016	Final comment period closed. CMS received 45 comments.

V. FDA Status

Surgical procedures per se are not subject to the Food and Drug Administration's (FDA) approval.

Inflatable penile prosthetic devices, rigid penile implants, testicular prosthetic implants, and breast implants have been approved and/or cleared by the FDA.

VI. General Methodological Principles

In general, when making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. (§ 1862 (a)(1)(A)). The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), evidence-based guidelines, professional society position statements, expert opinion, and public comments.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical question relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve health outcomes for patients.

A detailed account of the methodological principles of study design the agency staff utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, blinding of readers of the index test, and reference test results.

VII. Evidence

A. Introduction

Below is a summary of the evidence we considered during our review, primarily articles about clinical trials published in peer- reviewed medical journals. We also considered articles cited by the requestor, articles identified in public comments, as well as those found by a CMS literature review. Citations are detailed below.

B. Literature Search Methods

CMS staff extensively searched for primary studies for gender dysphoria. The emphasis focused less on specific surgical techniques and more on functional outcomes unless specific techniques altered those types of outcomes.

The reviewed evidence included articles obtained by searching literature databases and technology review databases from PubMed (1965 to current date), EMBASE, the Agency for Healthcare Research and Quality (AHRQ), the Blue Cross/Blue Shield Technology Evaluation Center, the Cochrane Collection, the Institute of Medicine, and the National Institute for Health and Care Excellence (NICE) as well as the source material for commentary, guidelines, and formal evidence-based documents published by professional societies. Systematic reviews were used to help locate some of the more obscure publications and abstracts.

Keywords used in the search included: Trans-sexual, transgender, gender identity disorder (syndrome), gender dysphoria and/or hormone therapy, gender surgery, genital surgery, gender reassignment (surgery), sex reassignment (surgery) and/or quality of life, satisfaction-regret, psychological function (diagnosis of mood disorders, psychopathology, personality disorders), suicide (attempts), mortality, and adverse events-reoperations. After the identification of germane publications, CMS also conducted searches on the specific psychometric instruments used by investigators.

Psychometric instruments are scientific tools used to measure individuals' mental capabilities and behavioral style. They are usually in the form of questionnaires that numerically capture responses. These tools are used to create a psychological profile that can address questions about a person's knowledge, abilities, attitudes and personality traits. In the evaluation of patients with gender dysphoria, it is important that both validity and reliability be assured in the construction of the tool (validity refers to how well the tool actually measures what it was designed to measure, or how well it reflects the reality it claims to represent, while reliability refers to how accurately results of the tool would be replicated in a second identical piece of research). Reliability and validity are important because when evaluating patients with gender dysphoria most of the variables of interest (e.g., satisfaction, anxiety, depression) are latent in nature (not directly observed but are rather inferred) and difficult to quantify objectively.

Studies with robust study designs and larger, defined patient populations assessed with objective endpoints or validated test instruments were given greater weight than small, pilot studies. Reduced consideration was given to studies that were underpowered for the assessment of differences or changes known to be clinically important. Studies with fewer than 30 patients were reviewed and delineated, but excluded from the major analytic framework. Oral presentations, unpublished white papers, and case reports were excluded. Publications in languages other than English were excluded. The CMS initial internal search for the proposed decision memorandum was limited to articles published prior to March 21, 2016. The CMS internal search for the final decision memorandum continued through articles published prior to July 22, 2016.

Included studies were limited to those with adult subjects. Review and discussion of the management of children and adolescents with the additional considerations of induced pubertal delay are outside the scope of this NCD. In cases where the same population was studied for multiple reasons or where the patient population was expanded over time, the latest and/or most germane sections of the publications were analyzed. The excluded duplicative publications are delineated.

CMS also searched Clinicaltrials.gov to identify relevant clinical trials. CMS looked at trial status including early termination, completed, ongoing with sponsor update, and ongoing with estimated date of completion. Publications on completed trials were sought. For this final decision, CMS also reviewed all evidence submitted via public comment.

C. Discussion of Evidence

The development of an assessment in support of Medicare coverage determinations is based on the same general question for almost all national coverage analyses (NCAs): "Is the evidence sufficient to conclude that the application of the item or service under study will improve health outcomes for Medicare patients?" For this specific NCA, CMS is interested in answering the following question:

Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?

The evidence reviewed is directed towards answering this question.

1. Internal Technology Assessment

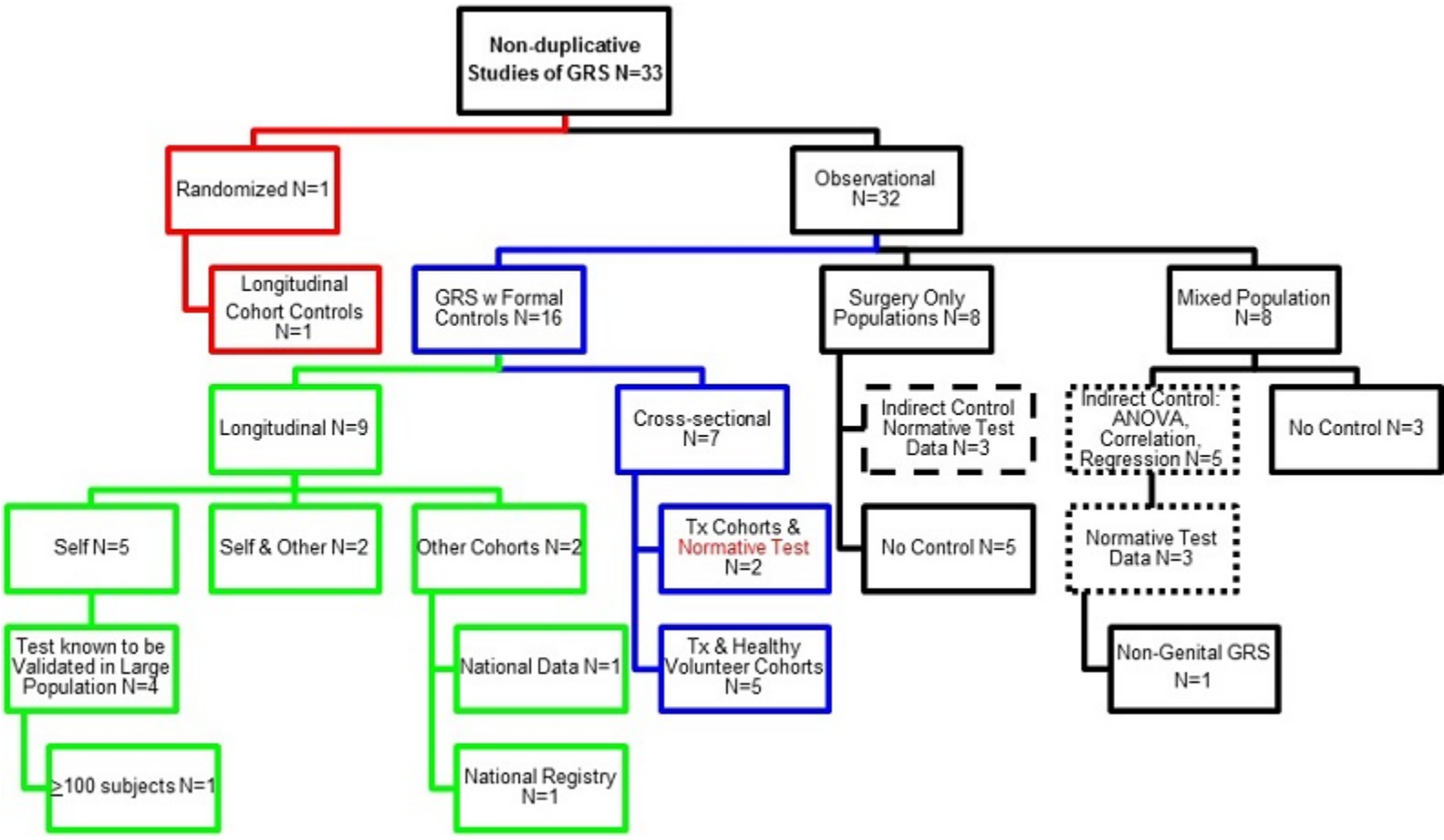
CMS conducted an extensive literature search on gender reassignment related surgical procedures and on facets of gender dysphoria that provide context for this analysis. The latter includes medical and environmental conditions.

CMS identified numerous publications related to gender reassignment surgery. A large number of these were case reports, case series with or without descriptive statistics, or studies with population sizes too small to conduct standard parametric statistical analyses. Others addressed issues of surgical technique.

CMS identified and described 36 publications on gender reassignment surgery that included health outcomes. Because the various investigators at a site sometimes conducted serial studies on ever-enlarging cohort populations, studied sub-populations, studied different outcomes, or used different tools to study the same outcomes, not all study populations were unique. To reduce bias from over-lapping populations, only the latest or most germane publication(s) were described. Subsumed publications were delineated.

Of these 36 publications, two publications used different assessment tools on the same population, and, so for the purposes of evaluation, were classified as one study (Udeze et al., 2008; Megeri and Khoosal, 2007). A total of 33 studies were reviewed (See Figure 1). Appendices C, D, and F include more detail of each study. The publications covered a time span from 1979 to 2015. Over half of the studies were published after 2005.

Figure 1. Studies of Gender Reassignment Surgery (GRS)



ANOVA=Analysis of Variance Normative=Psychometric Tests with known normative for large populations

Figure 1 Legend: The studies in Figure 1 are categorized into three groups. The first group, depicted by the colored

boxes (red, blue, and green), had explicit controls. There was a single randomized study. The remainder in the first group were observational studies. These were subdivided into longitudinal studies and cross-sectional studies. The second group, depicted by black boxes (starting with the surgery only population box) consisted of surgical series. The third group, depicted by black boxes (starting with mixed population), was composed of patients whose treatment could involve a variety of therapeutic interventions, but who were not stratified by that treatment.

When looking at the totality of studies, the 33 studies could be characterized by the following research design groups:

a. Observational, mixed population of surgical and non-surgical patients without stratification

Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol. 2011 Apr;164(4):635-42. Epub 2011 Jan 25.

Asscheman et al. conducted a retrospective, non-blinded, observational study of mortality using a longitudinal design to assess a mixed population treated with hormones, as well as, reassignment surgery in comparison to a population-based cohort. The study was not designed to assess the specific impact of gender reassignment surgery on clinical outcomes.

The investigators assessed mortality in patients who (a) were from a single-center, unspecified, Dutch university specialty clinic, (b) had initiated cross-sex hormone treatment prior to July 1, 1997, and (c) had been followed (with or without continued hormone treatment) by the clinic for at least one year or had expired during the first year of treatment. The National Civil Record Registry (Gemeentelijke Basis Administratie) was used to identify/confirm deaths of clinic patients. Information on the types or hormones used was extracted from clinic records, and information on the causation of death was extracted from medical records or obtained from family physicians. Mortality data for the general population were obtained through the Central Bureau of Statistics of the Netherlands (Centraal Bureau voor Statistiek). Mortality data from Acquired Immune Deficiency Syndrome (AIDS) and substance abuse were extracted from selected Statistics Netherlands reports. The gender of the general Dutch population comparator group was the natal sex of the respective gender dysphoric patient groups.

A total of 1,331 patients who met the hormone treatment requirements were identified (365 female-to-male [27.4%]; 966 male- to-female [72.6%]; ratio 1:2.6). Of these, 1,177 (88.4%) underwent reassignment surgery (343 [94.0% of female-to-male entrants]; 834 [86.3% of male-to-female entrants]; ratio difference 1:2.4 with a p-value $p<0.0001$). Later calculations did not distinguish between those with hormone therapy alone versus those with hormone therapy plus reassignment surgery. The mean age at the time of hormone initiation in female-to-male and male-to-female patients was 26.1±7.6 (range 16–56) years and 31.4±11.4 (range 16–76) years respectively, although the male-to-female subjects were relatively older ($p<0.001$). The mean duration of hormone therapy in female-to-male and male-to-female patients was 18.8±6.3 and 19.4±7.7 years respectively.

There were a total of 134 deaths in the clinic population using hormone therapy with or without surgical reassignment. Of these patients, 12 (3.3%) of the 365 female-to-male patients and 122 (12.6%) of the 966 male-to-female patients died. All-cause mortality for this mixed population was 51% higher and statistically significant (Standardized Mortality Ratio [SMR] 95% confidence interval [CI]) 1.47-1.55) for males-to-females when compared to males in the general Dutch population. The increase in all-cause mortality (12%) for females-to-males when compared to females in the general Dutch population was not statistically significant (95% CI 0.87-1.42).

Ischemic heart disease was a major disparate contributor to excess mortality in male-to-female patients but only in older patients (n=18, SMR 1.64 [95% CI 1.43-1.87]), mean age [range]: 59.7 [42-79] years. Current use of a

particular type of estrogen, ethinyl estradiol, was found to contribute to death from myocardial infarction or stroke (Adjusted Hazard Ratio 3.12 [95% CI 1.28-7.63], p=0.01). There was a small, but statistically significant increase in lung cancer that was thought to possibly be related to higher rates of smoking in this cohort.

Other contributors to the mortality difference between male-to-female patients and the Dutch population at large were completed suicide (n=17, SMR 5.70 [95% CI 4.93-6.54]), AIDS (n=16, SMR 30.20 [95% CI 26.0-34.7]), and illicit drug use (n=5, SMR 13.20 [95% CI 9.70-17.6]). An additional major contributor was "unknown cause" (n=21, SMR 4.00 [95% CI 3.52-4.51]). Of the 17 male-to-female hormone treated patients who committed suicide, 13 (76.5%) had received prior psychiatric treatment and six (35.3%) had not undergone reassignment surgery because of concerns about mental health stability.

Overall mortality, and specifically breast cancer and cardiovascular disease, were not increased in the hormone-treated female-to-male patients. Asscheman et al. reported an elevated SMR for illicit drug use (n=1, SMR 25 [6.00-32.5]). This was the cause of one of the 12 deaths in the cohort.

This study subsumes earlier publications on mortality (Asscheman et al. 1989 [n=425]; Van Kesteren et al. 1997 [n=816]).

Gómez-Gil E, Zubiaurre-Elorza L, Esteva I, Guillamon A, Godás T, Cruz Almaraz M, Halperin I, Salamero M. Hormone-treated transsexuals report less social distress, anxiety and depression. Psychoneuroendocrinology. 2012 May;37(5):662-70. Epub 2011 Sep 19.

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a cross-sectional design and non-specific psychiatric distress tools in Spain. The investigators assessed anxiety and depression in patients with gender dysphoria who attended a single-center specialty clinic with comprehensive endocrine, psychological, psychiatric, and surgical care. The clinic employed World Professional Association for Transgender Health (WPATH) guidelines. Patients were required to have met diagnostic criteria during evaluations by 2 experts. Investigators used the Hospital Anxiety and Depression Scale (HADS) and the Social Anxiety and Distress Scale (SADS) instruments. The SADS total score ranges from 0 to 28, with higher scores indicative of more anxiety. English language normative values are 9.1±8.0. HAD-anxiety and HAD-depression total score ranges from 0 to 21, with higher scores indicative of more pathology. Scores less than 8 are normal. ANOVA was used to explore effects of hormone and surgical treatment.

Of the 200 consecutively selected patients recruited, 187 (93.5% of recruited) were included in the final study population. Of the final study population, 74 (39.6%) were female-to-male patients; 113 (60.4%) were male-to-female patients (ratio 1:1.5); and 120 (64.2%) were using hormones. Of those using hormones, 36 (30.0%) were female-to-male; 84 (70.0%) were male-to-female (ratio 1:2.3). The mean age was 29.87±9.15 years (range 15-61). The current age of patients using hormones was 33.6±9.1 years (n=120) and older than the age of patients without hormone treatment (25.9±7.5) (p=0.001). The age at hormone initiation, however, was 24.6±8.1 years.

Of those who had undergone reassignment surgery, 29 (36.7%) were female-to-male; 50 (63.3%) were male-to-female (ratio 1:1.7). The number of patients not on hormones and who had undergone at least one gender-related surgical procedure (genital or non-genital) was small (n=2). The number of female-to-male patients on hormones who had undergone such surgery (mastectomy, hysterectomy, and/or phalloplasty) was 28 (77.8%). The number of male-to-female patients on hormones who had undergone such surgery (mammoplasty, facial feminization, buttock feminization, vaginoplasty, orchiectomy, and/or vocal feminization (thyroid chondroplasty) was 49 (58.3%).

Analysis of the data revealed that although the mean scores HAD-Anxiety, HAD-Depression, and SADS were statistically lower (better) in those on hormone therapy than in those not on hormone therapy, the mean scores for

HAD-Depression and SADS were in the normal range for gender dysphoric patients not using hormones. The HAD-Anxiety score was 9 in transsexuals without hormone treatment and 6.4 in transsexuals with hormone treatment. The mean scores for HAD-Anxiety, HAD- Depression, and SADS were in the normal range for gender dysphoric patients using hormones. ANOVA revealed that results did not differ by whether the patient had undergone a gender related surgical procedure or not.

Gómez-Gil E, Zubiaurre-Elorza L, de Antonio I, Guillamon A, Salamero M. Determinants of quality of life in Spanish transsexuals attending a gender unit before genital sex reassignment surgery. Qual Life Res. 2014 Mar;23(2):669-76. Epub 2013 Aug 13.

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a non-specific quality of life tool. There were no formal controls for this mixed population ± non-genital reassignment surgery undergoing various stages of treatment.

The investigators assessed quality of life in the context of culture in patients with gender dysphoria who were from a single-center (Barcelona, Spain), specialty and gender identity clinic. The clinic used WPATH guidelines. Patients were required to have met diagnostic criteria during evaluations by both a psychologist and psychiatrist. Patients could have undergone non-genital surgeries, but not genital reassignment surgeries (e.g., orchiectomy, vaginoplasty, or phalloplasty). The Spanish version of the World Health Organization Quality of Life-Abbreviated version of the WHOQOL-100 (WHOQOL- BREF) was used to evaluate quality of life, which has 4 domains (environmental, physical, psychological, and social) and 2 general questions. Family dynamics were assessed with the Spanish version of the Family Adaptability, Partnership Growth, Affection, and Resolve (APGAR) test. Regression analysis was used to explore effects of surgical treatment.

All consecutive patients presenting at the clinic (277) were recruited and, 260 (93.9%) agreed to participate. Of this number, 59 of these were excluded for incomplete questionnaires, 8 were excluded for prior genital reassignment surgery, and 193 were included in the study (the mean age of this group was 31.2±9.9 years (range 16-67). Of these, 74 (38.3%) were female-to-male patients; 119 (61.7%) were male-to-female patients (ratio1:1.6). Of these, 120 (62.2%) were on hormone therapy; 29 (39.2%) of female-to-male patients had undergone at least 1 non-genital, surgical procedure (hysterectomy n=19 (25.7%); mastectomy n=29 (39.2%)); 51 (42.9%) of male-to-female patients had undergone at least one non-genital surgical procedure with mammoplasty augmentation being the most common procedure, n=47 (39.5%), followed by facial feminization, n=11 (9.2%), buttocks feminization, n=9 (7.6%), and vocal feminization (thyroid chondroplasty), n=2 (1.7%).

WHOQOL-BREF domain scores for gender dysphoric patients with and without non-genital surgery were: "Environmental" 58.81±14.89 (range 12.50-96.88), "Physical" 63.51±17.79 (range 14.29-100), "Psychological" 56.09+16.27 (range 16.67- 56.09), "Social" 60.35±21.88 (range 8.33-100), and "Global QOL and Health" 55.44+27.18 (range 0-100 with higher score representing better QOL). The mean APGAR family score was 7.23±2.86 (range 0-10 with a score of 7 or greater indicative of family functionality).

Regression analysis, which was used to assess the relative importance of various factors to WHOQOL-BREF domains and general questions, revealed that family support was an important element for all four domains and the general health and quality- of-life questions. Hormone therapy was an important element for the general questions and for all of the domains except "Environmental." Having undergone non-genital reassignment surgery, age, educational levels, and partnership status, did not impact domain and general question results related to quality of life.

Hepp U, Kraemer B, Schnyder U, Miller N, Delsignore A. Psychiatric comorbidity in gender identity disorder. J Psychosom Res. 2005 Mar;58(3):259-61.

Hepp et al. conducted a single-site (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design. There was some acquisition of retrospective data. The investigators assessed current and lifetime psychiatry co-morbidity using structured interviews for diagnosis of Axis 1 disorders (clinical syndromes) and Axis 2 disorders (developmental or personality disorders) and HADS for dimensional evaluation of anxiety and depression. Statistical description of the cohort and intra-group comparisons was performed. Continuous variables were compared using t-tests and ANOVA.

A total of 31 patients with gender dysphoria participated in the study: 11 (35.5%) female-to-male; 20 (64.5%) male-to-female (ratio 1:1.8). The overall mean age was 32.2±10.3 years. Of the participants, seven had undergone reassignment surgery, 10 pre- surgical patients had been prescribed hormone therapy, and 14 pre-surgical patients had not been prescribed hormone therapy. Forty five and one half percent of female-to-male and 20% of male-to-female patients did not carry a lifetime diagnosis of an Axis 1 condition. Sixty three and six tenths percent of female-to-male and 60% of male-to-female patients did not carry a current diagnosis of an Axis 1 condition. Lifetime diagnosis of substance abuse and mood disorder were more common in male-to-female patients (50% and 55% respectively) than female-to-male patients (36.4% and 27.3% respectively). Current diagnosis of substance abuse and mood disorder were present in male-to-female patients (15% and 20% respectively) and absent in female-to-male patients. One or more personality disorders were identified 41.9%, but whether this was a current or lifetime condition was not specified. Of the patients, five (16.1%) had a Cluster A personality disorder (paranoid-schizoid), seven (22.6%) had a Cluster B personality disorder (borderline, anti-social, histrionic, narcissistic), six (19.4%) had a Cluster C personality disorder (avoidant, dependent, obsessive-compulsive), and two (6.5%) were not otherwise classified.

HADS scores were missing for at least one person. The HADS test revealed non-pathologic results for depression (female-to-male: 6.64±5.03; male-to-female: 6.58±4.21) and borderline results for anxiety (female-to-male: 7.09±5.11; male-to-female: 7.74±6.13, where a result of 7-10 = possible disorder). There were no differences by natal gender. The investigators reported a trend for less anxiety and depression as measured by HADS in the patients who had undergone surgery.

Johansson A, Sundbom E, Höjerback T, Bodlund O. A five-year follow-up study of Swedish adults with gender identity disorder. Arch Sex Behav. 2010 Dec;39(6):1429-37. Epub 2009 Oct 9.

Johansson et al. conducted a two center (Lund and Umeå, Sweden) non-blinded, observational study using a semi-cross-sectional design (albeit over an extended time interval) using a self-designed tool and Axis V assessment. The study was prospective except for the acquisition of baseline Axis V data. There were no formal controls in this mixed population with and without surgery.

The investigators assessed satisfaction with the reassignment process, employment, partnership, sexual function, mental health, and global satisfaction in gender-reassigned persons from two disparate geographic regions. Surgical candidates were required to have met National Board of Health and Welfare criteria including initial and periodic psychiatric assessment, ≥1 year of real-life experience in preferred gender, and ≥1 year of subsequent hormone treatment. In addition, participants were required to have been approved for reassignment five or more years prior and/or to have completed surgical reassignment (e.g., sterilization, genital surgery) two or more years prior. The investigators employed semi-structured interviews covering a self-designed list of 55 pre-formulated questions with a three or five point ordinal scale. Clinician assessment of Global Assessment of Functioning (GAF; Axis V) was also conducted and compared to initial finding during the study. Changes or differences considered to be biologically significant were not pre- specified except for GAF, which pre-specified a difference to mean change ≥5 points. Statistical corrections for multiple comparisons were not included. There was no stratification by treatment.

Of the pool of 60 eligible patients, 42 (70.0% of eligible) (17 [40.5 %] female-to-male; 25 [59.5%] male-to-female;

ratio 1:1.5) were available for follow-up. Of these, 32 (53.3% of eligible) (14 [43.8%] female-to-male; 18 [56.2%] male-to-female [ratio 1:1.3]) had completed genital gender reassignment surgery (not including one post mastectomy), five were still in the process of completing surgery, and five (one female-to-male; four male- to-female; ratio 1:4) had discontinued the surgical process prior to castration and genital surgery.

The age (ranges) of the patients at entry into the program, reassignment surgery, and follow-up were 27.8 (18-46), 31.4 (22- 49), and 38.9 (28-53) years in the female-to-male group respectively and 37.3 (21-60), 38.2 (22-57), and 46.0 (25.0-69.0) years in the male- to-female group respectively. The differences in age by cohort group were statistically significant. Of participants, 88.2% of all enrolled female-to-male versus 44.0% of all enrolled female-to-male patients had cross-gender identification in childhood (versus during or after puberty) ($p<0.01$).

Although 95.2% of all enrolled patients self-reported improvement in GAF, in contrast, clinicians determined GAF improved in 61.9% of patients. Clinicians observed improvement in 47% of female-to-male patients and 72% of male-to- female patients. A ≥5 point improvement in the GAF score was present in 18 (42.9%). Of note, three of the five patients who were in the process of reassignment and five of the five who had discontinued the process were rated by clinicians as having improved.

Of all enrolled 95.2% (with and without surgery) reported satisfaction with the reassignment process. Of these 42 patients, 33 (79%) identified themselves by their preferred gender and nine (21%) identified themselves as transgender. None of these nine (eight male-to-female) had completed reassignment surgery because of ambivalence secondary to lack of acceptance by others and dissatisfaction with their appearance. Of the patients who underwent genital surgery (n=32) and mastectomy only (n=one), 22 (66.7%) were satisfied while four (three female-to-male) were dissatisfied with the surgical treatment.

Regarding relationships after surgery, 16 (38.1%) (41.2% of female- to-male; 36.0% of male-to-female patients) were reported to have a partner. Yet more than that number commented on partner relationships: (a) 62.2 % of the 37 who answered (50.0% of female- to- male; 69.6% of male-to-female patients) reported improved partner relationships (five [11.9%] declined to answer.); (b) 70.0% of the 40 who answered (75.0% of female-to-male; 66.7% of male-to-female patients) reported an improved sex life. Investigators observed that reported post-operative satisfaction with sex life was statistically more likely in those with early rather than late cross-gender identification. In addition 55.4% self-reported improved general health; 16.1% reported impaired general health; 11.9% were currently being treated with anti-depressants or tranquilizers.

This study subsumes earlier work by Bodlund et al. (1994, 1996). The nationwide mortality studies by Dhejne et al. (2011) may include all or part of this patient population.

Leinung M, Urizar M, Patel N, Sood S. Endocrine treatment of transsexual persons: extensive personal experience. Endocr Pract. 2013 Jul-Aug;19(4):644-50. (United States study)

Leinung et al. conducted a single-center (Albany, New York) a partially prospective, non-blinded, observational study using a cross-sectional design and descriptive statistics. There were no formal controls. The investigators assessed employment, substance abuse, psychiatric disease, mood disorders, Human Immunodeficiency Virus (HIV) status in patients who had met WPATH guidelines for therapy, and who had initiated cross-sex hormone treatment.

A total of 242 patients treated for gender identity disorder in the clinic from 1992 through 2009 inclusive were identified. The number of those presenting for therapy almost tripled over time. Of these patients, 50 (20.7%) were female-to-male; 192 (79.3%) male-to-female (ratio 1:3.8).

The age of female-to-male and male-to-female patients with gender dysphoria at the time of clinic presentation was 29.0 and 38.0 years respectively.

The female-to-male and male-to-female patients with gender dysphoria at the time of hormone initiation were young: 27.5 and 35.5 years old respectively ($p<0.5$). Of the male-to-female cohort, 19 (7.8%) had received hormone therapy in the absence of physician supervision; Of the patient population, 91 (37.6%) had undergone gender-reassignment surgery (32 female-to-male [64.0% of all female-to- male; 35.2% of all surgical patients]; 59 male-to-female [30.7% of all male-to-female; 64.8% of all surgical patients]; ratio 1:1.8).

Psychiatric disease was more common in those who initiated hormone therapy at an older age (>32 years) 63.9% versus 48.9% at a younger age and by natal gender (48.0% of female-to-male; 58.3% male-to-female). Mood disorders were more common in those who initiated hormone therapy at an older age (>32 years) 52.1% versus 36.0% at a younger age and this finding did not differ by natal gender (40.0% of female-to-male; 44.8% male-to-female). The presence of mood disorders increased the time to reassignment surgery in male-to-female patients.

Motmans J , Meier P, Ponnet K, T'Sjoen G. Female and male transgender quality of life: socioeconomic and medical differences. J Sex Med. 2012 Mar;9(3):743-50. Epub 2011 Dec 21.

Motmans et al., conducted a prospective, non-blinded, observational study using a cross-sectional design and a non-specific quality of life tool. No concurrent controls were used in this study. Quality of life in this Dutch-speaking population was assessed using the Dutch version of a SF-36 (normative data was used). Participants included subjects who were living in accordance with the preferred gender and who were from a single Belgian university specialty clinic at Ghent. The Dutch version of the SF-36 questionnaire along with its normative data were used. Variables explored included employment, pension status, ability to work, being involved in a relationship. Also explored, was surgical reassignment surgery and the types of surgical interventions. Intragroup comparisons by transgender category were conducted, and the relationships between variables were assessed by analysis of variance (ANOVA) and correlations.

The age of the entire cohort (n=140) was 39.89±10.21 years (female-to-male: 37.03±8.51; male-to-female: 42.26±10.39). Results of the analysis revealed that not all female-to-male patients underwent surgical reassignment surgery and, of those who did, not all underwent complete surgical reassignment. The numbers of female-to-male surgical interventions were: mastectomy 55, hysterectomy 55, metaoidplasty eight (with five of these later having phalloplasty), phalloplasty 40, and implantation of a prosthetic erectile device 20. The frequencies of various male-to-female surgical interventions were: vaginoplasty 48, breast augmentation 39, thyroid cartilage reduction 17, facial feminization 14, and hair transplantation three.

The final number of subjects with SF-36 scores was 103 (49 [47.6%] female-to-male; 54 [52.4%] male-to-female; ratio 1:1.1). For this measure, the scores for the vitality and mental health domains for the final female-to-male cohort (n= 49 and not limited to those having undergone some element of reassignment surgery) were statistically lower: 60.61±18.16 versus 71.9±18.31 and 71.51±16.40 versus 79.3±16.4 respectively. Scores were not different from the normative data for Dutch women: vitality: 64.3±19.7 or mental health 73.7±18.2. None of the domains of the SF-36 for the final male-to-female cohort (n=54 and not limited to those having undergone some element of reassignment surgery) were statistically different from the normative data for Dutch women.

Analysis of variance indicated that quality of life as measured by the SF-36 did not differ by whether female-to-male patients had undergone genital surgery (metaoidoplasty or phalloplasty) or not. Also, ANOVA indicated that quality of life as measured by the SF-36 did not differ by whether male-to-female patients had undergone either breast augmentation or genital surgery (vaginoplasty) or not.

Whether there is overlap with the Ghent populations studied by Heylens et al. or Weyers et al. is unknown.

Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 2006 Nov;15(9):1447-57. Epub 2006 Jun 7. (United States study)

Newfield et al. conducted a prospective, observational internet self-report survey of unknown blinding status using a cross- sectional design and a non-specific quality of life tool in a mixed population with and without hormone therapy and/or reassignment surgery. There were no formal controls.

The investigators recruited natal female participants identifying as male using email, internet bulletin boards, and flyers/postcards distributed in the San Francisco Bay Area. Reduction of duplicate entries by the same participant was limited to the use of a unique user name and password.

The investigators employed the Short-Form 36 (SF-36) Version 2 using U.S. normative data. They reported using both male and female normative data for the comparator SF-36 cohort. Data for the eight domains were expressed as normative scoring. The Bonferroni correction was used to adjust for the risk of a Type 1 error with analyses using multiple comparisons.

A total of 379 U.S. respondents classified themselves as males-or-females to males with or without therapeutic intervention. The mean age of the respondents who classified themselves as male or female-to-male was 32.6±10.8 years. Of these 89% were Caucasian, 3.6% Latino, 1.8% African American, 1.8% Asian, and 3.8% other. Of these, 254 (67.0%) reported prior or current testosterone use while 242 (63.8%) reported current testosterone use. In addition, 136 (36.7%) reported having had "top" surgery and 11 (2.9%) reported having "bottom" surgery.

Complete SF-36 data were available for 376 U.S. respondents. For the complete, non-stratified U.S. cohort the Physical Summary Score (53.45±9.42) was statistically higher (better) than the natal gender unspecified SF-36 normative score (50±10) (p=<0.001), but was within one standard deviation of the normative mean. The Mental Summary Score (39.63±12.2) was statistically lower (worse) than the natal gender unspecified SF-36 normative score (50±10) (p<0.001), but was well within two standard deviations of the normative mean. Subcomponents of this score: Mental Health (42.12±10.2), Role Emotional (42.42±11.6), Social Functioning (43.14±10.9), and Vitality (46.22±9.9) were statistically lower (worse) than the SF-36 normative sub-scores, but well within one standard deviation of the normative sub- score means. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

Additional intragroup analyses were conducted, although the data were not stratified by type of therapeutic intervention (hormonal, as well as, surgical). Outcomes of hormone therapy were considered separately and dichotomously from reassignment surgery. The Mental Summary Score was statistically higher (better) in those who had "Ever Received Testosterone" (41.22±11.9) than those with "No Testosterone Usage" (36.08±12.6) (p=0.001). The Mental Summary Scores showed a trend towards statistical difference between those who "Ever Received Top Surgery" (41.21±11.6) and those without "Top Surgery" (38.01±12.5) (p=0.067). These differences were well within one standard deviation of the normative mean. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

b. Observational, surgical series, without concurrent controls

Blanchard R, Steiner BW, Clemmensen LH. Gender dysphoria, gender reorientation, and the clinical management of transsexualism. J Consult Clin Psychol. 1985 Jun; 53(3):295-304.

Blanchard et al. conducted a single-center (Ontario, Canada), prospective, non-blinded, cross-sectional study using a self-designed questionnaire and a non- specific psychological symptom assessment with normative data. The investigators assessed social adjustment and psychopathology in patients with gender dysphoria and who were at least one year post gender reassignment surgery. Reassignment surgery was defined as either vaginoplasty or mastectomy/construction of male chest contour with or without nipple transplants, but did not preclude additional procedures. Partner preference was determined using Blanchard's Modified Androphilia-Gynephilia Index, and the nature and extent of any psychopathology was determined with the Symptom Check List 90-Revised (SCL-90R). Differences in test scores considered to be biologically significant were not pre-specified in the methods.

Of the 294 patients (111 natal females and 183 natal males, ratio: 1:1.65) initially evaluated, 263 were diagnosed with gender dysphoria. Of these 79 patients participated in the study (38 female-to-male; 32 male-to-female with male partner preference; 9 male-to-female with female partner preference). The respective mean ages for these 3 groups were 32.6, 33.2, and 47.7 years with the last group being older statistically (p=0.01).

Additional surgical procedures in female-to-male patients included: oophorectomy/hysterectomy (92.1%) and phalloplasty (7.9%). Additional surgical procedures in male-to-female patients with male partner preference included facial hair electrolysis 62.5% and breast implantation (53.1%). Additional procedures in male-to-female patients with female partner preference included facial hair electrolysis (100%) and breast implantation (33.3%). The time between reassignment surgery and questionnaire completion did not differ by group.

Psychopathology as measured by the Global Severity Index of the SCL-90R was absent in all three patient groups. Interpretation did not differ by the sex of the normative cohort.

Of participants, 63.2% of female-to-male patients cohabitated with partners of their natal gender; 46.9% of male-to-female patients with male partner preference cohabitated with partners of their natal gender; and no male-to-female patients with female partner preference cohabitated with partners of their natal gender.

Of participants, 93.7% reported that they would definitely undergo reassignment surgery again. The remaining 6.3% (one female-to-male; one male-to-female with male partner preference; three male-to-female with female partner preference) indicated that they probably would undertake the surgery again. Post hoc analysis suggested that the more ambivalent responders had more recently undergone surgery. Of responders, 98.7% indicated that they preferred life in the reassigned gender. The one ambivalent subject was a skilled and well compensated tradesperson who was unable to return to work in her male dominated occupation.

Eldh J, Berg A, Gustafsson M. Long-term follow up after sex reassignment surgery. Scand J Plast Reconstr Surg Hand Surg. 1997 Mar;31(1):39-45.

Eldh et al. conducted a non-blinded, observational study using a prospective cross-sectional design with an investigator designed questionnaire and retrospective acquisition of pre-operative data. The investigators assessed economic circumstances, family status, satisfaction with surgical results, and sexual function in patients who had undergone gender reassignment surgery.

Of the 175 patients who underwent reassignment surgery in Sweden, 90 responded. Of this number, 50 were female-to-male and 40 were male-to-female (ratio: 1:0.8). Patients reportedly were generally satisfied with the appearance of the reconstructed genitalia (no numbers provided). Of the patients who had undergone surgery prior to 1986, seven (14%) were dissatisfied with shape or size of the neo-phallus; eight (16%) declined comment. There were 14 (35%), with 12 having surgery prior to 1986 and two between 1986 and 1995 inclusive, were moderately satisfied because of insufficient vaginal volume; 8 (20%) declined comment. A neo-clitoris was not constructed until the later surgical cohort. Three of 33 reported no sensation or no sexual sensation. Eight had difficulties

comprehending the question and did not respond.

A total of nine (18%) patients had doubts about their sexual orientation; 13 (26%) declined to answer the question. The study found that two female-to- male patients and two male-to-female patients regretted their reassignment surgery and continued to live as the natal gender, and two patients attempted suicide.

Hess J, Rossi Neto R, Panic L, Rübben H, Senf W. Satisfaction with male-to-female gender reassignment surgery. Dtsch Arztebl Int. 2014 Nov 21;111(47):795-801.

Hess at al. conducted a prospective, blinded, observational study using a cross-sectional design and a self-designed anonymous questionnaire. The investigators assessed post-operative satisfaction in male-to-female patients with gender dysphoria who were followed in a urology specialty clinic (Essen, Germany). Patients had met the ICD-10 diagnostic criteria, undergone gender reassignment surgeries including penile inversion vaginoplasty, and a Likert-style questionnaire with 11 elements. Descriptive statistics were provided.

There were 254 consecutive eligible patients who had undergone surgery between 2004 and 2010 identified and sent surveys, of whom 119 (46.9%) responded anonymously. Of the participants, 13 (10.9%) reported dissatisfaction with outward appearance and 16 (13.4%) did not respond; three (2.5%) reported dissatisfaction with surgical aesthetics and 25 (21.0%) did not respond; eight (6.7%) reported dissatisfaction with functional outcomes of the surgery and 26 (21.8%) did not respond; 16 (13.4%) reported they could not achieve orgasm and 28 (23.5%) did not respond; four (3.4%) reported feeling completely male/more male than female and 28 (23.5%) did not respond; six (5.0%) reported not feeling accepted as a woman, two (1.7%) did not understand the question, and 17 (14.3%) did not respond; and 16 (13.4%) reported that life was harder and 24 (20.2%) did not respond.

Lawrence A. Patient-reported complications and functional outcomes of male-to-female sex reassignment surgery. Arch Sex Behav. 2006 Dec;35(6):717-27. Epub 2006 Nov 16. (United States study)

Lawrence conducted a prospective, blinded observational study using a cross-sectional design and a partially self-designed quality of life tool using yes/no questions or Likert scales. The investigator assessed sexual function, urinary function, and other pre/post-operative complications in patients who underwent male-to-female gender reassignment surgery. Questions addressed core reassignment surgery (neo-vagina and sensate neo-clitoris) and related reassignment surgery (labiaplasty, urethral meatus revision, vaginal deepening/widening, and other procedures), use of electrolysis, and use of hormones.

Questionnaires were designed to be completed anonymously and mailed to 727 eligible patients. Of those eligible, 232 (32%) returned valid questionnaires. The age at the time reassignment surgery was 44±9 (range 18-70) years and mean duration after surgery was 3±1 (range 1-7) years.

Happiness with sexual function and the reassignment surgery was reported to be lower when permanent vaginal stenosis, clitoral necrosis, pain in the vagina or genitals, or other complications such as infection, bleeding, poor healing, other tissue loss, other tissue necrosis, urinary incontinence, and genital numbness were present. Quality of life was impaired when pain in the vagina or genitals was present.

Satisfaction with sexual function, gender reassignment surgery, and overall QOL was lower when genital sensation was impaired and when vaginal architecture and lubrication were perceived to be unsatisfactory. Intermittent regret regarding reassignment surgery was associated with vaginal hair and clitoral pain. Vaginal stenosis was associated with surgeries performed in the more distant past; whereas, more satisfaction with vaginal depth and width was present in more recent surgical treatment.

Salvador J, Massuda R, Andreazza T, Koff WJ, Silveira E, Kreische F, de Souza L, de Oliveira MH, Rosito T, Fernandes BS, Lobato MI. Minimum 2-year follow up of sex reassignment surgery in Brazilian male-to-female transsexuals. Psychiatry Clin Neurosci. 2012 Jun; 66(4):371-2. PMID: 22624747.

Salvador et al. conducted a single center (Port Alegre, Brazil) prospective, non-blinded, observational study using a cross-sectional design (albeit over an extended time interval) and a self-designed quality of life tool. The investigators assessed regret, sexual function, partnerships, and family relationships in patients who had undergone gender reassignment surgery at least 24 months prior.

Out of the 243 enrolled in the clinic over a 10 year interval, 82 underwent sex reassignment surgery. There were 69 participants with a minimum 2-year follow up, of whom 52 patients agreed to participate in the study. The age at follow-up was 36.3±8.9 (range 15-58) years with the time to follow-up being 3.8±1.7 (2-7) years. A total of 46 participants reported pleasurable neo-vaginal sex and post-surgical improvement in the quality of their sexual experience. The quality of sexual intercourse was rated as satisfactory to excellent, average, unsatisfactory, or not applicable in the absence of sexual contact by 84.6%, 9.6%, 1.9%, and 3.8% respectively. Of the participants, 78.8% reported greater ease in initiating and maintaining relationships; 65.4% reported having a partner; 67.3% reported increased frequency of intercourse; 36.8% reported improved familial relationships. No patient reported regret over reassignment surgery. The authors did not provide information about incomplete questionnaires.

Tsoi WF. Follow-up study of transsexuals after sex-reassignment surgery. Singapore Med J. 1993 Dec; 34(6):515-7.

Tsoi conducted a single-center (Singapore) prospective, non-blinded, observational study using a cross-sectional design and a self-designed quality of life tool. The investigator assessed overall life satisfaction, employment, partner status, and sexual function in gender-reassigned persons who had undergone gender reassignment surgery between 1972 and 1988 inclusive and who were approximately 2 to 5 years post-surgery. Acceptance criteria for surgery included good physical health, good mental health, absence of heterosexual tendencies, willingness to undergo hormonal therapy for ≥6 months, and willingness to function in the life of the desired gender for ≥6 months. Tsoi also undertook retrospective identification of variables that could predict outcomes.

The size of the pool of available patients was not identified. Of the 81 participants, 36 (44.4%) were female-to-male and 45 (55.6%) were male-to-female (ratio 1:1.25).

The mean ages at the time of the initial visit and operation were: female-to-male 25.4±4.4 (range 14-36) and 27.4 ±4.0; (range 14-36); male-to-female 22.9±4.6 (range 14-36) and 24.7±4.3 (14-36) years respectively. Of all participants, 14.8% were under age 20 at the time of the initial visit. All were at least 20 at the time of gender reassignment surgery. The reported age of onset was 8.6 years for female-to-male patients and 8.7 years for male-to-female patients.

All participants reported dressing without difficulty in the reassigned gender; 95% of patients reported good or satisfactory adjustment in employment and income status; 72% reported good or satisfactory adjustment in relationships with partners. Although the quality of life tool was self-designed, 81% reported good or satisfactory adjustment to their new gender, and 63% reported good or acceptable satisfaction with sexual activity. Of the female-to-male patients, 39% reported good or acceptable satisfaction with sex organ function in comparison to 91% of male-to-female patients ($p<0.001$). (The author reported that a fully functioning neo-phallus could not be constructed at the time.) The age of non-intercourse sexual activity was the only predictor of an improved outcome.

Weyers S, Elaut E, De Sutter P, Gerris J, T'Sjoen G, Heylens G, De Cuypere G, Verstraelen H. Long-term assessment of the physical, mental, and sexual health among transsexual women. J Sex Med. 2009 Mar;6(3):752-60. Epub 2008 Nov 17.

Weyers at al. (2009) conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments including a non-specific quality of life tool and a semi-specific quality of life tool (using normative data) along with two self-designed tools.

The investigators assessed general quality of life, sexual function, and body image from the prior four weeks in Dutch-speaking male-to-female patients with gender dysphoria who attended a single-center (Ghent, Belgium), specialized, comprehensive care university clinic. Investigators used the Dutch version of the SF-36 and results were compared to normative data from Dutch women and U.S. women. The 19 items of the Dutch version of the Female Sexual Function Index (FSFI) were used to measure sexual desire, function, and satisfaction. A self-designed seven question visual analog scale (VAS) was used to measure satisfaction with gender related body traits and appearance perception by self and others. A self-designed survey measured a broad variety of questions regarding personal medical history, familial medical history, relationships, importance of sex, sexual orientation, gynecologic care, level of regret, and other health concerns. For this study, hormone levels were also obtained.

The study consisted of 50 (71.5% of the eligible recruits) participants. Analysis of the data revealed that the patient's average age was 43.1 ±10.4 years, and all of the patients had vaginoplasty. This same population also had undergone additional feminization surgical procedures (breast augmentation 96.0%, facial feminization 36.0%, vocal cord surgery 40.0%, and cricoid cartilage reduction 30.0%). A total of two (4.0%) participants reported "sometimes" regretting reassignment surgery and 23 (46.0%) were not in a relationship. For the cohort, estradiol, testosterone, and sex hormone binding globulin levels were in the expected range for the reassigned gender. The SF-36 survey revealed that the subscale scores of the participants did not differ substantively from those of Dutch and U.S. women. VAS scores of body image were highest for self-image, appearance to others, breasts, and vulva/vagina (approximately 7 to 8 of 10). Scores were lowest for body hair, facial hair, and voice characteristics (approximately 6 to 7 of 10).

The total FSFI score was 16.95±10.04 out of a maximal 36. The FSFI scores averaged 2.8 (6 point maximum): satisfaction 3.46±1.57, desire 3.12+1.47, arousal 2.95±2.17, lubrication 2.39±2.29, orgasm 2.82±2.29, and pain 2.21±2.46. Though these numbers were reported in the study, data on test population controls were not provided.

A post hoc exploration of the data suggested the following: perceived improvement in general health status was greater in the subset that had undergone reassignment surgery within the last year; sexual orientation impacted the likelihood of being in a relationship; SF-36 scores for vitality, social functioning, and mental health were nominally better for those in relationships, but that overall SF-36 scores did not differ by relationship status; sexual orientation and being in a relationship impacted FSFI scores; and reported sexual function was higher in those with higher satisfaction with regards to their appearance.

Wierckx K, Van Caenegem E, Elaut E, Dedecker D, Van de Peer F, Toye K, Weyers S, Hoebeke P, Monstrey S, De Cuypere G, T'Sjoen G. Quality of life and sexual health after sex reassignment surgery in transsexual men. J Sex Med. 2011 Dec;8 (12):3379-88. Epub 2011 Jun 23.

Wierckx at al. conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments (a non-specific quality of life tool with reported normative data along with three self-designed tools). The investigators assessed general quality of life, sexual relationships, and surgical complications in Dutch-speaking female-to-male patients with gender dysphoria who attended a single-center, specialized, comprehensive care, university clinic (Ghent, Belgium). Investigators used the Dutch version of the SF-36 with 36 questions, eight subscales, and two domains evaluating physical and mental health. Results were compared to normative data from Dutch women and Dutch men. Self -designed questionnaires to evaluate aspects of medical history, sexual functioning (there were separate versions for those with and without partners), and surgical results were also used. The Likert-style format was used for many of the questions.

A total of 79 female-to-male patients with gender dysphoria had undergone reassignment surgery were recruited; ultimately, 47 (59.5%) chose to participate. Three additional patients were recruited by other patients. One of the 50 participants was later excluded for undergoing reassignment surgery within the one year window. The age of patients was: 30±8.2 years (range 16 to 49) at the time of reassignment surgery and 37.1 ±8.2 years (range 22 to 54) at the time of follow-up. The time since hysterectomy, oopherectomy, and mastectomy was 8 years (range 2 to 22). The patient population had undergone additional surgical procedures: metaidoiplasty (n=9; 18.4%), phalloplasty (n=8 after metaidoiplasty, 38 directly; 93.9% total), and implantation of erectile prosthetic device (n=32; 65.3%). All had started hormonal therapy at least two years prior to surgery and continued to use androgens.

The SF-36 survey was completed by 47 (95.9%) participants. The "Vitality" and the "Mental Health" scales were lower than the Dutch male population: 62.1±20.7 versus 71.9±18.3 and 72.6±19.2 versus 79.3±16.4 respectively. These subscale scores were equivalent to the mean scores of the Dutch women.

None of the participants were dissatisfied with their hysterectomy-oopherectomy procedures; 4.1% were dissatisfied with their mastectomies because of extensive scarring; and 2.2% were dissatisfied with their phalloplasties. Of the participants, 17.9% were dissatisfied with the implantation of an erectile prosthetic device; 25 (51.0%) reported at least one post-operative complication associated with phalloplasty (e.g., infection, urethrostenosis, or fistula formation); 16 (50.0% of the 32 with an erectile prosthetic device) reported at least one post-operative complication associated with implantation of an erectile prosthetic (e.g., infection, leakage, incorrect positioning, or lack of function).

A total of 18 (36.7%) participants were not in a relationship; 12.2% reported the inability to achieve orgasm with self-stimulation less than half the time; 12.2% did not respond to the question. Of those participants with partners, 28.5% reported the inability to achieve orgasm with intercourse less than half the time and 9.7% did not respond to this question. Also, 61.3% of those with partners reported (a) no sexual activities (19.4%) or (b) activities once or twice monthly (41.9%), and there were 12.9% who declined to answer.

c. Observational, surgical patients, cross-sectional, with controls

Ainsworth TA, Spiegel JH. Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Qual Life Res. 2010 Sep;19(7):1019-24.

Ainsworth and Spiegel conducted a prospective, observational study using a cross-sectional design and a partially self-designed survey tool. The blind status is unknown. Treatment types served as the basis for controls.

The investigators, head and neck surgeons who provided facial feminization services, assessed perception of appearance and quality of life in male-to-female subjects with self-reported gender dysphoria. Patients could have received no therapeutic intervention, hormone therapy, reassignment surgery, and/or facial feminization surgery and an unrestricted length of transition. (Transition refers to the time when a transgender person begins to live as the gender with which they identify rather than the gender assigned at birth.) Criteria for the various types of interventions were not available because of the survey design of the study. Patients were recruited via website or at a 2007 health conference. Pre-specified controls to eliminate duplicate responders were not provided. The investigators employed a self-designed Likert-style facial feminization outcomes evaluation questionnaire and a "San Francisco 36" health questionnaire. No citations were provided for the latter. It appears to be the Short-form (SF) 36-version 2. Changes or differences considered to be biologically significant were not pre-specified. Power corrections for multiple comparisons were not provided.

The investigators reported that there were 247 participants. (The numbers of incomplete questionnaires was not reported.) Of the 247 participants, 25 (10.1%) received only primary sex trait reassignment surgery, 28 (11.3%)

received facial surgery without primary sex trait reassignment surgery, 47 (19.0%) received both facial and primary sex trait reassignment surgery, and 147 (59.5%) received neither facial nor reassignment surgery.

The mean age for each of these cohorts was: 50 years (no standard deviation [S.D.]) only reassignment surgery, 51 years (no S.D.) only facial surgery, 49 years (no S.D.) both types of surgery, and 46 years (no S.D.) (neither surgery). Of the surgical cohorts: 100% of those who had undergone primary sex trait reassignment surgery alone used hormone therapy, 86% of those who had undergone facial feminization used hormone therapy, and 98% of those who had undergone both primary sex trait reassignment surgery and facial feminization used hormone therapy. In contrast to the surgical cohorts, 66% of the "no surgery" cohort used hormonal therapy, and a large proportion (27%) had been in transition for less than one year.

The investigators reported higher scores on the facial outcomes evaluation in those who had undergone facial feminization. Scores of the surgical cohorts for the presumptive SF-36 comprehensive mental health domain did not differ from the general U.S. female population. Scores of the "no surgery" cohort for the comprehensive mental health domain were statistically lower than those of the general U.S. female population, but within one standard deviation of the normative mean. Mean scores of all the gender dysphoric cohorts for the comprehensive physical domain were statistically higher than those of the general female U.S. population, but were well within one standard deviation of the normative mean. Analyses of inter-cohort differences for the SF-36 results were not conducted. Although the investigators commented on the potential disproportionate impact of hormone therapy on outcomes and differences in the time in "transition", they did not conduct any statistical analyses to correct for putative confounding variables.

Kraemer B, Delsignore A, Schnyder U, Hepp U. Body image and transsexualism. Psychopathology. 2008;41(2):96-100. Epub 2007 Nov 23.

Kraemer et al. conducted a single center (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design comparing pre-and post- surgical cohorts. Patients were required to meet DSM III or DSM IV criteria as applicable to the time of entry into the clinic. Post-surgical patients were from a long-term study group (Hepp et al., 2002). Pre-surgical patients were recent consecutive referrals. The assessment tool was the Fragebogen zur Beurteilung des eigenen Korpers (FBeK) which contained three domains.

There were 23 pre-operative patients: 7 (30.4%) female-to-male and 16 (69.6%) male-to-female (ratio 1:2.3). There were 22 post-operative patients: 8 (36.4 %) female-to-male and 14 (63.6%) male-to-female (ratio 1:1.8). The mean ages of the cohorts were as follows: pre-operative 33.0±11.3 years; post-operative 38.2±9.0 years. The mean duration after reassignment surgery was 51±25 months (range 5-96).

The pre-operative groups had statistically higher insecurity scores compared to normative data for the natal sex: female-to-male 9.0±3.8 versus 5.1±3.7; male-to-female 8.1±4.5 versus 4.7±3.1 as well as statistically lower self-confidence in one's attractiveness: female-to-male 3.1±2.9 versus 8.9±3.1; male-to-female 7.0±2.9 vs 9.5±2.6.

Mate-Kole C, Freschi M, Robin A. Aspects of psychiatric symptoms at different stages in the treatment of transsexualism. Br J Psychiatry. 1988 Apr;152: 550-3.

Mate-Kole at al. conducted a single site (London, United Kingdom) prospective non-blinded, observational study using a cross-sectional design and two psychological tests (one with some normative data). Concurrent controls were used in this study design. The investigators assessed neuroticism and sex role in natal males with gender dysphoria. Patients at various stages of management, (i.e., under evaluation, using cross-sex hormones, or post reassignment surgery [6 months to 2 years]) were matched by age of cross-dressing onset, childhood neuroticism, personal psychiatric history, and family psychiatric history. Both a psychologist and psychiatrist conducted assessments. The

instruments used were the Crown Crisp Experiential Index (CCEI) for psychoneurotic symptoms and the Bem Sex Role Inventory. ANOVA was used to identify differences between the three treatment cohorts.

For each cohort, investigators recruited 50 male-to-female patients from Charing Cross Hospital. The mean ages of the three cohorts were as follows: 34 years for patients undergoing evaluation; 35 years for wait-listed patients; and 37 years for post-operative patients. For the cohorts, 22% of those under evaluation, 24% of those on hormone treatment only, and 30% of those post-surgery had prior psychiatric histories, and 24%, 24%, while 14% in each cohort, respectively, had a history of attempted suicide. More than 30% of patients in each cohort had a first degree relative with a history of psychiatric disease.

The scores for the individual CCEI domains for depression and somatic anxiety were statistically higher (worse) for patients under evaluation than those on hormone treatment alone. The scores for all of the individual CCEI domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were statistically lower in the post-operative cohort than in the other two cohorts.

The Bem Sex Role Inventory masculinity score for the combined cohorts was lower than for North American norms for either men or women. The Bem Sex Role Inventory femininity score for the combined cohorts was higher than for North American norms for either men or women. Those who were undergoing evaluation had the most divergent scores from North American norms and from the other treatment cohorts. Absolute differences were small. All scores of gender dysphoric patients averaged between 3.95 and 5.33 on a 7 point scale while the normative scores averaged between 4.59 and 5.12.

Wolfradt U, Neumann K. Depersonalization, self-esteem and body image in male-to-female transsexuals compared to male and female controls. Arch Sex Behav. 2001 Jun;30(3):301-10.

Wolfradt and Neumann conducted a controlled, prospective, non-blinded, observational study using a cross-sectional design. The investigators assessed aspects of personality in male-to-female patients who had undergone vocal cord surgery for voice feminization and in healthy non-transgender volunteers from the region. The patients had undergone gender reassignment surgery 1 to 5 years prior to voice surgery. The volunteers were matched by age and occupation.

The primary hypothesis was that depersonalization, with the sense of being detached from one’s body or mental processes, would be more common in male-to- female patients with gender dysphoria. German versions of the Scale for Depersonalization Experiences (SDPE), the Body Image Questionnaire (BIQ), a Gender Identity Trait Scale (GIS), and the Self-Esteem Scale (SES) were used in addition to a question regarding global satisfaction. Three of the assessments used a 5 point scale (BIQ, GIS, and SDPE) for questions. One used a 4 point scale (SES). Another used a 7 point scale (global satisfaction). The study consisted of 30 male-to-female patients, 30 healthy female volunteers, and 30 healthy male volunteers. The mean age of study participants was 43 years (range 29- 67).

Results of the study revealed that there were no differences between the three groups for the mean scores of measures assessing depersonalization, global satisfaction, the integration of masculine traits, and body-image-rejected (subset). Also, the sense of femininity was equivalent for male-to-female patients and female controls and higher than that in male controls. The levels of self-esteem and body image-dynamic (subset) were equivalent for male-to-female patients and male controls and higher than that in female controls, and none of the numeric differences between means exceeded 0.61 units.

Kuhn A, Bodmer C, Stadlmayr W, Kuhn P, Mueller M, Birkhäuser M. Quality of life 15 years after sex reassignment surgery for transsexualism. Fertil Steril. 2009 Nov;92(5):1685-1689.e3. Epub 2008 Nov 6.

Kuhn et al. conducted a prospective, non-blinded, observational study using a cross-sectional design and semi-matched control cohort. The investigators assessed global satisfaction in patients who were from gynecology and endocrinology clinic (Bern, Switzerland), and who had undergone some aspect of gender reassignment surgery in the distant past, but were still receiving cross-sex hormones from the clinic. The quality of life assessment tools included a VAS and the King's Health Questionnaire (KHQ), which consists of eight domains with scores between zero and five or one and five, with lower scores indicating higher preference. The KHQ and the numerical change/difference required for clinical significance (≥5 points in a given domain, with higher scores being more pathologic) were included in the publication. Twenty healthy female controls from the medical staff who had previously undergone an abdominal or pelvic surgery were partially matched by age and body mass index (BMI), but not sex. No corroborative gynecologic or urologic evaluations were undertaken.

Of the 55 participants, three (5.4%) were female-to-male and 52 (94.5%) were male-to-female (ratio 1:17.3). Reassignment surgery had been conducted 8 to 23 years earlier (median 15 years). The median age of the patients at the time of this study was 51 years (range 39-62 years). The patients had undergone a median of nine surgical procedures in comparison to the two undergone by controls. Reassignment patients were less likely to be married (23.6% versus 65%; p=0.002); partnership status was unknown in five patients. The scores of VAS global satisfaction (maximal score eight) were lower for surgically reassigned patients (4.49±0.1 SEM) than controls (7.35±0.26 SEM) (p<0.0001).

The abstract stated that quality of life was lower in reassignment patients 15 years after surgery relative to controls. One table in the study, Table 2, delineated statistically and biologically significant differences for four of the eight KHQ domains between the patients and controls: physical limitation: 37.6±2.3 versus 20.9±1.9 (p<0.0001), personal limitation: 20.9±1.9 versus 11.6±0.4 (p<0.001), role limitation: 27.8+2.4 versus 34.6+1.7 (p=0.046), and general health: 31.7±2.2 versus 41.0±2.3 (p<0.02). There is a related paper by Kuhn et al. 2006.

Haraldsen IR, Dahl AA. Symptom profiles of gender dysphoric patients of transsexual type compared to patients with personality disorders and healthy adults. Acta Psychiatr Scand. 2000 Oct;102(4):276-81.

Haraldsen and Dahl conducted a single-center (Oslo, Norway) partially prospective, non-blinded, observational study using a cross-sectional design and a non-specific psychometric test. There was a control group, but it was not concurrent.

In the germane sub-study, the investigator assessed psychopathology in patients with gender dysphoria. Patients, who were independently evaluated by two senior psychiatrists, were required to meet DSM III-R or DSM IV diagnostic criteria and the Swedish criteria for reassignment surgery. The Norwegian version of the SCL-90 was used. The testing was conducted from 1987 to 1989 for those who had undergone reassignment surgery between 1963 and 1987 and from 1996 to 1998 for pre- surgical patients who had applied for reassignment surgery between 1996 and 1998. In addition, Axis I, Axis II, and Axis V (Global Functioning) was assessed.

Of 65 post–surgical and 34 pre-surgical patients, 59 post-surgical and 27 pre-surgical patients ultimately entered the study. The combined cohorts consisted of 35 (40.7%) female-to-male patients and 51 (59.3%) male-to-female patients (ratio 1:1.5). The ages were female-to-male 34±9.5 years and female-to-male 33.3±10.0 years. The other control group consisted of patients with personality disorder. Of these, 101 (27 men (33.9±7.3 years) and 74 women (31.6±8.2) were tested during a treatment program. One year later, 98% were evaluated. A total of 28 (32.5%) of the pre- and post- reassignment surgery patients had an Axis I diagnosis compared to 100 (99.0%) of those with personality disorders. Depression and anxiety were the most common diagnoses in both groups, but were approximately three to four times more common in the personality disorder cohort. Seventeen (19.8%) of the pre- and post-reassignment surgery patients had an Axis II diagnosis whereas the mean number of personality disorders in the personality disorder cohort was 1.7±1. The Global Assessment of Function was higher (better) in the gender

dysphoric groups (78.0±8.9) than in the personality disorder cohort (53.0±9.0).

Global Severity Indices (GSI) were highest for those with personality disorder regardless of gender and exceeded the cut-point score of 1.0. The GSI scores for females-to-males and males-to-females were 0.67±57 and 0.56±0.45. Although they were nominally higher than the healthy normative controls (males: 0.32±0.36 and females 0.41±0.43), they were well within the non- pathologic range. The same was true for the subscales.

SCL-90 GSI scores did not differ substantively between pre- and post-surgical patients, nor did the SCI subscale scores differ substantively between pre- and post-surgical patients. Any small non-significant differences tracked with the age and sex differences.

Beatrice J. A psychological comparison of heterosexuals, transvestites, preoperative transsexuals, and postoperative transsexuals. J Nerv Ment Dis. 1985 Jun;173(6):358-65. (United States study)

Beatrice conducted a prospective, non-blinded, observational study using a cross-sectional design and control cohorts in the U.S. The investigator assessed psychological adjustment and functioning (self-acceptance) in male-to-female patients with gender dysphoria (with and without GRS), transvestites from two university specialty clinics, and self-identified heterosexual males recruited from the same two universities. The criteria to qualify for the study included being known to the clinic for at least one year, cross-dressing for at least one year without arrest, attendance at 10 or more therapy sessions, emotionally self-supporting, and financially capable of payment for reassignment surgery, and all of these criteria were met by the pre-operative cohort as well as the post-operative cohort. The cohorts were matched to the post-operative cohort (age, educational level, income, ethnicity, and prior heterosexual object choice). The post-operative cohort was selected not on the basis of population representation, but on the basis of demographic feasibility for a small study. The instruments used were the Minnesota Multiphasic Personality Inventory (MMPI) and the Tennessee Self-Concept Scale (TSCS). Changes or differences considered to be biologically significant were not pre-specified.

Of the initial 54 recruits, ten subjects were left in each of the cohorts because of exclusions identified due to demographic factors. The mean age of each cohort were as follows: pre-operative gender dysphoric patients 32.5 (range 27-42) years, postoperative patients 35.1 (30-43) years old, transvestite 32.5 (29-37) years old, and heterosexual male 32.9 (28-38) years old. All were Caucasian. The mean age for cross-dressing in pre-operative patients (6.4 years) and post-operative patients (5.8 years) was significantly lower than for transvestites (11.8 years).

The scores for self-acceptance did not differ by diagnostic category or surgical status as measured by the TSCS instrument. As measured by the T-scored MMPI instrument (50±10), levels of paranoia and schizophrenia were higher for post-operative (GRS) patients (63.0 and 68.8) than transvestites (55.6 and 59.6) and heterosexual males (56.2 and 51.6). Levels of schizophrenia were higher for pre-operative patients (65.1) than heterosexual males (51.6). There were no differences between patients with gender dysphoria. Scores for the Masculine-Feminine domain were equivalent in those with transvestitism and gender dysphoria with or without surgery, but higher than in heterosexual males. The analysis revealed that despite the high level of socio-economic functioning in these highly selected subjects, the MMPI profiles based on the categories with the highest scores were notable for antisocial personality, emotionally unstable personality, and possible manic psychosis in the pre-operative GRS patients and for paranoid personality, paranoid schizophrenia, and schizoid personality in the post-operative GRS patients. By contrast, the same MMPI profiling in heterosexual males and transvestites was notable for the absence of psychological dysfunction.

d. Observational, surgical patients, longitudinal, with controls

Dhejne C, Lichtenstein P, Boman M, Johansson A, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One. 2011;6(2):e16885. Epub 2011 Feb 22.

Dhejne et al. conducted a retrospective, non-blinded, observational study of nation-wide mortality using a longitudinal and a population-based matched cohort. The investigators assessed conditions such as, but not limited to, mortality, suicide attempts, psychiatric hospitalization, and substance abuse in gender-reassigned persons and randomly selected unexposed controls matched by birth year and natal sex (1:10) as well as by birth year and the reassigned gender (1:10). Data were extracted from national databases including the Total Population Register (Statistics Sweden), the Medical Birth Register, the Cause of Death Register (Statistics Sweden), the Hospital Discharge Register (National Board of Health and Welfare), the Crime Register (National Council of Crime), and those from the Register of Education for highest educational level. The criteria required to obtain the initial certificate for reassignment surgery and change in legal status from the National Board of Health and Welfare were the 2002 WPATH criteria and included evaluation and treatment by one of six specialized teams, name change, a new national identity number indicative of gender, continued use of hormones, and sterilization/castration. Descriptive statistics with hazard ratios were provided.

Investigators identified 804 patients with gender identity disorder (or some other disorder) in Sweden during the period from 1973 to 2003 inclusive. Of these patients, 324 (40.3%) underwent gender-reassignment surgery (133 female-to-male [41.0%]; 191 male-to-female [59.0%]; ratio 1:1.4). The average follow-up time for all-cause mortality was 11.4 years (median 9.1). The average follow-up time for psychiatric hospitalization was 10.4 years (median 8.1).

The mean ages in female-to-male and male-to-female reassigned patients were: 33.3±8.7 (range 20–62) and 36.3± 10.1 (range 21–69) years, respectively. Immigrant status was two times higher in reassigned patients (n=70, 21.6%) than in either type of control (birth [natal] sex matched n=294 [9.1%] or reassigned gender matched n=264 [8.1%]). Educational attainment (10 or more years) was somewhat lower for reassigned patients (n=151 [57.8%]) than in either type of control (birth sex matched n=1,725 [61.5%] or reassigned gender matched n=1804 [64.3%]) (cohort data were incomplete). The biggest discordance in educational attainment was for female-to-male reassigned patients regardless of the control used. Prior psychiatric morbidity (which did not include hospitalization for gender dysphoria) was more than four times higher in reassigned patients (n=58, 17.9%) than in either type of control (birth sex matched n=123 [3.8%] or reassigned gender matched n=114 [3.5%]).

All-cause mortality was higher for patients who underwent gender reassignment surgery (n=27 [8.3%]) than in controls (hazard ratio 2.8 [CI 1.8-4.3]) even after adjustment for covariants (prior psychiatric morbidity and immigration status). Divergence in the survival curves began at 10 years. Survival rates at 20 year follow-up (as derived from figure 1) were: female control 97%, male controls 94%, female-to-male patients 88%, and male-to-female patients 82%. The major contributor to this mortality difference was completed suicide (n=10 [3.1%]; adjusted hazard ratio 19.1 [CI 5.8-62.9]). Mortality due to cardiovascular disease was modestly higher for reassigned patients (n=9 [2.8%]) than in controls (hazard ratio 2.5 [CI 1.2-5.3]).

Suicide attempts were more common in patients who underwent gender reassignment surgery (n= 29 [9.0%] than in controls (adjusted hazard ratio 4.9 [CI 2.9–8.5]). Male-to-female patients were at higher adjusted risk for attempted suicide than either control whereas female-to-male patients were at higher adjusted risk compared to only male controls and maintained the female pattern of higher attempted suicide risk. Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common in reassigned persons n= 64 [20.0%] than in controls (hazard ratio 2.8 [CI 2.0–3.9]) even after adjusting for prior psychiatric morbidity. Hospitalization for substance abuse was not greater than either type of control.

The nationwide mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landén (1998) patient population and much of the Dhejne et al. (2014) population.

Dhejne C, Öberg K, Arver S, Landén M. An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. Arch Sex Behav. 2014 Nov;43(8):1535-45. Epub 2014 May 29 and Landén M, Wålinder J, Hambert G, Lundström B. Factors predictive of regret in sex reassignment. Acta Psychiatr Scand. 1998 Apr;97(4):284 (Dhejne et al., 2014; Landén et al., 1998) Sweden-All

Dhejne et al. conducted a non-blinded, observational study that was longitudinal for the capture of patients with "regret" in a national database. This same group (Landén et al., 1998) conducted a similar study along with retrospective acquisition of clinical data to explore the differences between the cohorts with and without regret. There were no external controls; only intra- group comparisons for this surgical series.

The investigators assessed the frequency of regret for gender reassignment surgery. Data were extracted from registries at the National Board of Health and Welfare to which patients seeking reassignment surgery or reversal of reassignment surgery make a formal application and which has maintained such records since a 1972 law regulating surgical and legal sex reassignment. The investigators reviewed application files from 1960 through 2010. The specific criteria to qualify for gender surgery were not delineated. Patients typically underwent diagnostic evaluation for at least one year. Diagnostic evaluation was typically followed by the initiation of gender confirmation treatment including hormonal therapy and real-life experience. After two years of evaluation and treatment, patients could make applications to the national board. Until recently sterilization or castration were the required minimal surgical procedures (Dhejne et al., 2011). Secular changes in this program included consolidation of care to limited sites, changes in accepted diagnostic criteria, and provision of non-genital surgery, e.g., mastectomy during the real- life experience phase, and family support.

There were 767 applicants for legal and surgical reassignment (289 [37.7%] female-to-male and 478 [62.3%] male-to-female; ratio 1:1.6). The number of applicants doubled each ten year interval starting in 1981.

Of the applicants, 88.8% or 681 (252 [37.0%] female-to-male and 429 [63.0%] male-to-female; ratio 1:1.7] had undergone surgery and changed legal status by June 30, 2011. This number included eight (four [50.0%] female-to-male and four [50.0%] male to female; ratio 1:1) people who underwent surgery prior to the 1972 law. This number appears to include 41 (two [4.9%] female-to-male and 39 [95.1%] male-to-female; ratio 1:19.5) people who underwent surgery abroad at their own expense (usually in Thailand or the U.S.). This cohort (6% of 681) includes one person who was denied reassignment surgery by Sweden.

Twenty-five (3.3%) of the applications were denied with the two most common reasons being an incomplete application or not meeting the diagnostic criteria. An additional 61(8.0%) withdrew their application, were wait-listed for surgery, postponed surgery (perhaps in hopes of the later revocation of the sterilization requirement), or were granted partial treatment.

The formal application for reversal of the legal gender status, the "regret rate", was 2.2%. No one who underwent sex- reassignment surgery outside of Sweden (36 of these 41 had surgery after 1991) has requested reversal. The authors noted, however, that this preliminary number may be low because the median time interval to reversal request was eight years-only three of which had elapsed by publication submission- and because it was the largest serial cohort. This number did not include other possible expressions of regret including suicide (Dhejne et al., 2011).

Dhejne et al. in 2014 reported that the female-to-male (n=5): male-to-female (n=10) ratio among those who made formal applications for reversal was 1:2. The investigators also reported that the female-to-male applicants for reversal were younger at the time of initial surgical application (median age 22 years) than the complete female-to-

male cohort at the time of surgical application (median age 27 years). By contrast the male-to-female applicants for reversal were older at the time of initial surgical application (median age 35 years) than the complete male-to-female cohort at the time of initial surgical application (median age 32 years). Other clinical data to explore the differences between the cohorts with and without regret were not presented in this update publication.

In their earlier publication, in addition to determining a regret rate (3.8%), Landén et al. extracted data from medical records and government verdicts. Pearson Chi-square testing with Yates' correction for small sample sizes was used to identify candidate variables predictive of regret. They observed that: (a) 25.0% of the cohort with regrets and 11.4% of the cohort without regrets were unemployed, (b) 16.7% of the cohort with regrets and 15.4% of the cohort without regrets were on "sick benefit", (c) 15.4% of the cohort with regrets and 13.9% of the cohort without regrets had problems with substance abuse, (d) 69.2% of the cohort with regrets and 34.6% of the cohort without regrets had undergone psychiatric treatment, (e) 15.4% of the cohort with regrets and 8.8% of the cohort without regrets had a mood disorder, and (f) 15.4% of the cohort with regrets and 1.5% of the cohort without regrets had a psychotic disorder.

The putative prognostic factors that were statistically different between the cohorts with and without regret included prior psychiatric treatment, a history of psychotic disorder, atypical features of gender identity, and poor family support. Factors that trended towards statistical difference included having an unstable personality, sexual orientation and transvestitism. Univariate regression analyses further clarified the most important variables. These variables were tested with logistic regression. Initial modeling included the variable "history of psychotic disorder". Although this variable was predictive, it was excluded from future analyses because it was already a contraindication to reassignment surgery. Additional multivariate regression analyses identified poor family support as the most predictive variable and atypical features of gender identity as the second most important variable. Presence of both variables had a more than additive effect.

The nationwide mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landén (1998) patient population and most of the Dhejne (2014) population. There is a related paper by Landén et al. 1998b that included the criteria to qualify for surgical intervention at that time.

Heylens G, Verroken C, De Cock S, T'Sjoen G, De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. J Sex Med. 2014 Jan;11(1):119-26. Epub 2013 Oct 28.

Heylens et al. conducted a prospective, non-blinded observational study using a longitudinal design in which patients served as their own controls. They used a non-specific psychiatric test with normative data along with two self-designed questionnaires. The investigators assessed psychosocial adjustment and psychopathology in patients with gender identity disorders. Patients were to be sequentially evaluated prior to institution of hormonal therapy, then 3 to 6 months after the start of cross-sex hormone treatment, and then again one to 12 months after reassignment surgery. The Dutch version of the SCL-90R with eight subscales (agoraphobia, anxiety, depression, hostility, interpersonal sensitivity, paranoid ideation/psychoticism, and sleeping problems) and a global score (psycho-neuroticism) was used serially. A seven parameter questionnaire was used serially to assess changes in social function. Another cross-sectional survey assessed emotional state. The cohorts at each time point consisted of patients who were in the treatment cohort at the time and who had submitted survey responses.

Ninety of the patients who applied for reassignment surgery between June 2005 and March 2009 were recruited. Fifty seven entered the study. Forty-six (51.1% of the recruited population) underwent reassignment surgery. Baseline questionnaire information was missing for 3 patients. Baseline SCL-90 scores were missing for 1 patient but included SCL-90 scores from some of the 11 recruits who had not yet undergone reassignment surgery. Time point 2 (after hormone therapy) SCL-90 information was missing for 10, but included SCL-90 scores from some of the 11

recruits who had not yet undergone reassignment surgery. At time point 3, 42 (91.3% of those who underwent reassignment surgery) patients completed some part of the SCL-90 survey and the psychosocial questionnaires. Some questionnaires were incomplete. The investigators reported response rates of 73.7% for the psychosocial questionnaires and 82.5% for the SCL-90.

Of those who responded at follow-up after surgery, 88.1% reported having good friends; 52.4% reported the absence of a relationship; 47.6% had no sexual contacts; 42.9% lived alone; 40.5% were unemployed, retired, students, or otherwise not working; 2.4% reported alcohol abuse; and 9.3% had attempted suicide. The frequency of these parameters reportedly did not change statistically during the study interval, but there was no adjustment for the inclusion of patients who did not undergo surgery.

In a cross-sectional, self-report mood survey, of the 42 study entrants who completed the entire treatment regimen including reassignment surgery and the final assessment (refers to the initial 57) reported improved body-related experience (97.6%), happiness (92.9%), mood (95.2%), and self-confidence (78.6%) and reduced anxiety (81.0%). Of participants, 16.7% reported thoughts of suicide. Patients also reported on the intervention phase that they believed was most helpful: hormone initiation (57.9%), reassignment surgery (31.6%), and diagnostic-psychotherapy phase (10.5%).

The global “psycho-neuroticism” SCL-90R score, along with scores of 7 of the 8 subscales, at baseline were statistically more pathologic than the general population. After hormone therapy, the score for global “psycho-neuroticism” normalized and remained normal after reassignment surgery. More specifically the range for the global score is 90 to 450 with higher scores being more pathologic. The score for the general population was 118.3±32.4. The respective scores for the various gender dysphoric cohorts were 157.7±49.8 at initial presentation, 119.7±32.1 after hormone therapy, and 127.9±37.2 after surgery. The scores for the general population and the scores after either hormone treatment or surgical treatment did not differ.

Kockott G, Fahrner EM. Transsexuals who have not undergone surgery: a follow-up study. Arch Sex Behav. 1987 Dec;16 (6):511-22.

Kockott and Fahrner conducted a single center (Munich, Germany) prospective, observational study using a longitudinal design. Treatment cohorts were used as controls, and patients served as their own controls. The investigators assessed psychosocial adjustment in patients with gender identity issues. Patients were to have met DSM III criteria. Trans-sexuality, transvestitism, and homosexuality were differentiated. The criteria required for patients to receive hormone therapy and/or reassignment surgery were not delineated. After receiving hormone therapy, patients were later classified by surgical reassignment status (pre-operative and post-operative) and desire for surgery (unchanged desire, hesitant, and no longer desired).

The first investigative tool was a semi-structured in-person interview consisting of 125 questions. The second investigative tool was a scale that organized the clinical material into nine domains which were then scored on a scale. The Psychological Integration of Trans-sexuals (PIT) instrument developed according to the scale used by Hunt and Hampson (1980) for assessment of 17 post-operative patients. There were 15 interviews and two separate interviewers. There were 80 patients identified, but 58 (72.5%) patients (26 pre-operative; 32 post-operative) were ultimately included in the analysis. The duration of follow-up was longer for post-operative patients (6.5 years) than for pre-operative patients (4.6 years) (including time for one patient subsequently excluded). The mean age of the post-operative patients was 35.5±13.1 years, and the age of the patients who maintained a continued desire for surgery was 31.7±10.2 years. The age of the patients who hesitated about surgery was somewhat older, 40.3±9.4 years. The age of the patients who were no longer interested in surgery was 31.8±6.5 years. All were employed or in school at baseline. Patients with hesitation were financially better-off, had longer-standing relationships even if unhappy, and had a statistical tendency to place less value on sex than those with an unchanged wish for surgery.

Post-operative patients more frequently reported contentment with the desired gender and the success of adaption to the gender role than the pre-operative patients with a persistent desire for surgery. Post-operative patients more frequently reported sexual satisfaction than pre-operative patients with a continuing desire for surgery. Post-operative patients also more frequently reported financial sufficiency and employment than pre-operative patients with a persistent desire for surgery. Suicide attempts were stated to be statistically less frequent in the post-surgical cohort.

Psychosocial adjustment scores were in the low end of the range with "distinct difficulties" (19-27) at the initial evaluation for the post-operative patients (19.7), the pre-operative patients with a persistent wish for surgery (20.2), and the hesitant patients (19.7). At initial evaluation, psychosocial adjustment scores for patients no longer wanting surgery were at the high end of the range with "few difficulties" (10-18). At the final evaluation, Psychosocial adjustment scores were at the high end of the range "few difficulties" (10-18) for the post-operative patients (13.2) and the patients no longer wanting surgery (16.5). Psychosocial adjustment scores at the final evaluation were in the borderline range between "few difficulties" (10-18) and "distinct difficulties" (19-27) for both the pre-operative patients with a persistent desire for surgery (18.7), and the hesitant patients (19.1).

The changes in the initial score and the final follow-up score within each group were tracked and reported to be statistically significant for the post-operative group, but not for the other groups. Statistical differences between groups were not presented. Moreover, the post-operative patients had an additional test immediately prior to surgery. The first baseline score (19.7) would have characterized the patients as having "distinct difficulties" in psychosocial adjustment while the second baseline score (16.7) would have categorized the patients as having "few difficulties" in psychosocial adjustment despite the absence of any intervention except the prospect of having imminent reassignment surgery. No statistics reporting on the change between scores of the initial test and the test immediately prior to surgery and the change between scores of the test immediately prior to surgery and the final follow-up were provided.

Meyer JK, Reter DJ. Sex reassignment. Follow-up. Arch Gen Psychiatry. 1979 Aug;36(9):1010-5. (United States study)

Meyer and Reter conducted a single-center (Baltimore, Maryland, U.S.) prospective, non-blinded, observational study using a longitudinal design and retrospective baseline data. Interview data were scored with a self-designed tool. There were treatment control cohorts, and patients served as their own controls. The investigators assessed patients with gender dysphoria. The 1971 criteria for surgery required documented cross-sex hormone use as well as living and working in the desired gender for at least one year in patients subsequently applying for surgery. Clinical data including initial interviews were used for baseline data. In follow-up, the investigators used extensive two to four hour interviews to collect information on (a) objective criteria of adaptation, (b) familial relationships and coping with life milestones, and (c) sexual activities and fantasies. The objective criteria, which were the subject of the publication, included employment status (Hollingshead job level), cohabitation patterns, and need for psychiatric intervention. The investigators designed a scoring mechanism for these criteria and used it to determine a global adjustment score. The score value or the change score that was considered to be biologically significant was not pre-specified in the methods.

The clinic opened with 100 patients, but when the follow-up was completed, 52 patients were interviewed and 50 gave consent for publication. Of these, 15 (four female-to-male, 11 male-to-female; ratio 1:2.8) were part of the initial operative cohort, 14 (one female-to-male; 13 male-to-female; ratio 1:13) later underwent reassignment surgery at the institution or elsewhere, and 21 (five female-to-male; 16 male-to-female; ratio 1:3.2) did not undergo surgery. The mean ages of these cohorts were 30.1, 30.9, and 26.7 years respectively. The mean follow-up time was 62 months (range 19-142) for those who underwent surgery and 25 months (range 15-48) for those who did not. Socioeconomic status was lowest in those who subsequently underwent reassignment surgery.

Of patients initially receiving surgery, 33% had some type of psychiatric contact prior to the initial clinic evaluation and 8% had psychiatric contact during the follow-up. Of the patients who had not under gone surgery or who had done so later, 72% had some type of psychiatric contact prior to the initial clinic evaluation and 28% had psychiatric contact during follow-up. There was a single female-to-male patient with multiple surgical complications who sought partial reassignment surgery reversal.

The adjustment scores improved over time with borderline statistical significance for the initial operative group and with statistical significance for the never operated group. The absolute score value at follow-up was the same for both groups (1.07+1.53 and 1.10+1.97 respectively). By contrast, the adjustment scores did not improve for those who were not in the cohort initially approved for surgery, but who subsequently underwent surgery later. This was particularly true if the surgery was performed elsewhere. The absolute score value at follow-up was 0.21+1.89.

Related papers include Meyer et al. (1971), Meyer et al. (1974a-d), and Derogatis et al. (1978) along with commentary response by Fleming et al. (1980).

Rakic Z, Starcevic V, Maric J, Kelin K. The outcome of sex reassignment surgery in Belgrade: 32 patients of both sexes. Arch Sex Behav. 1996 Oct;25(5):515-25.

Rakic et al. single-center (Belgrade, Yugoslavia) conducted a prospective, non-blinded, observational study using a cross-sectional design and an investigator- designed quality of life tool that asked longitudinal (pre- and post-treatment) questions. Patients served as their own controls. The authors state that the study was not designed to assess the predictors of poor outcomes.

The investigators assessed global satisfaction, body image, relationships, employment status, and sexual function in patients with gender dysphoria who underwent reassignment surgery between 1989 and 1993 and were at least six months post-operative. The criteria to qualify for gender surgery were delineated (1985 standards from the Harry Benjamin International Gender Dysphoria Association) and included cross-gender behavior for at least one year and sexual orientation to non-natal sex. The questionnaire consisted of 10 questions using yes/no answers or Likert-type scales. Findings were descriptive without statistical analysis. As such, changes or differences considered to be biologically significant were not pre-specified, and there were no adjustments for multiple comparisons.

Of the 38 patients who had undergone reassignment surgery, 34 were eligible for the study and 32 participated in the study (two were lost to follow-up and four were in the peri-operative period) - 10 (31.2%) female-to-male and 22 (68.8%) male-to-female (ratio 1:2.2). The duration of follow-up was 21.8 ±13.4 months (range 6 months to 4 years). The age was female-to-male 27.8±5.2 (range 23-37) and male-to-female 26.4±7.8 (range 19-47).

Using an investigator-designed quality of life tool, all patients reported satisfaction with having undergone the surgery. Of the total participants, four (12.5%) (all male-to-female) and eight (25%) (87.5% male-to-female) reported complete dissatisfaction or partial satisfaction with their appearance. Regarding relationships, 80% of female-to-male and 100% of male-to-female patients were dissatisfied with their relationships with others prior to surgery; whereas, no female-to-male patients and 18.1% of male-to-female patients were dissatisfied with relationships after surgery. Regarding sexual partners, 60% of female-to-male and 72.7% of male-to-female patients reported not having a sexual partner prior to surgery; whereas, 20% of female-to-male patients and 27.3% of male-to-female patients did not have a sexual partner after surgery. Of those with partners at each time interval, 100% of female-to-male and 50% of male-to-female patients reported not experiencing orgasm prior to surgery; whereas, 75% of female-to-male and 37.5% of male-to-female patients reported not experiencing orgasm after surgery.

Ruppin U, Pfäfflin F. Long-term follow-up of adults with gender identity disorder. Arch Sex Behav. 2015 Jul;44(5):1321-9. Epub 2015 Feb 18.

Ruppin and Pfafflin conducted a single-center (Ulm, Germany) partially prospective, non-blinded, observational study using a longitudinal design and non-specific psychometric tests and a self-designed interview tool and questionnaire. Patients served as their own controls.

The investigators assessed psychological symptoms, interpersonal difficulties, gender role stereotypes, personality characteristics, societal function, sexual function, and satisfaction with new gender role in patients with gender dysphoria. Patients were required to have met the ICD-10 criteria for trans-sexualism, been seen by the clinic by prior to 2001, and completed an official change in gender including name change prior to 2001. Assessment tools included German versions of standardized surveys with normative data: the SCL 90R, the Inventory of Interpersonal Problems (IIP), Bem Sex Role Inventory (BSRI), and the Freiburg Personality Inventory (FPI-R), along with semi-structured interviews with self-designed questionnaires. The prospective survey results were compared to retrospective survey results. Changes or inter-group differences considered to be biologically significant were not pre-specified. Diagnostic cut points were not provided. Statistical corrections for multiple comparisons were not included.

Overall, 140 patients received recruitment letters and then 71 (50.7%) agreed to participate. Of these participants, 36 (50.7%) were female-to-male; 35 (49.3%) were male-to-female (ratio 1:0.97). The ages of the patients were: 41.2±5.78 years (female-to-male) and 52.9±10.82 years (male-to-female). The intervals for follow-up were 14.1±1.97 years and 13.7±2.17 years, respectively.

All female-to-male patients had undergone mastectomy; 91.7% had undergone oopherectomy and/or hysterectomy; 61.1% had undergone radial forearm flap phalloplasty or metaoidioplasty. Of male-to-female patients, 94.3% had undergone vaginoplasty and perhaps an additional procedure (breast augmentation, larynx surgery, or vocal cord surgery). Two male-to-female patients had not undergone any reassignment surgery, but were still included in the analyses.

A total of 68 patients ranked their well-being as 4.35±0.86 out of five (three patients did not respond to this question). Of respondents, 40% reported not being in a steady relationship. Regular sexual relationships were reported by 57.1% of 35 female- to-male respondents and 39.4% of 33 male-to-female respondents (three patients did not respond to this question). A total of 11 patients reported receiving out-patient psychotherapy; 69 did not express a desire for gender role reversal (two did not respond to this question). The response rate was less than 100% for most of the self-designed survey questions.

Changes from the initial visit to the follow-up visit were assessed for the SCL-90R in 62 of 71 patients. The effect size was statistically significant and large only for the “Interpersonal Sensitivity” scale (one of 10 parameters). The absolute magnitude of mean change was small: from 0.70±0.67 to 0.26±0.34 (scale range 0-4). The duration of follow-up did not correlate with the magnitude of change on the various scales. Differences in baseline SCL-90R scores of 62 participants were compared with the score of 63 of the 69 eligible recruits who declined to enter the study and were notable for higher “Depression” scores for the latter.

Changes from the initial visit to the follow-up visit were assessed for the IIP in 55 of 71 patients. The effect size was statistically significant and large only for the “Overly Accommodating” scale (one of eight parameters). The absolute magnitude of mean change was small: from 11.64±5.99 to 7.04±4.73 (scale range 0-32). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the FPI-R in 58 of 71 patients. The effect size was statistically significant and large only for the “Life Satisfaction” scale (one of 12 parameters). The absolute magnitude of mean change was substantive: from 4.43±2.99 to 8.31±2.63 (scale range 0-12). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the BSRI in 16 of 36 female to male patients and 19 of 35 male to female patients. The "Social Desirability" score increased for the female-to-male respondents. At endpoint, both categories of respondents reported androgynous self-images.

This current report is an update of prior publications by Pfafflin including work with Junge which was published in a variety of formats and initially in German.

Smith YL, Van Goozen SH, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005 Jan;35(1):89-99.

Smith et al. conducted a single-center (Amsterdam, Netherlands) prospective, non-blinded, observational study using a longitudinal design and psychological function tools. Patients served as their own control prior to and after reassignment surgery. The investigators assessed gender dysphoria, body dissatisfaction, physical appearance, psychopathology, personality traits, and post-operative function in patients with gender dysphoria. Patients underwent some aspect of reassignment surgery. The test instruments included the Utrecht Gender Dysphoria Scale (12 items), the Body Image Scale adapted for a Dutch population (30 items), Appraisal of Appearance Inventory (3 observers, 14 items), the Dutch Short MMPI (83 items), the Dutch version of the Symptom Checklist (SCL)(90 items), and clinic-developed or modified questionnaires. Pre-treatment data was obtained shortly after the initial interview. Post- surgery data were acquired at least one year post reassignment surgery.

Three hundred twenty five consecutive adolescents and adults were screened for the study. One-hundred three (29 [28.2%] female-to-male patients and 74 [71.8%] male-to-female patients [ratio 1:2.6]) never started hormone therapy; 222 (76 [34.2%] female-to-male patients and 146 [65.8%] male-to-female patients [ratio 1:1.9]) initiated hormone therapy. Of the patients who started hormone therapy, 34 (5 [14.7%] female-to-male patients and 29 [85.3%] male-to-female patients [ratio 1:5.8]) discontinued hormone therapy.

Subsequently, the study analysis was limited to adults. One hundred sixty-two (58 [35.8%] female-to-male and 104 [64.2%] male-to-female [ratio 1:1.8]) were eligible and provided pre-surgical test data, and 126 (77.8% of eligible adults) (49 [38.9%] female-to-male and 77 [61.1%] male-to-female [ratio 1:1.6]) provided post-surgical data. For those patients who completed reassignment, the mean age at the time of surgical request was 30.9 years (range 17.7-68.1) and 35.2 years (range 21.3-71.9) years at the time of follow-up. The intervals between hormone treatment initiation and surgery and surgery and follow-up were 20.4 months (range 12 to 73) and 21.3 months (range 12 to 47) respectively.

Of the 126 adults who provided post-surgical data, 50 (40.0%) reported having a steady sexual partner, three (2.3%) were retired, and 58 (46.0%) were unemployed. Regarding regret, six patients expressed some regret regarding surgery, but did not want to resume their natal gender role, and one male-to-female had significant regret and would not make the same decision.

Post-surgery Utrecht dysphoria scores dropped substantially and approached reportedly normal values. The patients' appearance better matched their new gender. No one was dissatisfied with his/her overall appearance at follow-up. Satisfaction with primary sexual, secondary sexual, and non-sexual body traits improved over time. Male-to-female patients, however, were more dissatisfied with the appearance of primary sex traits than female-to-male patients. Regarding mastectomy, 27 of 38 (71.1%) female-to-male respondents (not including 11 non-respondents) reported incomplete satisfaction with their mastectomy procedure. For five of these patients, the incomplete satisfaction was because of scarring. Regarding vaginoplasty, 20 of 67 (29.8%) male-to-female respondents (not including 10 non-respondents) reported incomplete satisfaction with their vaginoplasty.

Most of the MMPI scales were already in the normal range at the time of initial testing and remained in the normal

range after surgery. SCL global scores for psycho- neuroticism were minimally elevated before surgery 143.0±40.7 (scoring range 90 to 450) and normalized after surgery 120.3±31.4. (An analysis using patient level data for only the completers was not conducted.)

Udeze B, Abdelmawla N, Khoosal D, Terry T. Psychological functions in male-to- female people before and after surgery. Sexual and Relationship Therapy. 2008 May; 23(2):141-5. (Not in PubMed) and Megeri D, Khoosal D. Anxiety and depression in males experiencing gender dysphoria. Sexual and Relationship Therapy. 2007 Feb; 22(1):77-81. (Not in PubMed)

Udeze et al. conducted a single-center (Leicester, United Kingdom) prospective, non-blinded, longitudinal study assessing a randomized subset of patients who had completed a non-specific psychological function tool prior to and after male-to-female reassignment surgery. Patients served as their own controls. The investigators used the WPATH criteria for patient selection. Psychiatric evaluations were routine. All patients selected for treatment were routinely asked to complete the self-administered SCL-90R voluntarily on admission to the program and post-operatively. A post-operative evaluations (psychiatric and SCL-90R assessment) were conducted within six months to minimize previously determined loss rates. The patient pool was domestic and international. There were 546 gender dysphoric patients from all over the United Kingdom and abroad, of whom 318 (58.2%) progressed to surgery. Of these, 127 were from the local Leicester area in the United Kingdom and 38 (29.9%) progressed to surgery. The mean age for the selected male-to-female patients at the time of study was 47.33±13.26 years (range 25 to 80) and reflected an average wait time for surgery of 14 months (range 2 months to 6 years). For this investigation, 40 male-to-female subjects were prospectively selected.

The raw SCL-90 global scores for psycho-neuroticism were unchanged over time: 48.33 prior to surgery and 49.15 after surgery. If the scale was consistent with T-scoring, the results were non-pathologic. No psychiatric disorders were otherwise identified prior to or after surgery.

Investigators from the same clinical group (Megeri, Khoosal, 2007) conducted additional testing to specifically address anxiety and depression with the Beck Depression Inventory, General Health Questionnaire (with 4 subscales), HADS, and Spielberger State and Trait Anxiety Questionnaire (STAI-X1 and STA-X2). The test population and study design appear to be the same. No absolute data were presented. Only changes in scores were presented. There were no statistically significant changes.

e. Randomized, surgical patients, longitudinal, with controls

Mate-Kole C, Freschi M, Robin A. A controlled study of psychological and social change after surgical gender reassignment in selected male transsexuals. Br J Psychiatry. 1990 Aug;157:261-4.

Mate-Kole at al. conducted a prospective, non-blinded, controlled, randomized, longitudinal study using investigator-designed patient self-report questionnaires and non-specific psychological tests with some normative data. The investigators assessed neuroticism and sex role in natal males with gender dysphoria who had qualified for male-to-female reassignment surgery at a single-center specialty clinic (London, United Kingdom). Forty sequential patients were alternately assigned to early reassignment surgery or to standard wait times for reassignment surgery. Patients were evaluated after acceptance and 2 years later. The criteria used to qualify for gender surgery were the 1985 standards from the Harry Benjamin International Gender Dysphoria Association. These included a ≥2 year desire to change gender, a ≥1 year demonstrable ability to live and be self-supporting in the chosen gender, and psychiatric assessment for diagnosis and reassessment at six months for diagnostic confirmation and exclusion of psychosis.

Reassignment surgery was defined as orchidectomy, penectomy, and construction of a neo-vagina. The instruments used were the CCEI for psychoneurotic symptoms and the Bem Sex Role Inventory along with an incompletely

described investigator- designed survey with questions about social life and sexual activity.

The mean age and range of the entire cohort was 32.5 years (21-53). Members of the early surgery cohort had a history of attempted suicide (one patient), psychiatric treatment for non-gender issues (six patients), and first degree relatives with psychiatric histories (four patients). Members of the standard surgery cohort were similar, with a history of attempted suicide (two patients), psychiatric treatment for non-gender issues (five patients), and first degree relatives with psychiatric histories (six patients). The early surgery group had surgery approximately 1.75 years prior to the follow-up evaluation. In both groups, cross-dressing began at about age 6.

At baseline, the Bem Sex Role Inventory femininity scores were slightly higher than masculinity scores for both cohorts and were similar to Bem North American female normative scores. The scores did not change in either group over time.

At baseline, the scores for the CCEI individual domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were similar for the cohorts. The total CCEI scores for the two cohorts were consistent with moderate symptoms (Birchnell et al. 1988). Over the two year interval, total CCEI scores increased for standard wait group and approached the relatively severe symptom category. During the same interval, scores dropped into the asymptomatic rage for the post-operative patients.

The investigator-designed survey assessed changes in social and sexual activity of the prior two years, but the authors only compared patients in a given cohort to themselves. Though the researchers did not conduct statistical studies to compare the differences between the two cohorts, they did report increased participation in some, but not all, types of social activities such as sports (solo or group), dancing, dining out, visiting pubs, and visiting others. Sexual interest also increased. By contrast, pre-operative patients did not increase their participation in these activities.

2. External Technology Assessments

a. CMS did not request an external technology assessment (TA) on this issue.

b. There were no AHRQ reviews on this topic.

c. There are no Blue Cross/Blue Shield Health Technology Assessments written on this topic within the last three years.

d. There were two publications in the COCHRANE database, and both were tangentially related. Both noted that there are gaps in the clinical evidence base for gender reassignment surgery.
Twenty Years of Public Health Research: Inclusion of Lesbian, Gay, Bisexual, and Transgender Populations Boehmer U. Am J Public Health. 2002; 92: 1125–30.

"Findings supported that LGBT issues have been neglected by public health research and that research unrelated to sexually transmitted diseases is lacking."

A systematic review of lesbian, gay, bisexual and transgender health in the West Midlands region of the UK compared to published UK research. West Midlands Health Technology Assessment Collaboration. Health Technology Assessment Database. Meads, et al., 2009. No.3.

"Further research is needed but must use more sophisticated designs with comparison groups. This systematic review demonstrated that there are so many gaps in knowledge around LGBT health that a wide variety of studies are needed."

e. There were no National Institute for Health and Care Excellence (NICE) reviews/guidance documents on this

topic.

f. There was a technology assessment commissioned by the New Zealand Ministry of Health and conducted by New Zealand Health Technology Assessment (NZHTA) (Christchurch School of Medicine and the University of Otago).

Tech Brief Series: Transgender Re-assignment Surgery Day P. NZHTA Report. February 2002;1(1). http://nzhta.chmeds.ac.nz/publications/trans_gender.pdf

The research questions included the following:
1. Are there particular subgroups of people with transsexualism who have met eligibility criteria for gender reassignment surgery (GRS) where evidence of effectiveness of that surgery exists?

2. If there is evidence of effectiveness, what subgroups would benefit from GRS?"

The authors concluded that there was not enough evidence to answer either of the research questions.

3. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Meeting

CMS did not convene a MEDCAC meeting.

4. Evidence-Based Guidelines

a. American College of Obstetricians and Gynecologists (ACOG)

Though ACOG did not have any evidence-based guidelines on this topic, they did have the following document:
Health Care for Transgender Individuals: Committee Opinion
Committee on Health Care for Underserved Women; The American College of Obstetricians and Gynecologists. Dec 2011, No. 512. Obstet Gyncol. 2011;118:1454-8.

"Questions [on patient visit records] should be framed in ways that do not make assumptions about gender identity, sexual orientation, or behavior. It is more appropriate for clinicians to ask their patients which terms they prefer. Language should be inclusive, allowing the patient to decide when and what to disclose. The adoption and posting of a nondiscrimination policy can also signal health care providers and patients alike that all persons will be treated with dignity and respect. Assurance of confidentiality can allow for a more open discussion, and confidentiality must be ensured if a patient is being referred to a different health care provider. Training staff to increase their knowledge and sensitivity toward transgender patients will also help facilitate a positive experience for the patient."

b. American Psychiatric Association

Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder. Byne, W, Bradley SJ, Coleman E, Eyler AE, Green R, Menvielle EJ, Meyer-Bahlburg HFL, Richard R. Pleak RR, Tompkins DA. Arch Sex Behav. 2012; 41:759–96.

The American Psychiatric Association (APA) was unable to identify any Randomized Controlled Trials (RTCs) regarding mental health issues for transgender individuals.

"There are some level B studies examining satisfaction/regret following sex reassignment (longitudinal follow-up after an intervention, without a control group); however, many of these studies obtained data retrospectively and without a control group (APA level G). Overall, the evidence suggests that sex reassignment is associated with an

improved sense of well-being in the majority of cases, and also indicates correlates of satisfaction and regret. No studies have directly compared various levels of mental health screening prior to hormonal and surgical treatments on outcome variables; however, existing studies suggest that comprehensive mental health screening may be successful in identifying those individuals most likely to experience regrets."

Relevant Descriptions of APA Evidence Coding System/Levels:

[B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally. Does not meet standards for a randomized clinical trial."

[G] Other. Opinion-like essays, case reports, and other reports not categorized above."

c. Endocrine Society

Endocrine Treatment of Transsexual Persons: an Endocrine Society Clinical Practice Guideline.

Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ 3rd, Spack NP, Tangpricha V, Montori VM; Endocrine Society. J Clin Endocrinol Metab. 2009; 94:3132-54.

This guideline primarily addressed hormone management and surveillance for complications of that management. A small section addressed surgery and found the quality of evidence to be low.

"This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low."

d. World Professional Association for Transgender Health (WPATH)

Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (Version 7). Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, Fraser L, Green J, Knudson G, Meyer WJ, Monstrey S, Adler RK, Brown GR, Devor AH, Ehrbar R, Ettner R, Eyler E, Garofalo R, Karasic DH, Lev AI, Mayer G, Meyer-Bahlburg H, Hall BP, Pfäfflin F, Rachlin K, Robinson B, Schechter LS, Tangpricha V, van Trotsenburg M, Vitale A, Winter S, Whittle S, Kevan R. Wylie KR, Zucker K.
www.wpath.org/_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf
Int J Transgend. 2011;13:165–232.

The WPATH is "an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect in transsexual and transgender health."

WPATH reported, "The standards of care are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria—broadly 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) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b)."

The WPATH standards of care (SOC) "acknowledge the role of making informed choices and the value of harm-

reduction approaches."

The SOC noted, "For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered. The number and type of interventions applied and the order in which these take place may differ from person to person (e.g., Bockting, Knudson, & Goldberg, 2006; Bolin, 1994; Rachlin, 1999; Rachlin, Green, & Lombardi, 2008; Rachlin, Hansbury, & Pardo, 2010). Treatment options include the following:

- Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one's gender identity);
- Hormone therapy to feminize or masculinize the body;
- Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience."

e. American Psychological Association

Suggested citation until formally published in the American Psychologist: American Psychological Association. (2015): *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People Adopted by the Council of Representatives, August 5 & 7, 2015. www.apa.org/practice/guidelines/transgender.pdf*

"The purpose of the Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (hereafter Guidelines) is to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people."

"These Guidelines refer to psychological practice (e.g., clinical work, consultation, education, research, training) rather than treatment."

5. Other Reviews

a. Institute of Medicine (IOM)

The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding. Robert Graham (Chair); Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. (Study Sponsor: The National Institutes of Health). Issued March 31, 2011. http://www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and- Transgender-People.aspx

"To advance understanding of the health needs of all LGBT individuals, researchers need more data about the demographics of these populations, improved methods for collecting and analyzing data, and an increased participation of sexual and gender minorities in research. Building a more solid evidence base for LGBT health concerns will not only benefit LGBT individuals, but also add to the repository of health information we have that pertains to all people."

"Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population. Scientific rigor includes incorporating and monitoring culturally competent study designs, such as the use of appropriate measures to identify participants and

implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination."

b. National Institutes of Health (NIH)

National Institutes of Health Lesbian, Gay, Bisexual, and Transgender (LGBT) Research Coordinating Committee. Consideration of the Institute of Medicine (IOM) report on the health of lesbian, gay, bisexual, and transgender (LGBT) individuals. Bethesda, MD: National Institutes of Health; 2013. http://report.nih.gov/UploadDocs/LGBT%20Health%20Report_FINAL_2013-01-03-508%20compliant.pdf

In response to the IOM report, the NIH LBGT research Coordinating Committee noted that most of the health research for this set of populations is "focused in the areas of Behavioral and Social Sciences, HIV (human immunodeficiency virus)/AIDS, Mental Health, and Substance Abuse. Relatively little research has been done in several key health areas for LGBT populations including the impact of smoking on health, depression, suicide, cancer, aging, obesity, and alcoholism."

6. Pending Clinical Trials

ClinicalTrials.gov
There is one currently listed and recently active trial directed at assessment of the clinical outcomes pertaining to individuals who have had gender reassignment surgery. The study appears to be a continuation of work conducted by investigators cited in the internal technology assessment.

NCT01072825 (Ghent, Belgium sponsor) European Network for the Investigation of Gender Incongruence (ENIGI) is assessing the physical and psychological effects of the hormonal treatment of transgender subjects in two years prior to reassignment surgery and subsequent to surgery. This observational cohort study started in 2010 and is still in progress.

7. Consultation with Outside Experts

Consistent with the authority at 1862(l)(4) of the Act, CMS consulted with outside experts on the topic of treatment for gender dysphoria and gender reassignment surgery.

Given that the majority of the clinical research was conducted outside of the United States, and some studies either took place in or a suggested continuity-of-care and coordination-of-care were beneficial to health outcomes, we conducted expert interviews with centers across the U.S. that provided some form of specialty-focused or coordinated care for transgender patients. These interviews informed our knowledge about the current healthcare options for transgender people, the qualifications of the professionals involved, and the uniqueness of treatment options. We are very grateful to the organizations that made time to discuss treatment for gender dysphoria with us.

From our discussions with the all of the experts we spoke with, we noted the following practices in some centers: (1) specialized training for all staff about transgender healthcare and transgender cultural issues; (2) use of an intake assessment by either a social worker or health care provider that addressed physical health, mental health, and other life factors such as housing, relationship, and employment status; (3) offering primary care services for transgender people in addition to services related to gender-affirming therapy/treatments; (4) navigators who connected patients with name-change information or other legal needs related to gender; (5) counseling for individuals, groups, and families; (6) an informed-consent model whereby individuals were often referred to as

"clients" instead of "patients," and (7) an awareness of depression among transgender people (often measured with tools such as the Adult Outcomes Questionnaire and the Patient Health Questionnaire).

8. Public Comments

We appreciate the thoughtful public comments we received on the proposed decision memorandum. In CMS' experience, public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. All comments that were submitted without personal health information may be viewed in their entirety by using the following link: https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=282&ExpandComments=n#Results

a. Initial Comment Period: December 3, 2015 – January 2, 2016

During the initial comment period, we received 103 comments. Of those, 78% supported coverage of gender reassignment surgery, 15% opposed, and 7% were neutral. The majority of comments supporting coverage were from individuals and advocacy groups.

b. Second Comment Period: June 2, 2016 – July 2, 2016

During the second 30-day public comment period, we received a total of 45 public comments, 7 of which were not posted on the web due to personal health information content. Overall, 82% supported coverage of gender reassignment surgery, 11% opposed, and 7% were neutral or silent in their comment whether they supported or opposed coverage. Half of the comments were submitted by individuals who expressed support for coverage of gender reassignment surgery (51%). We also received comments from physicians, providers, and other health professionals who specialize in healthcare for transgender individuals (17%). We received one comment from a municipality, the San Francisco Department of Public Health. Associations (American Medical Association, American College of Physicians, American Academy of Nursing, American Psychological Association, and LBGT PA Caucus) and advocates (Center for American Progress with many other signatories, Jamison Green & Associates) also submitted comments.

Below is a summary of the comments CMS received. In some instances, commenters identified typographical errors, context missed, and opportunities for CMS to clarify wording and classify articles for ease of reading in the memorandum. As noted earlier, when appropriate and to the extent possible, we updated the decision memorandum to reflect those corrections, improved the context, and clarified the language. In light of public comments, we re-evaluated the evidence and our summaries. We updated our summaries of the studies and clarified the language when appropriate.

1. Contractor Discretion and National Coverage Determination

Comment: Some commenters, including advocates, associations, and providers, supported CMS' decision for MAC contractor discretion/case-by-case determination for gender reassignment surgery. One stakeholder stated, "We agree with the conclusion that a NCD is not warranted at this time."

Response: We appreciate the support and understanding among stakeholders for our proposed decision to have the MACs determine coverage on a case-by-case basis. We have clarified in this final decision memorandum that

coverage is available for gender reassignment surgery when determined reasonable and necessary and not otherwise excluded by any other relevant statutory requirements by the MAC on a case-by-case basis. "The case-by-case model affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule." (78 Fed. Reg. 48165 (August 7, 2013)).

Comment: Some commenters cautioned that CMS' choice to not issue a NCD at this time must not be interpreted as a national non-coverage determination or used in any way to inappropriately restrict access to coverage for transgender Medicare beneficiaries or other transgender individuals. Multiple commenters indicated their disappointment that CMS did not propose a National Coverage Determination (NCD) and, instead, chose to continue to have local MACs make the coverage decisions on a case-by-case basis. Commenters stated this could result in variability in coverage.

Response: We appreciate the comments. We are not issuing a NCD at this time because the available evidence for gender reassignment surgery provides limited data on specific health outcomes and the characteristics of specific patient populations that might benefit from surgery. In the absence of a NCD, the MAC's use the same statutory authority as NCDs, section 1862(a)(1)(A) of the Social Security Act (the Act). Under section 1862(a)(1)(A) an item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. While CMS did not have enough evidence to issue a NCD, we believe the MACs will be able to make appropriate coverage decisions on a case-by-case basis taking into account individual characteristics of the Medicare beneficiary.

Comment: Some commenters sought a NCD that would establish guidelines for coverage and include elements such as a prescribed set of surgeries and a shared decision making element.

Response: For the reasons stated above, we are not issuing a NCD at this time and, therefore, are not establishing specific gender reassignment surgery coverage guidelines for the Medicare program. We generally agree that shared decision-making is a fundamental approach to patient-centered health care decisions and strongly encourage providers to use these types of evidence based decision aids. We have not found a shared decision aid on GRS and encourage the development of this necessary element to conduct formal shared-decision making.

Comment: Some commenters expressed concern that there is a misunderstanding of transgender individuals as having a disorder or being abnormal. Some commenters indicated a history of bias and discrimination within society as a whole that has occurred when transgender individuals have sought health care services from the medical community. Some commenters are concerned that the decision not to make a NCD will subject individuals seeking these services to corporate bias by Medicare contractors.

Response: We acknowledge the public comments and that there has been a transformation in the treatment of individuals with gender dysphoria over time. In this NCA, we acknowledge that gender dysphoria is a recognized Diagnostic and Statistical Manual of Mental Disorders (DSM) condition. With respect to the concern about potential bias by Medicare contractors, we have no reason to expect that the judgments made on specific claims will be influenced by an overriding bias, hostility to patients with gender dysphoria, or discrimination. Moreover, the Medicare statue and our regulations provide a mechanism to appeal an adverse initial decision if a claim is denied and those rights may include the opportunity for judicial review. We believe the Medicare appeals process would provide an opportunity to correct any adverse decision that was perceived to have been influenced by bias.

Comment: Commenters mentioned the cost of gender reassignment surgery could influence MAC decision making.

Response: The decisions on whether to cover gender reassignment surgery in a particular case are made on the basis of the statutory language in section 1862 of the Social Security Act that establish exclusions from coverage and

would not depend on the cost of the procedure.

2. Coverage with Evidence Development and Research

Comment: In our proposed decision memorandum, we specifically invited comments on whether a study could be developed that would support coverage with evidence development (CED). One organization commented, "We strongly caution against instituting a CED protocol." Commenters were opposed to coverage limited in clinical trials, suggesting that such coverage would restrict access to care. Several commenters provided suggested topics for clinical research studies for the transgender population. For example, one commenter suggested a study of non-surgical treatment for transgender children prior to puberty.

Response: While we appreciate the comments supporting further research, in general, for gender reassignment surgery, we agree that CED is not the appropriate coverage pathway at this time. While CED is an important mechanism to support research and has the potential to be used to help address gaps in the current evidence, we are not aware of any available, appropriate studies, ongoing or in development, on gender reassignment surgery for individuals with gender dysphoria that could be used to support a CED decision.

3. Gender Reassignment Surgery as Treatment

Comment: One group of commenters requested that CMS consider that, "The established medical consensus is that GRS is a safe, effective, and medically necessary treatment for many individuals with gender dysphoria, and for some individuals with severe dysphoria, it is the only effective treatment."

Response: We acknowledge that GRS may be a reasonable and necessary service for certain beneficiaries with gender dysphoria. The current scientific information is not complete for CMS to make a NCD that identifies the precise patient population for whom the service would be reasonable and necessary.

4. Physician Recommendations

Comment: Several commenters stated that gender reassignment surgery should be covered as long as it was determined to be necessary, or medically necessary by a beneficiary's physician.

Response: Physician recommendation is one of many potential factors that the local MAC may consider when determining whether the documentation is sufficient to pay a claim.

5. WPATH Standards of Care

Comment: Several commenters suggested that CMS should recommend the WPATH Standards of Care (WPATH) as the controlling guideline for gender reassignment surgery. They asserted it could satisfy Medicare's reasonable and necessary criteria for determining coverage on a case-by-case basis.

Response: Based on our review of the evidence and conversations with the experts and patient advocates, we are aware some providers consult the WPATH Standards of Care, while others have created their own criteria and requirements for surgery, which they think best suit the needs of their patients. As such, and given that WPATH acknowledges the guidelines should be flexible, we are not in the position to endorse exclusive use of WPATH for coverage. The MACs, Medicare Advantage plans, and Medicare providers can use clinical guidelines they determine useful to inform their determination of whether an item or service is reasonable and necessary. When making this

determination, local MACs may take into account physician's recommendations, the individual's clinical characteristics, and available clinical evidence relevant to that individual.

6. Scope of the NCA Request

Comment: One commenter stated that CMS did not address the full scope of the NCA request.

Response: The formal request for a NCD is publicly available on our tracking sheet. (https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id282.pdf) The letter did not explicitly seek a national coverage determination related to counseling or hormone therapies, but focused on surgical remedies. CMS is aware that beneficiaries with gender dysphoria use a variety of therapies.

Comment: Other commenters stated the scope of the proposed decision is unnecessarily broad because it discussed therapies other than surgery. They suggested this discussion could lead to the unintended consequence of restricting access to those services for transgender Medicare beneficiaries and other transgender individuals.

Response: As we noted in our proposed decision, our decision focused only on gender reassignment surgery. In the course of reviewing studies related to those surgeries, occasionally authors discussed other therapies that were mentioned in our summaries of the evidence. To the extent possible, we have modified our decision to eliminate the discussion of other therapies which were not fully evaluated in this NCA.

7. NCA Question

Comment: Some commenters expressed concern about the phrasing of the question in this NCA.

Response: The phrasing of the research question is consistent with most NCAs and we believe it is appropriate.

8. Evidence Summary and Analysis

Comment: Several commenters disagreed with our summary of the clinical evidence and analysis. A few commenters contended that the overall tone of the review was not neutral and seemed biased or flawed. One commenter noted that the Barrett publication was available on the Internet.

Response: We appreciate the comments that identified technical errors, and we made the necessary revisions to this document. However, we disagree with the contention that our evidence review was not neutral and seemed biased or flawed. We believe that the summary and analysis of the clinical evidence are objective. As with previous NCAs, our review of the evidence was rigorous and methodical. Additionally, we reviewed the Barrett publication, but it did not meet our inclusion criteria to be included in the Evidence section.

9. Evidence Review with Transgender Experts

Comment: Several commenters requested that CMS re-review the clinical evidence discussed in the proposed decision memorandum with outside experts in the field of transgender health and transition/gender reassignment-related surgeries. Several offered the expertise within their organization to assist in this effort.

Response: We appreciate these comments and the transgender health community's willingness to participate. For

this NCA we discussed gender reassignment surgery protocols with experts, primarily in coordinated care settings. Additionally, the public comment periods provide opportunities for expert stakeholder input. According to our process for all NCAs, we do not jointly review evidence with external stakeholders but have carefully reviewed the very detailed comments submitted by a number of outside experts in transgender health care.

10. Previous Non-Coverage NCD

Comment: One commenter noted that they thought research studies for gender reassignment surgery could not take place when the old NCD that prohibited coverage for gender reassignment surgery was in effect.

Response: CMS does not directly conduct clinical studies or pay for research grants. Some medical services are non-covered by Medicare; however, national non-coverage does not preclude research via a number of avenues and other funding entities such as the National Institutes of Health. In this instance, the previous NCD did not preclude interested parties from funding research for gender reassignment surgery that could have been generalizable to the Medicare population.

11. How the Medicare Population Differs from the General Population

Comment: One commenter questioned how the Medicare population differed from the general population, and why any differences would be important in our decision-making.

Response: The Medicare population is different from the general population in age (65 years and older) and/or disability as defined by the Social Security Administration. Due to the biology of aging, older adults may respond to health care treatments differently than younger adults. These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility. All of these factors can impact health outcomes. The disabled Medicare population, who are younger than age 65, is different from the general population and typical study populations due to the presence of the causes of disability such as psychiatric disorders, musculoskeletal health issues, and cardiovascular issues.

12. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

Comment: One commenter suggested CMS should have convened a MEDCAC for this topic.

Response: We appreciate the comment. Given the limited evidence, we did not believe a MEDCAC was warranted according to our guidance document entitled "Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee" (https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html).

13. §1557 of the Affordable Care Act (ACA)

Comment: Some commenters asserted that by not explicitly covering gender reassignment surgery at the national level, CMS was discriminating against transgender beneficiaries in conflict with Section 1557 of the Accountable Care Act (ACA).

Response: This decision does not affect the independent obligation of covered entities, including the Medicare program and MACs, to comply with Section 1557 in making individual coverage decisions. In accordance with Section 1557, MACs will apply neutral nondiscriminatory criteria when making case-by-case coverage determinations related

to gender reassignment surgery.

14. Medicaid

Comment: Some commenters observed that some states cover gender reassignment surgery through Medicaid or require commercial insurers operating in the state to cover the surgery.

Response: We appreciate the information about Medicaid and state requirements; however, State decisions are separate from Medicare coverage determinations. We make evidence-based determinations based on our statutory standards and processes.

15. Commercial Insurers

Comment: In several instances, commenters told us that the healthcare industry looks to CMS coverage determinations to guide commercial policy coverage.

Response: CMS makes evidence-based national coverage determinations based on our statutory standards and processes as defined in the Social Security Act, which may not be the same standards that are used in commercial insurance policies or by other health care programs. In addition as noted above, the Medicare population is different (e.g., Medicare covers 95% of adults 65 and older) than the typical population under commercial insurers. We do not issue coverage decisions to drive policy for other health organizations' coverage in one way or the other.

16. Healthcare for Transgender Individuals

Comment: Numerous professional associations wrote to CMS to explain their support for access to healthcare for transgender individuals.

Response: CMS recognizes that transgender beneficiaries have specific healthcare needs. Many health care treatments are available. We encourage all beneficiaries to utilize their Medicare benefits to help them achieve their best health.

17. Intended Use of the Decision Memorandum

Comment: Several commenters expressed concern that the analysis provided in the proposed and final decision memorandums may be used by individuals, entities, or payers for purposes unrelated to Medicare such as denial of coverage for transgender-related surgeries.

Response: The purpose of the decision memoranda is to memorialize CMS' analysis of the evidence, provide responses to the public comments received, and to make available the clinical evidence and other data used in making our decision consistent with our obligations under the § 1862 of the Act. The NCD process is open and transparent and our decisions are publicly available. Congress requires that we provide a clear statement of the basis for our determinations. The decision memoranda are an important part of the record of the NCD. Our focus is the Medicare population which, as noted above, is different than the general population in a number of ways. Other entities may conduct separate evidence reviews and analyses that are suited for their specific populations.

18. Cost Barriers to Care and Effects

Comment: A few commenters stated that without Medicare coverage, surgery is difficult to afford and there may be a risk of negative consequences for the individual. One commenter suggested that CMS should consider prior-authorization for these surgeries.

Response: CMS is aware that paying out-of-pocket for medical care is a strain on a beneficiary's finances. We are also aware of beneficiaries' hesitancy to undergo surgery prior to knowing whether or not Medicare will pay the claim. Gender reassignment surgeries are not the only procedures whereby payment is not determined until after the provider submits the claim to Medicare. Importantly, documentation for the claims need to be explicit about what procedures were performed and include the appropriate information in the documentation to justify using the code or codes for surgery. Of note, CMS has claims data that indicate Medicare has paid for gender reassignment surgeries in the recent past. Determining which services are designated for prior-authorization is outside of the scope of the NCA process.

19. Surgical Risks and Benefits

Comment: A number of commenters conveyed the benefits of gender reassignment surgery, while other commenters expressed concern that gender reassignment surgery was harmful.

Response: We appreciate these comments.

20. Expenditure of Federal Funds

Comment: Some commenters opposed spending Medicare program funds on gender reassignment surgery for a variety of reasons. For example, some commenters believe it is an "elective" procedure. Other commenters suggested that funds should first be spent on other priorities such as durable medical equipment (DME) or mobility items such as power chairs; increasing reimbursement to providers; or that spending should be limited to the proportion to the transgender adult population in the Medicare program.

Response: The purpose of this NCA is to determine whether or not CMS should issue a NCD to cover surgery for patients who have gender dysphoria. NCAs do not establish payment amounts or spending priorities and, therefore, these comments are outside the scope of this consideration.

VIII. CMS Analysis

National coverage determinations are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under § 1862(l)(6) of the Act. In general, in order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage.

Moreover, in most circumstances, the item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A)). The Supreme Court has recognized that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." Heckler v. Ringer, 466 U.S. 602, 617 (1984). See also, 78 Fed. Reg. 48,164, 48,165 (August 7, 2013)

When making national coverage determinations, we consider whether the evidence is relevant to the Medicare

beneficiary population. In considering the generalizability of the results of the body of evidence to the Medicare population, we carefully consider the demographic characteristics and comorbidities of study participants as well as the provider training and experience. This section provides an analysis of the evidence, which included the published medical literature and guidelines pertaining to gender dysphoria, that we considered during our review to answer the question:

Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?

CMS carefully considered all the studies listed in this decision memorandum to determine whether they answered the question posed in this NCA. While there appears to be many publications regarding gender reassignment surgery, it became clear that many of the publications did not meet our inclusion/exclusion criteria as explained earlier in the decision memorandum.

Thirty-three papers were eligible based on our inclusion/exclusion criteria for the subsequent review (Figure 1). All studies reviewed had potential methodological flaws which we describe below.

A. Quality of the Studies Reviewed

Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up (Appendices C and F). The impact of a specific therapeutic intervention can be difficult to determine when there are multiple serial treatments such as psychotherapy, hormone treatment and surgery. To reduce confounding, outcome assessment just prior to and after surgery such as in a longitudinal study would be helpful. The objective endpoints included psychiatric treatment, attempted suicide, requests for surgical reversal, morbidity (direct and indirect adverse events), and mortality (Appendix F). CMS agrees with the utility of these objective endpoints. Quality of life, while important, is more difficult to measure objectively (Appendix E).

Of the 33 studies reviewed, published results were conflicting – some were positive; others were negative. Collectively, the evidence is inconclusive for the Medicare population. The majority of studies were non-longitudinal, exploratory type studies (i.e., in a preliminary state of investigation or hypothesis generating), or did not include concurrent controls or testing prior to and after surgery. Several reported positive results but the potential issues noted above reduced strength and confidence. After careful assessment, we identified six studies that could provide useful information (Figure 1). Of these, the four best designed and conducted studies that assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies did not demonstrate clinically significant changes or differences in psychometric test results after GRS. (Heylens et al., 2014; Ruppin, Pfafflin, 2015; Smith et al., 2005; Udeze et al., 2008) (Appendix C Panel A and Appendix G.)

Two studies (three articles) assessed functional endpoints (request for surgical reassignment reversal and morbidity/mortality) (Dhejne et al., 2011; Dhejne et al., 2014 along with Landén et al., 1998) (Figure 1 and Appendix C, Panel A and Appendix G). Although the data are observational, they are robust because the Swedish national database is comprehensive (including all patients for which the government had paid for surgical services) and is notable for uniform criteria to qualify for treatment and financial coverage by the government. Dhejne et al. (2014) and Landén et al. (1998) reported cumulative rates of requests for surgical reassignment reversal or change in legal status of 3.3% while Dhejne et al. (2014) reported 2.2%. The authors indicated that the later updated calculation had the potential to be an underestimate because the most recent surgical cohorts were larger in size and had shorter periods of follow-up.

Dhejne et al., (2011) tracked all patients who had undergone reassignment surgery (mean age 35.1 years) over a 30 year interval and compared them to 6,480 matched controls. The study identified increased mortality and psychiatric hospitalization compared to the matched controls. The mortality was primarily due to completed suicides (19.1-fold greater than in control Swedes), but death due to neoplasm and cardiovascular disease was increased 2 to 2.5 times as well. We note, mortality from this patient population did not become apparent until after 10 years. The risk for psychiatric hospitalization was 2.8 times greater than in controls even after adjustment for prior psychiatric disease (18%). The risk for attempted suicide was greater in male-to-female patients regardless of the gender of the control. Further, we cannot exclude therapeutic interventions as a cause of the observed excess morbidity and mortality. The study, however, was not constructed to assess the impact of gender reassignment surgery *per se.*

We believe at minimum study designs should have a pre-test/post-test longitudinal design accompanied by characterization of all patients lost to follow-up over the entire treatment series as well as those patients who did not complete questionnaires, and the use of psychometric quality-of-life tools which are well validated with linkage to "hard" (objective) patient outcomes in this particular patient population (Trentacosti 2007, PRO 2009) (Appendices C and D).

Patient Care

Clinical evidentiary questions regarding the care of patients with gender dysphoria remain. Many of the publications focused on aspects of surgical technique as opposed to long-term patient outcomes. The specific type(s) of gender/sex reassignment surgery (e.g., genital, non-genital) that could improve health outcomes in adults remain(s) uncertain because most studies included patients who had undertaken one or more of a spectrum of surgical procedures or did not define the specific types of surgical procedures under study. Furthermore, surgical techniques have changed significantly over the last 60 years and may not reflect current practice (Bjerrome Ahlin et al., 2014; Doornaert, 2011; Green, 1998; Pauly, 1968; Selvaggi et al., 2007; Selvaggi, Bellringer, 2011; Tugnet et al., 2007; Doornaert, 2011).

The WPATH care recommendations present a general framework and guidance on the care of the transgender individual. The standards of care are often cited by entities that perform gender reassignment surgery. WPATH notes, "More studies are needed that focus on the outcomes of current assessment and treatment approaches for gender dysphoria." Appendix D in the WPATH Standards of Care briefly describes their evidence base and acknowledges the historical problems with evidentiary standards, the preponderance of retrospective data, and the confounding impact of multiple interventions, specifically distinguishing the impact of hormone therapy from surgical intervention.

Additionally, CMS met with several stakeholders and conducted several interviews with centers that focus on healthcare for transgender individuals in the U.S. Primary care rather than gender reassignment surgery was often the main focus. Few of the U.S.-based reassignment surgeons we could identify work as part of an integrated practice, and few provide the most complex procedures.

Psychometric Tools

CMS reviewed psychometric endpoints because gender dysphoria (inclusive of prior nomenclature) describes an incongruence between the gender assigned at birth and the gender(s) with which the person identifies.

The psychometric tools used to assess outcomes have limitations. Most instruments that were specific for gender dysphoria were designed by the investigators themselves or by other investigators within the field using limited populations and lacked well documented test characterization. (Appendices E and F) By contrast, test instruments with validation in large populations were non-specific and lacked validation in the gender dysphoric patient populations. (Appendices E and F). In addition, the presentation of psychometric results must be accompanied by

enough information about the test itself to permit adequate interpretation of test results. The relevant diagnostic cut-points for scores and changes in scores that are clinically significant should also be scientifically delineated for interpretation.

Generalizability

It is difficult to generalize these study results to the current Medicare population. Many of the studies are old given they were conducted more than 10 years ago. Most of these studies were conducted outside of the U.S. in very different medical systems for treatment and follow-up. Many of the programs were single-site centers without replication elsewhere. The study populations were young and without significant physical or psychiatric co-morbidity (Appendix D). As noted earlier, psychiatric co-morbidity may portend poor outcomes (Asscheman et al., 2011; Landén et al., 1998).

Knowledge Gaps

This patient population faces complex and unique challenges. The medical science in this area is evolving. This review has identified gaps in the evidentiary base as well as recommendations for good study designs. The Institute of Medicine, the National Institutes of Health, and others also identified many of the gaps in the data. (Boehmer, 2002; HHS-HP, 2011; IOM, 2011; Kreukels-ENIGI, 2012; Lancet, 2011; Murad et al., 2010; NIH-LGBT, 2013) The current or completed studies listed in ClinicalTrials.gov are not structured to assess these gaps. These gaps have been delineated as they represent areas in which patient care can be optimized and are opportunities for much needed research.

B. Health Disparities

Four studies included information on racial or ethnic background. The participants in the three U.S. based studies were predominantly Caucasian (Beatrice, 1985; Meyer, Reter, 1979; Newfield et al., 2006). All of the participants in the single Asian study were Chinese (Tsoi, 1993). Additional research is needed in this area.

C. Summary

Based on an extensive assessment of the clinical evidence as described above, 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.

The knowledge on gender reassignment surgery for individuals with gender dysphoria is evolving. Much of the available research has been conducted in highly vetted patients at select care programs integrating psychotherapy, endocrinology, and various surgical disciplines. Additional research of contemporary practice is needed. To assess long-term quality of life and other psychometric outcomes, it will be necessary to develop and validate standardized psychometric tools in patients with gender dysphoria. Further, patient preference is an important aspect of any treatment. As study designs are completed, it is important to include patient-centered outcomes.

Because CMS is mindful of the unique and complex needs of this patient population and because CMS seeks sound data to guide proper care of the Medicare subset of this patient population, CMS strongly encourages robust clinical studies with adequate patient protections that will fill the evidence gaps delineated in this decision memorandum. As the Institute of Medicine (IOM, 2011) importantly noted: "Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population.

Scientific rigor includes incorporating and monitoring culturally competent study designs, such as the use of appropriate measures to identify participants and implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination."

IX. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We have a received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination on whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery would be reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination relating to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

A. Appendix A

Diagnostic & Statistical Manual of Mental Disorders (DSM) Criteria for Disorders of Gender Identity since 1980

DSM Version	**Condition Name**	**Criteria**	**Criteria**	**Comments**
DSM III 1980 *Chapter: Psychosexual Disorders*	**Trans-sexualism** *302.5x [Gender Identity*	Required A (cross-gender identification) and B (aversion to	Sense of discomfort and inappropriateness about one's anatomic sex. Wish to be rid of one's own genitals and	Further characterization by sexual orientation Distinguished

	Disorder of Child-hood (302.6)]	one's natal gender) criteria Dx excluded by physical intersex condition Dx excluded by another mental disorder, e.g., schizophrenia	to live as a member of the other sex. The disturbance has been continuous (not limited to periods of stress) for at least 2 years.	from Atypical Gender Identity Disorder 302.85
DSM III-Revised **1987** *TS classified as an Axis II dx (personality disorders and mental retardation) in a different chapter. GID included under Disorders Usually First Evident in Infancy, Childhood, Adolescence*	**Trans-sexualism** *(TS) (302.50) [GID of C]*	Required A and B criteria	Persistent discomfort and sense of inappropriateness about one's assigned sex. Persistent preoccupation for at least 2 years with getting rid of one's 1^{o} and 2^{o} sex characteristics and acquiring the sex characteristics of the other sex. Has reached puberty	Further characterization by sexual orientation Distinguished from Gender Identity Disorder of Adolescence or Adulthood, Non-trans-sexual Type • e.g., cross-dressing not for the purposes of sexual excitement Gender Identity Disorder Not Otherwise Specified 302.6 • e.g., intersex conditions Gender Identity Disorder Not Otherwise Specified 302.85 • e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
	GID of adulthood,			

	non-trans-sexual type, added			
DSM IV **1994** *Chapter: Sexual & Gender Identity Disorders*	**Gender Identity Disorder** in Adolescents and Adults (302.85) (Separate criteria & code for children, but same name)	Required A and B criteria Dx excluded by physical intersex condition	Cross-gender identification • e.g., Stated desire to be another sex • e.g., Desire to live or be treated as a member of the other sex • e.g., conviction that he/she has the typical feelings and reactions of the other sex • e.g., frequent passing as the other sex Persistent discomfort with his/her sex or sense of inappropriateness in the gender role of that sex. • e.g., belief the he/she was born the wrong sex • e.g., preoccupation with getting rid of 1^{o} and 2 ^{o} sex characteristics &/or acquiring sexual traits of the other sex • Clinically significant distress or impairment in social, occupational, or other important areas of functioning	Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise Specified 302.6 • e.g., intersex conditions • e.g., stress related cross-dressing • e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
DSM IV-Revised **2000** *Chapter: Sexual & Gender Identity Disorders*	**Gender Identity Disorder** (Term trans-sexual-ism eliminated)	Required A & B criteria Dx excluded by physical intersex condition	Cross-gender identification • e.g., stated desire to be the other sex • e.g., desire to live or be treated as the other sex • e.g., conviction that he/she has the typical feelings & reactions of the other sex	Outcome may depend on time of onset Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise

			• e.g., frequent passing as the other sex Persistent discomfort with his or her sex OR sense of inappropriateness in the gender role of that sex • e.g., belief the he/she was born the wrong sex • e.g., preoccupation with getting rid of 1^{o} and 2 ^{o} sex characteristics &/or acquiring sexual traits of the other sex Clinically significant distress or impairment in social, occupational, or other important areas of functioning	Specified 302.6 • e.g., intersex conditions • e.g., stress related cross-dressing • e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
DSM V **2013** *Separate Chapter from Sexual Dysfunctions & Paraphilic Disorders*	**Gender Dysphoria** *(302.85)*	Gender nonconformity itself not considered to be a mental disorder The dysphoria associated with the gender incongruence is Eliminates A & B criteria Considers gender incongruence to be a spectrum Considers intersex/ "disorders of sex development" to be a	• Marked discordance between natal 1^{o} and 2^{o} sex characteristics* and experienced/expressed gender • Conviction that he/she has the typical feelings & reactions of the other sex (or some alternative gender) • Marked desire to be the other sex (or some alternative gender) • Marked desire to desire be treated as the other sex (or some alternative gender) • Marked desire to be rid of natal 1^{o} and 2^{o} sex characteristics** • Marked desire to acquire 1^{o} and 2^{o} sex characteristics of the other sex (or some alternative gender) Clinically significant	Includes diagnosis for post transition state to permit continued treatment access Includes disorders of sexual development such as congenital hyperplasia and androgen insensitivity syndromes

		subsidiary and not exclusionary to dx of GD	distress or impairment in social, occupational, or other important areas of functioning * or in young adolescents, the anticipated 2^{o} sex characteristics ** or in young adolescents, prevent the development of the anticipated 2^{o} sex characteristics ≥ 6 month marked discordance between natal gender & experienced/expressed gender as demonstrated by ≥ 6 criteria: • Strong desire to be of the other gender or an insistence that one is of another gender. • Strong preference for cross-gender roles in make-believe play. • Strong preference for the toys, games, or activities of the other gender. • Strong preference for playmates of the other gender. • In boys, strong preference for cross-dressing; in girls, strong preference for wearing masculine clothing • In boys, rejection of masculine toys, games, activities, avoidance of rough and tumble play; in girls, rejection of feminine toys, games, and activities.	
	Unspecified Gender Dysphoria		This category applies to presentations in which sx c/w gender	

	(302.6) (F64.9)		dysphoria that cause clinically significant distress or impairment, but do not meet the full criteria for gender dysphoria & the reason for not meeting the criteria is not provided.	
	Specified Gender Dysphoria 302.6 (F64.8)		If the reason that the presentation does not meet the full criteria is provided then this dx should be used	

C/W=consistent with Dx=diagnosis GD=gender dysphoria Sx=symptoms TS=transsexual 1^{o}=primary 2^{o}=secondary

B. Appendix B

1. General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant

outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.

- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e.g., using registries or surveys)
Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and

consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of

the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix C

Patient Population: Enrolled & Treated with Sex Reassignment Surgery Loss of Patients & Missing Data

Panel A (Controlled Studies)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Dhejne 2011	Longitudinal Controlled	804 w GD	324	324 (100%)	-
Dhejne 2014 Landén	Longitudinal for test variable Controlled	767 applied for SRS 25 applications denied. 61 not granted full legal status 15 formal applications for surgical reversal	681	681 (100%)	NA: Clinical data extracted retrospectively in earlier paper
Heylens	Longitudinal Controlled	90 applicants for SRS 33 excluded 11 later excluded had not yet received SRS by study close.	57 (→46)	46 (80.7%) Only those w SRS evaluated	Psycho-social survey missing data for 3 at baseline & 4 after SRS. SCL90 not completed by 1 at baseline, 10 after hormone tx, & 4 after SRS →missing data for another 1.1% to 11.1%.
Kockott	Longitudinal Controlled	80 applicants for SRS 21 excluded	59	32 (54.2%) went to surgery	1 preoperative patient was later excluded b/c lived completely in aspired gender w/o SRS. Questions on financial sufficiency not answered by 1 surgical pt. Questions on sexual satisfaction & gender contentment not answered by 1 & 2 patients awaiting surgery respectively.
Mate-Kole 1990	Longitudinal Controlled	40 sequential patients of accepted patients. The number in the available patient pool was not specified.	40	20 (50%) went to surgery	-
Meyer	Longitudinal Controlled	Recruitment pool: 100 50 were excluded.	50	15 (30%) had undergone surgery 14 (28%) underwent surgery later	The assessments of all were complete

Rakic	Longitudinal Controlled	92 were evaluated 54 were excluded from surgery 2 post SRS were lost to follow-up 2 post SRS were excluded for being in the peri-operative period	32	32 (100%)	Questionnaire completed by all.
Ruppin	Longitudinal Controlled	The number in the available patient pool was not specified. 140 received recruitment letters. 69 were excluded	71	69 (97.2%)	The SCL-90, BSRI, FPI-R, & IPP tests were not completed by 9, 34, 13, &16 respectively. Questions about romantic relationships, sexual relationships, friendships, & family relationships were not answered by 1, 3, 2, & 23 respectively. Questions regarding gender security & regret & were not answered by 1& 2 respectively.
Smith	Longitudinal Controlled	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. 103 were excluded from additional tx	162	162 (100%)	36 to 61 (22.2%-37.6% of those adults w pre-SRS data) did not complete various post-SRS tests.
Udeze Megeri	Longitudinal Controlled	International patient w GD 546 & post SRS 318. 40 M to F subjects were prospectively selected.	40	40 (100%)	-
Ainsworth	Internet/convention Survey Cross-sectional Controlled	Number of incomplete questionnaires not reported	247	72 (29.1%) 75 (30.6%) facial 147 (59.5%) had received neither facial nor reassignment surgery	-
Beatrice	Cross-sectional Controlled	14 excluded for demographic matching reasons	40	10 (25%)	The assessments were completed by all
Haraldsen	Cross-sectional Controlled	Recruitment pool: 99	86	59 (68.6%)	-
Kraemer	Cross-sectional	The number in the	45	22 (48.9%)	-

	Controlled	available patient pool was not specified.			
Kuhn	Cross-sectional Controlled	The number in the available patient pool was not specified.	75	55 (73.3%)	-
Mate-Kole 1988	Cross-sectional Controlled	150 in 3 cohorts. Matched on select traits. The number in the available patient pool was not specified.	150	50 (66.7%)	-
Wolfradt	Cross-sectional Controlled	The number in the available patient pool was not specified.	90	30 (33.3%)	-

Panel B (Surgical Series: No Concurrent Controls)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Blanchard et al.	Cross-sectional Control: Normative test data	294 clinic patients w GD had completed study questionnaire 116 authorized for GRS. 103 completed GRS & 1 yr post-operative. 24 excluded	79	79(100%)	-
Weyers et al.	Cross-sectional Control: Normative test data	>300 M to F patients had undergone GRS 70 eligible patients recruited 20 excluded	50	50 (100%)	SF-26 not completed by 1
Wierckx et al.	Cross-sectional except for recall questions Control: Normative test data	79 F to M patients had undergone GRS & were recruited. 3 additional non-clinic patients were recruited by other patients. 32 excluded initially; 1 later.	49	49 (100%)	SF-36 test not completed by 2. Questions regarding sexual re-lationship, sex function, & surgical satisfaction were answered by as few as 27, 28, 32 respectively.
Eldh et al.	Cross-sectional except for 1 variable Control: Self for 1 variable-employ-ment	136 were identified. 46 excluded	90	90 (100%)	Questions regarding gender iden-tity, sex life, acceptance, & overall satisfaction were not answered by 13, 14, 14 & 16 respectively. Employment data missing for 11.
Hess et al.	Cross-sectional No control	254 consecutive eligible patients post GRS identified & sent surveys. 135 excluded.	119	119 (100%)	Questions regarding the esthetics, functional, and social outcomes of GRS were not answered by 16 to 28 patients.
Lawrence	Cross-sectional	727 eligible patients	232	232	-

	No control	were recruited. 495 were excluded		(100%)	
Salvador et al.	Cross-sectional No control	243 had enrolled in the clinic 82 completed GRS 69 eligible patients were identified. 17 excluded.	52	52 (100%)	-
Tsoi	Cross-sectional No control	The number in the available patient pool was not specified.	81	81 (100%)	-

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Gómez-Gil et al. 2012	Cross-sectional No direct control: Analysis of variance	200 consecutive patients were recruited. 13 declined participation or were excluded for incomplete questionnaires.	187	79 (42.2%)	See prior box.
Hepp et al.	Cross-sectional No direct control: Analysis of variance	The number in the available patient pool was not specified.	31	7 (22.6%)	HADS test not completed by 1
Motmans et al.	Cross-sectional No direct control: Analysis of variance & regression	255 with GD were identified. 77 were excluded.	148 (→140)	Not clearly stated. At least 103 underwent some form of GRS.	8 later excluded for incomplete SF-36 tests. 37 w recent GRS or hormone initiation were excluded from analysis of SF-36 results→103.
Newfield et al.	Internet survey Cross-sectional No direct control: Analysis of variance	Number of incomplete questionnaires not reported 446 respondents; 384 U.S respondents 62 non-U.S. respondents excluded from SF-36 test results 8 U.S. respondents excluded	376 (U.S.)	139 to 150 (37.0-39.9%) in U.S.	-
Gomez-Gil et al. 2014	Cross-sectional No direct control: Analysis w regression	The number in the available patient pool was not specified. 277 were recruited. 25 excluded	252(→193)	80 (41.4%) non-genital surgery	59 were excluded for incomplete questionnaires. See prior box.
Asscherman	Longitudinal No analysis by tx	The number in the available patient pool	1331	1177 (88.4%)	-

	status	was not specified.			
Johansson et al.	Cross-sectional except for 1 variable No analysis by tx status except for 1 question	60 eligible patients 18 excluded.	42	32 (76.2% of enrolled & 53.3% of eligible) (genital surgery)	-
Leinung et al.	Cross-sectional No analysis by tx status	242 total clinic patients	242	91 (37.6%)	Employment status data missing for 81 of all patients

*Data obtained via a survey on a website and distributed at a conference
B/C=because
BSRI=Bem Sex Role Inventory
F=Female
FP-R=Freiberg Personality Inventory
GD=Gender dysphoria
GID=Gender identity disorder
HADS=Hospital Anxiety & Depression Scale
IPP=Inventory of Interpersonal Problems
M=Male
NA=Not applicable
SCL-90=Symptom Checklist-90
SF-36=Short Form 36
GRS=Sex reassignment surgery
Tx=Treatment
W/o=without

Appendix D

Demographic Features of Study Populations

Panel A (Controlled Studies)

Author	**Age (years; mean, S.D., range)**	**Gender**	**Race**
Ainsworth	Only reassignment surgery:50 (no S.D.) Only facial surgery: 51 (no S.D.) Both types of surgery: 49 (no S.D.) Neither surgery: 46 (no S.D.)	247 M to F	-
Beatrice	Pre-SRS M to F: 32.5 (27-42), Post-SRS: 35.1 (30-43)	20 M to F plus 20 M controls	100% Caucasian
Dehjne 2011	Post-SRS: all 35.1±9.7 (20-69), F to M 33.3+8.7 (20–62), M to F 36.3+ 10.1(21–69)	133 (41.0%) F to M, 191 (59.0%) M to F; ratio 1:1.4	-
Dhejne 2014 Landén	F to M SRS cohort: median age 27 M to F SRS cohort: median age 32 F to M applicants for reversal: median age 22 M to F applicants for reversal: median age 35	767 applicants for legal/surgical reassignment 289 (37.7%) F to M, 478 (62.3%) M to F; ratio 1:1.6 681 post SRS & legal change 252 (37.0%) F to M, 429 (63.0%) M to F; ratio 1:1.7	-

		15 applicants for reversal 5 (33.3%) F to M, 10 (66.7%) M to F; ratio 1:2	
Haraldsen	Pre-SRS & Post-SRS: F to M 34±9.5, F to M 33.3±10.0 Post-SRS cohort reportedly older. No direct data provided.	Pre & Post SRS 35 (40.7%) F to M, 51 (59.3%) M to F; ratio 1:1.5	-
Heylens	-	11 (19.3% of 57) F to M, 46 (80.7%); ratio 1:4.2 (80.7% underwent surgery)	-
Kockott	Pre-SRS (continued wish for surgery): 31.7±10.2 Post-SRS: 35.5±13.1	Pre-SRS (continued wish for surgery) 3 (25%) F to M, 9 (75%) M to F; ratio 1:3 Post SRS: 14 (43.8%) F to M, 18 (56.2%) M to F; ratio 1:1.3	-
Kraemer	Pre-SRS: 33.0±11.3, Post-SRS: 38.2±9.0	Pre-SRS 7 F to M (30.4%), 16 M to F (69.6%); ratio 1:2.3 Post-SRS 8 F to M (36.4%), 14 M to F (63.6%); ratio 1:1.8	-
Kuhn	All post SRS: median (range): 51 (39-62) (long-term follow-up)	3 (5.4%) F to M, 52 (94.5%) M to F; ratio 1:17.3.	-
Mate-Kole 1988	Initial evaluation: 34, Pre-SRS: 35, Post-SRS: 37	150 M to F	-
Mate-Kole 1990	Early & Usual wait SRS: 32.5 years (21-53)	40 M to F	-
Meyer	Pre-SRS: 26.7 Delayed, but completed SRS: 30.9 Post-SRS: 30.1	Pre-SRS: 5 (23.8%) F to M, 16 (76.2%) M to F; ratio 1:3.2 Delayed, but completed SRS: 1 (7.1%) F to M, 13 (92.9%) M to F; ratio 1:13 Post-SRS: 4 (26.7%) F to M, 11 (73.3%) M to F; ratio 1:2.8	86% Caucasian
Rakic	All: 26.8±6.9 (median 25.5, range 19-47), F to M: 27.8±5.2 (median 27, range 23-37), M to F: 26.4±7.8 (median 24, range 19-47).	10 (31.2%) F to M, 22 (68.8%) M to F; ratio 1:2.2	-
Ruppin	All: 47.0±10.42 (but 2 w/o SRS) (13.8±2.8 yrs post legal name change) (long-term follow-up) F to M: 41.2±5.78, M to F 52.9±10.82	36 (50.7%) F to M, 35 (49.3%) M to F; ratio 1:0.97	-
Smith	Time of surgical request for post-SRS: 30.9 (range 17.7-68.1) Time of follow-up for post-SRS: 35.2 (range 21.3-71.9)	Pre-SRS: 162: 58 (35.8%) F to M, 104 [64.2%] M to F; ratio 1:1.8 Post-SRS: 126: 49 (38.9%) F to M, 77 (61.1%) M to F; ratio 1:1.6	-
Udeze Megeri	M to F: 47.33±13.26 (range 25-80).	40 M to F	-
Wolfradt	Patients & controls: 43 (range 29-67).	30 M to F plus 30 F controls plus 30 M controls.	-

*Data obtained via a survey on a website and distributed at a conference SD=Standard deviation

Panel B (Surgical Series: No Concurrent Controls)

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Blanchard et al.	F to M: 32.6, M to F w M partner preference: 33.2, F to M w F partner preference: 47.7 years	Post-GRS: 47 (45.6%) F to M, 56 (54.4%) M to F; ratio 1:1.19. In study: 38 (48.1%) F to M, 32 (40.5%) M to F w M partner preference, 9 (11.4%) M to F w F partner preference; ratio 1:0.8: 0.2	-
Weyers et al.	Post-GRS M to F: 43.1 ±10.4 (long-term follow-up)	50 M to F	-
Wierckx et al.	Time of GRS: 30±8.2 years (range 16 to 49) Time of follow-up: 37.1 ±8.2.4 years (range 22 to 54)	49 M to F	-
Eldh et al.	-	50 (55.6%) F to M, 40 (44.4%) M to F; ratio 1:0.8 There is 1 inconsistency in the text suggesting that these should be reversed.	-
Hess et al.	-	119 M to F	-
Lawrence	Time of GRS: 44±9 (range 18-70)	232 M to F	-
Salvador et al.	Time of follow-up for post-GRS: 36.28±8.94 (range 18-58) (Duration of follow-up: 3.8±1.7 [2-7])	52 M to F	-
Tsoi	Time of initial visit: All: 24.0±4.5, F to M: 25.4±4.4 (14-36), M to F: 22.9±4.6 (14-36). Time of GRS: All: 25.9±4.14, F to M: 27.4±4.0 (20-36), M to F: 24.7+4.3 (20-36).	36 (44.4%) F to M, 45 (55.6%) M to F; ratio 1:1.25	0% 100% Asian

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Gómez-Gil et al. 2012	W & W/O GRS: All: 29.87±9.15 (range 15-61), W/O hormone tx: 25.9±7.5, W current hormone tx: 33.6±9.1. (At hormone initiation: 24.6±8.1).	W/O hormone tx: 38 (56.7%) F to M, 29 (43.3%) M to F; ratio 1:0.8. W hormone tx: 36 (30.0%) F to M, 84 (70.0%) M to F; ratio 1:2.3. Post-GRS: 29 (36.7%) F to M, 50 (63.3%) M to F; ratio 1:1.7.	-
Hepp et al.	W & W/O GRS: 32.2±10.3	W & W/O GRS: 11 (35.5%) F to M; 20 (64.5%) M to F; ratio 1:1.8.	-
Motmans et al.	W & W/O GRS: All (n=140) : 39.9±10.2, F to M: 37.0±8.5, M to F: 42.3±10.4	W & W/O GRS: N=140 63(45.0%) F to M, 77 (55.0%) M to F; ratio 1:1.2 N=103 49 (47.6%) F to M; 54 (52.4%) M toF; ratio 1:1.1	-
Newfield et al.	W & W/O GRS: U.S.+ non-U.S. : 32.8±11.2, U.S. 32.6±10.8	W & W/O GRS: U.S.+ non-U.S.: F to M, 438, U.S.: F to M: 376	89% of 336 respondents Caucasian
Gomez-Gil, et al. 2014	W & W/O Non-genital GRS: 31.2±9.9 (range 16-67).	W & W/O Non-genital GRS: 74 (38.3%) F to M, 119 (61.7%) M to	-

		F; ratio1:1.6.	
Asscherman	Time of hormone tx: F to M: 26.1±7.6 (16–56), M to F: 31.4±11.4 (16–76)	Met hormone tx requirements: 365 (27.4%) F to M, 966 (72.6%) M to F; ratio 1:2.6. Post-GRS: 343 (29.1%) F to M, 834 (70.9%) M to F; ratio 1:2.4.	-
Johanssen	Time of initial evaluation: F toM: 27.8 (18-46), M to F 37.3 (21-60). Time of GRS: F to M: 31.4 (22-49), M to F 38.2 (22-57). Time of follow-up for post-GRS: F to M: 38.9 (28-53), M to F 46.0 (25-69) (Long-term follow-up)	Approved for GRS: 21 (35%) F to M, 39 (65%) M to F; ratio 1:1.9) Post GRS: 14 (43.8%) F to M; 18 (56.2%) M to F; ratio 1:1.3)	-
Leinung et al.	Time of hormone initiation : F to M: 27.5, M to F 35.5	W & W/O GRS: 50 (20.7%) F to M, 192 M to F (79.3%); ratio 1:3.8. Post-GRS: 32 F to M (35.2%); 59 (64.8%) M to F; ratio 1:1.8.	-

Appendix E

Psychometric and Satisfaction Survey Instruments

Instrument Name and Developer	**Development and Validation Information**
APGAR Family Adaptability, Partner-ship Growth, Affection, and Resolve *Smilkstein*	Published in 1978 Initial data: 152 families in the U.S. A "friends" component was added in 1983. Utility has challenged by many including Gardner 2001
Beck Depression Inventory *Beck, Ward, Mendelson, Mock, & Erbaugh*	Published initially in 1961 with subsequent revisions It was initially evaluated in psychiatric patients in the U.S.A. Salkind (1969) evaluated its use in 80 general outpatients in the UK. Itis copyrighted and requires a fee for use
Bem Sex Role Inventory *Bem*	Published 1974 Initial data: 100 Stanford Undergraduates 1973 update: male 444; female 279 1978 update: 470; female 340
Body Image Questionnaire *Clement & Lowe*	Validity study published 1996 (German) Population: 405 psychosomatic patients, 141 medical students, 208 sports students
Body Image Scale *Lindgren & Pauly (Kuiper, Dutch adaptation 1991)*	1975 Initial data: 16 male and 16 female transsexual patients in Oregon
Crown Crisp Experiential Index (formerly Middlesex Hospital Questionnaire)	Developed circa 1966 Manual published 1970 Initial data: 52 nursing students while in class in the UK

Crown & Crisp	
(2nd) European Quality of Life Survey *Anderson, Mikuliç, Vermeylen, Lyly-Yrjanainen, & Zigante,*	Published in 2007 The pilot survey was tested in the UK and Holland with 200 interviews. The survey was revised especially for non-response questions. Another version was tested in 25 persons of each of the 31 countries to be surveyed. Sampling methods were devised. 35,634 Europeans were ultimately surveyed. Additional updates
Female Sexual Function Index *Rosen, Brown, Heiman, Leiblum, Meston, Shabsigh, Ferguson, D'Agostino Wiegel, Meston, & Rosen*	Published in 2000 Initial data: 131 normal controls & 128 age-matched subjects with female sexual arousal disorder from 5 U.S. research centers. Updated 2005: the addition of those with hypoactive sexual desire disorder, female sexual orgasm disorder, dyspareunia/vaginismus, & multiple sexual dysfunctions (n=568), plus more controls (n=261).
Fragebogen zur Beurteilung des eigenen Korpers *Strauss*	Published 1996 (German)
Freiberg Personality Inventory *Fahrenberg, Hampel, & Selg*	7th edition published 2001, 8th edition in 2009 (Not in PubMed) German equivalent of MMPI
"gender identity disorder in childhood" *Smith, van Goozen, Kuiper, & Cohen-Kettenis*	11 items derived from the Biographical Questionnaire for Trans-sexuals (Verschoor Poortinga 1988) (Modified by authors of the Smith study)
Gender Identity Trait Scale *Altstotter-Gleich*	Published 1989 (German)
General Health Questionnaire *Goldberg & Blackwell (initial study)* *Goldberg & Williams (manual)*	Initial publication 1970 Manual published ?1978, 1988 (Not in PubMed) Initial data: 553 consecutive adult patients in a single UK primary care practice were assessed. Sample of 200 underwent standardized psychiatric interview. Developed to screen for hidden psychological morbidity. Proprietary test. Now 4 versions.
Hospital Anxiety & Depression Scale *Zigmond & Snaith*	Published in 1983 Initial data: Patients between 16 & 65 in outpatient clinics in the UK >100 patients; 2 refusals. 1st 50 compared to 2nd 50.
Inventory of Interpersonal Problems *Horowitz*	Published 1988 Initial data: 103 patients about to undergo psychotherapy; some patients post psycho-therapy (Kaiser Permanente-San Francisco) Proprietary test
King's Health Questionnaire	1997 Initial data: 293 consecutive women referred for urinary

Kelleher, Cardozo, Khullar, & Salvatore	incontinence evaluation in London Comparison to SF-36
Minnesota Multi-phasic Personality Inventory *Hathaway & McKinley* *Butcher, Dahlstrom, Graham, & Tellegen*	Published in 1941 Updated in 1989 with new, larger, more diverse sample. MMPI-2: 1,138 men & 462 women from diverse communities & several geographic regions in the U.S.A. The test is copyrighted.
Modified Androphia-Gynephilia Index	Neither the underlying version or the Blanchard modified version could be located in PubMed (Designed by the author of the Blanchard et al. study)
"post-operative functioning 13 items" *Doorn, Kuiper, Verschoor, Cohen-Kettenis*	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
"post-operative functioning 21 items" *Doorn, Kuiper, Verschoor, Cohen-Kettenis*	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
Scale for Depersonalization Experiences *Wolfradt*	Unpublished manuscript 1998 (University of Halle) (Designed by 1 of the authors of the Wolfradt study)
"sex trait function" *Cohen-Kettenis & van Goozen*	Published 1997 Assessed in 22 adolescents (Designed by 1 of the authors of the Smith Study)
Self-Esteem Scale *Rosenberg*	Published 1965 (Not in PubMed) Initial data: 5,024 high-school juniors & seniors from 10 randomly selected New York schools
Short-Form 36 *RAND* *Ware & Sherbourne1992* *McHorney, Ware, & Raczek 1993*	Originally derived from the Rand Medical Outcomes Study (n=2471 in version 1; 6742 in version 2 1989). The earliest test version is free. Alternative scoring has been developed. There is a commercial version with a manual.
Social Anxiety & Distress Scale *Watson & Friend*	Initial publication in1969 Requires permission for use
Social Support Scale *Van Tilburg 1988*	Published 1988 (Dutch) (Not in PubMed)
Spielberger State & Trait Anxiety Questionnaire *Spielberger, Gorsuch, Lushene, Vagg, & Jacobs*	Current format published in 1983 Proprietary test
Symptom Checklist-90 *Derogatis, Lipman, Covi* *Derogatis & Cleary*	Published in 1973 & 1977 Reportedly with normative data for psychiatric patients (in- & out-patient) & normal subjects in the U.S. Has undergone a revision Requires qualification for use
Tennessee Self-Concept	In use prior to 1988 publication.

Scale *Fitts & Warren*	Initial data: 131 psychiatric day care patients. Updated manual published 1996. Update population >3000 with age stratification. No other innformation available. Requires qualification for use
Utrecht Gender Dysphoria Scale *Cohen-Kettenis & van Goozen*	Published in 1997 Initial population: 22 transgender adolescents who underwent reassignment surgery. (Designed by 1 of the authors of the Smith study)
WHO-Quality of Life (abbreviated version) *Harper for WHO group*	Field trial version released 1996 Tested in multiple countries. The Seattle site consisted of 192 of the 8294 subjects tested). Population not otherwise described. The minimal clinically important difference has not been determined. Permission required

Althof et al., 1983; Greenberg, Frank, 1965; Gurtman, 1996; Lang, Vernon, 1977; Paap et al., 2012; Salkind et al., 1969; Vacchiano, Strauss, 1968.

Appendix F

Endpoint Data Types and Sources

Panel A (Controlled Studies)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Substantive &/or Accessible Normative Data	Investigator-designed	Other	Other
Dhejne 2011	Yes	-	-	-	-	Mortality (Suicide, Cardiovascular Disease [possible adverse events from Hormone Tx], Cancer), Psych hx & hospitalization, Suicide attempts
Dhejne Landén	Yes	-	-	-	Includes demographics*	Education, Employment, Formal application for reversal of status, Psych dx & tx, Substance abuse** More elements in earlier paper
Beatrice	-	MMPI form R, TSCS	-	-	Demographic	Education, Income, Relationships

Haraldsen	-	SCL-90/90R	-	-	Demographic	DSM Axis 1, II, V (GAF), Substance abuse
Heylens	-	SCL-90	-	Yes-2	Demographic	Employment, Relationships, Substance abuse, Suicide attempts
Ainsworth	-	Likely SF-36v2*	-	Yes-1	Demographic	-
Ruppin	-	SCL-90R	BSRI, FPI-R, IIP	Yes-2	Demographic	Adverse events from surgery, Employment, Psych tx, Relationships, Substance abuse
Smith	-	MMPI-short, SCL-90?R	BIS, UGDS, ? Cohen-Kettenis', Doorn's x2, (Gid-c, SSS)	Yes-1 or 2	Demographic	Adverse events from surgery, Employment, Relationships
Udeze Megeri	-	SCL-90R	BDI, GHQ, HADS,STAI-X1, STAI-X2	-	-	Psych eval & ICD-10 dx
Kuhn	-	-	KHQ	Yes-1	Demographic	Relationships
Mate-Kole 1990	-	-	BSRI, CCEI	Yes-1	Demographic	Employment (relative change), Psych hx, Suicide hx
Wolfradt	-	-	BIQ, GITS, SDE, SES	Yes-1	-	-
Kraemer	-	-	FBeK	-	Demographic	-
Mate-Kole 1988	-	-	BSRI, CCEI	-	Demographic	Employment, Psych hx, Suicide hx,
Kockott	-	-	-	Yes-1	Demographic	Employment, Income, Relationships, Suicide attempts
Meyer	-	-	-	Yes-1	Demographic	Education, Employment, Income, Psych tx, Phallus removal request
Rakic	-	-	-	Yes-1	Demographic	Employment, Relationships

Panel B (Surgical Series: No Concurrent Controls)

Author	**National Data**	**Instrument w Substantive Normative Data**	**Instrument w/o Sub-stantive &/or Accessible Normative Data**	**Investigator-designed**	**Other**	**Other**
Weyers	-	SF-36	FSFI	Yes-2	Demographic	Hormone levels, Adverse events from surgery, Relationships
Blanchard	-	SCL-90R	(AG)	Yes-1	Demographic	Education, Employment, Income,

						Relationships, Suicide (Incidental finding)
Wierckx	-	SF-36	-	Yes-3	Demographic	Hormone levels, Adverse events from surgery, Relationships
Eldh	-	-	-	Yes-1	-	Adverse events from surgery, Employment, Relationships, Suicide attempts
Hess	-	-	-	Yes-1	-	-
Lawrence	-	-	-	Yes-4	Demographic	Adverse events from surgery
Salvador	-	-	-	Yes-1	Demographic	Relationships
Tsoi	-	-	-	Yes-1	Demographic	Education, Employment, Relationships (relative change)

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	**National Data**	**Instrument w Substantive Normative Data**	**Instrument w/o Sub-stantive &/or Accessible Normative Data**	**Investigator-designed**	**Other**	**Other**
Asscheman et al.	Yes	-	-	-	Demographic	Mortality (HIV, Possible adverse events from Hormone Tx, Substance abuse, Suicide)
Motmans et al.	-	SF36 EQOLS (2nd)	-	-	Demographic	Education, Employment, Income, Relationships
Newfield et al.	-	SF-36v2	-	-	Demographic	Income
Gómez-Gil et al. 2014	-	WHOQOL-BREF	APGAR	Yes-1	Demographic	Education, Employment, Relationships
Gómez-Gil et al. 2012	-	-	HADS, SADS	-	Demographic	Education, Employment, Living arrangements
Hepp et al.	-	-	HADS	-	Demographic	DSM Axis 1& II Psych dx
Johansson et al.	-	-	-	Yes-1	Demographic	Axis V change (Pt & Clinician) Employment (relative change) Relationship (relative change)

Leinung et al.	-	-	-	-	Demographic	Employment, Disability, DVT, HIV status, Psych dx

*Listed as San Francisco-36 in manuscript

** From medical charts & verdicts ?=Possibly self-designed

AG=Androphilia-Gynephilia Index (investigator designed 1985) (used more for classification)

APGAR=Family Adaptability, Partnership growth, Affection, and Resolve

BDI=Beck Depression Inventory

BIQ=Body Image Questionnaire

BIS=Body Image Scale

BSRI=Bem Sex Role Inventory

CCEI=Crown Crisp Experiential Index

Cohen-Kettenis'= Sex trait function (An author helped design)

Dorn's x2= Post-operative functioning 13 items (An author helped design)

Post-operative functioning 21 items (An author helped design)

EQOLS (2nd)=2nd European Quality of Life Survey

FBeK=Fragebogen zur Beurteilung des eigenen Korpers

FPI-R=A version of the Freiberg Personality Inventory

FSFI+Female Sexual Function Index

GHQ=General Health Questionnaire

Gid-c=Gender identity disorder in childhood (used more for predictors) (An author helped design)

GITS=Gender Identity Trait Scale

HADS=Hospital Anxiety Depression Scale

IIP=Inventory of Interpersonal Problems

KHQ=King's Health Questionnaire

MMPI=Minnesota Multi-phasic Personality Inventory

SADS=Social Anxiety & Distress Scale

SCL-90 (±R)=A version of the Symptom Checklist 90

SDE=Scale for Depersonalized Experiences (An author designed)

SES=Self-Esteem Scale

SF-36 (v2)=Short Form-36(version2)

SSS=Social Support Scale (used more for predictors)

STAI-X1, STAI-X2=Spielberger State and Trait Anxiety Questionnaire

TSCS=Tennessee Self-Concept Scale

UGDS=Utrecht Gender Dysphoria Scale (An author helped design)

WHOQOL-BREF=World Health Organization-Quality of Life (abbreviated version)

Appendix G.

Longitudinal Studies Which Used Patients as Their Own Controls and Which Used Psychometric Tests with Extensive Normative Data or Longitudinal Studies Which Used National Data Sets

Author		**Test**	**Patient and Data Loss**	**Results**
		Psychometric Test		
Heylens et al. Belgium 2014		SCL-90R	90 applicants for SRS were recruited. • 8 (8.9%) declined participation.	At t=0, the mean global "psychoneuroticism" SCL-90R score, along with scores of 7 of 8 subscales, were statistically

			• 12 (13.3%) excluded b/c GID-NOS dx. • 12 (13.3%) did not complete the treatment sequence b/c of psychiatric/physical co-morbidity, personal decision for no tx, or personal decision for only hormone tx. • 1 (1.1%) committed suicide during follow-up. 57 (63.3% of recruited) entered the study. • 1 (12.2% of initial recruits) had not yet received SRS by study close. →**46 (51.1% of recruited) underwent serial evaluation** • The test was not completed by 1 at t=0, 10 at t=1 (after hormone tx), & 4 at t=2 (after SRS) →**missing data for another 1.1% to 11.1%.**	more pathologic than the general population. After hormone tx, the mean score for global "psychoneuroticism" normalized & remained normal after reassignment surgery.
Ruppin,Pfafflin, Germany 2015		SCL-90R	The number in the available patient pool was not specified. 140 received recruitment letters. • 2 (1.4% of those with recruitment letters) had died. • 1 (0.7%) was institutionalized. • 5 (3.6%) were ill. • 8 (5.7%) did not have time. • 8 (5.7%) stated that GD was no longer an issue. • 8 (5.7%) provided no reason. • 28 (20.0%) declined further contact. • 9 (6.4%) were lost to follow-up. →**71 (50.7%) agreed**	At t=0, the "global severity index "SCL-90R score was 0.53±0.49. At post-SRS follow-up the score had decreased to 0.28±0.36. The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 0-4. In the same way, all of the subscale scores were statistically different, but the effect size was reported as large only for "interpersonal sensitivity": 0.70±0.67 at t=0 and 0.26±0.34 post-SRS.

			to participate. • **2 (1.4%) had not undergone SRS** • The test was not completed by 9. →**missing data for another 6.4%.**	
Smith et al. Holland 2005		MMPI SCL-90	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. • 103 (31.7%) were not eligible to start hormone tx & real-life experience. • 34 (10.7%) discontinued hormone tx 162 (an unknown percentage of the initial recruitment) provided pre-SRS test data. • **36 to 61 (22.2%-37.6% of those adults w pre-SRS data) did not complete post-SRS testing.**	Most of the MMPI scales were already in the normal range at the time of initial testing. At t=0, the global "psychoneuroticism" SCL-90 score, which included the drop-outs, was 143.0±40.7. At post SRS-follow-up, the score had decreased to 120.3±31.4. The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 90 to 450, with higher scores consistent with more psychological instability.
Udeze, et al. 2008 Megeri, Khoosal 2007 UK		SCL-90R	The number in the available patient pool was not specified. 40 subjects were prospectively selected. • Post-operative testing was conducted within 6 months to minimize previously determined loss rates.	At t=0, the mean raw global score was 48.33. At post-SRS follow-up, the mean score was 49.15. There were no statistically significant changes in the global score or for any of the subscales.
	National Databases			
Dehjne Sweden 2011		Swedish National Records	804 with GID in Sweden 1973 to 2003 were identified. • 480 (59.7%) did not apply or were not approved for SRS 324 (40.3%) underwent SRS. • All were followed. 3240 controls of the natal sex and 3240 controls of the reassigned gender	All cause mortality was higher (n=27[8%]) than in controls (H.R 2.8 [1.8-4.3]) even after adjustment for covariants. Divergence in survival curves was observed after 10 years. The major contributor was completed suicide (n=10 [3%]; adjusted H.R. 19.1 [5.8-62.9]). Suicide attempts were more

		were randomly selected from national records	common (n= 29 [9%]) than in controls (adjusted H.R. 4.9 [2.9–8.5]). Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common n= 64 [20%] than in controls (H.R. 2.8 [2.0–3.9]) even after adjusting for prior psychiatric morbidity.
Dhejne et al. 2014 Landén et al. 1998 Sweden	Swedish National Registry	767 applied for SRS/legal status (1960-2010) • 25 (3.3%) applications denied. • 61 (8.0%) not granted full legal status 681 (88.7%) underwent SRS. • All were followed.	15 formal applications for reversal to natal/original gender (2.2% of the SRS population) were identified thus far (preliminary number). (Does not reflect other manifestations of regret such as suicide.)

GID-NOS=Gender Identity Disorder-Not Otherwise Specified HR=Hazard Ratio SRS=Sex reassignment surgery Tx=Treatment

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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 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

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*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

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

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Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

Matthew Brackett DATE

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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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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*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
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

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Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

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Matthew Brackett DATE

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Ron DeSantis
Governor

Joseph A. Ladapo, MD, PhD
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

Treatment of Gender Dysphoria for Children and Adolescents

April 20, 2022

The Florida Department of Health wants to clarify evidence recently cited on a fact sheet released by the US Department of Health and Human Services and provide guidance on treating gender dysphoria for children and adolescents.

Systematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex. One review concludes that "hormonal treatments for transgender adolescents can achieve their intended physical effects, but **evidence regarding their psychosocial and cognitive impact is generally lacking**."

According to the Merck Manual, “gender dysphoria is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the sex assigned at birth.”

Due to the lack of conclusive evidence, and the potential for long-term, irreversible effects, the Department's guidelines are as follows:

- Social gender transition should not be a treatment option for children or adolescents.
- Anyone under 18 should not be prescribed puberty blockers or hormone therapy.
- Gender reassignment surgery should not be a treatment option for children or adolescents.
    - Based on the currently available evidence, "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an **unacceptably high risk of doing harm**."
- Children and adolescents should be provided social support by peers and family and seek counseling from a licensed provider.

These guidelines do not apply to procedures or treatments for children or adolescents born with a genetically or biochemically verifiable disorder of sex development (DSD). These disorders include, but are not limited to, 46, XX DSD; 46, XY DSD; sex chromosome DSDs; XX or XY sex reversal; and ovotesticular disorder.

The Department’s guidelines are consistent with the federal Centers for Medicare and Medicaid Services age requirement for surgical and non-surgical treatment. These guidelines are also in line with the guidance, reviews, and recommendations from Sweden, Finland, the United Kingdom, and France.

Parents are encouraged to reach out to their child’s health care provider for more information.

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

April 20, 2022

Tom Wallace
Deputy Secretary for Medicaid
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308

Dear Deputy Secretary Wallace:

On April 20, 2022, the Florida Department of Health released guidance on the treatment of gender dysphoria for children and adolescents.[1] The Florida Medicaid program does not have a policy on whether to cover such treatments for Medicaid recipients diagnosed with gender dysphoria. Please determine, under the process described in Florida Administrative Code Rule 59G-1035, whether such treatments are consistent with generally accepted professional medical standards and not experimental or investigational. Pursuant to Rule 59G-1035(5), I look forward to receiving your final determination.

Sincerely,

Simone Marstiller
Secretary

[1] *See* https://www.floridahealth.gov/newsroom/2022/04/20220420-gender-dysphoria-press-release.pr.html (last visited Apr. 20, 2022).

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Sincerely,

Simone Marstiller
Secretary

[1] *See* https://www.floridahealth.gov/newsroom/2022/04/20220420-gender-dysphoria-press-release.pr.html (last visited Apr. 20, 2022).

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

TALLAHASSEE DIVISION

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

AUGUST DEKKER, et al.,

Plaintiffs,

vs.

JASON WEIDA,

Defendant.

_____/

DEPOSITION OF: ANN DALTON

DATE: TUESDAY, JANUARY 24, 2023

TIME: 10:04 A.M. - 6:05 P.M.

PLACE: AGENCY FOR HEALTH CARE ADMINISTRATION
2727 MAHAN DRIVE
TALLAHASSEE, FLORIDA 32308

STENOGRAPHICALLY REPORTED BY: GREG T. SMITH

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S T I P U L A T I O N S

It is hereby stipulated and agreed by and between the counsel for the respective parties and the deponent that the reading and signing of the deposition transcript be reserved.

P R O C E E D I N G S

THE COURT REPORTER: Do you swear or affirm that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: Yes.

ANN DALTON,

having first been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. DEBRIERE:

Q. Ms. Dalton, have you ever had your deposition taken before?

A. Yes.

Q. Okay. So I'm just going to walk through some preliminary issues and go over some basic instructions that you've probably heard a million times, and then I'll get started with the questioning.

A. Okay.

MS. DUNN: Sorry. Before we start, can we introduce everybody who is on the phone.

MS. DEBRIERE: Absolutely. Thank you, Chelsea.

Before we start, we want to introduces folks on the phone.

MS. DUNN: I think there's one person who is currently muted. Someone just joined.

Shani, are you there?

MS. RIVAUX: Good morning. This is Shani Rivaux.

MS. DEBRIERE: Anyone else, Chelsea?

MS. DUNN: There is one person. I just don't know who it is.

MS. DEBRIERE: Is anybody else there?

MS. DUNN: It's a 305 number. So it's Miami.

MS. CHRISS: That's Jennifer.

MS. DEBRIERE: Okay. Jennifer Altman is the other person.

MS. DUNN: If folks on the line could mute their phones just so we don't have any background noise, that would be helpful. Thanks.

MS. DEBRIERE: So we're just going to mark exhibits as they're discussed. I'll be showing you papers to read off, and we'll just mark them as we move through. As I mark those exhibits, I'm going to read something called a Bates number; that just helps us track what pages we're on when we discuss things. If there's a Bates number, it's probably going to start with "DEF," then underscore, then the Bates number.

I'd like to go ahead and mark the notice of deposition as Exhibit 1. There's no Bates number on

that one.

MS. DUNN: And Catherine McKee just joined the line as well.

MS. DEBRIERE: It's just the notice that brings you here today.

(Plaintiff's Exhibit No. 1 was marked for identification.)

BY MS. DEBRIERE:

Q. So I'm going to be using the acronym GAPMS quite a bit. Do you know what that stands for?

A. Yes.

MS. DEBRIERE: And, Court Reporter, it's G-A-P-M-S.

BY MS. DEBRIERE:

Q. And it stands for generally accepted professional medical standards; which is set forth in 59G-1.035. You probably don't have that memorized. That's okay.

I will use the term "gender dysphoria," which is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth and the associated gender role and/or primary and secondary sex characteristics. When I use that term, can we just agree that's the definition I'm using?

A. Okay.

Q. I'm also going to be using the phrase "categorical exclusion of gender affirming care." And that's just the exclusion set out in 59G-1.050, Subpart 7. That's why we're here for today, for that exclusion of gender affirming care. Do you understand what I mean when I say that?

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

THE WITNESS: Yes.

BY MS. DEBRIERE:

Q. Well, I do want to make sure you understand what I'm talking about. Would you like to see a copy of the rule before we can agree on use of that phrase? Because as I use it, I do want to make sure we're talking the same thing.

A. Yeah.

MS. DEBRIERE: So we'll mark this as Exhibit 2. It's a copy of 59G-1.050.

(Plaintiff's Exhibit No. 2 was marked for identification.)

BY MS. DEBRIERE:

Q. If you scroll down to Subpart 7 -- scroll down; you're not a computer. If you follow down to Subpart 7 --

MR. PERKO: It's on the back of the page.
BY MS. DEBRIERE:
Q. So when I'm using the phrase "categorical exclusion of gender affirming care," I'm referring to that Subpart 7. Can we agree that that's the phrase that encompasses that portion of the rule?
MR. PERKO: I'm going to object to form.
But you can answer.
MS. DEBRIERE: Well, I think we do need -- Gary, I understand where you're coming from. But I think we just need to figure out a way to shorthand --
MR. PERKO: That's fine.
MS. DEBRIERE: -- that reference.
MR. PERKO: I'm just objecting to the use of "gender affirming care."
MS. DEBRIERE: Okay. How about "treatment for just gender dysphoria"? Would you --
MR. PERKO: That's fine.
BY MS. DEBRIERE:
Q. So we're going to use "categorical exclusion of treatment for gender dysphoria." And when I use that phrase -- categorical exclusion of treatment for gender dysphoria -- I'm referring to that Subpart 7. Can we agree to that?

A. Okay.

Q. I'm also going to use the term "EPSDT services"; which is an acronym for early and periodic screening, diagnostic, and treatment services. When I say "EPSDT," do you know what I mean when I say that?

A. Yes.

Q. So my name is Katy DeBriere. And I represent the plaintiffs August Dekker, Brit Rothstein, and Susan Doe and K.F.

I know you've been deposed before. I'm just going to go over some very brief instructions, just as a refresher.

If I ask a question ask and you don't understand it, don't try to, you know, understand what I'm saying and try to answer the question. Instead, just stop me and tell me to rephrase so that you understand the question. That's no problem at all.

A. Yes.

Q. And speaking one at a time -- I have a horrible habit of speaking over people. But we need to try and do our best to speak one at a time, so the court reporter can get down everything we say. I don't think you're going to have that problem, but I will. So please just let me finish my question before you answer. And I will do my best to do the same when you're

providing an answer back to me; okay?

A. Yes.

Q. Verbal answers -- again, it's clear that you understand. But as we move through, the court reporter can't record things like "uh-huh," or "huh-uh." So if you could just use "yes," or "no," or words whenever you are responding to a question; okay?

A. Yes.

Q. If you need to take a break for any reason, please feel free to ask me. Stop me; tell me you need to take a break. That's not going to be a problem at all. The only thing I ask is that you finish answering your question before we do.

A. Yes.

Q. Okay. Are you on any medications or other substances that can impact your memory today?

A. No.

Q. Can you state your name.

A. Ann Dalton.

Q. And, Ms. Dalton, what did you do to prepare for today?

A. I met with my attorneys.

Q. Okay. And how long did you meet with them for?

A. 45 minutes.

Q. Okay. Did you review any documents?

A. No.

Q. Okay. Can you describe your educational background for me.

A. I have master's degree in music from Florida State University and a bachelor's degree in music from Northern Kentucky University.

Q. What's your current position at the Agency for Health Care Administration?

MS. DEBRIERE: And, Court Reporter, probably throughout the deposition we'll be using "AHCA"; which is the acronym -- AHCA. Or I might reference "the agency" at times. And when I reference "the agency," I mean the Agency for Health Care Administration.

BY MS. DEBRIERE:

Q. So what is your current position at AHCA?

A. I'm the bureau chief of the Bureau of Medicaid Policy.

Q. How long have you worked in that role?

A. Since -- officially, since August 2021.

Q. Okay. What did you do prior to that role?

A. I was an AHCA administrator in the Bureau of Medicaid Policy.

Q. What does that mean to be an AHCA administrator?

A. I was a manager of a team -- the Program Authority Section in the Bureau of Medicaid Policy.

Q. What kind of responsibilities does that entail?

A. The Program Authorities Section was responsible for submitting and maintaining the Medicaid waivers, the Medicaid state plan with the federal partners at CMS; the promulgation of administrative rules; and the PACE program.

Q. And how long were you in that role for?

A. Since August 2018.

Q. What did you do prior to that?

A. I was a program administrator over a section in the Bureau of Medicaid Policy.

Q. And what responsibilities does that entail?

A. That section was titled Program Policy. And it was responsible for the Children's Health Insurance Program or CHIP Program; the provider enrollment policy; the eligibility rule; and a few other rule areas that I can't remember.

Q. What do you mean by eligibility rule? What's that?

A. The -- I don't remember the exact rule number. But it is the rule that outlines the eligibility criteria for recipients in the Medicaid program.

Q. Okay. Is that related to what category of

Medicaid someone would fall under in order to be eligible for Medicaid?

A. I believe so.

Q. Okay. And how long were you in that position for?

A. From January 2018 to August of 2018.

Q. And what did you do prior to that?

A. I worked at the Department of Elder Affairs as a senior management analyst in the Long Term Services and Supports Bureau.

Q. And how long were you in that role for?

A. From August 2017 to January 2018.

Q. Did that role require any knowledge about Medicaid?

A. Yes.

Q. And did that role require any knowledge about rulemaking?

A. Not the promulgation process itself, per Chapter 120; but the development of rule language, yes.

Q. Okay. And when did you start at DOEA?

A. June 2012.

Q. Okay. And so what other positions did you hold there between June 2012 and when you became the senior program management analyst?

A. I held various analyst positions within the

same unit.

Q. Okay. And did those other positions require knowledge of Medicaid?

A. Yes.

Q. And did those other positions require knowledge about rule promulgation?

A. The same as the senior management analyst would have.

Q. In your current role at AHCA, who is your direct supervisor?

A. Currently Brian Meyer is my direct supervisor.

Q. And who is that person's supervisor?

A. Jason Weida.

Q. And what is Brian Meyer's position at the agency?

A. These changes are recent. And I'm not sure of the exact title of his position.

Q. How is his position in relation to Tom Wallace? Or I should ask: What is Tom Wallace's position at the agency?

A. He's a deputy secretary at the agency.

Q. Does Brian Meyer supervise him?

A. No, I believe they're the same position.

Q. Okay.

A. But, again, these are recent changes, and I'm

not quite sure of the exact title.

Q. What was Brian Meyer's role before he changed into the role he currently is in?

A. He was assistant deputy secretary of operations.

Q. Okay. Is Brian within the Bureau of Medicaid Policy?

A. No.

Q. Okay. Is he within any specific bureau at the agency?

A. No.

Q. Describe your current role at the agency for me. What are the responsibilities?

A. I oversee the Bureau of Medicaid Policy. The Bureau of Medicaid Policy is responsible for the federal authorities; which are the contracts between us and the federal government that manage the Medicaid program in Florida. Promulgates -- we oversee the promulgation of all the rules and rule class 59G; which are the Medicaid rules. Oversee the coverage policy development; those coverage policies are promulgated in administrative rule, but outline the specific services and the criteria for reimbursement.

The administration of the CHIP program is also part of the bureau's responsibility. And the managed

care plan contracts -- the drafting of those contracts and policy actions related to the managed care program.

Q. What are coverage policies?

A. Coverage policies are documents that contain the information needed by providers and recipients that describes the service and also provides the information that they would need to be reimbursed -- providers would need to be reimbursed for a service. It describes who can provide the service, who can receive the service, and then any service criteria or details around that service.

Q. What do you mean "service criteria"? Can you explain that further.

A. A description of the service and then any exclusions, if there are any, pertaining to that service. It's different for each coverage policy.

Q. Okay. And what are coverage handbooks?

A. "Handbooks" is a term that we used to use at the agency. A lot of the coverage polices were -- they are now separate coverage policies, but they were contained in bigger handbooks that have since been kind of broken down to be more service specific. And so the term that we use now to describe the information that was previously contained in the handbooks is "coverage policy."

Q. Are the handbooks promulgated into rule?
A. Yes.
Q. And does the agency still rely on those handbooks in determining service eligibility?
A. If the information from a handbook was moved to a coverage policy, the coverage policy would be promulgated in the rule and the handbook would no longer be part of that rule.
Q. Can you give a recent example of the handbook information moving into a coverage policy rule.
A. It's not that recent, but it's the first one that comes to my mind -- is the Home Health Handbook was broken down into three coverage policies, I believe, around 2016. And those three policies are the Home Health Services Coverage Policy, Personal Care Services Coverage Policy, and the Private Duty Nursing Services Coverage Policy.
Q. Okay. And this will seem like a simple question. But where do those coverage policies -- can the public access those coverage policies?
A. Yes.
Q. And where would they access those coverage policies?
A. The agency has an external web page specific to all the coverage policies, fee schedules, reimbursement

policies.

Q. And the policies that are on that public facing website, are they all inclusive of the policies on which the agency relies for determining coverage? Strike that question.

Is it an exhaustive -- is what is contained on the agency's website, is it an exhaustive list of Medicaid coverage policies?

A. All the policies promulgated in class 59G. And the rules or links to the FAR notice are on our website, yes.

Q. Are there any coverage policies not on the website on which AHCA relies to determine coverage of Medicaid services?

A. Not that I'm aware of.

Q. What is a fee schedule?

A. A fee schedule is the document that provides information on billing codes, the description associated with a code, and the amount that Medicaid will reimburse for fee for service.

Q. What is fee for service?

A. Fee for service is a delivery system where the State pays providers directly -- reimburses them directly for the service provided.

Q. Is that in contrast to managed care?

A. It's a different delivery model.

Q. If a Medicaid service is listed on the fee schedule, does that mean Medicaid covers it?

I'll strike that. I think I can ask a question that well help here.

If a Medicaid service is on the fee schedule, does that mean Medicaid does not categorically exclude it?

MR. PERKO: Object to form.

MS. DEBRIERE: You can go ahead and answer if you understand. If you don't understand, please feel free to ask me to rephase.

THE WITNESS: I don't think I understand.

BY MS. DEBRIERE:

Q. If a Medicaid service is listed on a fee schedule, does that mean that Medicaid is willing to pay for it if the recipient meets all eligibility criteria for that service?

A. So the fee schedules have to be used in conjunction with the coverage policy. So, like I said, the fee schedule contains the coding that the provider needs to use in order to get reimbursed, and, in most cases, the amount and description. But the parameters of who can receive the service -- what kind of providers can get reimbursed for the service -- that's in the

coverage policy.

Q. Okay. What would it mean if a Medicaid service was not on the fee schedule?

A. So the fee schedule document and the term as we would use "fee schedule" does not include all of the services. Some of those are going to be found in the reimbursement methodology rules, if there's not a specific fee equated to a specific code. So there's also reimbursement methodology rules and documents as well.

Q. Are there services -- Medicaid services on the fee schedule that AHCA will not cover?

A. I don't know if there's any. But it would be -- any information about how the services covered would be included -- either on the fee schedule or in the coverage policy.

Q. Okay. Do your responsibilities currently include developing coverage policies for the Florida Medicaid program?

A. I oversee the teams that are responsible for that, yes.

Q. And who are those individuals? Or let's start with: Who are the teams?

A. The team primarily responsible for the majority of the coverage policies is the team managed by Jesse

Bottcher; he's the AHCA administrator. And he has three program administrators who report directly to him.

Q. And who are those people?

A. Christine Polacheck [phonetic], and she oversees the specialized services section. John Matson, he's the manager over at the primary and preventative services section. And then Tim Beaner is the manager over the behavioral health and behavioral analysis section.

Q. Are those the only teams over which you manage? Or are there other teams?

A. I have five AHCA administrator direct reports.

Q. Okay.

A. And then one program administrator direct report. So I have six direct management team reports.

Q. So who are the other ones?

A. Catherine Mcgrath is the AHCA administrator over the program authority section. Ashley Peterson is the AHCA administrator over at the pharmacy policy section. One of them is vacant -- the managed care contract AHCA administrator position. Devona Pickle, she is the AHCA administrator over the Canadian Prescription Drug Importation team. And Jesse Bottcher. And then Lakeva Campbell [phonetic] is a program administrator over the administrative unit who does the

administrative functions of the bureau.

Q. Who works under Jesse Bottcher?

A. That was Christine Polacheck, John Matson, and Tim Beaner.

Q. And do you know who Mr. Jeff English is?

A. Yes.

Q. And who is his supervisor?

A. His current supervisor is Cole Giering.

Q. Who is Mr. Giering's supervisor?

A. Catherine Mcgrath.

Q. And Mr. Bottcher -- does he supervise the person who undertakes GAPMS analysis?

A. The position that is designated to do the GAPMS is under Jesse Bottcher.

Q. Okay. And who does Ms. Peterson supervise?

A. The pharmacy policy team, which consists mostly of pharmacists within the bureau.

Q. How many pharmacists are there?

A. In Ashley's section, there are currently three.

Q. Do you know the names of any of those people?

A. Yes. Jessica Forbes, Kelly Rubin, Susan Williams.

Q. Are you familiar with a person named Nai Chen?

A. Yes.

Q. And who is his supervisor?

A. D.D. Pickle.
Q. And was Mr. Chen ever involved in the pharmacy policy? Did Mr. Chen ever work for the pharmacy policy unit?
A. No.
Q. How long has Mr. Chen been in that position?
A. I don't remember.
Q. More than a year?
A. Yes.
Q. More than two years?
A. I'm not sure.
Q. Okay. Does Mr. Chen in his position have any responsibilities over pharmacy coverage policies?
A. None that are currently promulgated.
Q. What about policies that are not promulgated?
A. I don't know if there's going to be the need for a coverage policy or what types of administrative rule we're going to need to implement the Canadian Prescription Drug Importation Program once that's federally approved -- which is why I answered how I did.
Q. Are there any other pharmacy related activities that Mr. Chen engaged in the past year?
A. Yes.
Q. What are those?
A. His -- he's part of the Canadian Prescription

Drug Importation Program team. And there has been pharmacy related activity regarding the SIP approval.

Q. What does SIP stand for? Or you can just describe it if that's easier.

A. It's the proposal or the importation program plan that the federal government authorized states to submit or request approval of in order to develop an importation program. And this was submitted to the FDA.

Q. What does the Canadian Prescription Drug Importation unit do?

A. Their primary responsibility is to implement the Canadian Prescription Drug Importation Program that was statutorily authorized -- and I think it was in 2019 -- which includes seeking that federal approval from the FDA and any implementation activities in managing the contract with LifeScience Logistics -- the agency's vendor who assists with that program.

Q. And did Mr. Chen over the past year have any responsibilities related to pharmacy activities that did not involve the Canadian Prescription Drug Importation Program?

A. Yes.

Q. And what were those?

A. I can't recall all the specific assignments. But he has helped with several research projects. I

think he has assisted Ashley's team with some questions or answering questions. And he's been available to assist with just different research projects.

Q. Was he involved at all with the categorical exclusion of treatment for gender dysphoria in developing the pharmacy coverage decisions related to that?

A. So when you ask that, you're specifically talking about the rule?

Q. I'm talking about the rule and the ways in which AHCA is implementing the rule.

A. I don't know to the extent -- I know that he assisted with research for the GAPMS report.

Q. Okay. And by GAPMS report, is that the report that is related to the categorical exclusion for treatment of gender dysphoria?

A. Yes.

Q. Why did Mr. Chen assist the pharmacy unit with the GAPMS report instead of the other pharmacists in the pharmacy policy unit? I'll strike that.

Why did Mr. Chen -- does the Canadian Prescription Drug Importation unit focus on pharmacy policies unrelated to the Canadian Prescription Drug Importation Program typically?

A. Since there's been such a long delay with the

federal approval of the Canadian Prescription Drug Importation Program, that team has assisted with various other projects within the bureau.

Q. Okay. Is that why Mr. Chen assisted with the GAPMS report for the exclusion of the treatment for gender dysphoria?

A. Yes.

Q. What types of services does AHCA develop coverage policies for? Actually -- I'm sorry; strike that. I apologize.

What does the Pharmacy Policy unit do?

A. Their job entails a lot of duties. Primarily they host and oversee the PNT and DUR meetings -- public meetings and the boards associated with that. They oversee the coverage policies specific to pharmacy. They assist with any contract language for the managed care contacts for pharmacy. They oversee the contract for our PBM contractor Magellan. Those are the primary duties.

Q. What does PBM stand for?

A. Pharmacy benefits manager.

Q. And what is that?

A. PBMs can have various duties. But the contract that I'm referring to is our rebate negotiation contract.

Q. Okay. And you said that PBM contract is with Magellan; is that correct?
A. Yes.
Q. Okay. What's DUR?
A. Drug Utilization Review Board.
Q. And I think you used one other acronym when you were discussing the public facing pharmacy meetings.
A. PNT.
Q. And what does that stand for?
A. I believe it's pharmaceuticals and therapeutics.
Q. Okay. And what is that?
A. All the responsibilities of that board are outlined in statute.
Q. Okay.
A. I can't think off the top of my head. But they meet quarterly. And we host those meetings and schedule them.
Q. Okay. A few more questions about Mr. Chen.
Is Mr. Chen a pharmacist?
A. I believe so.
Q. And is he the only pharmacist in the Canadian Prescription Drug Importation Program unit?
A. None of the other members of that team are pharmacists.

Q. So Mr. Chen is the only one?
A. Yes.
Q. Okay. Did any other pharmacist assist with the 2022 GAPMS relating to exclusion of treatment for gender dysphoria?
A. I don't know.
Q. What types of services does AHCA develop coverage policies for?
A. The coverage policies are -- outline the services that the State covers through the state plan -- Medicaid state plan or Medicaid waivers. So those are just any Medicaid related service.
Q. Does AHCA develop coverage policies for surgeries?
A. Yes.
Q. How about for prescription drugs?
A. Yes.
Q. Does AHCA develop coverage policies for every Medicaid service?
A. I don't know.
Q. Have you ever had a situation where a Medicaid recipient requests coverage for a service and there is no policy?
A. I personally have not, no.
Q. Okay. And what process does AHCA use to decide

whether to provide coverage of a Medicaid service?

A. That really depends on the specifics of what that service is.

Q. Does every service have a different process?

A. The process could vary based on what the service is that we are determining coverage for.

Q. Do you use the same process for developing pharmacy policy coverage?

A. I can't speak to the process or approach of the analysts. The process of promulgating the coverage policies into rule is always going to be in accordance with Chapter 120.

Q. During your time at AHCA, have you developed -- have you been involved in developing or has your team -- those you supervise -- been involved in developing new coverage policies to cover services?

A. Yes.

Q. Can you remember a specific service that you did that for?

A. Yes. We are currently in the process with promulgating the iBudget Waiver handbook. And as part of the updates to the handbook, one of those is to develop a new life skills development for Level 4 service. As part of that process, we also worked with our federal partners at CMS to get a waiver amendment

approved. That's a very recent example of a new service being developed.

Q. Do you have an example of a state plan service that you developed coverage for that's under current development?

A. Yes. We recently added some Puro Meno products to the DME fee schedule.

Q. And so in that instance, did you establish a coverage policy for those specific items of DME?

A. We did a coverage determination to determine if and how they could be included as a covered service as part of the DME service.

Q. And what is DME?

A. Durable medical equipment.

Q. And that includes medical supplies?

A. Yes.

Q. And Puro Meno would be a medical supply?

A. Yes.

Q. And you, to cover that service, incorporated it onto the fee schedule?

A. Yes.

Q. Did you do --

Okay. How did you assess whether to decide to incorporate Puro Meno into the fee schedule?

A. So I can't speak to all the steps that the

analyst -- the specific steps that they took. But just speaking overall, determined if we had the legislative and state plan authority to cover it; determined if it was -- if there would be a fiscal impact.

And we approach coverage like that example to, you know, try and make sure it's budget neutral since we are -- our coverage is driven by our general appropriations and our state general appropriations act. And then determined if and what types of updates would be needed to any of the Medicaid rules. That's the general process for determining that kind of coverage.

Q. So to make a coverage determination you look at your legislative authority -- authority under the state plan -- and you do a fiscal analysis and hope for budget neutrality. You check to see if there's any updates to Medicaid rules. Anything else?

A. Making sure that it's an allowable service under Medicaid, as well; which would entail that it meets all federal, state rules and regulations for coverage. But, like I said, all the details of the research that the team does -- I can't speak to exactly everything that they read or looked at.

Q. And if in that coverage determination you decide to cover that service, do you then incorporate it into the fee schedule?

A. In the example I gave, that's what we did, yes.
Q. Are there any situations where you would not incorporate it into the fee schedule?
A. Yes.
Q. What are those circumstances?
A. That would vary depending on what the actual request or coverage benefit is that we're looking.
Q. Can you think of an example?
A. Yes. Last legislative session, I believe it was, there was a specific language regarding the coverage of human donor milk and milk derivatives for inpatient use. Because it was under inpatient, that is a -- the reimbursement for that is different and isn't included in a fee schedule.
Q. Okay. That makes sense.
Once this coverage determination is made, do your responsibilities include reviewing that to determine whether to approve the decision?
A. Yes.
Q. And how do you go about doing that?
A. We usually meet with the team. We do a walkthrough, have discussions around the proposal and the recommendation. And then we put together -- depending on what the change is, put together a document to get approval from management -- upper management.

Q. Does that document have a specific title -- the same title every time?

A. No.

Q. How would you identify that document?

A. So if a fee schedule change was needed, there is a formal routing process for the rule promulgation process that would be routed through management and signed off on.

Q. Okay. Are there other documents that would be routed through management to be signed off on?

A. Yes.

Q. And what are the titles of those documents?

A. It depends on the situation. For example, we also have a steering committee at the agency for the division of Medicaid. And we call that a decision point that would be to the steering committee.

Q. Okay.

A. And the Medicaid director or agency leadership is part of that committee. And so that is also a way for us to get approval.

Q. For those coverage determinations that you reviewed and put together in a document for administrative review, who in the administration reviews that document?

A. Depends on what that is. So for administrative

rule -- that needs to be signed off by several agency leadership; including the general counsel, the agency secretary for a proposed rule. So it would depend on what the final document is who the final signatory would be.

Q. Distinct from implementation of the coverage determination, is there a review by the administration of just whether to cover the Medicaid service?

A. It depends on what the specific circumstances are.

Q. Okay. Can you think of an example of the administration reviewing a determination of whether to cover a service?

A. Can you be more specific? So the waiver example I used a while back would be signed to submit the waiver -- the iBudget waiver -- with the changes. That would have been signed by the Medicaid director prior to submission to federal CMS.

Q. How long have you been involved in the process of doing coverage determination?

A. Since my time at AHCA.

Q. Okay. So since -- I'm trying to take notes here. So since August of 2018?

A. January of 2018.

Q. January of 2018. Thank you.

And when you're making coverage determinations, you coordinate with AHCA rules unit if a rule change is needed; is that right?

A. Yes.

Q. Okay. Under what bureau does the AHCA rules unit fall?

A. Under the Bureau of Medicaid Policy.

Q. Okay. So under your unit?

A. In the bureau.

Q. I'm sorry. Under you're bureau?

A. Yes.

Q. And you coordinate with AHCA's pharmacy policy unit; which falls under your -- the pharmacy policy unit falls under your bureau as well; is that right?

A. Yes.

Q. Okay. Do you coordinate with other bureaus in developing coverage determinations?

A. Yes.

Q. Which ones?

A. All the bureaus in the division work closely together. And there have been some recent changes with that structure. But speaking prior to those changes, the Bureau of Medicaid Program Finance would be probably be the primary bureau; because they assist with determining or setting our fee schedules and our rates

and the methodologies and doing fiscal impact analyses -- data analytics -- Medicaid data analytics.

As part of the whole development package, we talk to all the bureaus because plan management operations can be affected if there is an update to the contracts. The Bureau of Medicaid Quality who monitors and oversees the provision of services through those contracts -- and they have various other duties. But depending on what the change is, we would communicate with most of the bureaus within the division.

Q. Okay. You just mentioned some recent changes in terms of that structure. What are those recent changes?

A. The Bureau of Medicaid Finance and Medicaid Data Analytics are reporting directly to Tom. And Plan Management Operations, Quality, and Policy are reporting directly to Brian Meyer.

Q. And why is that a change?

A. Previously I had been reporting directly to Tom Wallace.

Q. Is Brian Meyer's position a new one?

A. I don't know all the details of those changes.

Q. Okay. Who made the decision to make those changes?

A. I don't know.

Q. Okay. Who oversees the rules unit?
A. Cole Giering is program administrator of the rules unit.
Q. How long has he been in that position?
A. I'm not sure exactly. But it was since I've been bureau chief.
Q. Okay. So --
A. August of 2021.
Q. Thank you.
Do you coordinate -- in making coverage determinations, do you coordinate with the chief medical officer for AHCA?
A. Yes.
Q. Who is that?
A. Dr. Christopher Cogal.
Q. Can you describe how you coordinate with him, what that process looks like.
A. Again, it really depends on the specific question or policy we're reviewing. But it would consist of meetings or discussions.
Q. What types of things would you discuss?
A. So, for example -- I'm going to go back to the two examples of recent activity. So he wasn't involved in the iBudget Waiver changes at all. But for the human donor milk, he assisted when we had originally done the

legislative bill analysis when the legislation was first proposed. And so for the development of how to implement the changes, he was consulted. I don't know the specific conversation, but I do know that he was involved in that process.

Q. On what kind of expertise do you rely on him for? What kind of input does he provide in the process? Is it medical in nature?

A. I don't know.

Q. Okay.

A. To the extent -- I know he's an available resource for the team. But I don't know to the extent that -- of his involvement.

Q. When he gets involved, is it through a formal process? Or is it just a decision to reach out and ask him for advice? How would you characterize it?

A. From my experience at the bureau level, it's been more informal. I know that there have been -- he's been formally asked to review bill analysis or -- but how that process works, I don't know.

Q. Okay. Are there people under you who are more likely to communicate with Dr. Cogal?

A. I believe there's staff that communicate with him more than others, yes.

Q. What staff are those?

A. Ashley Peterson has been meeting with him on some projects lately. Again, it really depends on the project. But we are working with him on continuous glucose monitoring -- questions around coverage there. And Jesse Bottcher and his team.

Q. When you say Jesse Bottcher and his team, would that include the GAPMS process?

A. His team is responsible for it.

Q. In coordinating with Dr. Cogal -- in the coordination between Mr. Bottcher's team and Dr. Cogal, would that include the GAPMS process?

A. I don't know the extent to which he is involved in that.

Q. Okay. To your knowledge, has he ever been involved in that?

A. I don't know specifically.

Q. Have you and Dr. Cogal and anyone from Mr. Bottcher's team ever met to discuss the GAPMS process?

A. The process, yes. When I first took the role, we had met to talk through the process. But I can't remember the specific conversation.

Q. Okay. Switching gears a bit. When I use the term "Florida Medicaid managed care plan," do you know what it means?

A. Yes.
Q. What does that term mean?
A. Those are the managed care plans that the agency contracts with to provide the services through the managed care delivery model.
Q. Do Medicaid managed care plans have their own coverage policies?
A. The agency's coverage policies are incorporated into the managed care plan contracts by reference. And there are requirements outlined in the contract with how the managed care plans have to provide services.
Q. Are you aware of managed care plans having their own policies that incorporate Florida Medicaid's policies?
A. I don't know.
Q. Have you ever seen a copy of a Florida Medicare managed care plan document that discusses the coverage of a Florida Medicaid service?
A. I reviewed the plans' member handbooks or enrollee handbooks. And I've seen their resources available on their websites that weigh out what they cover. I can't remember if I've ever seen an official document titled "Coverage Policy."
Q. So my question is: Have you ever seen a document from a Medicaid managed care plan -- formal or

informal, it doesn't matter -- with information that contains the criteria used to determine if Florida Medicaid will cover a service?

A. I believe that information is in the handbooks. But I can't recall any specific documents drafted by the plans.

Q. What unit would be responsible for communicating with managed care plans about their coverage of Florida Medicaid services?

A. That would depend if they had a question for the agency on the agency's coverage of a covered service or a contractually required service. Those most likely would be sent to Medicaid policy.

Q. Okay.

A. To review.

MS. DEBRIERE: Okay. Yes. Definitely. Just a couple more questions, if that's okay.

BY MS. DEBRIERE:

Q. Are you okay Ms. Dalton?

A. Yes.

Q. Who would review those questions? Who specific -- like, what specific individuals?

A. It would depend on what the question was.

Q. Okay. If the managed care plan doesn't have a question, is there any process that exists that just

involves overseeing whether a Medicaid managed care plan is covering a Florida Medicaid service?

A. The Bureau of Plan Management Operations is the bureau that oversees the adherence to the contract. All the contract managers for the individual plans are housed there. So if it was a compliance question on if the managed care plan was following the requirements in the contract, that would be Plan Management Operations most likely who would be the first point of contact for the plans.

Q. Okay. Can MCOs create their own guidelines for implementing AHCA coverage policies?

A. I don't know.

Q. Who would know that?

A. It would be in the contracts.

Q. Okay.

A. The parameters around what their materials are allowed to contain and if the materials have to be reviewed and approved by the agency.

Q. Okay. And that would be the Bureau of Planned Management Operations who does that -- takes on that role? And if not, then who?

A. I believe it would depend on what the materials being reviewed are. Just like with reporting -- there are different report owners in different bureaus within

the division of Medicaid that review compliance with the -- the plan's compliance with the contracts. But the first point of contact for submitting those materials and making sure that they're submitted would be through Plan Management Operations.

Q. And who is that bureau chief? Remind me.

A. Pam Hall.

Q. Okay. One last question. Are you aware that MCOs have their own guidelines for specific types of Medicaid services?

A. I can't speak to that. I don't know.

Q. Do you know who would know?

A. Are you asking if it's a required -- or if they're allowed to --

Q. No. I'm just asking if you're aware. So are you aware that they have their own --

MR. PERKO: Asked and answered.

MS. DEBRIERE: -- criteria guidelines?

THE WITNESS: I would have to review the contract.

BY MS. DEBRIERE:

Q. Okay. So is that a no, you are not aware as we sit here today without having anything in front of you?

A. Correct. I don't know without seeing a specific example or reviewing the contract.

Q. Okay. Do you want to take a break?
A. Yes.
(Brief recess.)
BY MS. DEBRIERE:
Q. Ms. Dalton, just briefly -- when we took a break, did you discuss this deposition with anyone?
A. No.
Q. Did you discuss it with your attorneys?
A. Just briefly.
Q. Okay. When I use the term "quality improvement organizations" or QIOs, do you know what I mean?
A. Yes.
Q. What does that term mean?
A. Quality improvement organization.
Q. Yeah. Is eQHealth a QIO?
A. Yes.
Q. And what do they do?
A. I don't know the whole scope. But their main function in their contract with the agency is the -- to do prior authorization for fee for service services.
Q. Okay. What does prior authorization mean?
A. It's a utilization management tool to ensure that the services are in their scope, authorized, and appropriate.
Q. By "appropriate," what do you mean?

A. That the service that's being requested is allowable and delivered within the parameters of the Medicaid program.

Q. Who makes the request for prior authorization?

A. I don't know the details of how the process works.

Q. Okay. By parameters, do you mean the parameters set by AHCA's coverage policies?

A. Yes. And administrative rule.

Q. Okay. Is administrative rule distinct from a coverage policy?

A. Yes. Not all of the administrative rules incorporate a coverage policy by reference.

Q. Okay. So an example of that would be the definition of medical necessity -- would be an administrative rule that sets out the parameters for coverage but does not include a specific coverage policy?

A. The definition of medical necessity is actually in the definitions policy -- which is a document incorporated by reference into the text of the administrative rule.

Q. Okay. Do QIOs like eQHealth -- do they have their own coverage criteria they rely on?

A. Yes.

Q. Do you coordinate with QIOs regarding those coverage criteria?

A. I personally do not.

Q. Does anybody on your team?

A. The eQHealth contract is housed in the Bureau of Medicaid Quality.

Q. Okay.

A. So they would be a lead in managing of that contract and communicating with the vendor. But I do know that we have communicated with them in the past -- the Bureau of Medicaid Policy has.

Q. What types of things have you communicated about in the past?

A. The first example that comes to mind is recently the agency opened the definitions rule policy and did communicate that that rule was being opened with eQHealth.

Q. Okay. Are MCOs and QIOs bound by AHCA's coverage policies?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: As I stated before, the contract for the managed care plans incorporates the coverage policies by reference. And the plans are not allowed to be more restrictive than the coverage

policies. I don't know the specific language off the top of my head with the requirements of how they adhere to the policies. But that is in the contract.

BY MS. DEBRIERE:

Q. Okay. So the MCO's obligation to adhere to AHCA's coverage policies is set forth in the contract?

A. Yes.

Q. Okay. What about QIOs?

A. I don't know the specific language off the top of my head. But that information is also in the contracts on how the managed care plans' contracted QIO vendors are expected to operate.

Q. Okay. Is there a formal approval process for the QIO's coverage criteria?

A. I don't know.

Q. Is Magellan a QIO?

A. I don't know.

Q. Okay. Does Magellan conduct prior authorization of Florida Medicaid services?

A. I don't know.

Q. Does Magellan review the request of a Medicaid recipient to authorize prescription drug services in the Fee for Service program?

A. I don't know.

Q. Do you know what -- do you know if Magellan plays any role in determining coverage of pharmacy services under Florida Medicaid?

A. I believe the agency has a contract with them to adjudicate the claims. But I don't know the scope of that contract.

Q. What do you mean by adjudicate the claims?

A. I don't know the whole scope of that process or the contract.

Q. When you just use that phrase, what did you mean by that?

A. That they're involved in the reimbursement process.

Q. Okay. And would the reimbursement process involve determining the eligibility for the service itself?

A. I don't know the extent of that process.

Q. Would anybody at AHCA know or be able to answer that question?

A. I don't know.

Q. Moving back to coverage determinations undertaken by your bureau, who is the final decisionmaker as to whether AHCA will adopt that coverage determination?

A. Can you repeat the question.

Q. So earlier we were talking about your bureau undertaking coverage determinations of Florida Medicaid services; correct?

A. Yes.

Q. Who is -- before AHCA or anyone at AHCA can act on that determination, who is the final decisionmaker?

A. Again, it depends on the circumstances. And I can only speak to the signatory of who needs to be -- to officially sign off. But the example I used before for a federal authority submission, that would be whoever was designated from the agency as the Medicaid director or the Medicaid state plan approver.

Q. Okay.

A. And then administrative rule to actually complete the promulgation process. That's actually signed off by the head of the agency, which here would be our secretary.

Q. Okay. When coverage policies are promulgated, are there multiple drafts of those policies? Are there ever multiple drafts of those policies?

A. Can you repeat the question.

Q. When you're developing a coverage policy, are there multiple drafts?

A. It would it depend on what the change was.

Q. So there are times when coverage policies have

multiple drafts?

A. Yes.

Q. And how do you track any changes to those policies during the drafting process?

A. So specific to the coverage policy, we typically use a document called a revisions template; which tracks the changes being proposed.

Q. Okay. Is there a limit to the people who can make changes to the revisions document?

I'm sorry; the revision just tracks who has made the changes; is that right?

A. So it tracks what the old policy said, what the new changes are, if there's a reason for the change. I'm not sure if it includes who the requester of the change is.

Q. Okay. Does it record who is making the change?

A. I can't recall if that's on the template.

Q. Is anybody at AHCA allowed to make a change?

A. So for most of the coverage policies, there's a subject matter expert assigned to that program area who any changes would filter through. And then they have to work with the rules unit who is actually making the changes to the coverage policy and promulgating that through the rulemaking process.

Q. Okay. Just switching quickly to some specific

Medicaid services. Are coverage policies regarding surgery adopted into rule?

A. Yes.

Q. And are they in handbooks or a handbook?

A. I don't believe it's one specific handbook.

Q. Do you remember the names of any of the handbooks they are contained in?

A. We have a transplant services coverage policy.

Q. Okay.

A. Which I would consider inclusive of surgical. We have an inpatient services coverage policy. Without seeing the list of policies, I can't recall off the top of my head.

Q. Give me one second.

Would coverage policies about surgeries be in the Ambulatory and Surgical Center Services Policy?

A. I don't know the content of that policy off the top of my head.

Q. Okay. You said inpatient hospital services would contain surgery policies?

A. I don't know all the content in the policy without looking at it. But it...

Q. If it mentions surgery in the handbook, is it going to have a coverage policy related to it?

How would you know if a handbook covered

surgery or contained a surgery coverage policy in it?

A. I would have to read the handbook. Depending on what the specific question was, what type of surgery.

Q. Okay. What about prescription drug coverage policies? Are those adopted into rule?

A. I believe there is a rule specific to pharmacy policies and prescription drugs, yes.

Q. Okay. And then I'm just going to flip my computer around here and go to this page. We're looking at what's titled Agency for Health Care Administration Drug Criteria. AHCA.myFlorida.com/Medicaid/prescribed_drug_criteria.shtml.

And I assume, Ms. Dalton, I'm seeing here -- are you just seeing a list of drug criteria?

A. Yes.

Q. Is this an exhaustive list of the drug criteria that AHCA relies on?

A. I don't know.

Q. Who would know that?

A. Ashley Peterson and her team may be able to confirm.

Q. Okay. And why wouldn't this be an exhaustive list?

MR. PERKO: Object to form.

THE WITNESS: I'm not personally very familiar with this page.

MR. PERKO: Counsel, for the record, can we read the URL.

MS. DEBRIERE: Absolutely. Well, I think I -- Gary, do I not know what a URL is?

MR. PERKO: The website address.

MS. DEBRIERE: So I think we read most of it. But I can start with https://AHCA.myFlorida.com/Medicaid/prescribed_drug/drug_criteria.shtml.

MR. PERKO: Thank you.

MS. DEBRIERE: Absolutely.

BY MS. DEBRIERE:

Q. Do you know what categorical exclusion means?

MR. PERKO: I'm going to object to form. I guess I'm a bit confused, Counsel. You already defined what categorical exclusion means at the beginning of this deposition.

MS. DEBRIERE: Well, that's categorical exclusion -- you're right, Counsel. It contained the statement "categorical exclusion"; just categorical exclusion of a very specific set of services. The treatment for --

MR. PERKO: That wasn't the definition at the

beginning. But go ahead.

BY MS. DEBRIERE:

Q. How about this, Ms. Dalton: Can you provide an example of a categorical exclusion under Medicaid?

A. I can't think of an example. I'm familiar with the term. I cannot think of an example.

Q. Okay. I'm trying to think of one too.

Does AHCA -- does Florida Medicaid cover private duty nursing service for individuals over the age of 21?

A. Not through the state plan.

Q. Okay. Do they cover it through home and community based services with a Medicaid waiver?

A. Yes.

Q. Okay. And if Florida Medicaid does not cover private duty nursing services for individuals over 21 under the Medicaid state plan, is that a categorical exclusion?

A. Yes.

Q. And does the agency categorically exclude any Medicaid service for beneficiaries under the age of 21?

A. Can you repeat the question.

Q. I'm sorry. Bear with me one second, Ms. Dalton. I'll come back to that.

Do your responsibilities include ensuring that

coverage policies meet the standards under EPSDT?

A. The Bureau of Medicaid Policy doesn't oversee the monitoring of the adherence to the policies or the provision of services. In terms of ensuring that the policy language complies with the federal EPSDT requirements, yes.

Q. And how do you ensure that compliance when developing coverage policies?

A. It depends on the specific coverage policy. But the majority of the service specific coverage policies include language incorporating EPSDT by reference and language from the federal regulation.

Q. Generally speaking, what is that EPSDT requirement?

A. That the State must provide all medically necessary services to children ages under 21.

Q. Does the State have to provide a service under EPSDT to a Medicaid recipient under 21 if that service is experimental?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Do you know what I mean when I say experimental?

A. Yes.

Q. So same question. Does the State have to

provide coverage to children under age 21 if that health service is considered experimental?

MR. PERKO: Object to form.

THE WITNESS: The State is allowed to develop its own definition of medically necessary or medical necessity; which Florida has done and promulgated in administrative rule. And part of that definition does include the parameters by which a service would not be determined medically necessary; and, therefore, not required under the EPSDT.

BY MS. DEBRIERE:

Q. Okay. And that definition of medical necessity includes the requirement that the service not be experimental; correct?

A. I cannot recall the exact definition off the top of my head. But that is in -- promulgated in the definition coverage policy.

Q. When you say that is --

A. The definition of medical necessity.

MS. DEBRIERE: Okay. We can mark -- I have a copy of the rule so you can reference it. We can mark that as Exhibit 3. And that's 59G-1.010.

We might have forgotten to put a copy in. If we did, it's my fault.

MS. DUNN: I have a copy right here.

(Plaintiff's Exhibit No. 3 was marked for identification.)

MS. DUNN: Yeah. It's right there. Last definition on that page.

THE WITNESS: It doesn't seem to be the whole --

MS. DUNN: It's not.

MS. DEBRIERE: It's not. We ended it at "N," because it's a very large coverage policy and we are trying to save some trees.

BY MS. DEBRIERE:

Q. So if you look at the definition of "medically necessary" or "medical necessity," does that contain a requirement that the service not be experimental?

A. Yes.

Q. And so under EPSDT, can the agency deny a medical service to a child under 21 if they deem it to be experimental?

A. Yes.

Q. Okay. Who is responsible for compliance with EPSDT? Is it a specific person?

A. I don't know who is responsible.

Q. Is it someone within your bureau regarding EPSDT as it relates to the development of coverage policies?

A. There isn't a specific person in my bureau, no.
Q. Are there any written guidelines about ensuring compliance with EPSDT with developing coverage policies?
A. Can you repeat.
Q. Are there any written guidelines relied on to determine whether a coverage policy complies with EPSDT, other than that contained in the Federal Medicaid Act?
A. I don't know specific -- all the specific documents that the analysts rely on when developing the coverage policy. But as part of that process, the expectation is to review the federal guidelines and statute and other rules and regulations of governing the Medicaid program to ensure that the coverage policy adheres to the Medicaid program federally and state.
Q. And that's an expectation of the staff within your bureau?
A. Yes. It's the common practice when approaching research regarding changes to the policy -- a policy.
Q. Okay. When I use the term "comparability," do you know what I mean as it's laid out in regulations implemented in the Federal Medicaid Act?
A. You may have to give me some more context.
Q. So under the Federal Medicaid Act, there is a requirement that state agencies who administer Medicaid do so in a way that all Medicaid recipients receive

comparable services. Are you familiar with that requirement?

A. Vaguely sounds familiar.

Q. Is your bureau required to be familiar with that requirement in developing coverage policies?

A. I can't speak to that without more information.

Q. Okay. Is there anyone who can speak to the requirement -- is there anyone who can speak to ensuring that the policy comply with comparability under the Federal Medicaid Act?

A. So, again, I think it really would depend on what the specific question is regarding or which specific coverage policy. As I said before, a lot of the coverage policies have a specific subject matter expert with knowledge of that service area. So it just really would depend.

Q. Okay. I'm just going to make myself a note.

What is the purpose -- turning back to Exhibit 3 and the definition of medical necessity -- what's the purpose of AHCA's medical necessity standard?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Does AHCA's medical necessity standard have a purpose?

MR. PERKO: Object to form.

THE WITNESS: I don't know what you mean.
BY MS. DEBRIERE:
Q. What is the purpose of the definition of medical necessity?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. What do you use it for?
A. The definition is relied on a lot. Most of the service specific coverage policies refer and incorporate by reference the definitions policy and make a statement that the service must be medically necessary as part of the requirement for reimbursement.
Q. If a Medicaid recipient makes a request for a Medicaid service, in order for that service to be authorized, does it have to be medically necessary?
A. Yes.
Q. Do managed care plans rely on AHCA's medical necessity standard in their prior authorization process?
A. I can't recall the exact contract language. But, yes.
Q. And what about QIOs?
A. I don't know.
Q. Regardless of the method in which Medicaid is delivering the service -- fee for service or managed care -- in order for that surface to be authorized, does

it have to be medically necessary?

A. I don't know the details of the actual authorization process. I do know that the expectation from policy prospective is that the services have to be provided in accordance with the agency's coverage policies and administrative rules.

Q. And that includes the definition of medical necessity?

A. Yes.

Q. If AHCA finds that a Medicaid service is experimental, would AHCA or a contractor or managed care plan still review whether service meets other portions of AHCA's medical necessity definition?

A. I don't know the extent of their review.

Q. What about your review at AHCA for fee service?

A. Again, I don't know eQHealth or QIO vendors' process.

Q. Do all Florida Medicaid services require prior authorization?

A. I don't know. I don't believe so.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 4, which is the GAPMS Report on Cross-Sex Hormone Therapy, dated May -- I believe we did the May version.

So what I'm showing you is Bates stamped

beginning at Defendant 00126105. I should pull out my own copy.

And that continues through, Court Reporter -- this one is not Bates stamped. It's weird. This one doesn't have a copy. This copy is not Bates stamped. But it is entitled Cross-Sex Hormone Therapy GAPMS Determination Report With Recommendation.

That's very odd. Very odd. I don't think it's a huge deal.

(Plaintiff's Exhibit No. 4 was marked for identification.)

BY MS. DEBRIERE:

Q. So on the last two pages, Ms. Dalton, starting at "Coverage policy" -- and it starts, "Federal regulations."

"Federal regulations for Medicaid..." and continues on through the definition of medical necessity --

MR. PERKO: Can you give a page number.

MS. DEBRIERE: Oh, yes. Thank you, Gary.

So page 8, 9, and a tiny bit of the top of 10.

THE WITNESS: I'm there.

BY MS. DEBRIERE:

Q. Take all the time you need to read it. And

afterwards, if you can tell me if this is an accurate portrayal of the standard used to determine Florida Medicaid coverage for prescription drugs.

MR. PERKO: Do you have another copy?

Thank you.

BY MS. DEBRIERE:

Q. I think it starts at the top of page 8 -- middle of page 8. So reviewing that standard, is that what's used to determine whether Florida Medicaid will cover a prescription drug?

A. Can you direct me more to where you're referring. I read both pages 8 and 9, and I don't think I can speak to the specifics of all this information.

Q. Okay. When reviewing whether to cover a prescription drug, does AHCA look at -- here on page 8 it says AHCA is -- "The program is required to asses data on drug use against predetermined standards consistent with the following compendia." And then it lists three types of compendia and the peer reviewed medical literature. Is that an accurate statement of AHCA policy?

A. I don't know.

Q. Who would know that?

A. I don't know if I can speak for them. But I would ask one of the pharmacists.

Q. Would you ask Ashley Peterson? Or would you ask one of the pharmacists that works under her?

A. I specifically would go to Ashley, as she's my direct report. And then she would research the question for me.

Q. Okay. Would research involve asking one of her pharmacists?

A. I don't know. I can't speak for her process.

Q. So going to page 9, top of the page says, "In order to be reimbursed by Medicaid, a drug must be medically necessary."

Is that the same as the definition contained in the 59G-1.010 that we just reviewed -- Exhibit 3?

A. I don't understand what you mean by the same.

Q. Does medically necessary mean the same as the definition in the definitions policy?

A. I would think so.

Q. Okay. And it is, "Either prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in the Medicaid Act or prior authorized by a qualified clinical specialist approved by that agency."

Is this an accurate recitation of the standard AHCA uses to authorize prescription drug coverage?

A. I don't know.

Q. Would Ashley Peterson know that information -- her or her team?

A. I would think so, yes.

Q. Okay. The next thing it says, "The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows." And then it lists three criteria.

Reading over that statement, are these currently the criteria AHCA uses in authorizing drugs for off label purposes?

A. Again, I don't know.

Q. Would Ashley Peterson know the answer to that question?

A. I would think her team would, yes.

Q. Is this the type of information -- looking at this, is this the type of information that would be contained in a coverage policy adopted in rule?

A. I'm not sure.

Q. Why aren't you sure? What's throwing you about it?

A. I don't know the content of the rules off the top of my head.

Q. But I think my question is a little different. So does this appear to be the type of information that would be contained in a coverage policy adopted into

rule?

A. I can't speak to that. I don't know because of the reason I stated. I will say the coverage policies traditionally do not repeat regulation or requirements or information that are found elsewhere; for example, in Florida statute or in federal regulation. And each coverage policy is structured somewhat similarly, but does contain very different information. So I don't know if this is information that's found off the top of my head in one of our policies.

Q. Okay. I think you -- do all prescription drugs require prior authorization to be reimbursed by Medicaid?

A. I don't know.

Q. Who would know that?

A. I would think Ashley Peterson and her team. Or it might be available on the information on our website regarding pharmacy policy and authorization criteria.

Q. Okay. So Ms. Peterson would be familiar with authorization criteria for prescription drugs?

A. Yes. Or she would know where to look.

Q. Okay. Specifically related to pharmacy coverage policies, how are they developed?

A. The coverage of the pharmacy services is a little different than the other coverage policies. I

don't know all the details that go from the analysts into the developments. But because there is different statutory requirements -- Florida statutory requirements around pharmacy services, including the PNT and DUR board -- the process for overseeing the coverage of pharmacy services is a little different.

Q. In reviewing whether a prescription drug requires a coverage policy -- strike that.

Do you use the GAPMS process to determine pharmacy coverage -- to determine whether coverage of a prescription drug is experimental?

A. I don't know specifically for determining if a prescription drug is experimental. I don't know.

Q. When you develop coverage policies in your bureau, does that include a determination as to whether a service is experimental?

A. So the coverage policies are drafted specific to the covered services that we've been approved to provide.

Q. Okay.

A. By the federal government. So that is the driving factor on how we would initially approach the coverage and organize or draft a coverage policy asserting a service that we are authorized to provide.

Q. So separate and apart from developing coverage

policies, the responsibilities of your bureau also include determining whether a service is experimental; is that correct?

A. So that would be part of the GAPMS process that is outlined in administrative rule.

Q. Okay. Do you use the GAPMS process for prescription drugs?

A. Without researching or consulting others on the team for a specific example, I don't know the interplay between the different authorities and how that works.

Q. Which team is responsible for the GAPMS process?

A. That position is within the Medicaid -- Bureau of Medicaid Policy.

Q. Earlier speaking about teams under the bureau, which teams is responsible for the GAPMS process?

A. Jesse Bottcher is the manager over the position that is primarily responsible for the GAPMS process.

Q. Are there any other teams that are primarily responsible for the GAPMS process? Or is it only Jesse's team?

A. So in terms of listing that as a primary responsibility on a job description, that would be Jesse's team.

Q. Should the people on Jesse's team be aware of

every GAPMS process that's undertaken?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: So as the bureau chief of Policy, I do try to keep staff within the bureau aware of everything that's happening within the bureau -- especially when a determination has been made. Jesse's team would definitely need to be aware, because there could be potential impacts with a specific service coverage policy. But I do think every circumstance is different. So I can't say just in a general statement to your question.

BY MS. DEBRIERE:

Q. Would it be typical for Jesse's team to not be aware of a GAPMS report being developed?

A. I can't say if it would be typical. I have not overseen very many GAPMS in my time as bureau chief.

Q. So as the bureau chief with Jesse's team being primarily responsible for GAPMS, would you as that chief endeavor to ensure that Jesse's team was aware of all GAPMS reports being written?

A. Yes. We meet the managers on -- my direct reports and I meet regularly at least twice a week for an hour and discuss projects that are going on with each team and provide updates. So the ongoing bureau

activities are regularly discussed with the management team.

Q. Okay. Do you know what a drug compendium is?

A. I recognize the term, but don't think I can define it.

Q. Do you know which compendia are listed in the Federal Medicaid Act?

A. No.

Q. I'm just going to screen share again. I'm showing right now on my screen -- the URL is https://AHCA.myFlorida.com/Medicaid/prescribed_drug/pharm_thera/pdf/PDL.pdf. The title of this document is Preferred Drug List, Effective January 21st, 2023.

Do you know what the preferred drug list is?

A. Yes.

Q. What is it?

A. It's list of drugs developed that the managed care plans must adhere to. And it has to do with rebate negotiations and is recommended by the PMT committee.

Q. Perhaps you just answered this. But who develops the PDL?

A. The agency.

Q. What is the PMT committee's role in it?

A. Per statute, they make recommendations to the agency.

Q. Okay. Does the DUR have any role in developing the PDL?

A. I don't know. I don't believe so.

Q. And this PDL applies to managed care plans; is that correct?

A. And fee for service.

Q. Okay. So on here -- I'm going to have to do Control+F. Pardon; one second.

It's very small. So tell me if you need to make it any bigger.

Okay. On here you will see the drug estradiol -- e-s-t-r-a-d-i-o-l -- listed. And there is many versions here starting at it looks like this line continuing all the way down until we hit norethindrone AC. So the fact that estradiol is lied on the PDL, does that mean Florida Medicaid will cover it if the eligibility criteria are met? Excuse me. Scratch that.

Since estradiol is listed on this PDL, does it mean that Florida Medicare will cover it?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. If any drug is listed on the PDL, does that mean Florida Medicaid will cover it?

A. I don't know the interplay between the PDL and

the other rules and regulations covering pharmacy services.

Q. Okay. Over in this column at the top of page, it reads "Clinical PA required." And it also has a column for a minimum and a maximum age. What does clinical PA required mean?

A. Operationally, I don't know.

Q. Do you know it in any other version?

A. I understand the words. But I don't know in the context of the program or the PA process what that means.

Q. What does "PA" stand for?

A. Prior authorization.

Q. Okay. Is it possible that clinical PA -- so if we scroll down to estradiol -- this version with a minimum of an age of zero, maximum age of 999 -- and it says "no" under the column of clinical PA required, do you know what that means?

A. No.

Q. Who would know that?

A. Ashley Peterson and her team are lead on this.

Q. Do you know what it means to have a minimum age column? Why that's significant or why it's on there?

A. Specific to this document, no.

Q. Same with maximum age?

A. No, I don't know the reason why it's on there.
Q. Since you've been at the agency -- January 2018?
A. Yes.
Q. How many GAPMS processes have you been involved in?
A. Two completed. And maybe one or two discussions.
Q. How many pending?
A. I don't know.
Q. Do you know currently how many GAPMS are pending?
A. Clarify "pending."
Q. Why don't you tell me what you meant by completed.
A. Two that have been signed by agency leadership.
Q. Okay. And how many reports are in the stage of being written and not yet signed?
A. I don't know.
Q. To be clear, though, as bureau chief you meet weekly with Jesse Bottcher and his team who are primarily responsible for GAPMS.
A. I meet weekly with Jesse Bottcher and my team.
Q. Okay.
A. I don't regularly meet with the individual

teams, but with the managers.

Q. When you meet with Jesse, do you discuss GAPMS?

A. Not routinely. We have before.

Q. What are the other responsibilities of Jesse's team?

A. The three managers under Jesse each have units that are responsible for the developments of the service specific coverage policies. His team also oversees the eligibility policy and the provider enrollment policy, updates all the fee schedules -- so works closely with fiscal agent operations to ensure updates are made to the MMIS system and with Medicaid program financing the development of fee schedules. And that's the bulk of their responsibilities.

Q. So when you're meeting with Jesse weekly, what are you discussing about his team?

A. It depends on what -- the highest priority assignments are usually up first; things that are due that week.

Q. Okay. So you do not routinely discuss GAPMS -- that was your testimony just a second ago?

A. Yes. I wouldn't say that it's a subject that we discuss at every meeting or routinely at our individual meetings, no.

Q. And you organize what you discuss based on what

has the highest priority?

A. Yes, typically.

Q. Okay. How familiar with you with the GAPMS process?

A. In terms of all the research and everything that goes into developing, I'm not as familiar. But I am familiar with the routing process, the rule, the authority for that process.

Q. Okay. So just generally, what does AHCA use the GAPMS process for?

A. So if the agency receives a request for coverage -- typically that's how the process would be initiated. If the coverage was determined to not be something that the agency could proceed with -- possibly adding to the fee schedule or incorporating into a service definition -- then the GAPMS process would be used.

Q. Okay. How is the GAPMS process initiated?

A. I believe it's a rule how to.

Q. Would it be helpful if you had the rule in front of you?

A. Yes.

MS. DEBRIERE: Okay. Let's mark that as Exhibit 5. That's Rule 59G-1.035.

(Plaintiff's Exhibit No. 5 was marked for

identification.)
BY MS. DEBRIERE:
Q. So how is GAPMS initiated?
A. A request is submitted to the health services research inbox in the Medicaid Policy Bureau.
Q. Who can submit a request to that inbox?
MR. PERKO: Object to form.
THE WITNESS: I believe anyone can.
BY MS. DEBRIERE:
Q. Okay. Is that the only way that a request is submitted for AHCA to undertake a GAPMS?
A. No.
Q. What are other ways?
A. So in the contracts with the plans, there's also language on how a managed care plan can submit a request to the agency for review -- not necessarily through the health services inbox. I can't recall the exact direction. But there's also the opportunity for the clients to request a review.
Q. When that review is requested, is it -- is the standard process used? Is the standard GAPMS process used?
A. I'm not sure. I believe it may be expedited. But I'm not sure to the specifics of the process.
Q. Who would be most familiar with that process?

A. Either Jesse Bottcher or Jeffrey English.

Q. Okay. So you mentioned managed care plans can submit a request -- or anyone can submit a request through the health services inbox. Are there any other ways that a request can be submitted to the agency to undertake a GAPMS?

A. Yes.

Q. And what are those ways?

A. I don't know all the ways. But I can't think of us not approaching the process if we received a request outside of getting it specifically through the health services research inbox.

Q. How often --

A. Which is -- I'm hesitating because I couldn't see us not -- like, refusing to complete the process if it was received another way.

Q. How often does that happen?

A. So, like I said before, in my time as bureau chief, there haven't very many finalized GAPMS. Or that process has not been a part of my day-to-day work. So I'm not sure.

Q. Okay. So you cannot recall another way that a GAPMS request came to the agency, other than through a managed care plan or the health services inbox?

A. So for the most recent GAPMS report, that was a

request from -- I believe it was the secretary. But I don't know if it went through the inbox specifically or not.

Q. Okay. So that's another way that the GAPMS process can be requested -- is through the secretary?

A. That's the way that it has been.

Q. Okay. How many times?

A. I don't know.

Q. And when you say the most recent GAPMS report, do you mean the GAPMS report related to gender dysphoria?

A. Yes.

Q. When that request came in through the secretary, did the secretary identify why she was making that request?

And, I'm sorry, do you mean Secretary Marstiller?

A. Yes.

Q. Okay. Did she identify why she was making that request?

A. I can't recall the contents of the specific request.

Q. Did the request come -- who did the request from Marstiller go to?

A. I don't know.

Q. How did you find out about it?
A. I just can't remember if I was sent the letter in an email. But it was then discussed by my manager.
Q. And that manager was? Is?
A. At the time was Jason Weida, who is the assistant deputy secretary.
Q. And did you receive the letter from Secretary Marstiller before that discussion occurred?
A. Yes.
Q. And how long between receiving the letter and having -- how long past between receiving that letter and having that conversation with Mr. Weida?
A. I don't remember.
Q. Was it, like, hours? A day? Several days? Within the same week?
A. I don't remember.
Q. Okay. Was that discussion just between you and Mr. Weida? Or were there other people?
A. I don't remember in the initial conversation if there was anybody with me.
Q. Okay. Was it -- where did it take place?
A. I believe it was in Jason's office.
Q. Okay. Did Jason ask you to come to his office to have the conversation? How were you notified of the meeting?

A. I don't remember. We had standing meetings in his office; he was my -- or I was his direct report. So I don't remember if it was part of that when we were talking about assignments and priorities or separate. I can't remember.

Q. What was Mr. Weida's position at the time at the agency?

A. He was the assistant deputy secretary for Medicaid policy and quality.

Q. And then who is in that position prior to him?

A. I think Shevaun Harris.

Q. Okay.

A. There was a gap in between. But I think she was the last person.

Q. Okay. And who took that position after Mr. Weida?

A. That position is currently vacant.

Q. Okay. And has Brian Meyer ever held that position?

A. No.

Q. Okay. Prior to your meeting with Mr. Weida but after your received the request from Secretary Marstiller, did you communicate with anybody else about the request?

A. Can you repeat the question.

Q. Between the time that you received the request from Secretary Marstiller -- the letter -- and meeting with Mr. Weida, did you have a conversation with anyone else about the request?

A. I don't believe so.

Q. Okay. Were you surprised to see the request?

A. No.

Q. Why not?

A. Medicaid Policy -- I think we're unique in that bureau because no one day is exactly the same. There's always something new coming out from the federal government, from legislative action, from leadership. So I think that's kind of part of the job of being the bureau chief of Medicaid policy.

Q. Okay. What was -- when you met with Mr. Weida, did you develop a plan about how to honor the Secretary's request?

A. Yes.

Q. And what was that plan?

A. The team that was going to work on it was the Canadian Prescription Drug Importation Plan team; following the regular GAPMS process in terms of research and report and development.

Q. Did you identify who was going to be on that team?

A. Yes.
Q. And who did you identify?
A. Matt Brackett, Nai Chen, and D.D. Pickle.
Q. As part of that plan -- and to be clear, the secretary's request was specifically a request to undertake a GAPMS investigation?
A. Yes; to review through that process.
Q. Okay. And the team identified was Brackett, Chen -- and I forgot the --
A. Their manager, D.D. Pickle.
Q. D.D. Pickle. Thank you.
So you previously testified that the team primarily responsible for GAPMS was led by Jesse Bottcher. Why was Jesse Bottcher not part of the team to undertake this GAPMS?
A. So there was several factors considered. Matt Brackett has worked with the bureau a long time and previously had the position responsible for -- primarily responsible for the GAPMS. D.D. Pickle has also been with the bureau and agency a very long time. So I would say that the historical knowledge, the bandwidth -- having bandwidth to focus on completing the GAPMS -- were probably the two biggest factors.
Q. When you say bandwidth, what do you mean?
A. So that team -- their primary responsibility is

the Canadian Prescription Drug Importation Program, which is not approved federally. So our ability to move forward with the day-to-day operations and implementation of that program is stalled. Due to that, that team has been available to assist in other areas within the bureau when needed.

Q. Was the team that's primarily responsible for GAPMS -- were they overwhelmed with doing GAPMS at the time?

A. I don't know.

Q. But you used the fact that Mr. Brackett and D.D.'s team generally would have a lot of time to work on GAPMS as a deciding factor to pick the team for this report; is that right?

A. Yes.

Q. But you didn't first check whether the team that's primarily responsible for GAPMS would have the time to do the report?

A. No.

Q. Okay. How long has Mr. Chen been with the agency?

A. I don't remember.

Q. Would you classify him -- as you did Ms. Pickle and Mr. Brackett -- as being with the agency for a long time?

A. No.
Q. So he did not have that historical knowledge that Mr. Brackett and Ms. Pickle have with the agency?
A. No.
Q. And that was a deciding factor in picking the team?
A. Yes.
Q. When you met with Mr. Weida to pick this team, did Mr. Weida suggest the names or did you?
A. I believe I did.
Q. Okay. Other than the length of time at the agency and bandwidth, what criteria -- did Mr. Weida give you any criteria in terms of picking the team?
A. I don't think so, no.
Q. Did you use any other factors other than the length of time at the agency and bandwidth to select this team?
A. I think it's still the same as historical knowledge. But I have worked very closely with D.D. and Matt in my various positions. I knew Matt had some knowledge of previous similar requests, as well extensive knowledge of the standard GAPMS process. And it was a team of three that was available. So I think that still kind of historical knowledge and bandwidth were really the biggest factors.

Q. You said Mr. Brackett had experience with previous similar requests. What were those previous similar requests?

A. I believe there was a GAPMS request in the past before my time with the agency that had to do with hormone treatment.

Q. Would it be -- and it was hormone treatment. When you say a similar request, was it for GAPMS?

A. Yes.

Q. Would it have been the cross-sex hormone therapy GAPMS that is Exhibit 4?

A. No.

Q. How do you know?

A. The date on this. The one I was thinking of was much earlier before my time.

Q. Before your time -- do you have any sense of when that might be?

A. Maybe 2016 or 2017.

Q. Do you know who the Governor of Florida was in 2016 or 2017? I'm sorry. It's not a test, I promise.

Was it Rick Scott?

A. Yes.

Q. Okay. And was the interim secretary at the time at AHCA, was it Justin Senior?

A. Yes.

Q. And was Beth Kidder there at that time at AHCA?
A. Yes.
Q. And all of those people are listed on this Exhibit 4 --
A. So my document has Beth Kidder crossed out and looks to be a draft document from May 20th, 2022.
Q. Is there a name that replaced Beth Kidder on that?
A. Ashley Peterson.
Q. Okay. Do you know when Ashley Peterson joined AHCA?
A. I believe it was 2021.
Q. Okay. And is it --
MR. PERKO: Counsel, it's 1:30. Are we going to stop for lunch?
MS. DEBRIERE: We can if you want to.
MR. PERKO: Do you want to? It's up to you.
THE WITNESS: At some point.
MS. DEBRIERE: That's fine. Can I just finish up here real quick.
BY MS. DEBRIERE:
Q. So is it possible that this document was created in 2017?
A. I'm looking at a document that has track changes that appear to be since then. But I don't know.

Q. Why do those track changes appear to be since then?

A. Since the date was updated to May 20th, 2022.

Q. Okay. There's some editing in the column. It's very faint. Can you see it?

A. Yes.

Q. And the initials of editor appear to be GS.

A. Yes.

Q. Do you have any idea who that would be?

A. No.

Q. Do you know anybody here with the initials GS?

A. I'm sure somebody here has those initials, but I don't know off the top of my head.

Q. So Mr. Brackett was involved with a GAPMS related to cross-sex hormone therapy, but it wasn't necessarily this one; is that right?

A. I don't know the level of his involvement, but I know that he had some knowledge or knew about it.

Q. Okay. Did he do any other GAPMS related to the treatment of gender dysphoria?

A. I don't know.

Q. Mr. Chen -- did he have any previous experience with GAPMS?

A. I don't know.

Q. Ms. Pickle -- has she had any previous

experience with GAPMS?

A. I don't know.

Q. And you've explained why Mr. Brackett, Ms. Pickle, and Mr. Chen were selected for the team. Why was Mr. Bottcher not selected?

A. I can't recall all the details of the decision. But Jesse Bottcher's team is one of the busiest in the bureau, and has a lot of time sensitive work that they are constantly working on. So I think that had something to do with it, since he is the manager of an entire section.

Q. I think you had previously testified there weren't a lot of GAPMS pending at the time this request come through; is that right?

A. I didn't know the bandwidth or the workload.

Q. Okay. You didn't know the bandwidth. So you didn't know if, for example, Mr. English had the bandwidth to handle the GAPMS report?

A. No.

Q. Do you want to take a break?

A. Yes.

(Brief recess.)

BY MS. DEBRIERE:

Q. Previously before break we were talking about the selection of Mr. Brackett to be on the GAPMS report

team for gender dysphoria. And you mentioned that he had drafted previous similar GAPMS in the past. And I believe you used the example of cross-sex hormones.

Were there any other similar requests that he drafted related to gender dysphoria in the past?

MR. PERKO: Object to form.

THE WITNESS: Just to clarify, I'm not sure if he drafted it.

MS. DEBRIERE: I'm sorry; yes.

THE WITNESS: I know he had some historical knowledge of previous GAPMS.

MS. DEBRIERE: Okay.

THE WITNESS: So can you repeat your question.

BY MS. DEBRIERE:

Q. Did he have hysterical knowledge of previous GAPMS related to gender dysphoria?

A. Outside of the one that I referred to earlier?

Q. No, including that one.

A. Yes, I believe he had some historical knowledge of previous GAPMS.

Q. Other than the one you referenced earlier, are you aware of any other GAPMS that he was involved in related to gender dysphoria?

A. I don't know the extent of all the GAPMS he was involved in.

Q. Also earlier when you were discussing your responsibilities under GAPMS, you mentioned routing.

A. Yes.

Q. Can you describe that a little bit.

A. As the bureau chief of Bureau of Medicaid Policy, any official documents that leave the bureau are usually reviewed by me. And so routing process is the hierarchy of reviewers through wherever the final reviewer or signatory or approver. That's what I was referring to by routing process.

Q. Okay. Does every GAPMS report have a routing process?

A. Yes.

MS. DEBRIERE: Okay. Can I have the 2016 GAPMS routing form. And we'll mark it as Exhibit 6.

MS. DUNN: I can tell from this exhibit that when we printed these the Bates numbering got cut off. So I will look it up and read --

MS. DEBRIERE: That's a bummer.

MS. DUNN: I know.

(Plaintiff's Exhibit No. 6 was marked for identification.)

BY MS. DEBRIERE:

Q. Okay. So do you recognize this document?

A. Not this specific document. But this appears

to be a policy routing and tracking form.

Q. And is that form the same as the form you currently use to track -- to route and track?

A. Sometimes.

Q. What other forms do you use?

A. Prior to the pandemic, we used this form primarily. Since returning to the office there have been different variations of routing and tracking forms developed for different teams or documents -- types of documents.

Q. Do you use the same routing and tracking form for GAPMS?

A. So I've only approved two GAPMS in my time. And I can't remember if this was the -- this format was what was used to route it to me.

Q. Okay. But there was a form used to route it to you when you approved -- when you approved your two GAPMS?

A. I believe so.

Q. Okay. And on this GAPMS form, it says prepared by Monique Johnson. What does it mean to be prepared by? Was the form prepared by Ms. Johnson? Or was the GAPMS report prepared by Ms. Johnson?

A. I don't know.

MS. DEBRIERE: Okay. Could I see the 2022

GAPMS. This will be Exhibit 7.

(Plaintiff's Exhibit No. 7 was marked for identification.)

BY MS. DEBRIERE:

Q. So I'm handing you -- and Gary will want to take a look at it too -- again, the first page of the document is entitled "Medicaid Policy Routing and Tracking Form." If you go through the entire document, it should also include the June 20, 2022, GAPMS report on treatment of gender dysphoria.

MR. PERKO: I believe it was June 2nd.

MS. DEBRIERE: June 2nd. Excuse me.

BY MS. DEBRIERE:

Q. So looking at the document -- the first page, is this the Medicaid Policy Routing and Tracking Form that was associated with the GAPMS report on the treatment of gender dysphoria?

A. Yes.

Q. How do you know?

A. These are my initials.

Q. Okay. So you've seen this before?

A. Yes.

Q. I do want to point out "prepared by" here. What does that mean?

A. That Matt Brackett prepared the routing

package.

Q. Okay. Did he also prepare the GAPMS report itself?

A. Yes.

Q. Do you know if the person who prepares the routing and tracking form -- if they are the person who also prepares the GAPMS report?

A. Can you repeat the question.

Q. The person who prepares the Medicaid Policy Routing and Tracking Form, do they also prepare the GAPMS report itself?

A. I don't know how all the team members are instructed to fill out the report or -- I'm sorry -- fill out the tracking form.

Q. Is there any other way to determine who has prepared a GAPMS report?

A. I don't know. But speaking in general assignments -- these forms are used for other assignments. And there are a lot of assignments that are done collaboratively. So, yeah. I don't know specifically how else you would know just looking at documentation.

Q. Would that information be contained on an AHCA shared drive?

A. It's possible.

Q. Okay. Is there a reason the GAPMS report doesn't identify an author on the report?

A. I don't know.

Q. Okay. A couple other things. On the section line here, it says Canadian Prescription Drug Importation Program. But we have established this was the routing and tracking form for the GAPMS report related to the treatment of gender dysphoria. Are those two things related?

A. So the Canadian Prescription Drug Importation Program is the section of who developed the report. And it lets us know how the hierarchy of the routing should go through the management levels within the bureau and outside.

Q. So it was the Canadian Prescription Drug Importation unit who prepared the GAPMS report on the treatment for gender dysphoria?

A. So that's what I would interpret this section -- why it's listed there next to this section. It's the section responsible for routing and lets us know the hierarchy of the management.

Q. Okay. And then just looking down at the "Reviewed by and Routing Timelines," the start date is June 1st, 2022, for everybody except Mr. Wallace; who has a date of June 2nd, 2022. And the end date is June

1st, 2022, except for Mr. Wallace. Does that indicate that you Mr. Weida and Ms. Pickle all reviewed the report and signed off on it on the same day?

A. That the official routing and the signature occurred on the same day, yes.

Q. What do you mean by official routing?

A. So the date that this form and the final routing package was ready for signature.

Q. And what was continued in the final routing package?

A. I believe it was just the report.

Q. Okay. So the final report -- what was being tracked through this routing and tracking form?

A. Yes.

Q. Were there any attachments to the final report that were also reviewed?

A. The expert witness reports were also reviewed. But I can't remember if they were included in this routing package at the same time.

Q. Who reviewed those final expert reports?

A. I don't remember.

Q. Did you review them?

A. I don't remember if I reviewed them all. But I had seen them -- at least some of them. I can't remember if I reviewed them all formally.

Q. Okay. Turning just back to the general GAPMS process. Is the GAPMS process ever initiated to assess existing coverage of Medicaid services?

A. Can you repeat the question.

Q. Is the GAPMS process ever used to assess existing coverage of Medicaid services?

A. I don't know specifically.

Q. Okay. Who would know that?

A. Are you asking if it ever has or ever would?

Q. Ever would.

Would Ms. Pickle know that?

A. So my personal experience with the GAPMS process is somewhat limited. But it is such a unique process. I feel it's hard to answer that without each situation or each request that we would get would be unique, because that process is dealing with questions that fall outside of something that's easily answered policy question.

MS. DEBRIERE: Have we entered the GAPMS rule into evidence yet? Can we do that now. And that's to be 59G-1.0 -- I thought we had. Oh, it's 5. Okay. Sorry. That's my fault.

MR. PERKO: That's fine.

BY MS. DEBRIERE:

Q. So a couple questions about the language of the

rule. First under (1)(b), "health services" is defined as diagnostic tests, therapeutic procedures, or medical devices or technologies.

Under what category would prescription drugs fall in this definition?

A. I don't know.

Q. You are familiar with the GAPMS rule, though; correct?

A. Yes. I've read the GAPMS rule.

Q. Would prescription drugs fall under any of these categories?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I wasn't part of the original drafting of this rule text. So in order to interpret the policy, I would need to do research.

BY MS. DEBRIERE:

Q. Who would you ask?

A. I would probably start with Ashley Peterson.

Q. Okay. And going down to 3, the second sentence -- "The public may request that a health service be considered for coverage under the Florida Medicaid program by submitting a request."

What does this sentence mean to you?

A. There's much room for interpretation. It says

the public may request a public health service be considered for coverage.

Q. Does this sentence mean that the public may request that Florida Medicaid consider whether to exclude a service previously covered?

MR. PERKO: I'm going to object to form.

THE WITNESS: So I think it could. Not only do we update the coverage policies to include new services, but we do change the scope of a service as part of that process. So if there was a question that was not clear within the scope of the service, I can see how that might apply.

Or the example that you used earlier with a service that's only provided to under 21. If that service was -- if we received a request to make that service available for over 21. So I can think of examples where it wouldn't have to be a new service.

BY MS. DEBRIERE:

Q. Does this rule cover a public's request to take a service away?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know?

A. Public -- that would be a legal interpretation

or policy interpretation that would need consultation with the agency for me to answer.

Q. As the bureau chief of Medicaid Policy, you're responsible for developing coverage policies; correct?

A. I oversee the teams that develop coverage policies, yes.

Q. And you are responsible for overseeing the teams that develop administrative rules to implement those coverage policies; correct?

A. Yes.

Q. So you would be responsible for understanding how rules that implement coverage policies should be interpreted.

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Is it your responsibility to understand the content of this rule?

A. Yes.

Q. Okay. But you can't tell me how to interpret that second sentence in Subpart 3?

A. So if we received a request and I wasn't clear on the authority, there's several steps I would take to confirm that the agency's position is we have authority -- which would be to review any other applicable laws or regulations; would be to consult with

my team and with agency management and perhaps with legal if I was not sure whether a specific question or scenario that was received. We may not have the authority to take an action.

Q. So when reading the second sentence in Subpart 3 -- "The public may request a health service be considered for coverage" -- in order to understand what that sentence means, would you undertake any of the steps you just described?

A. It would depend on the exact question. If I wasn't clear with what the request was and how that authority applied, then I would take further steps to make sure that I understood how the rule applied to the request.

Q. Did you do that for -- okay. Okay. Let me make a note.

In the legal consultation part, it trigged me to remember just a housekeeping question. At lunch did you speak with your attorneys --

A. No.

Q. -- about the deposition?

A. No.

Q. Okay. Does the GAPMS process typically look at an individual service when you're undertaking analysis?

A. I don't know.

MS. DEBRIERE: Okay. Can I have either the Van Mol or Van Meter ATF. It doesn't matter. And we'll mark that as Exhibit 8.

(Plaintiff's Exhibit No. 8 was marked for identification.)

BY MS. DEBRIERE:

Q. So at the top of the page you have a -- did you approve this document?

A. Yes.

Q. Okay. So under "Reason for Occurrence," it says, "On April 20th, 2022, the Bureau of Medicaid Policy received a request for a time-sensitive analysis of service coverage. While such requests are typically for a single service or good --" Is that a correct statement?

A. I don't know.

Q. But you wrote this?

A. No. I signed this.

Q. Okay. Were you the one making the request?

A. No.

Q. Who was making the request?

A. Devona Pickle.

Q. Okay. Before you sign something, do you have to agree with the language contained therein?

A. Yes.

Q. So at the time you signed this, you agreed with the statement that such requests are typically for a single service or good?

A. Yes.

Q. Okay. But now you don't know if GAPMS are typically used for a single service or good?

A. My experience with GAPMS is limited. And I trust the expertise of my staff. And one of the reasons I asked or had recommended that this team be responsible was because of their historic knowledge of the GAPMS process.

Q. And when you say that, that includes D.D. Pickle; correct? You trust her expertise on the GAPMS process?

A. Yes.

Q. Okay. Are you aware of a standard operating procedure used for the GAPMS process?

A. I've heard mention of it. But I don't believe I've ever seen it.

Q. Who did you hear mention of it from?

A. I can't remember. Either Matt or Jesse.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 9, which is the GAPMS Decision Tree Checklist.

(Plaintiff's Exhibit No. 9 was marked for

identification.)

BY MS. DEBRIERE:

Q. Do you recognize this document, Ms. Dalton?

A. I believe I've seen this before.

Q. Do you know what it's used for?

A. I believe this was developed to determine if a request just goes through the coverage determination process or should be handled as a GAPMS.

Q. Okay. And tell me the difference between a coverage determination and something that needs to go through the GAPMS.

A. I don't know everything that goes into how that decision is concluded. But in general, a coverage determination is when it's very clear that the agency has the authority to add a service and that it meets all of the agency's rules and -- for example, an optional state plan service that the agency currently doesn't cover but is clearly allowed through federal CMS would be a coverage determination. Where the GAPMS process is driven by the rule you referenced earlier that describes when it's not clearly meeting all the requirements and laid out in the current coverage policies.

Q. So much earlier in the deposition you gave an example of a coverage determination of a medical supply for -- was it Amino Foods?

A. Puro Meno.

Q. Puro Meno Foods. Why didn't you use the GAPMS process for that? Did you use the GAPMS process for that?

A. No.

Q. Why not?

A. Because the agency already covered similar products.

Q. Okay. Was that the only factor in determining whether to assess it using GAPMS?

A. I don't remember the conversations with the team when I was briefed on the recommendation.

Q. Was a GAPMS Decision Tree Checklist done for Puro Meno Foods?

A. I don't believe so. I never saw one, no.

Q. Okay. Who undertakes the process to fill out the decision tree?

A. I don't know.

MS. DEBRIERE: I apologize. Can we take just a two-minute break.

MR. PERKO: Sure.

(Brief recess.)

BY MS. DEBRIERE:

Q. Do you know how to interpret the answers on a decision tree checklist?

A. No, I don't believe I've ever seen one filled out.

Q. Okay. There's a space here that says "GAPMS Topic." What would go in that space? Do you know?

A. I don't know.

Q. Would a decision tree checklist be generated for every GAPMS request that comes in?

A. I don't know.

Q. Who would know that?

A. I don't know. I don't know if this is still the internal process. I don't know.

Q. Who would know whether it was still the internal process?

A. Jesse Bottcher.

Q. Okay. Would the members of Jesse Bottcher's team also know?

A. No, I don't think anyone currently on his team would know.

Q. How about anybody previously on his team -- I'm sorry; back up.

So no one on Jesse Bottcher's team is in charge of the GAPMS process?

A. The GAPMS position is currently vacant.

Q. Would anybody who was in charge of the GAPMS process at some point know whether the decision tree

checklist is used in the GAPMS process?
A. I don't know.
Q. And there's only one position that would know that, and that is currently vacant; correct?
A. I believe so, yes.
Q. And what is that position called?
A. I believe it's a Government Analyst II.
Q. And so there's just that one position in charge of knowing the GAPMS process?
A. As far as I know, yes.
Q. Okay. We touched on this a bit earlier. Does AHCA use the GAPMS process for prescription drugs?
A. I don't know.
Q. When you were giving an example of similar requests that Mr. Brackett handled for GAPMS, the example you gave was cross hormone therapy; correct?
MR. PERKO: Object to form.
THE WITNESS: I believe that was the example I gave.
BY MS. DEBRIERE:
Q. And what is cross-sex hormone? What is a hormone?
A. I don't think I can recite the clinical definition.
Q. Is the hormone a prescribed drug?

A. I believe so.
Q. So then you're aware of one instance in which GAPMS was used for determining -- for assessing a prescription drug?
A. Yes.
Q. But you don't know generally if GAPMS is used to assess prescription drugs?
A. My knowledge of GAPMS is limited. So to speak in generalities -- but I do see where in 2016 there was the GAPMS on hormone suppression.
Q. Okay. Is GAPMS the only method AHCA relies on to determine whether a Medicaid service is experimental?
A. I don't know. I know we have a clinical trials coverage policy. So there may be circumstances where it's clear that coverage would be -- that coverage policy or the clinical trials rule would apply. And I don't know all the details of how the QIO vendors -- what that process, all that entails.
Q. Whether the QIO venders would determine whether something is experimental?
A. Or if it was clear the clinical trial policy would apply instead. So I don't know to the extent of if there could possibly be.
Q. What is the clinical trials policy?
A. It's a rule that outlines the agency's coverage

for recipients participating in a clinical trial.

Q. And what does that type of authorization entail?

A. I don't know the specifics.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should be excluded?

A. Can you repeat the question.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should not be covered?

A. I don't know the specifics. But if, for example, a pharmaceutical is not FDA approved, there would be perhaps, like, a different process where it wouldn't have to go through the process.

Q. What is the significance of a drug being FDA approved for the purposes of coverage?

A. I don't know the details.

Q. What do you know about it?

A. I believe there's federal requirements on if a drug is not FDA approved -- there is certain coverage requirements.

Q. Do you know if that relates to the compendia we were earlier talking about?

A. I don't know.

Q. Okay. If AHCA is determining whether a production drug is experimental, does AHCA consider whether the drug is FDA approved?

A. I believe so.

Q. If a particular use for a drug has been FDA approved, can AHCA deem the drug experimental for that use?

A. Can you repeat the question.

Q. If a particular use for a drug has been FDA approved, can AHCA deem that drug experimental for that use?

MR. PERKO: I'm going to object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. But FDA approval bears on a determination as to whether AHCA will cover a drug; is that correct?

A. Yes, I think it's considered.

Q. If it's not -- if a drug is not FDA approved, are there circumstances under which AHCA will still cover the drug?

A. I don't know. But I think there is federal regulations around what's allowable.

Q. In the Federal Medicaid Act?

A. I believe.

Q. You mentioned just a second ago, a clinical

trials coverage policy. Where does that policy live?

A. In Rule Class 59G on our website.

Q. If it's not there where would we find it?

A. In the Florida Administrative Code.

Q. It should be in Chapter 59G?

A. But it should be on our website.

Q. Okay. And it is adopted as a rule?

A. Yes.

Q. Okay. Once AHCA reaches a decision through the GAPMS process, describe the implementation of that decision.

A. So, again, in my experience -- I've only been bureau chief for two finalized decisions that were different. And I can't remember all the steps to implementation. But once a determination of any coverage is made, then there's a process of how to notify the public. There's a process for notifying the plans of changes if it affects the plans. There's a process of making sure that the -- any other associated rules that may be impacted are updated.

Q. Anything else?

A. If a training is needed, it depends on what it is. But there could be other.

Q. Who would you train?

A. So, again, just speaking generally -- the

managed care plans; the public; if it's fee for service, the providers; especially if it has to do with submitted claims.

Q. What are the two final reports that you have overseen as bureau chief?

A. So it was the GAPMS that we're discussing today.

Q. And, again, that's the one that relates to treatment of gender dysphoria?

A. Yes. And then the -- I can't remember the exact name of the other GAPMS. But it was through a managed care plan request.

Q. Was it an expedited GAPMS?

A. I don't believe so.

Q. Do you remember what the service was at issue?

A. I do not.

Q. Okay. And the process for an expedited GAPMS, that's different from the traditional GAPMS process?

A. I'm not sure of the differences outside of the timeframe.

Q. Is it different as to how you would inform the public about it?

A. I don't know. I can't recall what steps we took after notifying the plans of the final decision.

Q. Okay. Through the traditional GAPMS process --

do you have any GAPMS right now that are in the final stages?

A. No.

Q. Okay. And you don't know how many requests are currently pending?

A. I don't know.

Q. So the last GAPMS that was finalized was in June of 2022?

A. Yes.

Q. Okay. And now we're in February of 2023. And there's no GAPMS that are ready for finalization at this point?

A. I don't know what stages of development they are.

Q. Okay. Is there anything on your desk to review?

A. I don't know. I don't remember if I have anything pending.

Q. Okay. When you were meeting with Mr. Weida about the June 2022 GAPMS report related to the treatment for gender dysphoria, that report had not been drafted; correct?

A. Sorry. Can you repeat that.

Q. Yeah. Absolutely. So earlier you spoke to meeting with Mr. Weida once you received the request

from the secretary to undertake the GAPMS for treatment of gender dysphoria; do you remember?

A. Yes.

Q. During that meeting had the GAPMS report been drafted yet? I know it seems like a silly question. But I'm asking at face value.

At the time you met with Mr. Weida, had the GAPMS report been drafted yet?

A. The GAPMS report I was discussing with him? No.

Q. Okay. But you have a good memory of that report before it was even drafted; is that right? You were able to recount details to me about discussing that report about before it had been drafted; is that right?

A. Throughout the process there had been discussions. But I don't know if I remember all the details.

Q. What I'm wondering is just why that report sticks out in your mind, but now you can't recount any other GAPMS reports that are pending. Is there a reason for that?

A. I have a lot of documentS in my queue at any one time. And it's really on the onus of the analyst -- part of their job responsibilities -- to make sure assignments are completed and finalized and routed and

closed. So because there was discussion and updates on the status and progress of the report -- and it was not that long ago -- I remember having conversations about the report.

Q. There are GAPMS reports pending right now, though; right?

A. I don't know. I don't know what the GAPMS queue is right now.

Q. Okay. So you don't know if there's anything in the queue right now?

A. Correct.

Q. But you do remember details about the GAPMS report related to treatment of gender dysphoria?

A. Details on the process?

Q. Yeah.

A. Yes.

Q. Okay. When I say "rulemaking process," do you understand what I'm referring to?

A. Yes.

Q. And do your current responsibilities at AHCA include the rulemaking process?

A. Yes.

Q. Can you describe those responsibilities.

A. I review drafts of the coverage policy and the documents that go along with the rule promulgation

process. I sometimes participate in the public meetings and review provider alerts or other notices associated with the process.

Q. Anything else?

A. Not that I can think of.

Q. Okay. Do you ever review public comment associated with the rule?

A. It depends.

Q. So you have before?

A. More in my old role as the AHCA administrator.

Q. Okay. Can you remind me the dates you were in that role.

A. August 2018 to August 2021.

Q. And in your previous roles at AHCA as well as DOEA, you had rulemaking responsibilities; is that right?

A. DOEA was more of the drafting of the policy and not the promulgation process.

Q. Okay.

A. And then AHCA has been more on the promulgation process -- administrative process.

Q. So you'd say you had experience with Florida agency rulemaking?

A. Yes.

Q. When I say "rule workshop," do you understand

what I'm referring to?

A. Yes.

Q. When I say "rule hearing," do you understand what I'm referring to?

A. Yes.

Q. What is the difference?

A. Chapter 120 has different public meetings outlined in different stages of the process. The workshop as we use it here is primarily for the rule development stage of the administrative process. And the hearing occurs at the proposed rule stage.

Q. Okay. When you say the development of the rule, does that mean generally the rule language itself has not yet been drafted or proposed?

A. It depends.

Q. Okay. So is there a difference between workshop and hearing?

A. They're both public meetings meant to garner input from the public and make the public aware of the changes. But per Chapter 120, there are differences because of the different stages of the process.

Q. Okay. Why was there no public workshop held for the rule development of the change to Rule 1.050 excluding the treatment for gender dysphoria?

A. I don't know.

Q. Were you here were when that happened?
You were?
A. Yes.
Q. Okay. While here, have you had public comment on rule workshops for other rules?
A. Can you repeat the question.
Q. Since you've been here at AHCA, have you -- let me ask this question: When the rule was developed to exclude treatment of gender dysphoria per 1.050, were the you bureau chief for Medicaid Policy?
A. When the rule was promulgated?
Q. Well, when you were having the -- when you noticed the proposed rule and had the rule hearing.
A. For this specific rule?
Q. Yes.
A. Yes.
Q. Okay. In your role as bureau chief, have you ever -- in your role as bureau chief, have you been involved in rule workshops for other rules?
A. Yes.
Q. So why weren't you involved in the rule workshop for the exclusion of treatment for gender dysphoria; do you know?
A. I can't remember. I believe I was out of town.
Q. Okay. If you weren't out of town, would you

have been involved in it?

A. I don't remember the discussion around that. But I'm not always involved in the workshops or rules.

Q. How is that determined?

A. It depends on the circumstances and the content of the rule. But I can't remember the specific conversation when that was determined.

Q. Was there a public workshop for the exclusion of the treatment for gender dysphoria? There was only a public hearing; correct?

A. I know there was only one public meeting. I can't remember.

Q. Generally what's the process for planning a rule hearing?

A. We determine a date, a location, and who will be in attendance. And the date and location is included in the notice.

Q. And when you say who will be in attendance, who does that mean?

A. Who the subject matter experts or other agency staff will conduct the public meeting.

Q. Okay. And what do you mean by subject matter expert?

A. So I think I described it a little before how for most of the coverage areas there is a specific

analyst responsible for the development of that policy. So, for example, if there was a change to respiratory services, whoever that suggest matter expert or analyst is would typically be present at the workshop since they have the in-depth knowledge on the changes being proposed.

Q. Is that person always a person employed by the agency?

A. The subject matter expert for all our coverage policies are individuals employed with the agency.

Q. Okay. Are there any written protocols regarding the planning of a rule hearing?

A. I know we've developed process maps and procedures. But I don't know the details of planning a hearing specifically and how detailed those documents are on that process.

Q. What's a process map? What does that entail or detail?

A. There's a graphic that was created before my time that -- it's a real nice layout of the administrative rulemaking process.

Q. Okay.

A. And so it has -- it's a graphic, and it's one page. So it's easy to put on your wall.

Q. And your responsibilities include sometimes

attending rule hearings?

A. Yes.

Q. Since you've been the bureau chief, how many rule hearings have you attended?

A. I don't think I've attended any hearings.

Q. As a State agency employee -- either at DOEA or AHCA -- how many rule hearings have you attended?

A. So at DOEA I attended several AHCA rule hearings in the audience. In my previous position with the agency, I think it was only a handful.

Q. Does that mean five?

A. Yes; I'd say five or less.

Q. Okay. Who else from AHCA attends rule hearings? Let me ask this: Are there AHCA staff who attend rule hearings as part of their job description -- they have to be at every rule hearing?

A. I don't know if that's actually in the job descriptions. But Cole and his team -- since they set up the workshop or hearing or the public meeting -- their responsibilities include making sure they have the speaker list, making sure that everybody is escorted into the building, that the speakers can be heard. So they're in attendance for all of the public meetings.

Q. Okay. And do you know if they have any protocol off which they operate -- written protocol for

conducting the hearing?

A. I believe there's an internal process and process map. But I don't know the details off the top of my head what's included in that document.

Q. Is it the rules unit that is in possession of that document?

A. I would think so, yes.

Q. Okay. In your experience, aside from the agency who attends the hearing?

A. From the public?

Q. I mean, I think that would be the only other option; right?

What types of people from the public?

MR. PERKO: Object to form.

THE WITNESS: That would really depend on what the change is and who is impacted.

BY MS. DEBRIERE:

Q. In your experience attending public hearings -- rule hearings -- are there typically more than 25 people from the public that show up at the rule hearing?

A. I would say yes. Especially since the hearings are now -- have a virtual option. The majority of them are virtual and in person.

Q. Are there typically more than 25 people who show up in person?

A. So I haven't participated in all of them. In the last few that I participated in, there was not 25.

Q. In the last one you participated in how many were there?

A. Less than ten.

Q. Does AHCA ever invite specific persons from the public to attend the rule hearings?

A. Yes.

Q. And how do they do that invite?

A. A provider alert is sent out to the providers. Usually that goes along with the FAR notice that was posted and the public was noticed. If it's a sister agency, it might be by email. So if we believe a rule might impact a sister agency, we might reach out specifically.

Q. So other than posting the public notice and the FAR provider alerts and emails to potentially impacted sister agencies, is there any other way the agency invites specific people to attend the hearing?

A. I believe we sent calendar invites before.

Q. To what people? How did you decide on sending calendar invites?

A. The specific example I'm thinking of is a sister agency for the iBudget handbook. We invited ADP to participate and sent them a meeting invite so they

can block that time.

Q. Okay. Have you ever invited Medicaid recipients other than through the public notice to attend a rule hearing?

A. I don't know, outside of the public notice process.

Q. In your experience?

A. I personally have not.

Q. Okay. Do any State agencies in hosting a rule hearing, do they arrange for transportation for individuals from the public to attend that hearing?

MR. PERKO: Object to form.

THE WITNESS: I can't speak for any other agency. I don't know.

BY MS. DEBRIERE:

Q. What about at DOEA? Did that ever happen?

A. I don't believe I ever participated in an actual public meeting hosted by DOEA.

Q. That's right. You said that.

What about AHCA? Are you aware of AHCA ever arranging transportation for individuals from the public to attend a hearing?

A. Not that I'm aware of.

Q. Are you aware of anyone from the public being paid to attend a hearing?

A. No.
Q. Are you aware of anyone who is a subject matter expert being paid to attend a hearing?
A. I know we've reimbursed the subject matter experts. But I'm not sure if that was specifically -- attending the hearing was specifically included.
Q. And these are subject matter experts that are employed with the agency?
A. I don't know how that process works. But they're not full-time employees with the agency. I believe it's like consultants.
Q. Okay. What's the average length of a hearing?
A. I don't know the average. I know our public meetings typically range between 30 minutes and two hours.
Q. Okay. On average how many comments do agencies receive for a rule hearing? Is there an average?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Do you think 100 comments is a lot of public comments to receive at a hearing?
MR. PERKO: Same objection.
THE WITNESS: I really don't know.
BY MS. DEBRIERE:

Q. In your experience, does a State agency ask outside legal counsel to attend and perhaps in rule hearings?

A. Can you repeat the question.

Q. In your experience, does a State agency normally ask that outside legal counsel attend a rule hearing?

A. I don't know.

Q. When you planned this last rule hearing, did you ask outside legal counsel to attend?

A. Can you specify which hearing.

Q. Yeah. There was a hearing a couple of weeks ago on the change to the medical necessity definition.

A. Yes. The workshop.

Q. Workshop. Did you ask outside legal counsel to attend that workshop?

A. I personally did not.

Q. Did outside legal counsel attend that workshop?

A. I don't believe so.

Q. And have you ever attended a rule hearing where outside legal counsel was asked to participate in?

A. I can't recall if that circumstance has ever happened.

Q. So it's not usually -- it's not the standard course of things for outside legal counsel to attend?

A. Correct.

Q. All right. Turning to the exclusion for treatment of gender dysphoria under Rule 59G-1.050. Prior to the adoption of this exclusion, did any coverage policies regarding any of the services listed there -- sorry. Strike that.

Prior to the adoption of the exclusions set forth -- I'm not sure you're looking at the right rule. 59G-1.050. Exhibit 2. It would help me to tell you the exhibit number. And then it's Subpart 7.

So prior to the adoption of that rule -- that Subpart 7 -- did any coverage policies exist regarding the services that are now subject to that exclusion?

A. Can you repeat that question.

MS. DEBRIERE: Court Reporter, can you read back that last question.

(The preceding question was read back by the reporter.)

THE WITNESS: There was not a specific coverage policy for services for the treatment of gender dysphoria.

BY MS. DEBRIERE:

Q. Does that mean those services were never covered to treat gender dysphoria by Florida Medicaid?

A. I don't believe there was any policy language

that specifically outlined coverage of the services listed in this section.

Q. If there was no specific policy language, does that then mean those services were not covered to treat gender dysphoria by Florida Medicaid?

A. I don't know the extent to what providers were reimbursed for providing the services.

Q. So even if there wasn't a coverage policy specifically related to these services, it's possible that Florida Medicaid was covering the services for the treatment of gender dysphoria?

A. It's possible Florida Medicaid reimbursed for these.

Q. Are there circumstances in which AHCA might not have an explicit or affirmative coverage policy, but would consider a request for a service on a case-by-case basis?

A. Can you repeat the question.

Q. Are there circumstance in which AHCA might not have an explicit coverage policy regarding those services -- or any service -- but would consider a request for a service on a case-by-case basis?

A. I don't know specifically if it's case-by-case basis. But I believe that the plans -- that some of the request from the managed care plans may be specific to a

request for a specific coverage. So when plans request for a GAPMS to be provided, it could be being driven by a specific case.

Q. Okay. So even though a coverage policy does not exist regarding the coverage of a specific service, there are circumstances in which AHCA might still cover that service?

A. Yes.

And I apologize. On your last question I think I heard you specific about GAPMS, which is what I answered. So I apologize.

Q. That's okay. No, that's fine. You're referring to not the last question, but the question before that; is that right?

A. Yes.

Q. Okay. But your response on that last question, you understood the question?

A. Yes.

Q. Okay. Will Florida Medicaid cover an EPSDT service if that service is experimental?

A. So in order for an EPSDT service to be covered, it has to meet the definition of medical necessity.

Q. And that medical necessity definition includes the requirement that the service not be experimental?

A. Yes.

Q. Okay. So you received a request from Secretary Marstiller via email to engage in a GAPMS regarding treatment for gender dysphoria; correct?
A. I can't remember if it was email.
Q. Right. But you received the request somehow?
A. Yes.
Q. And roughly when was that; do you remember?
A. I don't remember.
Q. And then the next step was speaking with Mr. Weida about the letter?
A. Yes.
Q. And developing the plan as to who was going to --
A. Yes. Developing how the process would work.
Q. Were all the decisions reached in that one meeting with Mr. Weida?
MR. PERKO: Object to form.
THE WITNESS: No.
BY MS. DEBRIERE:
Q. Okay. So after that meeting with Mr. Weida, what happened next?
A. I can't remember the exact timeline of events. I know we met at some point with the Canadian Prescription Drug Importation team.
Q. And they were the ones who were put in charge

of doing this GAPMS?

A. Yes.

Q. Okay.

A. And there was several conversations following that.

Q. Were those conversations limited to yourself, Mr. Brackett, Mr. Chen, and Ms. Pickle? Or were there other people involved?

A. I can't remember the chronology. I know after the report and then into the rulemaking Cole Giering was brought into the conversation. Legal counsel -- there was conversations with the experts.

Q. Who were the experts?

A. I can't remember all their names. I don't know if we have that list here.

Q. Did you ever personally speak with any of the experts?

A. No.

Q. Are all the experts listed here on what would be will be your Exhibit 7 on page 45?

A. I believe so, yes.

Q. Was a Dr. Von Mol ever involved as an expert?

A. I believe so.

MS. DEBRIERE: And let me just mark this as Exhibit 10.

(Plaintiff's Exhibit No. 10 was marked for identification.)

BY MS. DEBRIERE:

Q. And this is a document -- an After the Fact Request Form Under 35K. This form is indicating what?

A. Consultant services for vendor name Andre Van Mol.

Q. And what kind of consulting services did Dr. Van Mol provide?

A. I don't know all the details of that -- what the contractor provided. But it was as part of the GAPMS process.

Q. Okay. Why was it time sensitive? It indicates on that form it was time sensitive. Why?

A. I don't know why the request was time sensitive.

Q. Who would know that?

A. I don't know.

Q. Okay. At any time throughout the process did you feel like there was an urgency to the development of the report and rule?

A. Yes. The time sensitive nature was communicated.

Q. By?

A. I don't know remember if it was in the original

request or if it was later in conversations with leadership. I can't remember exactly who. But I think the expectation to follow the process but work as quickly as possible was apparent.

Q. Okay. But you cannot provide me an explanation as to why it was identified as time sensitive?

A. Correct.

Q. I believe we already marked ATF to Dr. Van Meter as Exhibit 8.

Dr. Van Mol -- do you know if he attended the rule hearing for the exclusion of treatment for gender dysphoria?

A. I don't know.

Q. Okay. What does this document, Exhibit 8, indicate to you?

A. An approval for consultant services for vendor named Quintan Van Meter.

Q. Okay. And what kind of services did he provide in exchange for that reimbursement?

A. Consultant services.

Q. Consulting on what?

A. As part of the GAPMS process.

Q. Do you know what specific stages he provided consultation on?

A. I don't.

Q. Do you know whose idea it was to use him?
A. I don't.
Q. Do you know whose idea it was to retain any of the outside experts?
A. No.
Q. Was it internal to AHCA, that decision? Did someone at AHCA decide to retain outside experts?
A. I don't know.
Q. Who would have made that decision?
MR. PERKO: Asked and answered.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Are you aware of AHCA retaining outside experts for any other GAPMS report?
A. I don't know.
Q. Other than Dr. Van Meter and Dr. Van Moll -- I'm sorry.
Was there a Dr. Grossman involved in the process?
A. Yes.
Q. And what was Dr. Grossman's role?
A. I believe it was the same -- consultant services.
Q. For the development of the report?
A. Yes.

Q. Okay. Do you know if they were reimbursed to participate in the hearing?

A. I don't know.

Q. Okay. Were any of the -- other than Dr. Van Mol and Dr. Van Meter -- was Dr. Brignardello-Petersen reimbursed by AHCA for consultant services related to the development of the exclusion of treatment for gender dysphoria?

A. I don't know off the top of my head.

Q. What about Dr. James Cantor?

A. I don't know off the top of my head without consulting if there was an invoice.

Q. Is that true for all the experts?

A. I can't remember how exactly the contracts -- the contracted services were reimbursed.

Q. Were they reimbursed?

A. They were.

Q. Looking at Van Meter's form -- why did you sign that form for a $34,000 reimbursement if you didn't know what Van Meter was doing?

MR. PERKO: I'm going to object to form.

THE WITNESS: So I know that Van Meter was consulting as part of the project. I just don't know throughout the process all the specific details of that consultation.

BY MS. DEBRIERE:

Q. Would you assume each expert listed was similarly compensated for the amount that Dr. Van Meter and Van Mol were compensated?

A. I'm not going to assume. Just looking at the two invoices, they are very different.

Q. In what ways?

A. This one has a not to exceed amount. And then this one has as dollar amount.

Q. Okay. Is that the only way they're different?

A. No.

Q. How else are they different?

A. The one for Quinton Van Meter has specific information regarding his MFMP registration.

Q. What is MFMP?

A. My Florida Market Place.

Q. Okay. Any other ways that they're different?

A. Some of the other language is different. The dates are different. But aside from that, no.

Q. How often do you approve an After the Fact Request Form for reimbursement of outside expertise?

A. Not often.

Q. How many times have you done it for expertise not related to the treatment of gender dysphoria?

A. I can't recall if I actually approved the

invoice; but I believe there was a consultant for the Canadian Prescription Drug Importation Program at one point. And I just can't remember the time.

Q. Is that the only time you can remember?

A. Yes.

Q. Okay. So when you were approving these forms that don't come across your desk often, do they strike you as something that needed careful review?

A. The invoice itself?

Q. The reason for reimbursement.

A. Yes. But the invoice itself seems pretty straightforward that a reimbursement based on services provided -- that had already been provided would be signed.

Q. Did you do a carful review of the reason for reimbursement?

MR. PERKO: Object to form.

THE WITNESS: I guess I'm not sure what you mean by careful review. I personally was not involved in all of the consultation services provided. But I did meet with the team and knew that services were provided.

BY MS. DEBRIERE:

Q. Prior to you receiving this request for reimbursement, did you know these experts were being

relied on for consultation?
A. Yes.
Q. Did you have to approve that request?
A. I don't know if there was a request initiating the services. I don't remember.
Q. Was there a need to approve the decision to rely on outside experts?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. Was there a requirement that consulting with outside experts be approved prior to the consultation?
MR. PERKO: Object to form.
THE WITNESS: Can you repeat that question.
BY MS. DEBRIERE:
Q. Was there -- who consulted with the outside experts?
A. Again, I don't know the extent of what the consultation services were or who all was part of that.
Q. In order for them to -- in order for the team to develop the GAPMS report -- who wrote it -- in order for them to consult with outside experts, did it require your approval?
A. I don't recall ever approving them.
Q. And the team relying on outside experts to write the GAPMS report on gender dysphoria, did it

require the approval of D.D. Pickle?

MR. PERKO: Object to form.

THE WITNESS: I can't recall how the formal process was initiated.

And I do want to say relying on experts -- there was a lot of additional research done as well as part of the GAPMS process. So I wanted to clarify that.

BY MS. DEBRIERE:

Q. But part of writing the report was consulting with these outside experts; correct?

A. Yes.

Q. And you don't know who made the decision to consult with those experts; is that right?

A. Correct.

Q. Whoever made the decision -- we don't know who that is. But whoever made the decision, did they require approval before they could implement that decision?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. As the bureau chief who oversees the team who wrote this GAPMS report, did you have an expectation that they would come to you for approval to

consult with outside experts that would then be paid?
A. Can you repeat that.
Q. As the bureau chief, the person who oversees the team that wrote the GAPMS report on treatment for gender dysphoria, did you have an expectation that they first ask you permission before they consulted with outside experts who charged for their services?
A. No.
Q. Why didn't you have that expectation?
A. I can't really answer that, as I was not part of the decision to consult with the experts.
Q. Who was part of the decision?
A. I don't know.
Q. But you know you were not part of it. Okay.
At the bottom of the After the Request Form, it states -- for Dr. Van Mol, which is Exhibit 10 -- it states supervisor approval is required. What does that mean?
A. In the routing hierarchy for approval.
Q. Approval of what?
A. For invoices for My Florida Marketplace. I'm the direct supervisor of D.D. Pickle.
Q. So your approval is required for D.D. Pickle to pay this bill?
A. Yes.

Q. Okay. But your approval was not required for D.D. Pickle to incur this bill?

MR. PERKO: Object to form.

THE WITNESS: I don't remember if there was a formal approval to initiate the services.

BY MS. DEBRIERE:

Q. Did you have to have approval to authorize this payment to Dr. Van Mol?

A. I can't remember. I don't know where this goes next in the routing.

Q. Okay. Did you ask permission to approve this from anyone?

A. I can't remember a specific conversation. But I knew it was approved by the agency to consult with -- to have the consultant services.

Q. Okay. Related to that, the last sentence is -- how did you know that?

A. How did I know what? Can you repeat that.

Q. I think you had responded that you knew the agency had approved it. And so my question was: How did you know that?

A. I don't remember the specific conversation. But I do know that it was approved by leadership.

Q. And how do you know that?

A. There must have been a conversation. I just

can't remember an exact -- if there was an exact conversation or a document I signed. I can't remember.

Q. Okay. Do you remember who you had the conversation with or had the document signed by?

A. I don't remember.

Q. The last sentence under that first paragraph, it says, "Verification of the availability of funding and approval from executive leadership was obtained prior to any work being conducted for this project."

Who was that executive leadership?

A. The majority of my discussions were with my direct supervisor. But Tom Wallace ultimately signed the report. And I don't know outside of that who all was involved.

Q. Do you need a break?

A. Yeah.

(Brief recess.)

BY MS. DEBRIERE:

Q. Who decided the amount in those forms?

A. I don't know how the amount was negotiated.

Q. Did you follow up on the amount being requested -- ask any questions about it?

A. I can't remember if I asked any questions. But, again, as it states on the form -- the availability of funding approval for leadership.

Q. So you think whoever that leadership was had approved that amount?

A. I don't know how the reimbursement for the services was negotiated.

Q. Okay. So you didn't ask any questions about the amount or what it was being used for?

MR. PERKO: Object to form.

THE WITNESS: I knew what it was being used for. But I can't remember if I asked any questions about the amount.

MS. DEBRIERE: Okay.

THE WITNESS: I can't recall any.

BY MS. DEBRIERE:

Q. Are there any subject matter experts for the services listed in that exclusion that are full-time employees with the agency?

MR. PERKO: Object to form.

THE WITNESS: I don't believe so, since the services outlined in the policy were not clearly outlined in any existing coverage policy that would have had any subject matter expert assigned to the coverage policy.

BY MS. DEBRIERE:

Q. Do you have a subject matter expert in surgery?

A. I don't know if it's one person or more than

one. We have an area that's responsible for the coverage policies we talked about earlier that contain coverage for surgical procedures.

Q. So you have a subject matter expert for outpatient hospital services?

A. Yes.

Q. And do you have a subject matter expert for inpatient hospital services?

A. I don't know if it's the same person.

Q. Okay. But do you have a subject matter expert in inpatient, it just might be the same person?

A. There's a team responsible for oversight of those policies, yes.

Q. Was that team involved in the development of this GAPMS report?

A. Not to my knowledge. But I can't speak to all of the research and activities that were part of the completion of the project.

Q. Who is that team -- that team that are the suggest matter experts in inpatient and outpatient hospital services?

A. That would be John Matson under Jesse Bottcher who is responsible for primary and preventive surgeries, including dental.

Q. Okay. You had mentioned before the break that

you had communications about the development of the GAPMS report with legal counsel; is that correct?

A. I believe so. I can't remember if it was part of the report or part of the rule. I know for sure with the rulemaking process that legal is involved in that process normally. And they were in this instance as well.

Q. Did that legal include outside counsel?

A. I don't know. I don't remember meeting with outside counsel.

Q. Okay. You don't remember with meeting with Holtzman & Vogel, the law firm?

A. No.

Q. Did you communicate with any other State agencies like the Florida Department of Health about the GAPMS report?

A. I personally did not.

Q. Did anybody at the Agency for Health Care Administration?

A. I don't know.

Q. Did you communicate -- were there any communications between AHCA and the Governor about the development of this report?

A. I don't know.

Q. Did you personally communicate with the

Governor's office about the development of this report?

A. No.

Q. Did you personally communicate with the Governor's office about the exclusion of treatment for gender dysphoria?

A. No.

Q. Were there any communications between AHCA and people that provided public comment at the hearing?

A. I'm sorry; can you repeat the question.

Q. Were there any communications between AHCA -- prior to the hearing, were there any communications between AHCA and the people who provided public comment at the hearing?

A. I don't know.

Q. Did you personally communicate with anyone who provided public content at the hearing prior to the hearing?

A. No.

Q. Was anyone at AHCA aware that specific people would provide public content at the hearing prior to the hearing?

A. I don't know.

Q. Were you aware that there were any specific members of the public who would provide public comment at the hearing prior to the hearing?

A. No.
Q. The person who is identified as authoring the GAPMS report on gender dysphoria is Matt Brackett; correct?
A. Yes, he was the primary author.
Q. Do you recall a meeting between you, Mr. Weida, and Mr. Bottcher discussing who the author of the report would be?
A. I don't remember if Jesse was in any of the conversations.
Q. Okay. Did Jesse ever express a concern to you about someone -- anyone on his team drafting the GAPMS report on gender dysphoria treatment?
A. Prior to?
Q. At any time.
A. Can you say that again.
Q. Did Mr. Bottcher ever express to you concerns over someone on his team drafting the GAPMS report on the treatment for gender dysphoria?
A. Not that I can recall.
Q. Was the GAPMS decision tree used before you decided to undertake the GAPMS analysis that is contained in the June 2022 report?
A. I don't know.
Q. Who would have that information?

Did Secretary Marstiller in her letter to Tom Wallace -- did she direct Tom Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.

THE WITNESS: I can't recall the details of the letter.

MS. DEBRIERE: Me neither. Do we have a copy?

MS. CHRISS: It's the last page right there. It's Attachment A.

MS. DEBRIERE: Oh. It's the very back of Exhibit --

MR. PERKO: It's not attached to ours.

MS. DEBRIERE: Okay.

MS. DUNN: Why don't you pull it off and mark it as a separate exhibit.

MS. DEBRIERE: So we'll mark the letter from Simone Marstiller dated April 10th, 2022, as Exhibit 11. And that's Attachment A to the June 2022, GAPMS report related to the treatment for gender dysphoria.

(Plaintiff's Exhibit No. 11 was marked for identification.)

BY MS. DEBRIERE:

Q. So in this letter is Secretary Marstiller directing Mr. Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.
THE WITNESS: Yes.
BY MS. DEBRIERE:
Q. Do you think that Secretary Marstiller undertook a decision tree prior to writing this letter and sending it to Mr. Wallace?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Has the secretary of AHCA ever personally completed a decision tree on the GAPMS process?
A. I don't know.
Q. Would it be unusual if the secretary of AHCA completed a decision tree on the GAPMS process?
A. I don't know.
Q. Looking at the GAPMS report itself, does it contain a fiscal analysis?
A. I don't know off the top of my head.
Q. Yeah. No, take your time.
A. No, I do not see a fiscal analysis.
Q. Do you see anything related to cost effectiveness?
A. No.
Q. Do you know why that was not included?
A. No.

Q. Is budget neutrality in reaching a GAPMS decision important?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I know that that's something when determining a coverage determination that is taken into consideration. But specific to the GAPMS process, I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know that? Would the person responsible for writing GAPMS reports know that?

A. Yes. Or Jesse Bottcher or Matt Brackett.

Q. Or Jeff English?

A. Yes.

Q. Who decided which services would be assessed in the GAPMS report?

A. I don't know.

Q. So typically a request comes in from the public for a specific service. In this instance, the request came from the secretary; correct?

A. Yes.

Q. So would it have been the secretary who decided which services should be assessed?

A. I can't recall how the decision was made. I do know that that was part of conversations we had during this process. But I can't recall exactly how the

decision was finalized.

Q. Was there ever a discussion about narrowing the types of services to be included?

A. I don't recall specifically. I know that the coverage of behavioral health services was something that was always covered. But outside of that specifically, I can't remember.

Q. Was there ever any discussion about undertaking the GAPMS process for a set of services simultaneously as opposed to a single service?

A. Can you clarify.

Q. In the discussions about writing the report or assessing the services, were there ever any concerns raised about undertaking the process for a set of services as opposed to a single one?

A. I don't recall specifically.

Q. Was there any discussion about EPSDT?

A. I can't remember if it was specific to the development of the report or the rulemaking more specifically. But I believe there was.

Q. And what was discussed?

MR. PERKO: I'm going to object for a second. Did that include counsel? Did those discussions include counsel?

THE WITNESS: Yes.

MR. PERKO: And who was that?
THE WITNESS: I don't remember.
MR. PERKO: But it did include counsel?
THE WITNESS: I believe it was a discussion on the rulemaking with counsel.
MR. PERKO: I'm going to instruct the witness not to answer.
BY MS. DEBRIERE:
Q. Were all discussions had in front of counsel about EPSDT?
A. I don't remember.
Q. How about comparability?
MR. PERKO: I'll ask you the same thing.
THE WITNESS: Can you remind me what you're referencing when you say comparability. I think you mentioned that at the very beginning of the day.
MS. DEBRIERE: Comparability is a requirement under the Federal Medicaid Act in the administration of the coverage of the Medicaid services.
THE WITNESS: I don't recall.
BY MS. DEBRIERE:
Q. Were there communications with the Centers for Medicare and Medicaid Services about AHCA's decision to assess whether the services listed in the exclusion were experimental?

A. I don't know. I personally did not have any conversations.

Q. Who communicates with CMS about those kinds of things?

A. Those kinds of things, you mean changes in coverage?

Q. Does CMS ever reach out to AHCA about concerns they have about an action that they're taking related to Medicaid coverage?

A. Yes.

Q. Who would be the point person at AHCA to have those conversations?

A. So if an update to a federal authority were needed, that would be either Catherine Mcgrath or myself.

Q. Okay. You would not have had -- have you had any conversations with CMS about the GAPMS report related to the treatment of gender dysphoria?

A. No.

Q. Has Catherine?

A. Not to my knowledge.

Q. Have you had any conversations with CMS about the exclusion of the treatment for gender dysphoria as contained in Rule 59G-1.050?

A. I have not.

Q. Has Catherine?
A. Not to my knowledge.
Q. Has anybody else at AHCA?
A. I don't know.
Q. Okay. You mentioned a second ago that you weren't sure if you were talking about EPSDTs as it related to the report or the rulemaking. When you make that distinction, are you referring the writing of the report versus the adoption of the rule?
A. Yes.
Q. Okay. How was it decided that the conclusions from the GAPMS report should be adopted into rule?
A. I'm trying to remember the specific conversations. But I do believe those were conversations with counsel as well.
Q. Okay. The expedited GAPMS that you were involved in from start to finish, was that decision adopted into rule?
A. It was just one other GAPMS. And I don't believe any rule update was needed for that one.
Q. Why was a rule update needed for this GAPMS report?
MR. PERKO: If that's discussion with counsel, I will instruct you not to answer.
THE WITNESS: Because there was not any policy

language that clearly explained the coverage, it was determined that developing policy language was the best approach. Anything past that was -- how that process went was conversation with counsel.

BY MS. DEBRIERE:

Q. How often in your day-to-day in making decisions in your job do you have to consult with legal counsel?

A. Often.

Q. Okay. So does that mean -- okay. Like, every day?

A. I would say the majority of days.

Q. Okay.

A. And I'll just specify. I have some sort of contact or interaction with legal counsel.

Q. On most days?

A. Yes. And, again, because the rule promulgation does require review and some other documents we route are managed care contracts also route through legal. Just to give you examples of why it's quite often.

Q. They're all contacts with legal counsel about things related to the doing of your job?

A. The development of policy and -- yes.

Q. Okay. So there was -- you said there was -- the reason that it needed to be adopted into rule is

because there was no clear coverage policy on the services at issue; is that correct?

A. I can't remember all the factors that went into the decision. But I believe that was one of the factors when it was assessed that there was no coverage policy specific to the treatment of gender dysphoria.

Q. Were there existing coverage guidelines?

A. Not to my knowledge.

Q. At the time were you aware of existing pharmacy policies related to the treatment of gender dysphoria?

A. At what time? Can you specify.

Q. It was 2017/2016.

A. I was not with the agency in 2016. So I would not have been part of any development of policy at that time.

Q. But when you were deciding whether to adopt this exclusion into the rule, did you do any review of existing coverage guidelines or past coverage decisions?

A. I believe we did. But I can't recall the specifics.

Q. Did you review past GAPMS reports regarding the treatment of gender dysphoria?

A. I believe we did.

Q. And why weren't they enough to establish the coverage policy?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. 59G-1.050, Subpart 7 -- it bans Medicaid coverage for puberty blockers, hormones and surgery if done so to treat gender dysphoria; correct?

A. It covers that Medicaid does not cover those services for the treatment of gender dysphoria; correct.

Q. Does it distinguish between adults and children?

A. No.

Q. So the exclusion applies equally to both children and adults; is that correct?

A. Yes.

Q. Okay. And it excludes Medicaid coverage for puberty blockers and hormones and surgery to treat gender dysphoria, but it does not exclude Medicaid coverage for those services to treat other diagnoses; is that correct?

A. Correct.

Q. And I just forgot you answer; I apologize. Were you involved in the rule hearing held on July 8th regarding the exclusion set forth in 1.050?

A. No.

Q. Were you aware that outside legal counsel

participated in that hearing?

A. I don't know if I was made aware prior to today. I can't remember.

Q. At rule hearings you've been in in the past, do the State agencies have a panel of subject matter experts who respond to public comment during the hearing?

A. I can't cite the specific language, but it's actually required per Chapter 120 that the agency has subject matter experts who can speak to the contents of whatever is being discussed at a public meeting available.

Q. Other than the July 8th hearing, are you aware of any time that any agency has retained outside subject matter experts to participate on that panel?

A. I'm not aware of any.

Q. To your knowledge is this the only time AHCA has created a slogan to advertise the conclusion in its GAPMS memo?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Are you aware of the slogan "Let kids be kids"?

A. I've seen the website, yes.

Q. In your experience has AHCA ever designed a website page for any other rule adoption?

A. I can't remember if it was specific to rule adoption. But I can think of a couple of examples where we created web pages for policy updates; for example, for home and community based settings rule that was an administrative rule as well as a federal rule. There's a specific external web page for updates regarding that and information on that rule.

When we received the American Rescue Act funding approval, we created a web page with information on that funding and what those funding could be used for. So I feel like it's pretty common for us to update our external website when there's important information to communicate.

Q. In those other examples, did AHCA ever develop a slogan to go along with those web pages?

A. Not in the examples that I used, I don't think.

Q. Did they issue press releases?

A. The American Rescue Act funding may have had one. But I can't remember.

Q. Okay. Just going back quickly. My co-counsel has pointed out to me that in Chapter 120 it says that at the rule hearing agency staff must be available but not an expert. Do you think maybe you were confusing that requirement that an expert needs to be available under 120?

A. I think it says an agency staff with knowledge.

Q. Okay. "Ensure that staff are available to explain the agency's proposal and to respond to questions or comments regarding the rule." Is that the provision you were --

A. Yes.

Q. -- thinking of? Okay.

Typically when AHCA decides not to cover a particular service, where is that information included?

MR. PERKO: Object to form.

THE WITNESS: I think it depends on the policy. Each policy has different exclusions, if there are any, with the service. Or most of the coverage policies include a section specific to exclusions.

MS. DEBRIERE: Most of the policies? Is that what you said? I apologize.

THE WITNESS: Most of the coverage policies.

BY MS. DEBRIERE:

Q. Okay. And those coverage policies are service specific policies?

A. The examples I was thinking of, yes, were service specific coverage policies and include -- I can't remember exactly what section in the example of where to find that in the coverage policy. But, yes, it would include exclusion specific to the coverage that's

being described in the policy.

Q. Okay. The exclusion on the treatment of gender dysphoria, is it in a service specific coverage policy?

A. No. This is a general Medicaid policy. But it does include coverage information including what Florida Medicaid reimburses for and what it does not.

Q. Does it speak to the exclusion of any other services under Florida Medicaid but those services excluded for the treatment of gender dysphoria?

A. Yes.

Q. Which ones?

A. No. 4 is an example. (4)(b), that speaks to that Florida Medicaid does not cover continuous services after the emergency has been alleviated.

Q. Is that a specific service? Or is that the length of time for any service?

A. I apologize. It's emergency service. It's under the section for emergency Medicaid.

Q. But, again, is that speaking to the coverage of any service deemed emergency?

A. It's specific to emergency services provided to aliens who meet all Florida Medicaid eligibility requirements except for citizenship.

Q. It says an exclusion under Subpart 7 speaks specifically to the exclusion of sex reassignment

surgeries; correct?

A. Services for the treatment of gender dysphoria.

Q. But only three services.

A. Four.

Q. What are examples of procedures that alter primary or secondary sexual characteristics that are not related to surgery?

A. I don't know.

Q. Just going back to the surgery, why not include that in service specific policies that discuss surgery?

A. Can you repeat the question.

Q. Looking at the exclusion of sex reassignment surgeries, why was that not included in the coverage policies related to surgeries that we discussed earlier?

A. I don't recall the specific conversation on how it was decided that this was the most appropriate policy. And I do believe that most of that conversation was with counsel.

Q. So same question for puberty blockers. Why wouldn't you include that in a pharmacy coverage policy?

A. I don't know.

Q. And Subpart 7's subject line is "Gender Dysphoria"; correct?

A. Yes.

Q. And that's a diagnosis?

A. I don't know clinically the definition.
Q. We've been talking about the treatment of gender dysphoria; right?
A. Yes.
Q. So in order to exclude treatment of gender dysphoria, it would be the exclusion of a treatment for a diagnosis; correct?
A. Yes. But I can't speak to the specifics of the diagnosis or what that means in clinical terms.
Q. Okay. For the July 8th hearing, do you know how many public comments were submitted?
A. I don't know.
Q. Do you know if it was more than 100?
MR. PERKO: Asked and answered.
THE WITNESS: I know it was a lot.
BY MS. DEBRIERE:
Q. Okay. And do you know how long it took AHCA to review and consider the comments before adopting the final rule?
A. I don't know the length of time. But I know that all the public comments were reviewed.
Q. Who reviewed them?
A. I know Cole Giering did. I don't know if anybody else -- if anybody else did.
Q. Okay. So after the July 8th hearing up until

the final adoption of the rule, other than reviewing and considering public comment, what else did AHCA do before adopting the rule?

A. Can you repeat the question.

Q. So after the July 8th hearing up until the final adoption of the rule, other than reviewing public comment, what other activities did AHCA undertake in deciding to adopt the rule?

A. I don't know. I can't remember specific to this rule. But after it's been determined there's no changes needed to the rule, the filing for adoption would be the next step.

Q. How do you reach that decision that no changes should be made?

MR. PERKO: Object to form.

THE WITNESS: There's various factors involved in that decision. And it really depends on the specific circumstances.

MS. DEBRIERE: Okay. I don't know what it would be labeled, but do you have an exhibit -- it's an email from Ms. McGriff to Magellan.

MS. CHRISS: Yes. The email exchange between Magellan and AHCA.

MS. DEBRIERE: Thank you.

Court Reporter, just for your reference what we

just marked as Exhibit 12 is Bates stamped DEF_00288753 to 000288756.

(Plaintiff's Exhibit No. 12 was marked for identification.)

BY MS. DEBRIERE:

Q. So Magellan is emailing several people at AHCA. And she says, "Attached are the internal criteria not publicly posted."

What are the internal criteria?

A. I don't know.

Q. Does Magellan rely on internal criteria for the coverage of Medicaid services?

A. I don't know.

Q. What does "CCM" mean? It's right after that sentence. "Attached are the internal criteria 'not publicly posted' CCM."

A. I don't know.

Q. What does gender code mean?

A. I don't know.

Q. Do you know hot had significance of "B for both" is?

A. I do not.

Q. Who is Linda Simone Moore?

A. Who?

Q. So there's a sender up top here -- I'm sorry.

Leslie.

A. Moore-Simons.

Q. I need reading glasses. Leslie Moore-Simons. That's exactly right.

A. I don't know.

Q. Okay. Who is Susan Williams?

A. She works for Ashley Peterson in the pharmacy unit in the Bureau of Medicaid Policy.

Q. Okay. And who is Arlene Elliott? I'll just note the date that Arlene's email was sent was 8/21/2017.

A. Currently Arlene Elliott is in a different division at the Agency for Health Care Administration. But at this time, she was the AHCA administrator over the pharmacy policy section of the Bureau of Medicaid Policy.

Q. And what unit is she in now?

A. I don't know. She's no longer in the division of Medicaid.

Q. What division is she in?

A. I believe it's Health Quality Assurance.

Q. Do you know when she left her position in the Bureau of Medicaid Policy?

A. I believe it was spring or summer 2021. I'm not sure the exact date.

Q. Okay. Earlier in the exchange -- and yet dated later -- is the email dated April 20th, 2022, from Elica King-Wilson at Magellan. And she's included some language which she underlined and bolded. And it says, "All requests require vetting by AHCA before a final determination is made."

And it appears this is related to a final determination as to whether -- well, it says -- Leslie noted, "MMA does have an internal gender dysphoria criteria, which is attached."

MMA stands for?

A. I don't know in what context she's using it.

Q. Okay.

A. But to me, MMA would normally stand for managed medical assistance.

Q. I assume you're confused because this is coming from Magellan which is not a managed medical assistance program; is that right?

A. Yes. So I don't know if that's what she's referring to.

Q. And it says, "This internal document serves for GnRH analog use to delay puberty in adolescents with gender dysphoria." This document was provided by AHCA due to a fair hearing request received for Lupron for a recipient with this diagnosis" -- meaning gender

dysphoria. And it goes on with the underlying language that all of those requests -- coverage of Lupron for gender dysphoria -- need to be vetted by AHCA before a final determination is made.

Were you familiar with that process at all?

A. No. I don't know what process they were referring to.

Q. Would Ashley Peterson know?

A. I don't know. But she does work closely with Magellan.

Q. Okay. Did AHCA work with managed care plans to implement the exclusion in 1.050?

A. They were notified. But the specifics of how that communication happened, I can't recall.

MS. DEBRIERE: Okay. Can I have the SMMC Policy Transmittal relating to the Non-Coverage of Gender Dysphoria Treatment.

MS. DUNN: Do you want the policy or the emails?

MS. DEBRIERE: Could you do both.

MS. DUNN: Do you want them together?

MS. DEBRIERE: That would be great. But separate exhibits.

(Plaintiff's Exhibit No. 13 was marked for identification.)

(Plaintiff's Exhibit No. 14 was marked for identification.)

BY MS. DEBRIERE:

Q. So right now we're looking at an email that's Bates stamped DEF_000258835 to 000258838. It's an email from D.D. Pickle CC-ing you. And it's to Jason Weida.

In this -- I'm sorry. Looking specifically at an email dated August 22, 2022, from D.D. to Ashley Peterson and Matt Brackett. It states, "Ashley, Ann wants to include the 60-day language in the alert?"

What alert is D.D. Pickle referring to?

A. I believe it was the provider alert.

Q. And what's a provider alert?

A. It's the main way -- one of the main ways we communicate information to our providers and external stakeholders.

(Plaintiff's Exhibit No. 15 was marked for identification.)

BY MS. DEBRIERE:

Q. I'm handing you a document that's marked as Exhibit 15, called Florida Medicaid Health Care Alert Sign-Off Form, starting at Bates stamp DEF_000258839.

Is this the provider alert you were referring to?

A. Yes. It looks to be a provider alert regarding

the coverage of treatment for gender dysphoria.

MS. DEBRIERE: Okay. And then what was the transmittal?

MS. DUNN: It was 14.

BY MS. DEBRIERE:

Q. No. 14 -- can you look at that document. And that's Bates stamped DEF_000258833.

What is this document?

A. It looks to be a draft -- a policy transmittal.

Q. And who does that go to?

A. This specific one is marked to be sent to the medical assistance and specialty plans.

Q. Is that the final that was sent?

A. It does not appear so, no.

Q. Okay. How do you know that?

A. The policy transmittal number is not completed and it's not signed.

Q. Okay. Going back to the provider alert, was that the final that was sent?

A. I can't tell from this document if this was the final that was sent.

Q. Okay. Would you be able to tell from any of the versions whether it was the final?

A. Seeing the actual email alert would be how I would make sure. My team actually does not send out the

final provider alerts. So that's typically how I would look at the final version.

Q. Okay. And the policy transmittals and the provider alerts -- are those available on the agency's website? The finals?

A. Yes.

Q. Okay. So turning back to that email exchange where D.D. mentions you by name.

What is 60-day language?

A. I believe she's referring to the continuity of care.

Q. What is continuity of care?

A. It's a contract requirement for the plans to provide services for a period of time. I don't know if it's specific to when they change plans. I can't recall the exact contract language, but it's a contract provision.

Q. And are services previously being covered supposed to be continue being covered for 60 days according to the 60-day language?

A. I can't recall the exact parameters of the requirement.

Q. Do you recall why --

MR. PERKO: Counsel, we're getting on seven hours here.

BY MS. DEBRIERE:

Q. Do you recall why the 60-day language -- you wanted the 60-day language included in this alert?

A. I can't remember the conversation around this. And I can't speak for D.D.

Q. Well, D.D. is speaking for you; right?

The subject is "GD Policy Transmittal"; correct?

A. Yes.

Q. And what does "GD" stand for?

A. Based on the attachments, I would conclude that it is for gender dysphoria.

Q. Okay. And this would be discussion had after the rule was adopted excluding coverage of services for the treatment of gender dysphoria; correct?

A. Can you repeat that question.

Q. The date of this email is after the rule was adopted to exclude coverage of services for treatment of gender dysphoria.

A. I believe so.

Q. You don't recall why you thought it was important to have the 60-day language included in the alert?

A. I don't recall the specifics of the conversation. But I believe it was to ensure if there

was any current reimbursement or authorization that would apply.

Q. Current authorization of treatment of gender dysphoria?

A. Of the services listed in Rule 1.050, No. 7.

Q. Did any plans state to AHCA that they would continue coverage of the services excluded in the rule even though that rule had been adopted?

A. I don't know.

Q. Who would know that?

A. I don't know who it would have gone to. If there was a question, the communications typically go through the contract managers.

Q. Okay. Do you know if all plans have implemented the exclusion contained in the rule?

A. I don't know.

Q. Are you familiar with the variance and waiver process under Chapter 120?

A. Yes.

Q. Okay. What is the purpose of that statute?

MR. PERKO: Object to form; calls for a legal conclusion.

BY MS. DEBRIERE:

Q. What it the purpose of the variance and waiver process?

MR. PERKO: Object to form.
THE WITNESS: I don't know.
MR. PERKO: Counsel, we're getting on seven hours here.
MS. DEBRIERE: All right. Let me just consult with my team for just a second.
(Brief recess.)
MS. DEBRIERE: We'll all set with direct.
Thank you for your time, Ms. Dalton.
MR. PERKO: I don't have any questions.
THE COURT REPORTER: Would you like to read or waive?
THE WITNESS: Read.
THE COURT REPORTER: Would you like to order at this time?
MS. DEBRIERE: Yes.
THE COURT REPORTER: Would anybody like to order a copy?
MR. PERKO: Yes.
(This deposition was concluded at 6:05 p.m.)

_ _ _

CERTIFICATE OF OATH

STATE OF FLORIDA:
COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, do hereby certify that ANN DALTON personally appeared before me on January 24, 2023 and was duly sworn and produced her ID badge as identification.

Signed this 30TH day of JANUARY, 2023.

GREG T. SMITH

Notary Public, State of Florida
My Commission No.: GG933698
Expires: March 21, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA:

COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, certify that I was authorized to and did stenographically report the deposition of ANN DALTON; that a review of the transcript was requested; and that the foregoing transcript, pages 6 through 175, is a true and accurate record of my stenographic notes.

I further certify that I am not a relative, employee, or attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 30TH day of JANUARY, 2023.

Greg T. Smith

GREG T. SMITH

KATHERINE J. DEBRIERE, ESQUIRE
DEBRIERE@FLORIDAHEALTHJUSTICE.ORG

January 30, 2023

RE: Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

The above-referenced transcript is available for review.

(The witness/You) should read the testimony to verify its accuracy. If there are any changes, (the witness/you) should note those with the reason on the attached Errata Sheet.

(The witness/You) should, please, date and sign the Errata Sheet and email to the deposing attorney as well as to Veritext at Transcripts-fl@veritext.com and copies will be emailed to all ordering parties.

It is suggested that the completed errata be returned 30 days from receipt of testimony, as considered reasonable under Federal rules*, however, there is no Florida statute to this regard.

If the witness fails to do so, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

*Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e).

Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

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REASON_____

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

(WITNESS NAME) DATE

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Governor Ron DeSantis Urges Swift Approval of Florida's Canadian Prescription Drug Importation Program

On July 9, 2021, in News Releases, by Staff

FDA directed to work with states on importation program plans

TALLAHASSEE, Fla. – Nearly eight months ago, under the leadership of Governor Ron DeSantis, Florida submitted its Section 804 Importation Proposal (SIP) to the U.S. Department of Health and Human Services (HHS) for our state's Canadian Prescription Drug Importation Program – the first in the nation to do so. Today, President Biden directed the U.S. Food and Drug Administration (FDA) to work with states and tribes to safely import prescription drugs from Canada as outlined in the FDA's implementing regulations based in part off Florida's 2019 importation concept paper.

Since taking office, Governor Ron DeSantis has prioritized lowering the cost of prescription drugs for Floridians. In 2019, the Florida Legislature passed several pieces of legislation, including Florida's Canadian Drug Importation Program, to reform Florida's health care market by increasing transparency, empowering patients, and reducing costs. Florida's Canadian Drug Importation Program will improve access to essential medications to vulnerable citizens and potentially save the state between $80 to $150 million in the first year alone.

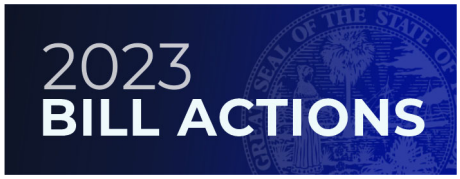
"In Florida, we've led the nation in creating a program to lower prescription drug costs through their importation from Canada," **said Governor Ron DeSantis**. "With the issuance of this new executive order directing the FDA to work with states, I expect no further delay in the approval of Florida's plan to import safe and effective prescription drugs. While Big Pharma and federal bureaucracy have continued to stand in the way, it's past time Florida taxpayers realized savings on these drugs."

In May of this year, Governor Ron DeSantis toured the facility secured by Florida to warehouse drugs procured through this program and called on the Biden Administration and leadership at HHS to approve Florida's SIP. Further, on June 1, 2021, Florida filed an Amicus brief in support of the HHS final rule implementing Section 804 of the Federal Food, Drug and Cosmetic Act, to facilitate the importation of prescription drugs.

Within 90 days of approval by the FDA, the Agency for Health Care Administration will finally be able to physically import prescriptions drugs, ensure customs inspections are complete and proper testing has taken place, and then fulfilling state agency orders. The state will begin by providing prescription drugs in a small number of drug classes which will include maintenance medications to help individuals that have chronic health conditions such as asthma, COPD, diabetes, HIV/AIDS and mental illness. These drugs will be for individuals who are under the care of the Agency for Persons with Disabilities (APD), Department of Children and Families (DCF), Department of Corrections (FDC), and Department of Health (DOH).

###

Comments are closed.



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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,	)	
	)	
Plaintiffs,	)	Case No: 4:22cv325
	)	
v.	)	Tallahassee, Florida
	)	October 12, 2022
SIMONE MARSTILLER, et al.,	)	
	)	9:33 AM
Defendants.	)	
_____	)	

TRANSCRIPT OF PRELIMINARY INJUNCTION PROCEEDINGS
BEFORE THE HONORABLE ROBERT L. HINKLE
UNITED STATES CHIEF DISTRICT JUDGE
(Pages 1 through 120)

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.

Q. Psychological conditions?
A. I do not make diagnoses, but we're trained in psychology and psychiatry. It's part of our medical licensing.
Q. Okay. But you are not a practicing psychologist?
A. That's correct.
Q. And you're not a practicing psychiatrist?
A. That's correct.
Q. And you have not met with any of the plaintiffs in this matter --
THE COURT: Mr. Charles, I sat through the voir dire. I'm not going to sit through it again on cross. You get one chance to ask some questions. You've asked those. Let's ask some new ones.
MR. CHARLES: Thank you, Your Honor.
BY MR. CHARLES:
Q. Dr. Laidlaw, you stated you don't follow the WPATH standards of care; is that right?
A. Yes.
Q. But you testified earlier you don't treat gender dysphoria; is that correct?
A. I don't treat gender dysphoria with hormones and surgeries.
Q. Dr. Laidlaw, are you aware that your opposition to gender-affirming care for the treatment of gender dysphoria in youth and adults is contrary to the vast majority of medical associations' recommendations?

A. Yes.
Q. Dr. Laidlaw, can you see the screen share that I've just enabled?
A. Yes, I can.
MR. CHARLES: Your Honor, can you see that as well?
THE COURT: I can. It's hiding under the table up here, but I've got it.
MR. CHARLES: Okay.
BY MR. CHARLES:
Q. Dr. Laidlaw, are you aware that the American Academy of Child and Adolescent Psychiatry supports gender-affirming care for youth?
A. I haven't looked at that specifically.
Q. Okay. And looking at the document here, I'll --
MR. CHARLES: Let me ensure -- Defense Counsel, can you view this document?
MR. PERKO: Yes.
MR. CHARLES: Okay. So I'd like to enter this as Exhibit P1.
BY MR. CHARLES:
Q. This is the -- Dr. Laidlaw, this is the "American Academy of Child and Adolescent Psychiatry Statement Responding to Efforts to Ban Evidence-Based Care for Transgender and Gender-Diverse Youth."
Do you see that?

A. Yes.
Q. And it's dated November 8, 2019?
A. Yes.
Q. And if you could, just read aloud for me that highlighted portion, please.
A. Sure.

Many reputable professional organizations, including the American Psychological Association, the American Psychiatric Association, the American Academy of Pediatrics, and the Endocrine Society, which represent tens of thousands of professionals across the United States, recognize natural variations in gender identity and expression and have published clinical guidance that promotes nondiscriminatory, supportive interventions for gender-diverse youth based on the current evidence base. These interventions may include, and are not limited to, social gender transition, hormone-blocking agents, hormone treatment, and affirmative psychotherapeutic modalities.

The American Academy of Child and Adolescent Psychiatry supports the use of current evidence-based clinical care with minors. AACAP strongly opposes any efforts -- legal, legislative, and otherwise -- to block access to these recognized interventions.

Q. Thank you.

THE COURT: You apparently asked to have this admitted into evidence. I don't think I've seen this, so this may not

have been in the record previously.

MR. CHARLES: Just one moment, Your Honor.

It wasn't, Your Honor, but I do have copies I can provide to the Court to so enter.

THE COURT: Didn't I require disclosures before today? If I didn't, it would certainly depart from the standard of care for judges.

MR. CHARLES: I apologize, Your Honor. I wasn't -- I didn't see that designation so -- in your order.

THE COURT: I may not have.

Do you object to the admission of this?

MR. PERKO: Yes, Your Honor, for the reasons you just stated.

Also, I would suggest that it's really irrelevant to this witness's testimony because it talks about the American Psychological Association. He's already testified he's not a psychologist.

THE COURT: You can't have it both ways.

I'll admit it subject to going back and looking at the scheduling orders and --

(Discussion was held.)

BY MR. CHARLES:

Q. Dr. Laidlaw, is what you just read consistent with your understanding of the position of these organizations?

A. Are you talking about the AACAP?

Q. Yes, let's start with that one.
A. Well, I'm just reading it now for the first time, so it must be -- it was 2019 -- unless they have changed their opinion.
Q. Okay. But you don't have any --
THE COURT: Let me just back up. I'm going to exclude the exhibit. I did require things to be disclosed, and you can't come up to the hearing and bring up a new exhibit that you didn't timely disclose.
MR. CHARLES: Okay.
THE COURT: So Plaintiffs' 1 is excluded.
The scheduling order is ECF No. 32.
MR. CHARLES: Okay. Thank you, Your Honor.
Ms. Markley, you can unpublish, please. Thank you.
BY MR. CHARLES:
Q. Dr. Laidlaw, are you aware that the American Academy of Family Physicians supports gender-affirming care for youth and adults?
A. Supports gender-affirming care for youth and adults?
Q. Yes. Do you need to me to repeat? Did you hear that?
A. They probably do. I don't know their exact statement.
Q. Okay. Are you aware that the American Academy of Family Physicians published a policy statement in July of 2022, approved by their board of directors, entitled "Care for the Transgender and Gender Nonbinary Patient"?

A. I have not read that particular document -- Family Practice Document.
Q. Okay. Are you aware that the American Academy of Family Physicians supports gender-affirming care as an evidence-informed intervention that can promote permanent health equity for gender-diverse individuals?
MR. PERKO: Your Honor, I would object for the same reasons. He's essentially reading from an exhibit that was not disclosed.
THE COURT: He's now exploring the witness's knowledge of the situation in the field. The objection is overruled.
BY MR. CHARLES:
Q. Dr. Laidlaw --
A. I'm not a family practice physician, so I don't keep up with --
Q. Just a moment. Sorry. Let me start over.
A. -- the literature of that organization.
Q. I'm sorry. Can you please repeat that?
A. I said I'm not a family practice physician; I'm an endocrinologist, so I don't keep up with whatever they're publishing.
Q. Okay. So I -- let me just ask you one more question about that brief -- or policy statement. Excuse me.
Are you aware that the American Academy of Family Physicians asserts the full spectrum of gender-affirming health

care should be legal and should remain a treatment decision between a physician and their patient?
A. I'm not surprised.
Q. Can -- so does that mean you are or are not aware?
A. I don't read the Family Practice documents, unless they are provided to me.
Q. Dr. Laidlaw, are you aware the American Academy of Pediatrics supports gender-affirming care for youth?
A. Yes.
Q. Dr. Laidlaw, are you aware that the American College of Obstetricians and Gynecologists has recommendations and conclusions that support gender-affirming care for youth and adults?
A. I'm not -- again, I'm not surprised, but I don't read their literature regularly for that purpose.
Q. Okay. Are you aware that the American College of Obstetricians and Gynecologists has conclusions that gender-affirming hormone therapy is not effective contraception?
A. That gender-affirming therapy is not effective contraception?
Q. Correct.
A. I have read that. I'm not sure if it was theirs or someone else who is publishing that. I'm aware of that concept.
Q. Can you repeat your answer? I didn't understand you.
A. I said I haven't read their statements specifically, but

I'm aware of the concept or proposition that gender-affirming hormones are not effective contraception.

Q. Okay. So you're not aware of the American College of Obstetricians and Gynecologists conclusion that it is not effective contraception?

A. I have not read their particular conclusion.

Q. Are you aware that the American College of Physicians, the largest medical specialty society in the world with 160,000 internal medicine and subspecialty members, supports public and private health care coverage of gender-affirming care?

A. I'm not aware that all 160,000 members voted to approve such a thing, but I'm aware that they have issued a statement like that.

Q. You are aware they issued such a statement?

A. Yes.

Q. Are you aware that in 2022, the American College of Physicians issued a brief supporting access to gender-affirming care and opposing discriminatory policies enforced against LGBTQ people and objected, in particular, to the interference with the physician-patient relationship and the penalization of evidence-based care?

A. I may have read that particular statement from that organization.

Q. Are you aware that the American Medical Association supports gender-affirming medical care for youth and adults?

A. Yes.
Q. Are you aware that in April of 2021, the American Medical Association wrote a letter to the National Governors Association objecting to the interference with health care of transgender children?
A. I believe I had come across that headline.
Q. Are you aware that the American Medical Association, in conjunction with GLMA, has issued a brief in support of public and private insurance coverage of gender-affirming care?
A. I'm not a member of the American Medical Association. I think only 20 percent of physicians in the nation are even a member. So I don't follow everything they say, but I do believe I read that document.
Q. Do you have evidence to support your assertion that only 20 percent of medical practitioners in the United States are members of the AMA?
A. I don't have a piece of paper with evidence, but that's my general understanding. I'm not a member.
Q. But you don't have any evidence today to point to to support that assertion?
A. No.
Q. Are you aware that in 2022, the American Medical Association reaffirmed it's resolution in support of private and public health care coverage for the treatment of gender dysphoria as recommended by a patient's physician in Resolution

Number 158.950?
A. I have not read that resolution.
Q. Are you aware, Dr. Laidlaw, that the American Psychological Association has guidelines that support access to gender-affirming care for youth and adults?
A. Yes.
Q. Are you aware that the American Psychological Association opposes gender-identity change efforts as a broad practice described as a range of techniques used by mental health professionals and nonprofessionals with the goal of changing gender identity, gender expression, or associated components of these, to be in alignment with gender role behaviors stereotypically associated with their sex assigned at birth?
A. Yes, I am aware.
Q. Are you aware that the American Psychiatric Association supports gender-affirming medical care for youth specifically?
A. Yes.
Q. Are you aware that the American Psychiatric Association has a position statement from 2018, supporting access to care for transgender and gender-variant individuals broadly?
A. Yes, I believe so.
Q. Are you aware that the Endocrine Society and the Pediatric Endocrine Society take the position that there is a durable biological underpinning to gender identity that should be considered in policy determinations?

A. I would have to read -- I have not read that particular statement from the Endocrine Society. I would like to see that before I make a -- conclude anything.
Q. Okay. Are you aware this determination was included in a position statement published in December of 2020?
A. I have read that position statement.
Q. And are you aware that the Endocrine Society and the Pediatric Endocrine Society take the position that medical intervention for transgender youth and adults is effective, relatively safe when appropriately monitored, and has been established as the standard of care?
A. Well, they wrote that it was not the standard of care in 2017, so they're contradicting themselves.
Q. Dr. Laidlaw, are you aware that that statement is contained in the transgender health position statement issued December 2020?
A. I believe I read that.
Q. And are you aware that the Endocrine Society and the Pediatric Endocrine Society take the position that federal and private insurers should cover such interventions as prescribed by a physician, as well as the appropriate medical screenings that are recommended for all body tissues that a person may have?
A. I believe I read something along those lines.
Q. Are you aware that the Pediatric Endocrine Society supports

gender-affirming care for youth?
A. Yes.
Q. Are you aware they published a position statement to that effect in April of 2021?
A. Yes. I wrote an article describing why their conclusions are false or incorrect.
Q. Are you aware the Pediatric Endocrine Society recommends an affirmative model of care that supports one's gender identity and follows a multidisciplinary approach that includes involvement of mental health professionals, patients and their families. Puberty suppression and/or gender-affirming hormone therapy is recommended within this evidence-based approach on a case-by-case basis as medically necessary and potentially lifesaving.
Are you aware that was contained in the Pediatric Endocrine Society statement?
A. I am aware that it's contained. I don't agree with it, but, yes, I'm aware.
THE COURT: If we're leading up to something, you can go ahead with all of this. If all you're doing is publishing stuff I've already read --
MR. CHARLES: No, Your Honor.
THE COURT: You're welcome to make a closing argument later and to go through all of this, but if -- this is an incredibly inefficient way to publish material.

MR. CHARLES: Your Honor --

THE COURT: So if that's all we are doing, let's move on.

MR. CHARLES: Thank you, Your Honor. I'm -- I do have a final comment for Dr. Laidlaw related to --

THE COURT: I've been patient through all that, and if you're setting up another question, that's fine.

MR. CHARLES: Okay. Thank you, Your Honor.

Just two more documents. I appreciate your patience.

BY MR. CHARLES:

Q. Dr. Laidlaw, are you aware the Society for Adolescent Health and Medicine supports gender-affirming care for youth?

A. No.

Q. Are you aware the Society for Adolescent Health and Medicine issued a statement in opposition to state legislation barring evidence-based treatment?

A. No.

Q. And, Dr. Laidlaw, are you aware that the World Medical Association, which includes 115 national medical associations, supports gender-affirming care?

A. No.

Q. So, Dr. Laidlaw, you're aware that your opinions related to gender-affirming care are in contrast to all of those medical associations' statements that we just reviewed?

MR. PERKO: Objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: Yeah. Sorry. Could you repeat the question?

BY MR. CHARLES:

Q. You are aware that your opinions against gender-affirming care for the treatment of gender dysphoria are contrary to the positions of the medical associations' statements we just reviewed?

A. Yes.

MR. CHARLES: Just one moment, Your Honor.

(Discussion was held.)

MR. CHARLES: No further questions, Your Honor.

THE COURT: Redirect?

MR. PERKO: Very briefly, Your Honor.

May it please the Court.

REDIRECT EXAMINATION

BY MR. PERKO:

Q. Dr. Laidlaw, you testified that you consider mental health effects of hormone therapy in your practice; is that correct?

A. That is correct.

Q. Okay. And why do you consider the potential mental health effects of hormone therapy in your practice?

MR. CHARLES: Objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: To give you maybe a more concrete

This is not quite an administrative review, but it's not that far off from it.

Tell me how long do you think -- I probably should have asked before I told you I was going to deny the preliminary injunction because answers change depending on which side thinks they won the preliminary injunction motion.

How long do you think you need to present this case fully? And if the answer is "I don't know," I guess I can just tell you to go talk to each other. But if you can give me a rough ballpark at this point, it will help.

MR. JAZIL: Your Honor, I'm happy to confer with my colleagues for the other side and get back to the Court.

THE COURT: It seems to me that you want to find out about the plaintiffs and their doctors and that's about it; right? I mean, you had all you had when you adopted the rule.

MR. JAZIL: Yes, Your Honor. I suppose -- there's a footnote in *Rush v. Parham* that discusses -- well, in my mind it opens up the possibility of additional evidence to provide to the Court on whether or not this is or isn't experimental, but --

THE COURT: At least tentatively I think that's right. I think the question is for me to decide based on the federal trial whether the State's determination is reasonable or not, and I think *Rush* says that's not an administrative review of what the State knew at the time. It's the question at the --

based on the evidence presented at the trial. So, yes, I think that's right.

MR. JAZIL: That's right.

THE COURT: And that goes back to my questions about the Florida administrative procedure. In a rule challenge in state court, they might be stuck with the record they put together to adopt the rule, but I don't think that's the case here.

MR. GONZALEZ-PAGAN: Your Honor, if I may, I just have a question on the Court's ruling.

Will the Court include in its order for representation as to what counsel has stated here today that there is a waiver procedure?

THE COURT: Yes, I will.

MR. GONZALEZ-PAGAN: Thank you, Your Honor.

THE COURT: I hope I express it accurately. I'll try to have it in -- an accurately narrow statement of the availability of an exception.

MR. JAZIL: Thank you, Your Honor.

THE COURT: You gave me a cite, and I didn't --

MR. JAZIL: Yes, Your Honor. It's 120.542.

THE COURT: 120.54(2)?

MR. JAZIL: No, Your Honor. It's, I think, 120.542.

Your Honor, with the Court's indulgence, I have one other issue. The trial date is set for August 7th. I'm in a

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

EXPERT REPORT OF STEPHEN B. LEVINE, M.D.

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I. CREDENTIALS

1. I am Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, became a Full Professor in 1985, and in 2021 was honored to be inducted into the Department of Psychiatry's "Hall of Fame."

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' sexuality and sexual relations, therapies for sexual problems, and the relationship between love, intimate relationships, and wider mental health. In 2005, I received the Masters' and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association.

3. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010), and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five previously solo-authored books for professionals, I have published *Psychotherapeutic Approaches to*

Sexual Problems (2020). The book has a chapter titled "The Gender Revolution."

4. In total I have authored or co-authored over 180 journal articles and book chapters, 27 of which deal with the issue of gender dysphoria. I was an invited member of a Cochrane Collaboration subcommittee that sought to publish a review of the scientific literature on the effectiveness of puberty blocking hormones and of cross-sex hormones for gender dysphoria for adolescents. Cochrane Reviews are a well-respected cornerstone of evidence-based practice, comprising a systematic review that aims to identify, appraise, and synthesize all the empirical evidence that meets pre-specified eligibility criteria in response to a particular research question.

5. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a

new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

6. In the course of my five decades of practice treating patients who suffered from gender dysphoria, I have at one time or another recommended or supported social transition, cross-sex hormones, and surgery for particular patients, but only after extensive diagnostic and psychotherapeutic work.

7. In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. In that litigation, the U.S. Court of Appeals for the First Circuit in a 2014 (En Banc) opinion cited and relied on my expert testimony. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.

8. In 2019, I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment of transgenderism and gender dysphoria, particularly as it relates to children, in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District, Dallas County, TX (the "*Younger* litigation").

9. In 2019, I provided written expert testimony in the landmark case in the United Kingdom in the case of *Bell v. The Tavistock and Portman NHS Foundation Trust*. I have provided expert testimony in other litigation as listed in

my curriculum vitae, which is attached as Exhibit "A".

10. I am regularly requested to speak on the topic of gender dysphoria and have given countless presentations to academic conferences and Departments of Psychiatry around the country. In May 2022, I organized and co-presented a symposium on the management of adolescent-onset transgender identity at American Psychiatric Association's Annual Meeting.

11. A fuller review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit "A".

12. I am being compensated for my time spent in connection with this case at a rate of $400.00 per hour. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

II. SUMMARY

1. A summary of the key points that I explain in this report is as follows:

a. Sex as defined by biology and reproductive function is clear, binary, and cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section III.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset, biological sex, mental health, intelligence, motivations for gender transition, socioeconomic status, country of origin, etc. Data from one population (e.g., adults) cannot be assumed to be applicable to others (e.g., children). (Section III.B.)

c. Among practitioners in the field, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria in children or adolescents. There are no generally accepted "standards of care" and existing studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals. The scientific basis for affirmative care is uncertain. (Section III.)

d. Transgender identity is not biologically based. Rather, gender dysphoria is a psychiatric condition that cannot be identified by any biological test or measurement. (Sections V.A, IV.B.)

e. Disorders of sexual development ("DSDs") are biological phenomena. It is an error to conflate and/or scientifically link DSDs with incidents of gender dysphoria. (Sections V.C, V.D.)

f. The large majority of children who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by

puberty or adulthood. Desistance is also increasingly observed among teens and young adults who have experienced "rapid onset gender dysphoria" — first manifesting gender dysphoria during or shortly after adolescence. (Section VI.A., VI.B.)

g. "Social transition" —the active affirmation of transgender identity—in young children is a powerful psychotherapeutic intervention that will substantially reduce the number of children "desisting" from transgender identity. Therefore, the profound implications of "affirmative" treatment—which include taking puberty blockers and cross-sex hormones—must be taken into account where social transition is being considered. (Section VII.A,, VII.B.)

h. Administration of puberty blockers is not a benign "pause" of puberty, but rather a powerful medical and psychotherapeutic intervention that almost invariably leads to persistence in a transgender identity and, ultimately, to the administration of cross-sex hormones. (Section VII.C.)

i. The knowledge base concerning the "affirmative" treatment of gender dysphoria available today has very low scientific quality with many relevant long-term implications remaining unknown. (Section VIII.A)

j. There are no studies that show that affirmation of transgender identity in young children reduces suicide or suicidal ideation, or improves

long-term outcomes, as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population. This is true before and after transition, hormones, and surgery. (Section VIII.B., VIII.C.)

k. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is scientifically baseless, and therefore unethical, to assert that a child or adolescent who express an interest in a transgender identity will kill him- or herself unless adults and peers affirm that child in a transgender identity. (Section IX.)

l. Hormonal interventions to treat gender dysphoria are experimental in nature and have not been shown to be safe, but rather put an individual at risk of a wide range of long-term and even life-long harms including: physical health risks; sterilization and the associated emotional response; impaired sexual response; surgical complications and life- long after-care; alienation of family and romantic relationships; elevated mental health risks of depression, anxiety, and substance abuse. (Section X.)

III. BACKGROUND ON THE FIELD

A. The biological baseline of the binary sexes

19. Biological sex is very well defined in all biological sciences including medicine. It is pervasively important in human development throughout the lifecycle.

20. Sex is not "assigned at birth" by humans visualizing the genitals of a newborn; it is not imprecise. Rather, it is clear, binary, and determined at conception. The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. As physicians know, sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. A publication of the federal government's National Institute of Health accurately summarizes the scientific facts:

> "Sex is a biological classification, encoded in our DNA. Males have XY chromosomes, and females have XX chromosomes. Sex makes us male or female. Every cell in your body has a sex— making up tissues and organs, like your skin, brain, heart, and
> stomach. Each cell is either male or female depending on whether you are a man or a woman." (NIH 2022.)

21. The binary of biological sex is so fundamental and wide-ranging in its effects on human (and mammal) development and physiology that since 2014 the NIH has required all funded research on humans or vertebrate animals to include

"sex as a biological variable" and give "adequate consideration of both sexes in experiments." (NIH 2015). In 2021, the Endocrine Society issued a position paper elaborating on the application of the NIH requirement. The Endocrine Society correctly stated that "Sex is a biological concept . . . all mammals have 2 distinct sexes;" that "biological sex is . . . a fundamental source of intraspecific variation in anatomy and physiology;" and that "In mammals, numerous sexual traits (gonads, genitalia, etc.) that typically differ in males and females are tightly linked to each other because one characteristic leads to sex differences in other traits." (Bhargava et al. 2021 at 221, 229.)

22. The Endocrine Society emphasized that "The terms sex and gender should not be used interchangeably," and noted that even in the case of those "rare" individuals who suffer from some defect such that they "possess a combination of male- and female-typical characteristics, those clusters of traits are sufficient to classify most individuals as either biologically male or female." They concluded, "Sex is an essential part of vertebrate biology, but gender is a human phenomenon. Sex often influences gender, but gender cannot influence sex." (Bhargava et al. 2021 at 220-221, 228.)

23. As these statements and the NIH requirement suggest, biological sex pervasively influences human anatomy, its development and physiology. This includes, of course, the development of the human brain, in which many sexually dimorphic characteristics have now been identified. In particular, the Endocrine

Society and countless other researchers have

determined that human brains undergo particular sex-specific developmental stages during puberty. This predictable developmental process is a genetically controlled coordinated endocrine response that begins with pituitary influences leading to increases in circulating sex hormones. (Bhargava et al. 2021 at 225, 229; Blakemore et al. 2010 at 926-927, 929; NIH

2001.).

24. Humans have viewed themselves in terms of binary sexes since the earliest historical records. Recognizing a concept of "gender identity" as something distinct from sex is a rather recent innovation whose earliest manifestations likely began in the late 1940s. Its usage became common in medicine in the 1980s and subsequently in the larger culture. Definitions of gender have been evolving and remain individual-centric and subjective. In a statement on "Gender and Health," the World Health Organization defines "gender" as "the characteristics of women, men, girls and boys that are socially constructed" and that "var[y] from society to society and can change over time," and "gender identity" as referring to "a person's deeply felt, internal and individual experience of gender." (WHO Gender and Health.) As these definitions indicate, a person's "felt" "experience of gender" is inextricably bound up with and affected by societal gender roles and stereotypes—or, more precisely, by the affected individual's *perception* of societal gender roles and stereotypes and their personal idiosyncratic meanings. Typically,

gendered persons also have subtly different, often idiosyncratic, reactions to societal gender roles and stereotypes without preoccupation with changing their anatomy.

25. Thus, the self-perceived gender of a child begins to develop along with the early stages of identity formation generally, influenced in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated

gender corresponding to the child's sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Is it a product of the quality of early life caregiver attachments? Does it stem from trauma-based rejection of maleness or femaleness, and if so, flowing from what trauma? Does it derive from a tense, chaotic interpersonal parental relationship without physical or sexual abuse? Is it a symptom of another, as of yet, unrevealed, emotional disturbance or neuropsychiatric condition (autism)? The answers to these relevant questions are not scientifically known but are not likely to be the same for every trans-identified child, adolescent, or adult.

26. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies

continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape, musculature, internal organ size, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation and ejaculation. These are genetically programmed biological consequences of sex—the actual meaning of sex over time. Among the consequences of sex is the evolution and consolidation of gender identity during childhood, adolescence, and adulthood.

27. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not biologically attainable. (Levine 2018 at 6; Levine 2016 at 238.) It is possible for some adolescents and adults to pass unnoticed—that is, to be perceived by most individuals as a member of the gender that they aspire to be—but with limitations, costs, and risks, as I detail

later.

B. Definition and diagnosis of gender dysphoria

28. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's genetically determined sex and the gender with which they identify or to which they aspire. Today's American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5-TR") employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

29. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after defining oneself as gay for several or more years and participating in a homosexual lifestyle; adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. (Levine 2021.)

30. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (Zucker 2018 at 10.) The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to

another.

31. The criteria used in DSM-5-TR to identify Gender Dysphoria include a number of signs of discomfort with one's natal sex and vary somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in . . . important areas of functioning" such as social, school, or occupational settings. The symptoms must persist for at least six months.

32. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that reflect constrictive notions of what men and women can be. (Levine 2017 at 7.) A young child's—or even an adolescent's—understanding of this topic is quite limited. Nor can they grasp what it may mean for their future to be sterile (Levine et al, 2022). These children and adolescents consider themselves to be relatively unique; they do not realize that discomfort with the body and perceived social role is neither rare nor new to civilization. What is new is that such discomfort is thought to indicate that they must be a trans person.

C. Impact of gender dysphoria on minority and vulnerable groups

33. Given that, as I discuss later, a diagnosis of gender dysphoria is now

frequently putting even young children on a pathway that leads to irreversible physical changes and sterilization by young adulthood, it should be of serious concern to all practitioners that minority and vulnerable groups are receiving this diagnosis at disproportionately high rates. These include: children of color (Rider et al. 2018), children with mental developmental disabilities (Reisner et al. 2015), children on the autistic spectrum (at a rate more than 7x the general population) (Shumer et al. 2016; van der Miesen et al. 2018), children with ADHD (Becerra-Culqui et al. 2018), children residing in foster care homes, adopted children (at a rate more than 3x the general population) (Shumer et al. 2017), victims of childhood sexual or physical abuse or other "adverse childhood events" (Thoma 2021 et al.; Newcomb et al. 2020; Kozlowska et al.,2021), children with a prior history of psychiatric illness (Edwards-Leeper et al. 2017; Kaltiala- Heino et al. 2015; Littman 2018), and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys) (Rider et al. 2018 at 4).

D. Three competing conceptual models of gender dysphoria and transgender identity

34. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the

distinctions.

35. Gender dysphoria is **conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering**, comparable to diseases that are curable before it spreads, such as melanoma or sepsis. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.

36. Gender dysphoria is a psychiatric, not a medical, diagnosis. Since its inception in DSM-III in 1983, it has always been specified in the psychiatric DSM manuals and has not been specified in medical diagnostic manuals. Notably, gender dysphoria is the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine 2016 at 240.)

37. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that may have been first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this

axiom. (Levine 2016 at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self or a sense of self impaired by later adversity or abuse. The purpose is to ameliorate suffering when the underlying problem cannot be solved. MHPs first work with the patient and (ideally) family to learn about the events and processes that may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play and adolescents work out their issues by adopting various interests and identity labels.

38. There is evidence among adolescents that peer social influences through "friend groups" (Littman 2018) or through the internet can increase the incidence of gender dysphoria or claims of transgender identity. Responsible MHPs will want to probe these potential influences to better understand what is truly deeply tied to the psychology of the patient, and what may instead be being "tried on" by the youth as part of the adolescent process of self-exploration and self-definition.

39. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve—often markedly—across the individual's lifetime. This includes

gender. Some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner. As I review later, however, this assertion is not supported by science.[1]

40. The third paradigm through which gender dysphoria is alternatively conceptualized is from **a sexual minority rights perspective**. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, and many mental health professionals. Obviously, however, this is not a medical or psychiatric perspective. Unfortunately, it appears to be the most powerful perspective that exists in the public, non- scientific debate.

E. Four competing models of therapy

41. Few would disagree that the human psyche is complex. Few would disagree that children's and adolescents' developmental pathways typically have surprising twists and turns. The complexity and unpredictability of childhood and adolescent development equally applies to

[1] Even the advocacy organization The Human Rights Campaign asserts that a person can have "a fluid or unfixed gender identity." https://www.hrc.org/resources/glossary-of-terms.

trans-identifying youth. Because of past difficulties of running placebo-controlled clinical trials in the transgender treatment arena, substantial disagreements among professionals about the causes of trans identities and their ideal treatments exist. These current disagreements might have been minimized if trans treated persons were carefully followed up to determine long term outcomes. They have not been. When we add to this to the very different current paradigms for understanding transgender phenomena, it is not scientifically surprising that disagreements are sharply drawn. It is with this in mind that I summarize below the leading approaches, and offer certain observations and opinions concerning them.

(1) The "watchful waiting" therapy model

42. In Section V.A below I review the uniform finding of eleven follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated by social transition approaches.

43. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach seeks to allow for the fluid nature of gender identity in children to naturally evolve— that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. Treating any other psychological co-morbidities—that is, other mental illnesses as defined by DSM-5-TR (separation anxiety disorder, attention deficit hyperactivity disorder, autism spectrum disorder, obsessive

compulsive disorder, etc), or subthreshold for diagnosis but behavioral problems that the child may exhibit (school avoidance, bedwetting, inability to make friends, aggression/defiance) without a focus on gender (**model #1**); and

b. No treatment at all for anything but a regular follow-up appointment. This might be labeled a "hands off" approach **(model #2**).

(2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)

44. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

45. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine 2017 at 8; Spiliatis 2019; Levine 2021.Levine et al, 2022) I and others have reported success in alleviating distress in this way for at least some patients, whether the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared or not. Relieving

accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

46. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" to be kind, compassionate, caring, noncompetitive, to love the arts, and to be devoted to others' feelings and needs. (Levine 2017 at 7.) Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture, and to be aggressive. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

47. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. They may enable the patient

to understand the commonality of discomfort with the body's physiology, the growth process, and the struggle to accept oneself during the pubertal developmental process. Patients need to understand that this discomfort with one's body, per se, and one's attractiveness relative to others, typically lasts for several years. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

48. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

49. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper on a patient who sought my therapeutic assistance to reclaim his male

gender identity after 30 years living as a woman and is in fact living as a man today. (Levine 2019.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. There are now a series of articles and at least one major book on the psychological treatment of adolescents. (D'Angelo et al. 2021 at 7-16; Evans & Evans 2021.) Among detransitioners, a large percentage express regret that their affirmative therapists did not recommend psychotherapy before encouraging hormonal treatment (*Littman, (2021). Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: A survey of 100 detransitioners. Archives of Sexual Behavior, 50(8)3353-3369). Exposito-Campos pointed out the large amount reports on detransition and the far greater traffic on various nonprofessional websites (Exposito-Campos, 2021)*

(3) The affirmation therapy model (model #4)

50. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc., associated with transgender identity. They argue that the child should be comprehensively re-socialized in grade school in their aspired-to gender. As I understand it, this is asserted as a reason why male students who assert a female gender identity must

be permitted to compete in girls' or women's athletic events. These advocates treat any question about the causes of the child's transgender identification as inappropriate. They may not recognize the child's ambivalence. They assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

51. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. This claim is simply not supported by the clinical data we have available to us. Indeed, available long-term data contradicts this claim. I address physical and mental health outcomes in Section VII below, and suicide in Section VIII below.

52. The commonly referenced scientific basis for affirmative care of both early life onset and adolescent onset gender dysphoria are two reports from deVries et al (2011, 2014) that seemingly demonstrated the resolution of gender dysphoria after a sequence of puberty blocking hormones, cross-sex hormones, and breast removal or vaginoplasty. However, recently three articles describing the distinct limitations of the "Dutch Protocol have been widely circulating throughout the world (Levine et al, 2022; Biggs, 2022, Abbruzzese et al, 2023) It is now apparent that the basis for such affirmative care is not scientifically solid. Rapid diffusion of the innovative Dutch Protocol occurred without the scientifically

required confirmatory more rigorous studies. The one attempt to repeat their protocol in the UK failed to demonstrate psychological benefits claimed by the Dutch studies. (Carmichael et al 2021).

53. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics and is not supported by science. Instead of science, this approach is currently being reinforced by an echo-chamber of approval from other like-minded child-oriented professionals who do not sufficiently consider the known negative medical and psychiatric outcomes of trans adults. Rather than recommend social transition in grade school, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents, and the MHP and the child, are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with by each of them.

54. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics. This, however, requires time and effort and for many parents, a challenge to find a therapist to do such work with them.

IV. THERE IS NO CONSENSUS OR AGREED "STANDARD OF CARE" CONCERNING THERAPEUTIC APPROACHES TO CHILD OR ADOLESCENT GENDER DYSPHORIA.

55. There is far too little firm clinical evidence in this field to permit any evidence-based standard of care. Given the lack of scientific evidence, it is neither surprising nor improper that—as I detailed in Section II—there is a diversity of views among practitioners as to as to the best therapeutic response for the child, adolescent, or young adult who suffers from gender dysphoria.

56. Reviewing the state of opinion and practice in 2021, the Royal Australian and New Zealand College of Psychiatrists observed that "There are polarised views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people." (RANZCP, 2021.) Similarly, a few years earlier prominent Dutch researchers noted: "[T]here is currently no general consensus about the best approach to dealing with the (uncertain) future development of children with GD, and making decisions that may influence the function and/or development of the child — such as social transition." (Ristori & Steensma 2016 at 18.)[2] In this Section, I comment on some of the more important areas of disagreement within the field.

[2] *See also* Zucker 2020 which questions the merit of social transition as a first-line treatment.

A. Experts and organizations disagree as to whether "distress" is a necessary element for diagnoses that justifies treatment for gender identity issues.

57. As outlined in Section II.B above, "clinically significant distress" is one of the criteria used in DSM-5 to identify gender dysphoria. This indicates a heightened level of distress that rises beyond a threshold level of social awkwardness or discomfort with the changing body. It is known that many trans-identified youth with incongruence between their sexed bodies and their gender identity choose not to take hormones; their incongruence is quite tolerable as they further clarify their sexual identity elements. This population raises the questions of what distress is being measured when DSM-5-TR criteria are met and what else might be done about it.

58. I note that there is no "clinically significant distress" requirement in World Health Organization's International Classification of Diseases (ICD-11) criteria for gender incongruence, which rather indicates "a marked and persistent incongruence between an individual´s experienced gender and the assigned sex." (World Health Organization 2019.)

59. Therefore, even between these two committee-based authorities, there is a significant disagreement as to what constitutes a gender condition justifying life-changing interventions. To my knowledge, some American gender clinics and practitioners are essentially operating under the ICD-11 criteria rather than the DSM-5-TR criteria, prescribing transition for children, hormonal

interventions for slightly older children, and different hormones for adolescents who assert a desire for a transgender identity whether or not they are exhibiting "clinically significant distress." Others adhere to the DSM-5 diagnostic standard.

60. It is ironic that affirmative care is said by advocates to be life enhancing and often to be lifesaving because of the risk of suicide. Based on the DSM-5-TR criterion, distress is required for the diagnosis and its subsequent hormonal and surgical treatments. Gender incongruence is often referred to as a unique form of suffering. Yet, ICD-11 the criteria for the diagnosis of Gender Incongruence do not require distress, just the wish to have the characteristics of the other sex and to change their own sex demarcating features. It seems that as the field moves on in time, the emphasis is on desire rather than distress, pain, or suffering.

61. I will add that even from within one "school of thought," it is not responsible to make a single, categorical statement about the proper treatment of children or adolescents presenting with gender dysphoria or other gender-related issues. There is no single pathway to the development of a trans identity and no reasonably uniform short- or long-term outcome of medically treating it. As individuals grow physically, mature psychologically, and experience or fail to experience satisfying romantic relationships, their life course depends on their differing psychological, social, familial, and life experiences. There should be no trust in assertions that trans identified youth must be treated in a particular manner

to avoid harm for two reasons: first, there is no systematic data on the nature of, and the rate of harms of either affirmative treatment, no treatment, or psychological only treatment. Second, as in other youthful psychiatric and other challenges, outcomes vary.

B. Opinions and practices vary widely about the utilization of social transition for children and adolescents.

62. The World Professional Association for Transgender Health (WPATH) has published a guidance document under the title of "standards of care." Below, I will provide some explanation of WPATH and its "Standards of Care," which are not the product of a strictly scientific organization, and are by no means accepted by all or even most practitioners as setting out best practices.

63. Here, however, I will note that WPATH does not take a position concerning whether or when social transition may be appropriate for pre-pubertal children. Instead, the WPATH "Standards of Care version 7" states that the question of social transition for children is a "controversial issue" and calls for mental health professionals to support families in what it describes as "difficult decisions" concerning social transition. Its version 8, however, no longer uses the word "controversial" even though it extensively discusses the dangers of harms versus the possibility of benefits of early transition (Coleman et al, 2022).

64. Dr. Erica Anderson is a prominent practitioner in this area who

identifies as a transgender woman, who was the first transgender president of USPATH, and who is a former board member of WPATH. Dr. Anderson recently resigned from those organizations and has condemned automatic approval of transition upon the request of a child or adolescent, noting that "adolescents . . . are notoriously susceptible to peer influence," that transition "doesn't cure depression, doesn't cure anxiety disorders, doesn't cure autism-spectrum disorder, doesn't cure ADHD," and instead that "a comprehensive biopsychosocial evaluation" should proceed allowing a child to transition. (Davis 2022.) And as I have explained previously, my own view based on 50 years of experience in this area favors strong caution before approving life-altering interventions such as social transition, puberty blockers, or cross-sex hormones.

C. The WPATH "Standards of Care" is not an impartial or evidence-based document.

65. Because WPATH is frequently cited by advocates of social, hormonal, and surgical transition, I provide some context concerning that private organization and its "Standards of Care."

66. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its

recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Harry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health (WPATH).

67. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization.

68. WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine 2016 at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs. Such views have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with "There are none. This is how it is done." Such a response does not accurately

reflect what is known, what is unknown, and the diversity of clinical approaches in this complex field.

69. The reviews of WPATH's 7th edition of standards of care published in 2021 by Dahlen et al and Sapir in 2022 have clarified the low quality, low reliability, and bias inherent in its recommendations. (Dahlen et al 2022) Its 8th edition, which is three times the length of the 7th, has not gained additional confidence in its scientific merit. The Standards of Care ("SOC") document is the product of an effort to be balanced, but it is not politically neutral. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. It articulates policy. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered. And, of course, once individuals have socially, medically, and surgically transitioned, WPATH members and the trans people themselves at the meetings are committed to supporting others in their transitions. Not only have some trans participants been distrustful or hostile to those who question the wisdom of these interventions, their presence makes it difficult for professionals to raise their concerns. Vocal trans rights advocates have a worrisome track record of attacking those who have alternative views. (Dreger 2015.McNamarra et al 2022) .

70. In recent years, WPATH has fully adopted some mix of the medical

and civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine 2016 at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance. In actual practice, that thoughtful person may be as young as age 11!

71. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists, psychologists, and pediatricians who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self- selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism and therefore, deviates from the philosophical core of medical science. There are pediatricians, psychiatrists, endocrinologists, and surgeons who object strongly, on professional grounds, to transitioning children and providing affirmation in a transgender identity as the first treatment option. WPATH does not speak for all of the medical profession.

72. In 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be

identified in the DSM as a pathology.[3] This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

73. In my experience some current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric co- morbidities. Further, being a mental health professional, per se, does not guarantee experience and skill in recognizing and effectively intervening in serious or subtle patterns. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical degrees. The 8th version of the SOC continues this tradition. When this document recommends a comprehensive psychiatric evaluation, it fails to elaborate its duration, the topics to be covered, and necessary treatment results of the commonly found previous and co-current psychiatric conditions.

[3] WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

D. Opinions and practices differ widely with respect to the proper role of psychological counseling before, as part of, or after a diagnosis of gender dysphoria.

74. In Version 7 of its Standards of Care, released in 2012, WPATH downgraded the role of counseling or psychotherapy, and the organization no longer sees psychotherapy without transition and hormonal interventions as a potential path to eliminate gender dysphoria by enabling a patient to return to or achieve comfort with the gender identity aligned with his or her biology. Around the world, many prominent voices and practitioners disagree. For example, renowned gender therapists Dr. Laura Edwards-Leeper and Dr. Erica Anderson (who, as mentioned above, identifies as a transgender woman) have recently spoken out arguing that children and adolescents are being subjected to puberty blockers and hormonal intervention far too quickly, when careful and extended psychotherapy and investigation for potential causes of feelings of dysphoria (such as prior sexual abuse) should be the first port of call and might resolve the dysphoria. (Edwards-Leeper & Anderson 2021; Davis 2022.)

75. In a recently published position statement on gender dysphoria, the Royal Australian and New Zealand College of Psychiatrists emphasized the critical nature of mental health treatment for gender dysphoric minors, stressing "the importance of the psychiatrist's role to undertake thorough assessment and evidence-based treatment ideally as part of a multidisciplinary team, especially highlighting co-existing issues which may need addressing and treating." The

Royal College also emphasized the importance of assessing the "psychological state and context in which Gender Dysphoria has arisen," before any treatment decisions are made. (RANZCP, 2021.)

76. Dr. Paul Hruz of the University of Washington St. Louis Medical School has noted, "The WPATH has rejected psychological counseling as a viable means to address sex– gender discordance with the claim that this approach has been proven to be unsuccessful and is harmful (Coleman et al. 2012). Yet the evidence cited to support this assertion, mostly from case reports published over forty years ago, includes data showing patients who benefited from this approach (Cohen-Kettenis and Kuiper 1984)." (Hruz 2020.)

77. In several recent publications, my colleagues and I have demonstrated that both the Endocrine Society's and WPATH's citations for the scientific basis of affirmative care of adolescents reference the same two Dutch studies. We have demonstrated in considerable details the limitations of these studies, their lack of applicability to today's transgendered youth, and the dangers of following therapeutic fashion rather than evidence-based medicine (Levine et al, 2022; Abbruzzese et al, 2023).

E. Opinions and practices vary widely with respect to the administration of puberty blockers and cross-sex hormones.

78. There is likewise no broadly accepted standard of care with respect to use of puberty blockers. The WPATH Standards of Care explicitly recognize the

lack of any consensus on this important point, stating: "Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. . . The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings."

79. The use of puberty blockers as a therapeutic intervention for gender dysphoria is often justified by reference to the seminal work of a respected Dutch research team that developed a protocol that administered puberty blockers to children no younger than age 14. However, it is well known that many clinics in North America now administer puberty blockers to children at much younger ages than the "Dutch Protocol" allows. (Zucker 2019.) The Dutch protocol only treated children with these characteristics: a stable cross gender identity from early childhood; dysphoria that worsened with the onset of puberty; were otherwise psychologically healthy; had healthy families; the patient and family agreed to individual and family counselling throughout the protocol. But the experience and results of the Dutch model is being used as a justification for giving puberty blockers to children who differ considerably from these criteria. Its authors have also recently noted this fact (de Vries 2020).

80. However, Zucker notes that "it is well known" that clinicians are administering cross-sex hormones, and approving surgery, at ages lower than the minimum age thresholds set by that "Dutch Protocol." (Zucker 2019 at 5.)

81. Similarly, at least one prominent clinic—that of Dr. Safer at Columbia's Mt. Sinai Medical Center—is quite openly admitting patients for even *surgical* transition who are not eligible under the criteria set out in WPATH's Standards of Care. A recent study published by Dr. Safer and colleagues revealed that of a sample of 139 individuals, 45% were eligible for surgery "immediately" under the center's own criteria, while only 15% were eligible under WPATH's criteria. That is, *three times* as many patients immediately qualified for surgery under the center's loose standards than would have qualified under WPATH criteria. (Lichenstein et al. 2020.)

82. Internationally, there has been a recent marked trend *against* use of puberty blockers, as a result of extensive evidence reviews by national medical bodies, which I discuss later. The main gender clinic in Sweden has declared that it will no longer authorize use of puberty blockers for minors below the age of 16. Finland has similarly reversed its course, issuing new guidelines that allow puberty blockers only on a case-by-case basis after an extensive psychiatric assessment. A landmark legal challenge against the UK's National Health Service in 2020 by "detransitioner" Keira Bell led to the suspension of the use of puberty blockers and new procedures to ensure better psychological care, as well as

prompting a thorough evidence review by the National Institute for Health and Care Excellence (NICE 2021a; NICE 2021b).[4] That review in 2022 reorganized trans adolescent care throughout the UK and emphasized the need to focus on the patients' psychological state rather than treat first the gender incongruence. Puberty blockers are not to be initially employed.

83. In this country, some voices in the field are now publicly arguing that *no* comprehensive mental health assessment at all should be required before putting teens on puberty blockers or cross-sex hormones (Ghorayshi 2022), while Dr. Anderson and Dr. Edwards-Leeper argue that U.S. practitioners are already moving too quickly to hormonal interventions. (Edwards-Leeper & Anderson 2021; Davis 2022.) It is evident that opinions and practices are all over the map.

1. In 2018, committee of the American Academy of Pediatricians issued a policy statement supporting administration of puberty blockers to children diagnosed with gender dysphoria. No other American medical association has endorsed the use of puberty blockers. Pediatricians are neither endocrinologists nor psychiatrists. Many pediatricians were horrified by the recommendation. Dr. James Cantor published a peer-reviewed paper detailing that the Academy's statement was not

[4] The decision requiring court approval for administration of hormones to any person younger than age 16 was later reversed on procedural grounds by the Court of Appeal and is currently under consideration by the UK Supreme Court.

evidence- based and misdescribed the few scientific sources it did reference. (Cantor 2019.) It has been well noted in the field that the AAP has declined invitations to publish any rebuttal to Dr. Cantor's analysis. But this is all part of ongoing debate, simply highlighting the absence of any generally agreed standard of care. In 2022, the same committee of the AAP modified their recommendation supporting alternative treatments but still held out that affirmative care is still a viable option. Evidence after all is required for policy decisions and the 2018 evidence base is now widely appreciated as insubstantial.

84. The 2017 Endocrine Society Guidelines themselves expressly state that they are *not* "standards of care." The document states: "The guidelines cannot guarantee any specific outcome, *nor do they establish a standard of care*. The guidelines are not intended to dictate the treatment of a particular patient." (Hembree et al. 2017 at 3895 (emphasis added).) Nor do the Guidelines claim to be the result of a rigorous scientific process. Rather, they expressly advise that their recommendations concerning use of puberty blockers are based only on "low quality" evidence.

85. The 2017 Guidelines assert that patients with gender dysphoria often must be treated with "a safe and effective hormone regimen. . ." Notably, however, the Guidelines do not make any firm statement that use of puberty blockers for this purpose *is* safe, and the Guidelines go no further than "suggest[ing]" use of puberty blockers—language the Guidelines warn represents

only a "weak recommendation." (Hembree 2017 at 3872.) Several authors have pointed out that not only were the Endocrine Society suggestions regarding use of puberty blockers reached on the basis of "low quality" evidence, but its not-quite claims of 'safety' and 'efficacy' are starkly contradicted by several in-depth evidence reviews. (Laidlaw et al., 2019; Malone et al. 2021.) The most recent systematic independent review of hormonal treatment of adolescents reaffiremed the poor quality of evidence making their use questionionalble (Brignardello-Peterson, & Wiercioch 2022). I detail these contradictory findings in more detail in Section VII below.

86. While there is too little meaningful clinical data and no consensus concerning best practices or a "standard of care" this area, there are long-standing ethical principles that do or should bind all medical and mental health professionals as they work with, counsel, and prescribe for these individuals.

87. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, principles of medical ethics prohibit the treatment.

V. TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED.

88. There is no medical consensus that transgender identity has any biological basis. Furthermore, there is considerable well-documented evidence that is inconsistent with the hypothesis of a biological basis for gender identity—at least in the large majority of currently-presenting patients.

A. No theory of biological basis has been scientifically validated.

89. At the outset, the attempt to identify a single, biological cause for psychiatric conditions (including gender dysphoria) has been strongly criticized as "out of step with the rest of medicine" and as a lingering "ghost" of an understanding of the nature of psychiatric conditions that is now broadly disproven. (Kendler 2019 at 1088-1089.) Gender dysphoria is defined and diagnosed only as a psychiatric, not a medical, condition. Courts need to have clarified that just because some physicians use medication and surgery to treat gender dysphoria does not make it a "medical condition" or that the psychological identity has been determined by a biological mechanism.

90. While some have pointed to very small brain scan studies as evidence of a biological basis, no studies of brain structure of individuals identifying as transgender have found any statistically significant correlation between any distinct structure or pattern and transgender identification, after controlling for sexual orientation and exposure to exogenous hormones. (Sarawat et al. 2015 at 202; Frigerio et al. 2021.)

91. Indeed, the Endocrine Society 2017 Guidelines recognizes: "With

current knowledge, we cannot predict the psychosexual outcome for any specific child" and "there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty." (Hembree et al. 2017 at 3876.)

92. In short, no biological test or measurement has been identified that provides any ability to predict which children will exhibit, and which children will persist in, gender dysphoria or a transgender identification. Unless and until such a test is identified, the theory of a biological basis is a hypothesis still searching for support. A hypothesis is not a fact, and responsible scientists will not confuse the two.

B. Large changes across time and geography in the epidemiology of transgender identification are inconsistent with the hypothesis of a biological basis for transgender identity.

93. In fact, there is substantial evidence that the "biological basis" theory is incorrect, at least with respect to the large majority of patients presenting with gender dysphoria today.

94. **Vast changes in incidence:** Historically, there were very low reported rates of gender dysphoria or transgender identification. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be at 2-14 per 100,000, or between 0.002% and 0.014%. (APA 2013 at 454.) Recently however, these numbers have increased dramatically, particularly in adolescent populations.

Recent surveys estimate that between 2-9% of high school students self- identify as transgender or "gender non-conforming." with a significantly large increase in adolescents claiming "nonbinary" gender identity as well. (Johns et al. 2019; Kidd et al. 2021.) Consistent with these surveys, gender clinics around the world have seen numbers of referrals increase rapidly in the last decade, with the Tavistock clinic in London seeing a 30-fold increase in the last decade (GIDS 2019), and similar increases being observed in Finland (Kaltiala-Heino et al. 2018), the Netherlands (de Vries 2020), and Canada (Zucker 2019). The rapid change in the number of individuals experiencing gender dysphoria points to social and cultural, not biological, causes.

95. **Large change in sex ratio:** In recent years there has been a marked shift in the sex ratio of patients presenting with gender dysphoria or transgender identification. The Tavistock clinic in London saw a ratio of 4 biological females(F):5 biological males(M) shift to essentially 11F:4M in a decade. (GIDS 2019.) One researcher summarizing multiple sources documented a swing of 1F:2M or 1F:1.4M through 2005 to 2F:1M generally (but as high as 7F:1M) in more recent samples. (Zucker 2019 at 2.) This phenomenon has been noted by Dr. Erica Anderson, who said: "The data are very clear that adolescent girls are coming to gender clinics in greater proportion than adolescent boys. And this is a change in the last couple of years. And it's an open question: What do we make of that? We don't really know what's going on. And we should be concerned about

it." (Davis 2022.) Again, this large and rapid change in who is experiencing gender dysphoria points to social, not biological, causes.

96. **Clustering**: Dr. Littman's recent study documented "clustering" of new presentations of gender dysphoria among natal females in specific schools and among specific friend groups. This again points strongly to social causes for gender dysphoria at least among the adolescent female population. (Littman 2018.)

97. **Desistance:** As I discuss later, there are very high levels of desistance among children diagnosed with gender dysphoria, as well as increasing (or at least increasingly vocal) numbers of individuals who first asserted a transgender identity during or after adolescence, underwent substantial medical interventions to "affirm" that trans-identity, and then "desisted" and reverted to a gender identity congruent with their sex. (See Section V.B below.) These narratives, too, point to a social and/or psychological cause, rather than a biological one.

98. **"Fluid" gender identification:** Advocates and some practitioners assert that gender identity is not binary but can span an almost endless range of gender identity self-labels, which a given individual may try on, inhabit, and often discard. (A recent article identifies 72.[5]) I have not heard any theory offered for how there is or could be a biological basis for gender identity as now expansively

[5] Allarakha, *What Are the 72 Other Genders?*, MedicineNet, available at: https://www.medicinenet.com/what_are_the_72_other_genders/article.html

defined.

99. I frequently read attempts to explain away the points in this Section V. They include: these problems always existed, but children are now learning that there are effective treatments for their dilemma and are simply seeking them. And children have hidden their trans identity throughout childhood and now that trans people are recognized and accepted, they are presenting themselves. And now pediatricians realize that girls can have gender dysphoria and are referring them to gender clinics. But these are all mere hypotheses unsupported by concrete evidence. One set of unproven hypotheses cannot provide support for the unproven hypothesis of biological basis. And none of these hypotheses could even potentially explain the failure of science thus far to identify any predictive biological marker of transgender identification.

100. **Therapies affect gender identity outcomes:** Finally, the evidence shows that therapeutic choices can have a powerful effect on whether and how gender identity does change, or gender dysphoria desists. Social transition of juveniles, for instance, strongly influences gender identity outcomes to such an extent that it has been described a "unique predictor of

persistence." (See Section VI.B below.) Again, this observation cuts against the hypothesis of biological origin.

C. Disorders of sexual development (or DSDs) and gender identity are very different phenomena, and it is an error to conflate the two.

101. Some have pointed individuals who suffer from disorders of sexual development (DSDs) as evidence that sex is not binary or clearly defined, or as somehow supporting the idea that transgender identification has a biological basis. I have extensively detailed that sex is clear, binary, and determined at conception. (Section III.) Here I explain that gender dysphoria is an entirely different phenomenon than DSDs—which unlike transgender identity are indeed biological phenomena. It is an error to conflate the two distinct concepts.

102. Every DSD reflects a genetic enzymatic defect with negative anatomic and physiological consequences. As the Endocrine Society recognized in a 2021 statement: "Given the complexities of the biology of sexual determination and differentiation, it is not surprising that there are dozens of examples of variations or errors in these pathways associated with genetic mutations that are now well known to endocrinologists and geneticists; in medicine, these situations are generally termed *disorders of sexual development* (DSD) or *differences in sexual development*." Gender Identity on the other hand is uniformly defined as a subjective "sense" of being, a feeling or state of mind. (Section II.C.)

103. The vast majority of those who experience gender dysphoria, or a

transgender identity, do not suffer from any DSD, nor from any genetic enzymatic disorder at all. Conversely, many who suffer from a DSD do not experience a gender identity different from their chromosomal sex (although some may). In short, those who suffer from gender dysphoria are not a subset of those who suffer from a DSD, nor are those who suffer from a DSD a subset of those

who suffer from gender dysphoria. The two are simply different phenomena, one physical with psychological effects , the other mental with physical effects only if treated medically or surgically. The issue here is not whether biological forces play a role in personality development; it is whether there is strong evidence that it is determinative. Science has come too far to revert to single explanations for gender dysphoria or any psychiatric diagnosis.

104. The importance of this distinction is evident from the scientific literature. For example, in a recent study of clinical outcomes for gender dysphoric patients, Tavistock Clinic researchers *excluded* from their analysis any patients who did not have "normal endocrine function and karyotype consistent with birth registered sex." (Carmichael et al. 2021 at 4.) In other words, the researchers specifically *excluded* from their study anyone who suffered from genetic-based DSD, or a DSD comprising any serious defect in hormonal use pathways, to ensure the study was focused only on individuals experiencing the psychological effects of what we might call "ordinary" gender dysphoria.

D. Studies of individuals born with DSDs suggest that there may be a biological predisposition towards *typical* gender identifications, but provide no support for a biological basis for *trans*gender identification.

105. Studies of individuals born with serious DSDs have been pointed to as evidence of a biological basis for transgender identification. They provide no such support.

106. One well-known study by Meyer-Bahlburg reviewed the case histories of a number of XY (i.e. biologically male) individuals born with severe DSDs who were surgically "feminized" in infancy and raised as girls. (Meyer-Bahlburg 2005.) The majority of these individuals nevertheless later adopted male gender identity—suggesting a strong biological predisposition towards identification aligned with genetic sex, even in the face of feminized genitalia from earliest childhood, and parental "affirmation" in a transgender identity. But at the same time, the fact that some of these genetically male individuals did *not* later adopt male

gender identity serves as evidence that medical and social influences can indeed encourage and sustain transgender identification.

107. Importantly, the Meyer-Bahlburg study did *not* include any individuals who were assigned a gender identity congruent with their genetic sex who subsequently adopted a *trans*gender identity. Therefore, the study can provide no evidence of any kind that supports the hypothesis of a biological basis for

*trans*gender identity. A second study in this area (Reiner & Gearhart 2004) likewise considered exclusively XY subjects, and similarly provides evidence only for a biological bias towards a gender identity congruent with one's genetic sex, even in the face of medical and social "transition" interventions. None of this provides any evidence at all of a biological basis for transgender identity.

VI. GENDER IDENTITY IS EMPIRICALLY NOT FIXED FOR MANY INDIVIDUALS.

108. There is extensive evidence that gender identity changes over time for many individuals.[6] That evidence is summarized below.

A. Most children who experience gender dysphoria ultimately "desist" and resolve to cisgender identification.

109. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition or puberty blocking hormone therapy, it does *not* persist through puberty.

110. A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria (11 studies), and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition."

[6] See n1 *supra*.

(Cantor 2019 at 1.) Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance . . . the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance." (Adelson et al. 2012 at 963; see also Cohen-Kettenis 2008 at 1895.) The Endocrine Society recognized this important baseline fact in its 2017 Guidelines. (Hembree 2017 at 3879.) It should be noted that the reason that the Dutch Protocol waited until age 14 to initiate puberty blockers was that it was well known that many children would desist if left free of hormonal intervention until that age.

111. Findings of high levels of desistance among children who experience gender dysphoria or incongruence have been reaffirmed in the face of critiques through thorough reanalysis of the underlying data. (Zucker 2018.)

112. As I explained in detail in Section V above, it is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist.

113. It does appear that prevailing circumstances during particularly formative years can have a significant impact on the outcome of a juvenile's gender dysphoria. A 2016 study reviewing the follow-up literature noted that "the period between 10 and 13 years" was "crucial" in that "both persisters and desisters stated that the changes in their social environment, the anticipated and

actual feminization or masculinization of their bodies, and the first experiences of falling in love and sexual attraction in this period, contributed to an increase (in the persisters) or decrease (in the desisters) of their gender related interests, behaviors, and feelings of gender discomfort." (Ristori & Steensma 2016 at 16.) As I discuss in Section VII below, there is considerable evidence that early transition and affirmation causes far more children to persist in a transgender identity.

B. Desistance is increasingly observed among teens and young adults who first manifest GD during or after adolescence.

114. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I have observed an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years, and young "detransitioners" (individuals in the process of reidentifying with their birth sex after having undergone a gender transition) are now receiving increasing attention in both clinical literature and social media channels.

115. Almost all scientific articles on this topic have appeared within the last few years.

Perhaps this historic lack of coverage is not entirely surprising – one academic who undertook an extensive review of the available scientific literature in 2021 noted that the phenomenon was "socially controversial" in that it "poses significant

professional and bioethical challenges for those clinicians working in the field of gender dysphoria." (Expósito Campos 2021 at 270.) This review reported on the multiple reasons for why individuals were motivated to detransition, which included coming to "understand[ ] how past trauma, internalized sexism, and other psychological difficulties influenced the experience of GD."

116. In 2021, Lisa Littman of Brown University conducted a ground-breaking study of 100 teenage and young adults who had transitioned and lived in a transgender identity for a number of years, and then "detransitioned" or changed back to a gender identity matching their sex. Littman noted that the "visibility of individuals who have detransitioned is new and may be rapidly growing." (Littman 2021 at 1.) Of the 100 detransitioners included in Littman's study, 60% reported that their decision to detransition was motivated (at least in part) by the fact that they had become more comfortable identifying as their natal sex, and 38% had concluded that their gender dysphoria was caused by something specific such as trauma, abuse, or a mental health condition. (Littman 2021 at 9.)

117. A significant majority (76%) did not inform their clinicians of their detransition. (Littman 2021 at 11.)

118. A similar study that recruited a sample of 237 detransitioners (the large majority of whom had initially transitioned in their teens or early twenties) similarly reported that a common reason for detransitioning was the subject's

conclusion that his or her gender dysphoria was related to other issues (70% of the sample). (Vandenbussche 2021.)

119. The existence of increasing numbers of youth or young adult detransitioners has also been recently noted by Dr. Edwards-Leeper and Dr. Anderson. (Edwards-Leeper & Anderson 2021.) Edwards-Leeper and Anderson noted "the rising number of detransitioners that clinicians report seeing (they are forming support groups online)" which are "typically youth who experienced gender dysphoria and other complex mental health issues, rushed to medicalize their bodies and regretted it." Other clinicians working with detransitioners have also noted the recent phenomenon. (Marchiano 2020.)

120. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle 2020; Littman 2021; Vandenbussche 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo 2018). As gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

121. A recent study from a UK adult gender clinic observed that 6.9% of those treated with gender-affirmative interventions detransitioned within 16 months, and another 3.4% had a pattern of care suggestive of detransition, yielding

a rate of probable detransition in excess of 10%. Another 21.7%, however, disengaged from the clinic without completing their treatment plan. While some of these individuals later re-engaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." (Hall et al. 2021).

122. Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for an average 5 years (17 months-10 years) prior to discontinuing. Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: "Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields" (Boyd et al. 2022 at 15.) Indeed, given that regret may take up to 8-11 years to materialize (Dhejne et al., 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but the Littman and Vandenbussche studies in 2021 both report that detransitioners from the recently transitioning cohorts feel they were rushed into medical gender-affirmative interventions with irreversible effects, often without

the benefit of appropriate, or in some instances any, psychologic exploration.

VII. TRANSITION AND AFFIRMATION ARE IMPORTANT PSYCHOLOGICAL AND MEDICAL INTERVENTIONS THAT CHANGE GENDER IDENTITY OUTCOMES.

A. If both a typical gender or a transgender long-term gender identity outcome are possible for a particular patient, the alternatives are not medically neutral.

123. Where a juvenile experiences gender dysphoria, the gender identity that is stabilized will have a significant impact on the course of their life. Living in a transgender identity for a time will make desistance, if it is ever considered, more difficult to accomplish.

124. If the juvenile desists from the gender dysphoria and becomes reasonably comfortable with a gender identity congruent with their sex—the most likely outcome from a statistical perspective absent affirming intervention—the child will not require ongoing pharmaceutical maintenance and will not have their fertility destroyed post-puberty.

125. However, if the juvenile persists in a transgender identity, under current practices, the child is most likely to require regular administration of hormones for the rest of their lives, exposing them to significant physical, mental health, and relational risks (which I detail in Section IX below), as well as being irreversibly sterilized chemically and/or surgically. The child is therefore rendered a "patient for life" with complex medical implications further to a scientifically

unproven course of treatment.

B. Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance.

126. Social transition has a critical effect on the persistence of gender dysphoria. It is evident from the scientific literature that engaging in therapy that encourages social transition before or during puberty—which would include participation on athletic teams designated for the opposite sex—is a psychotherapeutic intervention that dramatically changes outcomes. A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." (Guss et al. 2015 at 421.) Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker 2018 at 7.)

127. Indeed, a review of multiple studies of children treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, at least in the case of boys. That is, while, as I review above, studies conducted before the widespread use of social transition for young children reported desistance rates in the range of 80-98%, a more recent

study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker 2018 at 7[7]; Steensma et al. 2013.)[8] Another researcher observed that a partial or complete gender social transition prior to puberty "proved to be a unique predictor of persistence." (Singh et al. 2021 at 14.)

128. Some vocal practitioners of prompt affirmation and social transition even proudly claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross- gender identification desist in that identification and return to a gender identity consistent with their biological sex.[9] This is a very large change as compared to the desistance rates documented apart from social transition.

129. Even voices generally supportive of prompt affirmation and social transition are acknowledging a causal connection between social transition and this change in outcomes. As the Endocrine Society recognized in its 2017 Guidelines: "If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty. . .

[7] Zucker found social transition by the child to be strongly correlated with persistence for natal boys, but not for girls. (Zucker 2018 at 5.)

[8] Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma 2013 at 584.

[9] *See, e.g.,* Ehrensaft 2015 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted' and asked to return to his or her assigned gender."

[S]ocial transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence." (Hembree et al. 2017 at 3879.) The fact is that these unproven interventions with the lives of kids and their families have systematically documented outcomes. Given this observed phenomenon, I agree with Dr. Ken Zucker who has written that social transition in children must be considered "a form of psychosocial treatment." (Zucker 2020 at 1.)

130. Moreover, as I review below, social transition cannot be considered or decided alone. Studies show that engaging in social transition starts a juvenile on a "conveyor belt" path that almost inevitably leads to the administration of puberty blockers, which in turn almost inevitably leads to the administration of cross-sex hormones. The emergence of this well- documented path means that the implications of taking puberty blockers *and* cross-sex hormones must be taken into account even where "only" social transition is being considered or requested by the child or family. As a result, there are a number of important "known risks" associated with social transition.

C. Administration of puberty blockers is a powerful medical and psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance on the historically observed timeline.

131. It should be understood that puberty blockers are usually administered to early-stage adolescents as part of a path that includes social transition. Yet medicine does not know what the long- term health effects on

bone, brain, and other organs are of a "pause" between ages 11-16. Medicine also does not know if the long-term effects of these compounds are different in boys than in girls. The mental health professional establishment likewise does not know the long-term effects on coping skills, interpersonal comfort, and intimate relationships of this "pause" while one's peers are undergoing their maturational gains in these vital arenas of future mental health. I address medical, social, and mental health risks associated with the use of puberty blockers in Section X. Here, I note that the data strongly suggests that the administration of puberty blockers, too, must be considered to be a component of a "psychosocial treatment" with complex implications, rather than simply a "pause."

132. Multiple studies show that the large majority of children who begin puberty blockers go on to receive cross-sex hormones. (de Vries 2020 at 2.) A recent study by the Tavistock and Portman NHS Gender Identity Development Service (UK)—the world's largest gender clinic—found that 98% of adolescents who underwent puberty suppression continued on to cross-sex hormones. (Carmichael et al 2021 at 12.)[10]

133. These studies demonstrate that going on puberty blockers virtually eliminates the possibility of desistance in juveniles. Rather than a "pause," puberty

[10] *See also* Brik 2020 where Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones.

blockers appear to act as a psychosocial "switch," decisively shifting many children to a persistent transgender identity. Therefore, as a practical and ethical matter the decision to put a child on puberty blockers must be considered as the equivalent of a decision to put that child on cross-sex hormones, with all the considerations and informed consent obligations implicit in that decision.

VIII. TRANSITION AND AFFIRMATION ARE EXPERIMENTAL THERAPIES THAT HAVE NOT BEEN SHOWN TO IMPROVE MENTAL OR PHYSICAL HEALTH OUTCOMES BY YOUNG ADULTHOOD.

134. It is undisputed that children and adolescents who present with gender dysphoria exhibit a very high level of mental health comorbidities. (Section III.C.) Whether the gender dysphoria is cause or effect of other diagnosed or undiagnosed mental health conditions, or whether these are merely coincident comorbidities, is hotly disputed, but the basic fact is not.

135. It is important for all sides to admit that the knowledge base concerning the causes and treatment of gender dysphoria has low scientific quality. In evaluating claims of scientific or medical knowledge, it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data

comprising:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future. Reliance on a well-known, or well-credentialled "experts" or head of a gender clinic is sometimes referred to as eminence-based medicine. Their opinions do not garner as much respect from professionals as what follows;

b. A single case or series of cases (what could be called anecdotal evidence) (Levine 2016 at 239.);

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

136. Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment [T]he proposed benefits of

treatment to eliminate gender discordance … must be carefully weighed against … possible deleterious effects." (Adelson et al. at 968–69.) Similarly, the American Psychological Association has stated, "because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children." (APA 2015 at 842.)

137. Critically, "there are no randomized control trials with regard to treatment of children with gender dysphoria." (Zucker 2018 at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases, or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine 2016 at 239.)

138. Within the last two years, at least four formal, independent, systematic evidence reviews concerning hormonal interventions for gender dysphoria have been conducted. All four found all of the available clinical evidence to be very low quality.

139. The British National Health Service (NHS) commissioned formal "evidence reviews" of all clinical papers concerning the efficacy and safety of puberty blockers and cross- sex hormones as treatments for gender dysphoria. These evidence reviews were performed by the U.K. National Institute for Health and Care Excellence (NICE), applying the respected "GRADE" criteria for

evaluating the strength of clinical evidence.

140. Both the review of evidence concerning puberty blockers and the review of evidence concerning cross-sex hormones were published in 2020, and both found that *all* available evidence as to both efficacy and safety was "very low quality" according to the GRADE criteria. (NICE 2021a; NICE 2021b.) This work is sometimes referred to as the Cass Report.[11] "Very low quality" according to GRADE means there is a high likelihood that the patient *will not experience* the hypothesized benefits of the treatment. (Balshem et al. 2011.)

141. Similarly, the highly respected Cochrane Library—the leading source of independent systematic evidence reviews in health care—commissioned an evidence review concerning the efficacy and safety of hormonal treatments now commonly administered to "transitioning transgender women" (i.e., testosterone suppression and estrogen administration to biological males). That review, also published in 2020, concluded that "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." (Haupt et al. 2020 at 2.) It must be understood that both the NICE and the Cochrane reviews considered *all* published scientific studies concerning these treatments. Similarly, McMasters University's skillful

[11] https://cass.independent-review.uk/publications/ interim-report/

methodological unit recently reached the same conclusion (Brignardello-Peterson, & Wiercioch, 2022).

142. As to social transition, as I have noted above, considerable evidence suggests that socially transitioning a pre-pubertal child puts him or her on a path from which very few children escape—a path which includes puberty blockers and cross-sex hormones before age 18. And for some, surgery before the age of majority. A decision about social transition for a child must be made in light of what is known and what is unknown about the effects of those expected future interventions. Social transition, therefore, is not merely reversible behavioral change. It is the beginning of a medically dependent future and should be explained as such.

143. I discuss safety considerations in Section IX below. Here, I detail what is known about the effectiveness of social and hormonal transition and affirmation to improve the mental health of individuals diagnosed with gender dysphoria.

B. Youth who adopt a transgender identity show no durable improvement in mental health after social, hormonal, or surgical transition and affirmation.

144. As I noted above, the evidence reviews for the efficacy and safety of hormonal interventions published in 2020 concluded that the supporting evidence is so poor that there is "a high likelihood that the patient will not experience the hypothesized benefits of the treatment." There is now some concrete evidence that

on average they do not experience those benefits.

145. An important paper published in 2021 by Tavistock clinic clinicians provided the results of the first longitudinal study that measured widely used metrics of general psychological function and suicidality before commencement of puberty blockers, and then at least annually after commencing puberty blockers. After up to three years, they "found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm" as compared to the pre-puberty-blocker baseline evaluations. "Outcomes that were not formally tested also showed little change." (Carmichael at al. 2021 at 18-19.) Similarly, a study by Bränström and Pachankis of the case histories of a set of individuals diagnosed with GD in Sweden found no positive effect on mental health from hormonal treatment. (Landen 2020.)

146. A cohort study by authors from Harvard and Boston Children's Hospital found that youth and young adults (ages 12-29) who self-identified as transgender had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services. (Reisner et al. 2015 at 6.)

Similarly, a recent longitudinal study of transgender and gender diverse youth and young adults in Chicago found rates of alcohol and substance abuse "substantially higher than those reported by large population-based studies of youth and adults." (Newcomb et al. 2020 at 14.) Members of the clinical and research team at the prominent Dutch VU University gender dysphoria center recently compared mental health metrics of two groups of subjects before (mean age 14.5) and after (mean age 16.8) puberty blockers. But they acknowledged that the structure of their study meant that it "can . . . not provide evidence about . . . long-term mental health outcomes," and that based on what continues to be extremely limited scientific data, "Conclusions about the long-term benefits of puberty suppression should . . . be made with extreme caution." In other words, we just don't know. (van der Miesen et al. 2020 at 703.)

147. Kiera Bell, who was diagnosed with gender dysphoria at the Tavistock Clinic, given cross-sex hormones, and treated by mastectomy, before desisting and reclaiming her female gender identity, and a Swedish teen girl who appeared in a recent documentary after walking that same path, have both stated that they feel that they were treated "like guinea pigs," experimental subjects. They are not wrong.

148. A recent two-year prospective uncontrolled multisite NIMH study of 315 adolescents found that at the average age of 18 the primary benefit of hormones was happiness with their aesthetic appearance. The effects on

depression and anxiety were very small and highly variable. There were two suicides in the study population. (Chen et al, 2023). This work did not address the relevant long term mental health outcomes of such treatment before their two-year finding.

C. Long-term mental health outcomes for individuals who persist in a transgender identity are poor.

149. The responsible MHP cannot focus narrowly on the short-term happiness of the young patient, but must instead consider the happiness and health of the patient from a "life course" perspective. When we look at the available studies of individuals who continue to inhabit a transgender identity across adult years, the results are strongly negative.

150. In the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated rates of substance abuse as well as suicide. (Levine 2017 at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. (Dhejne et al. 2011; Simonsen et al. 2016.) The Swedish follow-up study similarly found a suicide rate in the post-SRS population 19.1 times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine 2017 at 10.)

151. A study in the American Journal of Psychiatry reported high mental

health utilization patterns of adults for ten years after surgery for approximately 35% of patients. (Bränström & Pachankis, 2020.) Indeed, earlier Swedish researchers in a long-term study of all patients provided with SRS over a 30-year period (median time since SRS of > 10 years) concluded that individuals who have SRS exhibit such poor mental health that they should be provided very long-term psychiatric care as the "final" transition step of SRS. (Dhejne et al. 2011, at 6-7.) Unfortunately, across the succeeding decade, in Sweden and elsewhere their suggestion has been ignored.

152. The most recent all-cause mortality study from the UK found a significant excess of deaths among trans individuals compared to age matched controls of both sexes. External causes of death (suicide, homicide, accidental poisoning) were particularly higher than control groups (Jackson et al, 2023).

153. I will note that these studies do not tell us whether the subjects first experienced gender dysphoria as children, adolescents, or adults, so we cannot be certain how their findings apply to each of these subpopulations which represent quite different pathways. But in the absence of knowledge, we should be cautious.

154. Meanwhile, no studies show that affirmation of pre-pubescent children or adolescents leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does "watchful waiting" or ordinary therapy.

155. The many studies that I have cited here warn us that as we look ahead to the patient's life as a young adult and adult, the prognosis for the physical health, mental health, and social well-being of the child or adolescent who transitions to live in a transgender identity is not good. Gender dysphoria is not "easily managed" when one understands the marginalized, vulnerable physical, social, and psychological status of adult trans populations.

IX. TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MAY INCREASE, THE RISK OF SUICIDE.

A. The risk of suicide among transgender youth is confused and exaggerated in the public mind.

156. While suicide is closely linked to mental health, I comment on it separately because rhetoric relating to suicide figures so prominently in debates about responses to gender dysphoria.

157. At the outset, I will note that any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is extremely rare, and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. Any suggestion otherwise is misinformed. Our focus for this topic, then, is on adolescents and adults.

158. Some authors have reported rates of suicidal thoughts and behaviors among trans- identifying teens or adults ranging from 25% to as high as 52%,

generally through non- longitudinal self-reports obtained from non-representative survey samples. (Toomey et al. 2018.) Some advocates of affirmative care assert that the only treatment to avoid this serious harm is to affirm gender identity. Contrary to these assertions, no studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a "watchful waiting" or a psychotherapeutic model of response, as I have described above. Rhetorical references to figures such as 40%—and some published studies—confuse suicidal thoughts and actions that represent a cry for help, manipulation, or expression of rage with serious attempts to end life. Such statements or studies ignore a crucial and long-recognized distinction.

159. I have included suicidality in my discussion of mental health above. Here, I focus on actual suicide. Too often, in public comment suicidal thoughts are blurred with suicide. Yet the available data tells us that suicide among children and youth suffering from gender dysphoria is extremely rare.

160. An important analysis of data covering patients as well as those on the waiting list (and thus untreated) at the UK Tavistock gender clinic—the world's largest gender clinic—found a total of only four completed suicides across 11 years' worth of patient data, reflecting an estimated cumulative 30,000 patient-years spent by patients under the clinic's care or on its waiting list. This corresponded to an annual suicide rate of 0.013%. The proportion of individual

patients who died by suicide was 0.03%, which is orders of magnitude smaller than trans adolescents who self-report suicidal behavior or thoughts on surveys. (Biggs 2022b.)

161. Thus, only a minute fraction of trans-identifying adolescents who report thoughts or conduct considered to represent "suicidality" commit suicide. I agree with Dr. Zucker that the assertion by, for example, Karasic and Ehrensaft (2015) that completed suicides among transgender youth are "alarmingly high" "has no formal and systematic empirical basis." (Zucker 2019 at 3.)

162. Professor Biggs of Oxford, author of the study of incidence of suicide among Tavistock clinic patients, rightly cautions that it is "irresponsible to exaggerate the prevalence of suicide." (Biggs 2022b at 4.) It is my opinion that telling parents—or even allowing them to believe from their internet reading—that they face a choice between "a live son or a dead daughter" is both factually wrong and unethical. Informed consent requires clinicians to tell the truth and ensure that their patients understand the truth. To be kind, the clinicians who believe such figures represent high risk of ultimate suicide in adolescence simply do not know the truth; they are ill-informed.

B. Transition of any sort has not been shown to reduce levels of suicide.

163. Every suicide is a tragedy, and steps that reduce suicide should be adopted. I have noted above that suicidality (that is, suicidal thoughts or behaviors, rather than suicide) is common among transgender adolescents and young adults

before, during, and after social and medical transition. If a medical or mental health professional believes that an individual he or she is diagnosing or treating for gender dysphoria presents a suicide risk, in my view it is unethical for that professional merely to proceed with treatment for gender dysphoria and hope that "solves the problem." Rather, that professional has an obligation to provide or refer the patient for evidence-based therapies for addressing depression and suicidal thoughts that are well-known to the profession. (Levine 2016 at 242.)

164. This is all the more true because there is in fact no evidence that social and/or medical transition reduces the risk or incidence of actual suicide. As there are no long-term comparative studies of gender dysphoric adolescents with suicidal ideation, per se, let alone a comparative study of those who were given hormones and those who did not take hormones, there is no scientific basis for declaring affirmative care as reducing suicidal risk. In his analysis of those who were patients of or on the waiting list of the Tavistock clinic, Professor Biggs found that the suicide rate was not higher among those on the clinic's waiting list (and thus as-yet untreated), than for those who were patients under care. (Biggs 2022b.) And as corrected, Bränström and Pachankis similarly acknowledge that their review of records of GD patients "demonstrated no advantage of surgery in relation to . . . hospitalizations following suicide attempts." (I assume for this purpose that attempts that result in hospitalization are judged to be so serious as to

predict a high rate of future suicide if not successfully addressed.")[12] Long-term life in a transgender identity, however, correlates with very high rates of completed suicide.

165. As with mental health generally, the patient, parent, or clinician fearing the risk of suicide must consider not just the next month or year, but a life course perspective.

166. There are now four long-term studies that analyze completed suicide among those living in transgender identities into adulthood. The results vary significantly but are uniformly highly negative. Dhejne reported a long-term follow-up study of subjects after sex reassignment surgery. Across the multi-year study, subjects who had undergone SRS committed suicide at 19.1 times the expected rate compared to general population controls matched by age and both sexes. MtF subjects committed suicide at 13.9 times the expected rate, and FtM subjects committed suicide at 40.0 times the expected rate. (Dhejne et al. 2011 Supplemental Table S1.)

167. Asscheman, also writing in 2011, reported results of a long-term follow-up of all transsexual subjects of the Netherlands' leading gender medicine clinic who started cross-sex hormones before July 1, 1997, a total of 1331

[12] Turban et al. (2020) has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

patients. Due to the Dutch system of medical and death records, extensive follow-up was achieved. Median follow-up period was 18.5 years. The mortality rate among MtF patients was 51% higher than among the age-matched general population; the rate of completed suicide among MtF patients was six times that of the age- matched general population. (Asscheman et al. 2011.)

168. Importantly, Asscheman et al. found that "No suicides occurred within the first 2 years of hormone treatment, while there were six suicides after 2-5 years, seven after 5-10 years, and four after more than 10 years of CSH treatment at a mean age of 41.5 years." (Asscheman et al. 2011 at 637-638.) This suggests that studies that follow patients for only a year or two after treatment are insufficient. Asscheman et al.'s data suggest that such short-term follow-up is engaging only with an initial period of optimism, and will simply miss the feelings of disillusion and the increase in completed suicide that follows in later years.

169. A retrospective, long-term study published in 2020 of a very large cohort (8263) of patients referred to the Amsterdam University gender clinic between 1972 and 2017 found that the annual rate of completed suicides among the transgender subjects was "three to four times higher than the general Dutch population." "[T]he incidence of observed suicide deaths was almost equally distributed over the different stages of treatment." The authors concluded that "vulnerability for suicide occurs similarly in the different stages of transition."

(Wiepjes et al. 2020.) In other words, neither social nor medical transition reduced the rate of suicide.

170. As with Asscheman et al., Wiepjes et al. found that the median time between start of hormones and suicide (when suicide occurred) was 6.1 years for natal males, and 6.9 years for natal females. Again, short- or even medium-term studies will miss this suicide phenomenon.

171. A 2021 study analyzed the case histories of a cohort of 175 gender dysphoria patients treated at one of the seven UK adult gender clinics who were "discharged" (discontinued as patients) within a selected one-year period. The authors reported the rather shocking result that 7.7% (3/39) of natal males who were diagnosed and admitted for treatment, and who were between 17 and 24 years old, were "discharged" because they committed suicide *during* treatment. (Hall et al. 2021, Table 2.)

172. None of these studies demonstrates that the hormonal or surgical intervention *caused* suicide. That is possible, but as we have seen, the population that identifies as transgender suffers from a high incidence of comorbidities that correlate with suicide. What these studies demonstrate—at the least—is that this remains a troubled population in need of extensive and careful psychological care that they generally do not receive, and that neither hormonal nor surgical transition and "affirmation" resolve their underlying problems and put them on the path to a stable and healthy life.

173. In sum, claims that affirmation will reduce the risk of suicide for children and adolescents are not based on science. Instead, transition of any sort must be justified, if at all, as a life-enhancing measure, not a lifesaving measure. (Levine 2016 at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

X. HORMONAL INTERVENTIONS ARE EXPERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.

174. A number of voices in the field assert that puberty blockers act merely as a "pause" in the process of puberty-driven maturation, suggesting that this hormonal intervention has been proven to be fully reversible. This is also an unproven belief.

175. On the contrary, no studies have been done that meaningfully demonstrate that either puberty blockers or cross-sex hormones, as prescribed for gender dysphoria, are safe in other than the short run. No studies have attempted to determine whether the effects of puberty blockers, as currently being prescribed for gender dysphoria, are fully reversible. There are only pronouncements. In fact, there are substantial reasons for concern that these hormonal interventions are not safe. Multiple researchers have expressed concern that the full range of possible harms have not even been correctly conceptualized.

176. Because, as I have explained in Section VI, recent evidence demonstrates that pre- pubertal social transition almost always leads to progression

on to puberty blockers which in turn almost always leads to the use of cross-sex hormones, physicians bear the ethical responsibility for a thorough informed consent process for parents and patients that includes this fact and its full implications. Informed consent does not mean sharing with the parents and patients what the doctor believes: it means sharing what is known and what is not known about the intervention. So much of what doctors believe is based on mere trust in what they have been taught. Neither they themselves nor their teachers may be aware of the scientific foundation and scientific limitations of what they are recommending.

A. Use of puberty blockers has not been shown to be safe or reversible for gender dysphoria.

177. As I noted above, the recent very thorough literature review performed for the British NHS concluded that *all* available clinical evidence relating to "safety outcomes" from administration of puberty blockers for gender dysphoria is of "very low certainty." (NHS 2020a at 6.)

178. In its 2017 Guidelines, the Endocrine Society cautioned that "in the future we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols" including "careful assessment of . . . the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development)." (Hembree et al. 2017 at 3874.) No such "careful" or

"rigorous" evaluation of these very serious safety questions has yet been done.

179. Some advocates assume that puberty blockers are "safe" because they have been approved by the Food and Drug Administration (FDA) for use to treat precocious puberty—a rare condition in which the puberty process may start at eight or younger. No such conclusion can be drawn. As the "label" for Lupron (one of the most widely prescribed puberty blockers) explains, the FDA approved the drug only *until* the "age was appropriate for entry into puberty." The study provides no information at all as to the safety or reversibility of instead *blocking* healthy, normally-timed puberty's beginning, and *throughout* the years that body-wide continuing changes normally occur. Given the physical, social, and psychological dangers to the child with precocious puberty, drugs like Lupron are effective in returning the child to a puerile state like their peers without a high incidence of significant side effects—that is, they are "safe" to reverse the condition. But use of drugs to suppress normal puberty has multiple organ system effects whose long-term consequences have not been investigated.

180. Systematic data reviews are scientifically more reliable than individual reports with definable methodologic limitations Without quoting extensively from the reviews done by Sweden, Finland, UK, and McMasters University, suffice it to say that their conclusions agree that the risks of puberty suppression and cross-sex hormones outweigh the possible benefits. They also point to the great unexplained increase in incidence of gender dysphoria, the

increased incidence of detransition and regret, and the lack of evidence of efficacy.[13](Swedish National Board of Health and Welfare, 2022).

181. **Fertility**: The Endocrine Society Guidelines rightly say that research is needed into the effect of puberty blockade on "gonadal function" and "sexual development." The core purpose and function of puberty blockers is to prevent the maturation of the ovaries or testes, the sources of female hormones and male hormones when stimulated by the pituitary gland. From this predictable process fertility is accomplished within a few years. Despite widespread assertions that puberty blockers are "fully reversible," there has been no study published on the critical question of whether patients ever develop normal levels of fertility if puberty blockers are terminated after a "prolonged delay of puberty." The 2017 Endocrine Society Guidelines are correct that are no data on achievement of fertility "following prolonged gonadotropin suppression" (that is, puberty blockade). (Hembree et al. 2017 at 3880.)

182. **Bone strength**: Multiple studies have documented adverse effects from puberty blockers on bone density. (Klink et al. 2015; Vlot et al. 2016; Joseph et al. 2019.) The most recent found that after two years on puberty blockers, the bone density measurements for a significant minority of the children had declined to clinically concerning levels. Density in the spines of some subjects fell to a level found in only 0.13% of the population. (Biggs 2021.) Some other studies have

[13] https:/www.sociialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-7799.pdf

found less concerning effects on bone density. While the available evidence remains limited and conflicting, it is not possible to conclude that the treatment is "safe."

183. **Brain development:** Important neurological growth and development in the brain occurs across puberty. The anatomic and functional effect on brain development of blocking the natural puberty process has not been well studied. A prominent Australian clinical team recently expressed concern that "no data were (or are) available on whether delaying the exposure of the brain to a sex steroid affects psychosexual, cognitive, emotional, or other neuropsychological maturation." (Kozlowska et al. 2021 at 89.) In my opinion, given the observed correlation between puberty and brain development, the default hypothesis must be that there *would* be a negative impact. For the purpose of protecting patients all over the world, the burden of proof should be on advocates to first demonstrate to a reasonable degree of certainty that brain structure and its measurable cognitive and affect processing are not negatively affected. This recalls the ethical principle: Above All Do No Harm.

184. The Endocrine Society Guidelines acknowledge as much, stating that side effects of pubertal suppression "may include . . . unknown effects on brain development," that "we need more rigorous evaluations of . . . the effects of prolonged delay of puberty in adolescents on . . . the brain (including effects on cognitive, emotional, social, and sexual development)," and stating that "animal

data suggests there may be an effect of GnRH analogs [puberty blockers] on cognitive function." (Hembree et al. 2017 at 3874, 3882, 3883.) Given this concern, one can only wonder why this relevant question has not been scientifically investigated in a large group of natal males and females.

185. There has been a longitudinal study of one natal male child, assessed before, and again 20 months after, puberty suppression was commenced. It reported a reduction in the patient's "global IQ," measured an anomalous absence of certain structural brain development expected during normal male puberty, and hypothesized that "a plausible explanation for the G[lobal] IQ decrease should consider a disruption of the synchronic [i.e., appropriately timed] development of brain areas by pubertal suppression." (Schneider et al. 2017 at 7.) This should cause parents and practitioners serious concern.

186. Whether any impairment of brain development is "reversed" upon later termination of puberty blockade has, to my knowledge, not been studied at all. As a result, assertions by medical or mental health professionals that puberty blockade is "fully reversible" are unjustified and based on hope rather than science.

187. Without a number of additional case studies—or preferably statistically significant clinical studies—two questions remain unanswered: Are there brain anatomic or functional impairment from puberty blockers? And are the documented changes reversed over time when puberty blockers are stopped? With

these questions unanswered, it is impossible to assert with certainty that the effects of this class of medications are "fully reversible." Such an assertion is another example of ideas based on beliefs rather than on documentation, on hope not science.

188. **Psycho-social harm**: Puberty is a time of stress, anxiety, bodily discomfort during physical development, and identity formation for *all* humans. No careful study has been done of the long-term impact on the young person's coping skills, interpersonal comfort, and intimate relationships from remaining puerile for, e.g., two to five years while one's peers are undergoing pubertal transformations, and of then undergoing an artificial puberty at an older age. However, pediatricians and mental health professionals hear of distress, concern, and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines witnessing their peers developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine 2018 at 9.) Social anxiety and social avoidance are common findings in the evaluation of trans-identified children and teens. Are we expected to believe that creating years of being further different than their peers has no lasting internal consequences? Do we ignore Adolescent Psychiatry's knowledge of the importance of peer groups among adolescents?

189. We simply do not know what all the psychological impacts of NOT grappling with puberty at the ordinary time may be, because it has not been studied. And we have no information as to whether that impact is "fully reversible."

190. In addition, since the overwhelming proportion of children who begin puberty blockers continue on to cross-sex hormones, it appears that there is an important element of "psychological irreversibility" in play. The question of to what extent the physical and developmental impacts of puberty blockers might be reversible is an academic one, if psycho- social realities mean that very few patients well ever be able to make that choice once they have started down the road of social transition and puberty blockers.

B. Use of cross-sex hormones in adolescents for gender dysphoria has not been shown to be medically safe except in the short term.

191. As with puberty blockers, all evidence concerning the safety of extended use of cross-sex hormones is of "very low quality." The U.K. NICE evidence review cautioned that "the safety profiles" of cross-sex hormone treatments are "largely unknown," and that several of the limited studies that do exist reported high numbers of subjects "lost to follow-up," without explanation—a worrying indicator. (NICE 2020b.)

192. The 2020 Cochrane Review reported that: "We found insufficient evidence to determine the . . . safety of hormonal treatment approaches for

transgender women in transition." (Haupt et al. 2020 at 4.) Even the Endocrine Society tagged all its recommendations for the administration of cross-sex hormones as based on "low quality evidence." (Hembree et al. 2017 at 3889.)

193. **Sterilization**: It is undisputed, however, that harm to the gonads is an expected effect, to the extent that it must be assumed that cross-sex hormones will sterilize the patient. Thus, the Endocrine Society 2017 Guidelines caution that "[p]rolonged exposure of the testes to estrogen has been associated with testicular damage," that "[r]estoration of spermatogenesis after prolonged estrogen treatment has not been studied," and that "[i]n biological females, the effect of prolonged treatment with exogenous testosterone upon ovarian function is uncertain." (Hembree et al. 2017 at 3880.) [14]

194. The Guidelines go on to recommend that the practitioner counsel the patient about the (problematic and uncertain) options available to collect and preserve fertile sperm or ova before beginning cross-sex hormones. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender

[14] *See also* Guss et al. 2015 at 4 ("a side effect [of cross-sex hormones] may be infertility") and at 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman et al. 2015 at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

transition for any patient. What has been documented is te low rate of acceptance of banking sperm or ova in this population.

195. **Sexual response**: Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who did not go through puberty consistent with their sex and are then put on cross-sex hormones face significantly diminished sexual response as they enter adulthood and are unable ever to experience orgasm. In the case of males, the cross-sex administration of estrogen limits penile genital growth and function. In the case of females, prolonged exposure to exogenous testosterone impairs vaginal function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine 2018 at 6.) At the same time, prolonged exposure of females to exogenous testosterone often increases sexual drive to a distracting degree. It is likely that parents and physicians are uncomfortable discussing any aspects of genital sexual activity with patients. And these young often interpersonally sexually inexperienced patients are both too embarrassed to talk about the subject and too young to seriously consider the topic.

196. **Cardiovascular harm**: Several researchers have reported that cross-sex hormones increase the occurrence of various types of cardiovascular disease, including strokes, blood clots, and other acute cardiovascular events. (Getahun et al. 2018; Guss et al. 2015; Asscheman et al. 2011.) With that said, I agree with the

conclusion of the Endocrine Society committee (like that of the NICE Evidence Review) that: "A systematic review of the literature found that data were insufficient (due to very low–quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or venous thromboembolism in transgender males. Future research is needed to ascertain the potential harm of hormonal therapies." (Hembree et al. 2017 at 3891.) Future research questions concerning long-term harms need to be far more precisely defined. The question of whether cross-sex hormones are safe for adolescents and young adults cannot be answered by analogies to hormone replacement therapy in menopausal women (which is not a cross-sex usage). Medicine has answered safety questions for menopausal women in terms of cancer and cardiovascular safety: at what dose, for what duration, and at what age range. The science of endocrine treatment of gender dysphoric youth is being bypassed by short-term clinical impressions of safety even though physicians know that cardiovascular and cancer processes often develop over many years.

197. Further, in contrast to administration for menopausal women, hormones begun in adolescence are likely to be administered for four to six decades. The published evidence of adverse impact, coupled with the lack of data sufficient to reach a firm conclusion, make it irresponsible to assert that cross-sex hormones "are safe."

198. **Harm to family and friendship relationships:** As a psychiatrist, I recognize that mental health is a critical part of health generally, and that relationships cannot be separated from and profoundly impact mental health. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine 2017 at 5.) My concerns about this are based on decades of observations in my professional work with patients and their families. It is important to recognize that the tradition throughout medicine is the focus on the patient. This is true in adolescent medicine as well and seems natural and self-evident. However, when a trans identity occurs in a family, every member—parents, siblings, grandparents, etc—is affected. I am used to watching parents become depressed, siblings take sides, and family dysfunction increase. It is rare to find a medical or mental health professional whose work reflects that each of these family members are deeply connected and share in the uncertainties that are embedded in any trans identity.

199. **Sexual-romantic harms associated with transition:** After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential mates lose interest. When a trans person does not pass well, options are likely further diminished. But regardless of a person's appearance, these adults soon learn that many of their dates are looking for exotic sexual experiences rather than genuinely loving relationships. (Levine 2017 at 5, 13; Levine 2013 at 40.)

C. The timing of harms.

200. The multi-year delay between start of hormones and the spike in completed suicide observed by Professor Biggs in the Tavistock data (as discussed in Section VIII above) warns us that the safety and beneficence of these treatments cannot be judged based on short- term studies, or studies that do not continue into adulthood. Similarly, several of the harms that I discuss above would not be expected to manifest until the patients reaches at least middle-age. For example, stroke or other serious cardiovascular event is a complication that is unlikely to manifest during teen years even if its likelihood over the patient's lifetime has been materially increased via obesity, lipid abnormalities, and smoking. Regret over sterilization or over an inability to form a stable romantic relationship may occur sooner. Psychological challenges of being a trans adult may become manifest after the medical profession is only doing routine follow up care—or, in

many cases, has lost contact with the patient altogether. Because few, if any, clinics in this country are conducting systematic long-term follow-up with their child and adolescent patients, the doctors who counsel, prescribe, or perform hormonal and surgical therapies are unlikely ever to become aware of the later negative life impacts, however severe. These concerns are compounded by the findings in the recent "detransitioner" research that 76% did not inform their clinicians of their detransition. (Littman 2021.)

201. The possibility that steps along the transition and affirmation pathway, while lessening the pain of gender dysphoria in the short term, could lead to additional sources of crippling emotional and psychological pain, are too often not considered by advocates of social transition and not considered at all by the trans child. (Levine 2016 at 243.) Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view. Hopefully, so will the child's physician.

202. Individual patients often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health co-morbidities. In this way, transition can prevent them from mastering personal challenges at the appropriate time or directly

addressing conditions that require treatment. When the hoped-for "vanishing" of other mental health or social difficulties does not occur, disappointment, distress, and depression may ensue. It is noteworthy that half of the respondents to the larger "detransitioner" survey reported that their transition had not helped the gender dysphoria, and 70% had concluded that their gender dysphoria was related to other issues. (Vandenbussche 2021.) Without the clinical experience of monitoring the psychosocial outcomes of these young patients as they age into adulthood, many such professionals experience no challenge to their affirmative beliefs. But medical and mental health professionals who deliver trans affirmative care for those with previous and co-existing mental health problems have an ethical obligation to inform themselves, and to inform patients and parents, that these dramatic treatments are not a panacea.

203. In sum, whether we consider physical or mental health, science does not permit us to say that either puberty blockers or cross-sex hormones are "safe," and the data concerning the mental health of patients before, during, and after such treatments strongly contradict the assertion that gender dysphoria is "easily managed."

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct. Executed this 16th day of February, 2023.

Stephen B. Levine, M.D.

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Wiepjes, C. M., den Heijer, M., Bremmer, M. A., Nota, N. M., Blok, C. J. M., Coumou, B. J. G., & Steensma, T. D. (2020). *Trends in suicide death risk in transgender people: Results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017)*. ACTA PSYCHIATRICA SCANDINAVICA *141*(6) 486–491.

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Zucker, K. (2019). *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*. ARCHIVES OF SEXUAL BEHAVIOR 48(7) 1983–1992.

Zucker, K. (2020). *Different strokes for different folks.* CHILD ADOLESC MENT HEALTH 25(1): 36–37. https://doi: 10.1111/camh.12330.

Exhibit “A”

Stephen B. Levine, M.D. **Curriculum Vita**
February, 2022

Brief Introduction

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the author or coauthor of numerous books on topics relating to human sexuality and related relationship and mental health issues. Dr. Levine has been teaching, providing clinical care, and writing since 1973, and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. Dr. Levine has been co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992 to the present. He received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

Personal Information

Date of birth 1/14/42

Medical license no. Ohio 35-03-0234-L

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973- Assistant Professor of Psychiatry

1979- Associate Professor

1982- Awarded tenure

1985- Full Professor

1993- Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award-1990 and 2010 (Residency program)

Visiting Professorships

- Stanford University-Pfizer Professorship program (3 days)–1995
- St. Elizabeth's Hospital, Washington, DC –1998
- St. Elizabeth's Hospital, Washington, DC--2002

Named to America's Top Doctors consecutively since 2001

Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops

Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof

2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit

2018—Albert Marquis Lifetime Achievement Award from Marquis Who's Who. (Exceling in one's field for at least twenty years)

Professional Societies

1971- American Psychiatric Association; fellow; #19909

2005- American Psychiatric Association, Distinguished Life Fellow

1973- Cleveland Psychiatric Society

1973- Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974-Society for Sex Therapy and Research

- 1987-89-President

1983- International Academy of Sex Research

1983- Harry Benjamin International Gender Dysphoria Association

- 1997-8 Chairman, Standards of Care Committee

1994- 1999 Society for Scientific Study of Sex

Community Boards

1999-2002 Case Western Reserve University Medical Alumni Association

1996-2001 Bellefaire Jewish Children's Bureau

1999-2001 Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

a. Archives of Sexual Behavior
b. Annals of Internal Medicine
c. British Journal of Obstetrics and Gynecology
d. JAMA
e. Diabetes Care
f. American Journal of Psychiatry
g. Maturitas
h. Psychosomatic Medicine
i. Sexuality and Disability
j. Journal of Nervous and Mental Diseases
k. Journal of Neuropsychiatry and Clinical Neurosciences
l. Neurology
m. Journal Sex and Marital Therapy
n. Journal Sex Education and Therapy
o. Social Behavior and Personality: an international journal (New Zealand)
p. International Journal of Psychoanalysis
q. International Journal of Transgenderism
r. Journal of Urology
s. Journal of Sexual Medicine
t. Current Psychiatry
u. International Journal of Impotence Research
v. Postgraduate medical journal
w. Academic Psychiatry

Prospectus Reviewer

a. Guilford

b. Oxford University Press

c. Brunner/Routledge

d. Routledge

Administrative Responsibilities

Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

Co-leader of case conferences at DELRLLC.com

Expert testimony at trial or by deposition within the last 4 years

Provided expert testimony for Massachusetts Dept. of Corrections in its defense of a lawsuit brought by prisoner Katheena Soneeya, including by deposition in October 2018, and in-court testimony in 2019.

Provided expert testimony by deposition and at trial in *In the Interests of the Younger Children* (Dallas, TX), 2019.

Testified in an administrative hearing in *In the matter of Rhys & Lynn Crawford* (Washington State), March 2021.

Testified multiple times in juvenile court in *In the matter of Asha Kerwin* (Tucson, Arizona), 2021.

Provided expert testimony by deposition in *Kadel et al v. Folwell et al.* (North Carolina), 2021.

Consultancies

Massachusetts Department of Corrections—evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010.

California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies.

Virginia Department of Corrections –evaluation of an inmate.

New Jersey Department of Corrections—evaluation of an inmate.

Idaho Department of Corrections—workshop 2016.

Grant Support/Research Studies

TAP–studies of Apomorphine sublingual in treatment of erectile dysfunction.

Pfizer–Sertraline for premature ejaculation.

Pfizer–Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction.

NIH- Systemic lupus erythematosis and sexuality in women.

Sihler Mental Health Foundation

a. Program for Professionals
b. Setting up of Center for Marital and Sexual Health
c. Clomipramine and Premature ejaculation
d. Follow-up study of clergy accused of sexual impropriety
e. Establishment of services for women with breast cancer

Alza–controlled study of a novel SSRI for rapid ejaculation.

Pfizer–Viagra and self-esteem.

Pfizer- double-blind placebo control studies of a compound for premature ejaculation.

Johnson & Johnson – controlled studies of Dapoxetine for rapid ejaculation.

Proctor and Gamble: multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement.

Lilly-Icos—study of Cialis for erectile dysfunction.

VIVUS – study for premenopausal women with FSAD.

Palatin Technologies- studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration.

Medtap – interview validation questionnaire studies.

HRA- quantitative debriefing study for Female partners os men with premature ejaculation, Validation of a New Distress Measure for FSD.

Boehringer-Ingelheim- double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder.

Biosante- studies of testosterone gel administration for post menopausal women with HSDD.

J&J a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.

UBC-Content validity study of an electronic FSEP-R and FSDS-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD.

National registry trial for women with HSDD.

Endoceutics—two studies of DHEA for vaginal atrophy and dryness in post menopausal women.

Palatin—study of SQ Bremelanotide for HSDD and FSAD.

Trimel- a double-blind, placebo controlled study for women with acquired female orgasmic disorder.

S1 Biopharma- a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD.

HRA – qualitative and cognitive interview study for men experiencing PE.

Publications

A) Books

1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985

2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988; Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997

3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992

4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998

5) Editor, Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.

6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003

1. 2006 SSTAR Book Award: Exceptional Merit

7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006

8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals, 2nd edition. Routledge, New York, 2010.

9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.

10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016

B) Research and Invited Papers

When his name is not listed in a citation, Dr. Levine is either the solo or the senior author.

1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73

2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26

3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2

4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974:37:9-11.

5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334

6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453

7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579

8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238

9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427

10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350

11) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5

12) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92

13) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the dysfunction? Sexual Medicine Today 1977;1:13

14) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977

15) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597

16) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977;3:177-186

17) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15

18) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978;4:235-258

19) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978;113-958-962

20) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981;6:102-108

21) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113

22) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929

23) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8

24) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983;12:247-61

25) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173

26) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982;9:21-28

27) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982;8:316-324

28) Nymphomania. Female Patient 1982;7:47-54

29) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982;16:135-9

30) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62

31) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.

32) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

33) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984;86:412-418

34) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. Journal of Sex & Marital Therapy 1984;10:176-184

35) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984;13:287-9

36) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96

37) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-

38) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985

39) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI.

External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. Journal of Sex & Marital Therapy

40) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. Family Practice Research Journal 1988; 7:122-134

41) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987;13:35-44

42) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.

43) Lets talk about sex. National Hemophilia Foundation January, 1988

44) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988

45) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.

46) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. Urologic Clinics of North America 1988; 15(4):625-630

47) Bradley SJ, Blanchard R, Coates S, Green R, Levine S, Meyer-Bahlburg H, Pauly I, Zucker KJ. Interim report of the DSM-IV Subcommittee for Gender Identity Disorders. Archives of Sexual Behavior 1991;;20(4):333-43.

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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,

JASON WEIDA, in his official capacity as Secretary of the Florida Agency for Health Care Administration; and FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,

Defendants.

Civil Action No. 4:22-cv-00325-RH-MAF

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Expert Report of Paul W. Hruz, M.D., Ph.D.

Pursuant to 28 U.S.C. 1746, I declare:

1. I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this report. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit A to this report.

2. I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as Chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016. I am currently serving as Associate Fellowship Program Director at Washington University in St. Louis.

3. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. I also have a temporary license to practice telemedicine in Illinois during the COVID-19 pandemic. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.

4. I have published 62 scholarly articles over my academic career spanning over two decades. This includes peer-reviewed publications in the leading

journals in the fields of metabolism, cardiology, HIV, and ethics including the Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry and FASEB Journal. See Exhibit A.

5. I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports and PlosOne, assessing the quality of evidence that is put forward for publication. I have also been involved in the evaluation of clinical trials with colleagues. I have received over $4.6 million in governmental and non-governmental funding for scientific research including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J. Quick Award for Excellence in Biochemistry, the Eli Lilly Award for Outstanding Contribution to Drug Discovery, and the Julio V. Santiago Distinguished Scholar in Pediatrics Award.

6. During the more than 22 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington

University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents and clinical fellows in the practice of medicine.

7. My CV (Exhibit A) contains a complete list of the cases I have testified in as an expert witness either at trial or in deposition. Related to the litigation of issues of sex and gender, I have been designated as an expert witness in Joaquín Carcaño et al. v. Patrick McCrory (United States District Court, M.D. North Carolina), Jane Doe v. Board of Education of the Highland School District (United States District Court For the Southern District of Ohio Eastern Division, Case No. 2:16-CV-524), Adams v. St John's School Board (United States District Court For the Middle District of Florida, FL Civil Action No. 3:17-cv-00739-TJCJBT), Ashton Whitaker v. Kenosha Unified School District (United States District Court Eastern District of Wisconsin, Civ. Action No. 2:16-cv-00943), Terri Bruce v. State of South Dakota (The United States District Court District of South Dakota Western Division, Case No. 17-5080), Kadel vs. Falwell (The United States District Court For The Middle District Of North Carolina, Case No.: 1:19-cv-272-LCB-LPA), Brandt v Rutledge (The United States District Court Eastern District

of Arkansas Central Division, Case No. 4:21-CV-00450-JM), Eknes-Tucker vs Ivy (United States District Court Middle District of Alabama Northern Division, Case 2:22-cv-00184-LCB-SRW), D.H. et al. v. Snyder (United States District Court of Arizona, Case No. 4:20-cv-00335-SHR), Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children, and Bo v. Marshall (United States District Court For The Middle District Of Alabama Northern Division). I have also served as a science consultant or subjected written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (Bell v. Tavistock).

8. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

9. In my role as a scientist and as the Director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local, national, and international meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually

and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

10. In my 25 years of clinical practice, I have cared for children from birth to the completion of college in their early twenties who have a variety of hormone related diseases. This includes disorders of growth, puberty (both precocious and delayed), glucose homeostasis (both hypoglycemia and diabetes mellitus), adrenal function (both adrenal insufficiency and steroid excess), thyroid function, skeletal abnormalities, gonadal dysfunction (including polycystic ovarian syndrome and ovarian failure), hypopituitarism, and disorders of sexual development. Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for

this role based upon a special interest and professional knowledge and training in this patient population.

11. My opinions as detailed in this report are based upon my:

a. knowledge, training, and clinical experience in caring for thousands of patients over many years;
b. detailed methodological reviews of hundreds of relevant peer-reviewed science publications;
c. consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences;
d. publications in peer reviewed scientific journals;
e. editorial work for peer reviewed scientific journals; and,
f. peer reviewed research grant receipt and review work.

The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject, including hundreds of published, peer reviewed scientific research (and professional) articles.

12. My opinions and hypotheses in this matter are—as all expert reports—subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, and the limitations of social, biological, and medical science. I have not met with, or personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may

or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information.

Background on Sex and Gender

13. Sex is an objective biological trait intrinsically oriented toward specific roles in the conception and development of new members of a species. Both males and females contribute genetic information in distinct yet complimentary ways. Males have the role of delivering sperm produced by testes and the unique paternal DNA contained therein to a female. Females have the role of receiving this male genetic information to join with the maternal genetic information contained in ova produced by ovaries. Sex is not "assigned at birth"; it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades.

14. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appearance of the external genitalia is the primary methodology used by clinicians to

recognize sex. In cases where genital ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized. The measurement and assessment of biological sex has been documented by valid and reliable research published in credible journals, and is accepted by the relevant scientific community. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females).

15. For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality.

16. Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e., reproduction). Internal structures (e.g., gonad, uterus, vas deferens) normatively align in more than 99.9%+ of mammals with external genitalia, including humans.

17. Due to the complexity of the biological processes that are involved in normal sexual development, it is not surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births).[1] Defects can occur through either inherited or *de novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community.

18. The medical care of persons with DSDs is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to other diseases, diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal (e.g., assessments of objective, reliable evidence). In children with DSDs, characterization based upon phenotype alone does not reliably predict the sex chromosomes present nor does it necessarily correlate with potential for biological sexual function. Decisions on initial sex assignment in these very rare cases require detailed assessment of objective, reliable medical evidence by a team of expert

[1] See Sax, How common is Intersex? A response to Anne Fausto-Sterling, The Journal of Sex Research, 39:3, 174-178, DOI: 10.1080/00224490209552139 (2002).

medical providers. Previously, it was felt that a definitive sex assignment was necessary shortly after birth with the belief that this would allow patients with a disorder of sexual development to best conform to the assigned sex and so parents-caregivers could help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with confidence, a presumptive sex assignment is made. Factors used in making such decisions include karyotype (46XX, 46XY, or other), phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to a change in sex determination. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent.[2]

19. "Gender," a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions would therefore exist only in reference to subjective personal perceptions and feelings and societal expectations, not biology. The reliability and validity of various usages of the term "gender" is currently controversial and the relevant scientific community

[2] See Lee et al., Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care, Horm Res Paediatr 85, 158-180, doi:10.1159/000442975 (2016).

has accepted no use other than in relation to biological sex, which includes participate in activities related to reproduction. The dangers of incorrectly using the term "gender" in place of "sex" have been acknowledged by the Endocrine Society.[3]

20. "Gender identity" refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is controversial. There is no current worldwide definition of "gender identity" accepted by the relevant clinical communities. The measurement error rate for non-biological "gender identity" is unknown.

21. People who identify as "transgender" transiently or persistently experience a sex-discordant gender identity.[4]

Puberty

22. Puberty is "the morphological and physiological changes that occur in the growing boy or girl as the gonads change from the infantile to the adult state. These changes involve nearly all the organs and structures of the body but they do not begin at the same age nor take the same length of time to reach completion in

[3] See Bhargava et al., Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement, 42 *Endocrine reviews*, No. 3, pp. 219-58, https://doi.org/10.1210/endrev/bnaa034 (2021).
[4] APA, DSM-5, 451.

all individuals. Puberty is not complete until the individual has the physical capacity to conceive and successfully rear children."[5]

23. The principal manifestations of puberty are:

- The adolescent growth spurt; i.e., an acceleration followed by a deceleration of growth in most skeletal dimensions and in many internal organs.
- The development of the gonads.
- The development of the secondary reproductive organs and the secondary sex characters.
- Changes in body composition, i.e., in the quantity and distribution of fat in association with growth of the skeleton and musculature.
- Development of the circulatory and respiratory systems leading, particularly in boys, to an increase in strength and endurance.[6]

24. The ability to physically conceive children is made possible by the maturation of the primary sex characteristics, the organs and structures that are involved directly in reproduction. In boys, these organs and structures include the scrotum, testes, and penis while in girls they include the ovaries, uterus, and

[5] William A. Marshall and James M. Tanner, "Puberty," in Human Growth: A Comprehensive Treatise, Second Edition, Volume 2, eds. Frank Falkner and James M. Tanner (New York: Springer, 1986), 171.
[6] *Id.* at 171–72.

vagina. In addition to these primary sex characteristics, secondary sex characteristics also develop during puberty — the distinctive physical features of the two sexes that are not directly involved in reproduction. Secondary sex characteristics that develop in girls include "the growth of breasts and the widening of the pelvis" and in boys "the appearance of facial hair and the broadening of shoulders," while other patterns of body hair and changes in voice and skin occur during puberty in both girls and boys.[7]

25. Physicians characterize the progress of puberty by marking the onset of different developmental milestones. The earliest visible event, the initial growth of pubic hair, is known as "pubarche"; it occurs between roughly ages 8 and 13 in girls, and between ages 9.5 and 13.5 in boys.[8] In girls, the onset of breast development, known as "thelarche," occurs around the same time as pubarche.[9] "Menarche" is another manifestation of sexual maturation in females, referring to the onset of menstruation, which typically occurs at around 13 years of age and is generally a sign of the ability to conceive.[10] Roughly corresponding to menarche in girls is "spermarche" in boys; this refers to the initial presence of viable sperm in semen,

[7] Robert V. Kail and John C. Cavanaugh, Human Development: A Life-Span View, Seventh Edition (Boston, Mass.: Cengage Learning, 2016), 276.
[8] Jamie Stang and Mary Story, "Adolescent Growth and Development," in Guidelines for Adolescent Nutrition Services, eds. Jamie Stang and Mary Story (Minneapolis, Minn.: University of Minnesota, 2005), 4.
[9] *Id.* at 3.
[10] Marshall and Tanner, "Puberty," 191–192.

which also typically occurs around 13.[11] (The "-arche" in the terms for these milestones comes from the Greek for beginning or origin.)

26. Scientists distinguish three main biological processes involved in puberty: adrenal maturation, gonadal maturation, and somatic growth acceleration. "Adrenarche"—the beginning of adrenal maturation—begins between ages 6 and 9 in girls, and ages 7 and 10 in boys. The hormones produced by the adrenal glands during adrenarche are relatively weak forms of androgens (masculinizing hormones) known as dehydroepiandrosterone and dehydroepiandrosterone sulfate. These hormones are responsible for signs of puberty shared by both sexes: oily skin, acne, body odor, and the growth of axillary (underarm) and pubic hair.[12]

27. "Gonadarche"—the beginning of the process of gonadal maturation—normally occurs in girls between ages 8 and 13 and in boys between ages 9 and 14.[13] The process begins in the brain, where specialized neurons in the hypothalamus secrete gonadotropin-releasing hormone (GnRH).[14] This hormone is secreted in a cyclical or "pulsatile" manner—the hypothalamus releases bursts of GnRH,

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[11] *Id.* at 185.
[12] Sharon E. Oberfield, Aviva B. Sopher, and Adrienne T. Gerken, "Approach to the Girl with Early Onset of Pubic Hair," Journal of Clinical Endocrinology and Metabolism 96, no. 6 (2011): 1610–1622, http://dx.doi.org/10.1210/jc.2011-0225.
[13] Selma Feldman Witchel and Tony M. Plant, "Puberty: Gonadarche and Adrenarche," in Yen and Jaffe's Reproductive Endocrinology, Sixth Edition, eds. Jerome F. Strauss III and Robert L. Barbieri (Philadelphia, Penn.: Elsevier, 2009), 395.
[14] Allan E. Herbison, "Control of puberty onset and fertility by gonadotropin-releasing hormone neurons," Nature Reviews Endocrinology 12 (2016): 452, http://dx.doi.org/10.1038/nrendo.2016.70.

and when the pituitary gland is exposed to these bursts, it responds by secreting two other hormones.[15] These are luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which stimulate the growth of the gonads (ovaries in women and testes in men).[16] (The "follicles" that the latter hormone stimulates are not hair follicles but ovarian follicles, the structures in the ovaries that contain immature egg cells.) In addition to regulating the maturation of the gonads and the production of sex hormones, these two hormones also play an important role in regulating aspects of human fertility.[17]

28. As the gonadal cells mature under the influence of LH and FSH, they begin to secrete androgens (masculinizing sex hormones like testosterone) and estrogens (feminizing sex hormones).[18] These hormones contribute to the further development of the primary sex characteristics (the uterus in girls and the penis and scrotum in boys) and to the development of secondary sex characteristics (including breasts and wider hips in girls, and wider shoulders, breaking voices, and increased muscle mass in boys). The ovaries and testes both secrete androgens as

[15] *Id.* at 453.
[16] *Id.* at 454.
[17] *Id.* at 452.
[18] Michael A. Preece, "Prepubertal and Pubertal Endocrinology," in Human Growth: A Comprehensive Treatise, Volume 2, 212.

well as estrogens, however the testes secrete more androgens and the ovaries more estrogens.[19]

29. The gonads and the adrenal glands are involved in two separate but interrelated pathways (or "axes") of hormone signaling. These are the hypothalamic-pituitary-gonadal (HPG) axis and the hypothalamic-pituitary-adrenal (HPA) axis.[20] Though both play essential roles in puberty, it is, as just noted, the HPG axis that results in the development of the basic reproductive capacity and the external sex characteristics that distinguish the sexes.[21]

30. The third significant process that occurs with puberty, the somatic growth spurt, is mediated by increased production and secretion of human growth hormone, which is influenced by sex hormones secreted by the gonads (both testosterone and estrogen). Similar to the way that the secretion of GnRH by the hypothalamus induces the pituitary gland to secrete FSH and LH, in this case short

[19] Rex A. Hess, "Estrogen in the adult male reproductive tract: A review," Reproductive Biology and Endocrinology 1, (2003), https://dx.doi.org/10.1186/1477-7827-1-52; Henry G. Burger, "Androgen production in women," Fertility and Sterility 77 (2002): 3–5, http://dx.doi.org/10.1016/S0015-0282(02)02985-0.
[20] Russell D. Romeo, "Neuroendocrine and Behavioral Development during Puberty: A Tale of Two Axes," Vitamins and Hormones 71 (2005): 1–25, http://dx.doi.org/10.1016/S0083-6729(05)71001-3.
[21] Margaret E. Wierman and William F. Crowley, Jr., "Neuroendocrine Control of the Onset of Puberty," in Human Growth, Volume 2, 225.

pulses of a hormone released by the hypothalamus cause the pituitary gland to release human growth hormone.[22] This process is augmented by testosterone and estrogen. Growth hormone acts directly to stimulate growth in certain tissues, and also stimulates the liver to produce a substance called "insulin-like growth factor 1," which has growth-stimulating effects on muscle.[23]

31. The neurological and psychological changes occurring in puberty are less well understood than are the physiological changes. Men and women have distinct neurological features that may account for some of the psychological differences between the sexes, though the extent to which neurological differences account for psychological differences, and the extent to which neurological differences are caused by biological factors like hormones and genes (as opposed to environmental factors like social conditioning), are all matters of debate.

32. Scientists distinguish between two types of effects hormones can have on the brain: organizational effects and activational effects. Organizational effects are the ways in which hormones cause highly stable changes in the basic architecture of different brain regions. Activational effects are the more immediate and temporary effects of hormones on the brain's activity. During puberty, androgens

[22] Preece, *supra*, at 218–19.
[23] Udo J. Meinhardt and Ken K. Y. Ho, "Modulation of growth hormone action by sex steroids," Clinical Endocrinology65, no. 4 (2006): 414, http://dx.doi.org/10.1111/j.1365-2265.2006.02676.x.

and estrogens primarily have activating effects, but long before then they have organizational effects in the brains of developing infants and fetuses.[24]

33. In sum: Puberty involves a myriad of complex, related, and overlapping physical processes, occurring at various points and lasting for various durations. During this period of life, adrenarche and changes in the secretion of growth hormone contribute to the child's growth and development. With gonadarche, the maturation of sex organs begins and with normal maturation will lead to the emergence of reproductive capacity, as well as the development of the other biological characteristics that distinguish males and females.

Pediatric Endocrine Disorders and Treatments

34. The field of endocrinology is directed toward the care of hormone related diseases. Pediatric endocrine diseases include disorders of glucose regulation (hypoglycemia and diabetes mellitus), disorders of thyroid function (hyper and hypothyroidism), disorders of growth (e.g. short stature, acromegaly, obesity and poor weight gain), disorders of sexual development and function (e.g. genital am-

[24] Herting MM, Sowell ER. Puberty and structural brain development in humans. Front Neuroendocrinol. 2017 Jan;44:122-137. doi: 10.1016/j.yfrne.2016.12.003; Hornung J, Lewis CA, Derntl B. Sex hormones and human brain function. Handb Clin Neurol. 2020;175:195-207. doi: 10.1016/B978-0-444-64123-6.00014-X

biguity, precocious and delayed puberty, hypogonadism, polycystic ovarian syndrome), disorders of adrenal function (e.g. adrenal insufficiency and Cushing's syndrome), disorders of pituitary function, lipid disorders, and disorders of bone and mineral metabolism. For all of these conditions, there are objective physical and biochemical criteria for diagnosis and treatment with well-established normal reference ranges for hormones and metabolites.

35. Hormone interventions to suppress puberty were not developed for the purpose of treating children with gender dysphoria. Rather, they were first used as a way to normalize puberty for children who undergo puberty too early, a condition known as "precocious puberty."

36. For females, precocious puberty is defined by the onset of puberty before age 8, while for males it is defined as the onset of puberty before age 9.[25] Premature thelarche (the appearance of breast development) is usually the first clinical sign of precocious puberty in girls. For males, precocious puberty is

[25] Karen Oerter Klein, "Precocious Puberty: Who Has It? Who Should Be Treated?," Journal of Clinical Endocrinology and Metabolism 84, no. 2 (1999): 411, http://doi.org/10.1210/jcem.84.2.5533. See also: Frank M. Biro et al., "Onset of Breast Development in a Longitudinal Cohort," Pediatrics 132, no. 6 (2013): 1019–1027, http://dx.doi.org/10.1542/peds.2012-3773; Carl-Joachim Partsch and Wolfgang G. Sippell, "Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens," Human Reproduction Update 7, no. 3 (2001): 293, http://dx.doi.org/10.1111/j.1600-0463.2001.tb05760.x.

marked by premature testicular enlargement.[26] In addition to the psychological and social consequences that a child might be expected to suffer, precocious puberty can also lead to reduced adult height, since the early onset of puberty interferes with later bone growth.[27]

37. Precocious puberty is divided into two types, central precocious puberty (sometimes labeled "true precocious puberty") and peripheral precocious puberty (sometimes labeled "precocious pseudopuberty").[28] Central precocious puberty is caused by the early activation of the gonadal hormone pathway by GnRH, and is amenable to treatment by physicians. Peripheral precocious puberty, which is caused by secretion of sex hormones by the gonads or adrenal glands independent of signals from the pituitary gland, is less amenable to treatment. Effects of androgen or estrogen hypersecretion can be reduced by administration of drugs that block the activity of the sex hormone receptors. If a tumor is causing the disorder, surgical removal may be necessary.

38. Precocious puberty is rare, especially in boys. A recent Spanish study of central precocious puberty estimated the overall prevalence to be 19 in 100,000

[26] Anne-Simone Parent et al., "The Timing of Normal Puberty and the Age Limits of Sexual Precocity: Variations around the World, Secular Trends, and Changes after Migration," Endocrine Reviews 24, no. 5 (2011): 675, http://dx.doi.org/10.1210/er.2002-0019.
[27] Jean-Claude Carel et al., "Precocious puberty and statural growth," Human Reproduction Update 10, no. 2 (2004): 135, http://dx.doi.org/10.1093/humupd/dmh012.
[28] Partsch and Sippell, *supra*, at 294–95.

(37 in 100,000 girls affected, and 0.46 in 100,000 boys).[29] A Danish study of precocious puberty (not limited to central precocious puberty) found the prevalence to be between 20 to 23 per 10,000 in girls and less than 5 in 10,000 in boys.[30]

39. To diagnose central precocious puberty, hormones from the pituitary gland, LH and FSH, are objectively measured. This can sometime be done by measurement of baseline levels but often requires assessment after transient stimulation with GnRH. As discussed, these are two hormones that are made in the pituitary gland that signal to the gonads. In males, they lead to production of testosterone. In females, they lead to the production of estrogen. LH and FSH signaling are essential for normal sperm production and ovarian maturation in males and females, respectively.

40. Also subject to objective measurement when diagnosing and treating central precocious puberty are sex steroid hormones, either testosterone or estrogen, and bone growth.

41. Treatment for precocious puberty is somewhat counterintuitive. Rather than stopping the production of GnRH, physicians actually provide patients

[29] Leandro Soriano-Guillén et al., "Central Precocious Puberty in Children Living in Spain: Incidence, Prevalence, and Influence of Adoption and Immigration," Journal of Clinical Endocrinology and Metabolism 95, no. 9 (2011): 4307, http://dx.doi.org/10.1210/jc.2010-1025. In some cases, peripheral precocious puberty is caused by an underlying condition, such as a tumor, that can be treated.

[30] Grete Teilmann et al., "Prevalence and Incidence of Precocious Pubertal Development in Denmark: An Epidemiologic Study Based on National Registries," Pedriatics 116, no. 6 (2005): 1323, http://dx.doi.org/10.1542/peds.2005-0012.

more constant levels of synthetic GnRH (called GnRH analogues or GnRH agonists).[31] As discussed above, when produced endogenously (that is, by the body naturally), GnRH stimulates the pituitary gland to release gonad-stimulating hormones (gonadotropins, LH and FSH). When added exogenously, the additional GnRH "desensitizes" the pituitary, leading to a decrease in the secretion of gonadotropins, which in turn leads to the decreased maturation of and secretion of sex hormones by the gonads (ovaries and testes). The intent and effect of giving puberty blockers is identical when it is given to a male as when it is given to a female in this context: suppressing the secretion of gonadotropin hormones. Even the dosing is the same for males and females, and depends on the person's weight.

42. The first publication describing the use of GnRH analogues in children for precocious puberty appeared in 1981.[32] In the time since GnRH analogues were first proposed, they have become fairly well accepted as a treatment of precocious puberty, with one prominent GnRH analogue, Lupron, approved for that use by the FDA in 1993.[33] However, there remain some questions concerning the ef-

[31] William F. Crowley, Jr. et al., "Therapeutic use of pituitary desensitization with a long-acting LHRH agonist: a potential new treatment for idiopathic precocious puberty," Journal of Clinical Endocrinology and Metabolism 52, no. 2 (1981): 370–372, http://dx.doi.org/10.1210/jcem-52-2-370. (LHRH refers to "lutenizing hormone releasing hormone," another term for GnRH.)
[32] Crowley et al., *supra*, at 370–72.
[33] "Full Prescribing Information" for Lupron Depot-Ped, FDA.gov (undated), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020263s036lbl.pdf.

fectiveness of treatment with GnRH analogues. A 2009 consensus statement of pediatric endocrinologists concluded that GnRH analogues are an effective way to improve the height of girls with onset of puberty at less than 6 years of age, and also recommended the treatment be considered for boys with onset of precocious puberty who have compromised height potential.[34] Regarding the negative psychological and social outcomes associated with precocious puberty, the authors found that the available data were unconvincing, and that additional studies are needed.[35] Puberty blockers have recently been recognized to carry a risk of increased brain pressure that can adversely affect vision and cause severe headaches.[36]

43. When used to treat precocious puberty, the process of desensitization of the pituitary gland by synthetic GnRH is not permanent. After a patient stops taking the GnRH analogues, the pituitary will resume its normal response to the pulsatile secretion of GnRH by the hypothalamus, as evidenced by the fact that

[34] Jean-Claude Carel et al., "Consensus Statement on the Use of Gonadotropin-Releasing Hormone Analogs in Children," Pediatrics 123, no. 4 (2009): e753, http://dx.doi.org/10.1542/peds.2008-1783.
[35] *Id.*
[36] *Risk of pseudotumor cerebri added to labeling*, AAP (July 1, 2022), https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for.

children treated for precocious puberty using GnRH analogues will resume normal pubertal development, usually about a year after they withdraw from treatment.[37]

44. The goal of this treatment is to allow the child to have pubertal development enter the normal quiescence that is present at that age. This treatment helps to preserve their final adult height, by slowing the rate of bone age advancement. The goal is *not* to delay puberty beyond other children, as delaying too long can be adverse effects, including reduced bone marrow density, as discussed below.

45. In addition to being prescribed for children with precocious puberty, GnRH analogues have also been used in adults for a variety of indications, including hormone-sensitive tumors.[38] GnRH analogues have also been given to post-pubertal adolescents undergoing chemotherapy with drugs that can have toxic effects on the gonads.[39]

[37] Marisa M. Fisher, Deborah Lemay, and Erica A. Eugster, "Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant," The Journal of Pediatrics 164, no. 4 (2014): 3, http://dx.doi.org/10.1016/j.jpeds.2013.12.009.
[38] See Kumar & Sharma, Gonadotropin-Releasing Hormone Analogs: Understanding Advantages and Limitations, Journal of Human Reproductive Sciences 7, no. 3 (2014).
[39] Meli M, et al. Triptorelin for Fertility Preservation in Adolescents Treated With Chemotherapy for Cancer. J Pediatr Hematol Oncol. 40(4):269-276 (2018).

46. Sex steroids such as testosterone and estrogen are frequently used in the treatment of disorders of normal gonadal function. This includes hypogonadotropic hypogonadism, primary gonadal failure and delayed puberty.[40] In each of these conditions, there are objective laboratory tests that are used to diagnose these conditions and monitor response to treatment. Deficiency of sex steroids has bodily effects that extend beyond sexual function.[41] This includes significant effect on bone density, lean body mass, metabolism, immunity, and neural function.

47. There are major and highly significant differences between male and female responses to sex hormones.[42] Giving estrogen to a biological male is not equivalent to giving the same hormone to a biological female. Likewise, giving testosterone to a biological female is not equivalent to giving the same hormone to a biological male.[43] Differences are not limited to pharmacokinetic effect (i.e. how

[40] Kumar P, Kumar N, Thakur DS, Patidar A. Male hypogonadism: Symptoms and treatment. J Adv Pharm Technol Res. 2010 Jul;1(3):297-301. doi: 10.4103/0110-5558.72420. PMID: 22247861; PMCID: PMC3255409; Voutsadaki K, Matalliotakis M, Ladomenou F. Hypogonadism in adolescent girls: treatment and long-term effects. Acta Biomed. 2022 Oct 26;93(5):e2022317. doi: 10.23750/abm.v93i5.13719. PMID: 36300209; PMCID: PMC9686158.
[41] Alemany M. The Roles of Androgens in Humans: Biology, Metabolic Regulation and Health. Int J Mol Sci. 2022 Oct 8;23(19):11952. doi: 10.3390/ijms231911952. PMID: 36233256; PMCID: PMC9569951; Patel S, Homaei A, Raju AB, Meher BR. Estrogen: The necessary evil for human health, and ways to tame it. Biomed Pharmacother. 2018 Jun;102:403-411. doi: 10.1016/j.biopha.2018.03.078. Epub 2018 Mar 22. PMID: 29573619.
[42] See Madla et al., Let's talk about sex: Differences in drug therapy in males and females, *Advanced drug delivery reviews*, 113804. Advance online publication. https://doi.org/10.1016/j.addr.2021.05.014 (2021).
[43] See Soldin et al., Sex differences in pharmacokinetics and pharmacodynamics, Clinical pharmacokinetics, 48(3), 143–157 (2009); Pogun et al., Sex Differences in Drug Effects. In: Stolerman I.P. (eds) Encyclopedia of Psychopharmacology, Springer, Berlin, Heidelberg (2010).

drugs are absorbed, distributed throughout the body and metabolized) but are present even at the cellular level.[44] Sex steroids act by altering the expression of the genetic information present in all nucleated cells of the body. Epigenetic differences (i.e. chemical changes to DNA structure) result in sex-differential expression of over 6,500 genes in the body.[45] Consequences of a failure to recognize these differences can result in drug overdose, lack of treatment response, or serious side effects.

48. Several conditions in minors may indicate endocrinologic treatment with testosterone. For instance, primary hypogonadism from gonadal failure is caused damage or impaired function of the male testes. Secondary hypogonadism is caused by abnormalities in pituitary structure or function. Hypogonadism can be objectively diagnosed by measurement of testosterone (or its derivatives) and gonadotropin (LH and FSH) levels. When used for the treatment of affected males with hypogonadism, testosterone is administered to achieve levels that are normal

[44] See, e.g., Walker et al., Matters of the heart: Cellular sex differences, *Journal of molecular and cellular cardiology*, S0022-2828(21)00087-0. Advance online publication. https://doi.org/10.1016/j.yjmcc.2021.04.010 (2021).
[45] Gershoni, M., Pietrokovski, S. The landscape of sex-differential transcriptome and its consequent selection in human adults. *BMC Biol* **15**, 7 (2017). https://doi.org/10.1186/s12915-017-0352-z

for the individual's age. This requires careful monitored of serum testosterone levels, as excess levels can have serious adverse effects, including elevations of red blood cell counts, changes in blood pressure, and brain changes.[46]

49. Testosterone may also be used in males to treat delayed puberty. To treat the condition of constitutional delay (where the person has means to progress through puberty, but onset was delayed), the male would normally be given low doses of testosterone for 3-4 months to "prime the pump" for normal puberty. Assessment of this condition includes measuring levels of LH, FSH, and testosterone, as well as observation of testicular size. Once puberty has been initiated and is progressing, there is no need to administer ongoing testosterone therapy. The normal signals present within the body with the pituitary gland signaling to the testicles continue with maturation of the gonad leading to reproductive capacity.

50. Continuing to give external testosterone to a male in normal puberty would suppress the normal function of the testes and can lead to infertility—a result contrary to the goal of endocrinology, which is to restore health. Thus, for instance, a male adolescent undergoing normal puberty who simply desired increased

[46] Ohlander SJ, Varghese B, Pastuszak AW. Erythrocytosis Following Testosterone Therapy. Sex Med Rev. 2018 Jan;6(1):77-85. doi: 10.1016/j.sxmr.2017.04.001; Kienitz T, Quinkler M. Testosterone and blood pressure regulation. Kidney Blood Press Res. 2008;31(2):71-9. doi: 10.1159/000119417; Scarth M, Bjørnebekk A. Androgen abuse and the brain. Curr Opin Endocrinol Diabetes Obes. 2021 Dec 1;28(6):604-614. doi: 10.1097/MED.0000000000000675.

lean body mass (i.e., higher muscle mass) should not normally be given testosterone for that purpose, both because it is considered medically unnecessary and because of the adverse effects of extra testosterone. Among other reasons, these effects explain why testosterone is a controlled substance.

51. Outside the context of gender dysphoria, testosterone is not an indicated treatment for a female child or adolescent. Testosterone, or any androgen, would lead to virilization, which can come with serious adverse effects. This includes impaired fertility, alopecia (hair loss), disfiguring acne, and metabolic changes that increase risk of heart disease and diabetes.[47]

52. Estrogen can be given to young females for the same types of indications in males of either constitutional delay or hypogonadism, which could be either primary or secondary. Primary hypogonadism is caused by a defect in the presence or function of the ovaries. Secondary hypogonadism is caused by a defect in the structure or function of the pituitary gland. A female can experience premature ovarian insufficiency where the ovaries become inactive over time, both genetically and through environmental incidents. To diagnose these conditions, hormone levels can be objectively measured. This includes LH, FSH, estradiol, and

[47] Yang R, Yang S, Li R, Liu P, Qiao J, Zhang Y. Effects of hyperandrogenism on metabolic abnormalities in patients with polycystic ovary syndrome: a meta-analysis. Reprod Biol Endocrinol. 2016 Oct 18;14(1):67. doi: 10.1186/s12958-016-0203-8. PMID: 27756332; PMCID: PMC5069996

other levels. (Estradiol is a form of estrogen, and generally the main hormone followed and measured in female endocrinologic practice.) The physical response to the intervention can also be measured.

53. Estrogen treatments carry risks, including stroke, elevated blood pressure, and changes to bone development. Males are not generally prescribed estrogen (again, outside the context of gender dysphoria), and there is concern that the risks of estrogen are even higher in males.

Gender Dysphoria and Treatments

I. Diagnosis

54. In contrast to the conditions discussed above, gender dysphoria is not an endocrine disorder. Instead, it is a diagnostic term for "the distress that may accompany the incongruence between one's experienced or expressed gender and one's" biological sex.[48] Gender dysphoria is associated with high rates of comorbidity, including suicidal ideation, depression, anxiety, poverty, homelessness, eating disorders, and HIV infection.[49] Gender dysphoria as a psychiatric disorder should be distinguished from identifying as transgender and transsexual. As noted,

[48] APA, DSM-5, 451.
[49] M. D. Connolly et al., "The Mental Health of Transgender Youth: Advances in Understanding," J Adolesc Health 59, no. 5 (2016); Pinna F, et al. Italian Working Group on LGBTQI Mental Health. Mental health in transgender individuals: a systematic review. Int Rev Psychiatry.34(3-4):292-359 (2022).

people who identify as transgender "transiently or persistently identify with a gender different from their natal gender." Transsexual has an even more specific meaning; it "denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involved a somatic transition by cross-sex hormone treatment and genital surgery."[50]

55. The clinical assessment methodology in sex discordant gender medicine is currently limited to self-reported information from patients without objective scientific markers or medical tests. There are no reliable radiological, genetic, physical, hormonal, or biomarker tests that can establish gender identity or reliably predict treatment outcomes.

56. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the contributors to sex discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations creates challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition.

[50] APA, DSM-5, 451.

57. Assessment of gender dysphoria currently depends almost entirely upon unverified, self-reported evidence provided by patients. A patient's spoken or written reports of alleged "memories" of symptoms and behaviors are the only source of evidence for the diagnosis in many cases. This is a source of potentially profound unreliability in patient care as the relevant science documents that physicians are poor "lie detectors"—often no more reliable in discerning false reports than flipping a coin—and sometimes much worse. The relevant research also documents that even though humans (including therapists) are poor "lie detectors," many health professionals personally—and falsely—believe they are "experts" at this complex and difficult task.[51]

58. Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals report experiencing discordance in these distinct traits. Specifically, for example, biological females may report experiencing that they identify as males and biological males may report experiencing that they identify as females. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no

[51] See, e.g., Vrij, Aldert, Granhag, P. and Porter, S. (2010) Pitfalls and opportunities in nonverbal and verbal lie detection. Psychological Science In The Public Interest, 11 (3). pp. 89-121. ISSN 1529-1006 10.1177/1529100610390861.

known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity." There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments.

II. Treatments

59. Moving from diagnosis to treatment, three approaches have been proposed for treating children with gender dysphoria.[52]

A. Reparative Therapy

60. The first approach, sometimes called "reparative therapy," is directed toward actively supporting and encouraging children to identify with their biological sex. Reparative therapy views sex/gender identity discordance as a pathologic condition. Accordingly, understanding and addressing factors that lead to this condition form the primary focus of reparative therapy, with an explicit goal of realigning one's gender identity with one's biological sex. Components of this approach have included play therapy for children and adolescents, counseling for patients and their families to help them understand and address underlying psycho-

[52] See Zucker, On the "natural history" of gender identity disorder in children, J. Am. Acad. Child Adolesc. Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008).

logical dysfunction, and instruction on setting specific boundaries for behavior according to stereotypical gender norms.[53] Some have used the term conversion therapy to label efforts to realign gender identity with biological sex, but this ideologically loaded label has been used extensively in reference to same-sex attraction.[54]

B. Watchful Waiting

61. The second "neutral" or "watchful waiting" approach, motivated by understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing existing evidence (discussed next) showing that the vast majority of affected children if left alone are likely to eventually realign their reports of gender identification with their sex. This realignment of expressed gender identity to be concordant with sex is sometimes called "desistance."

62. The "watchful waiting" approach does not advocate doing nothing. Rather, it focuses on affirming the inherent dignity of affected people and supporting them in other aspects of their lives, including the diagnosis and treatment of any comorbidities, as individuals proceed through the various stages of physical and psychological development. For instance, the approach may include the use of

[53] Kenneth J. Zucker et al., "A Developmental, Biopsychosocial Model for the Treatment of Children with Gender Identity Disorder," Journal of Homosexuality 59, no. 3 (2012).
[54] D. C. Haldeman, "The Practice and Ethics of Sexual Orientation Conversion Therapy," J Consult Clin Psychol 62, no. 2 (1994)Kenneth J. Zucker, "Editorial: The Politics and Science of "Reparative Therapy"," Archives of Sexual Behavior 32, no. 5 (2003).

scientifically validated treatments (e.g., cognitive behavioral therapy) for the patient's anxiety, depression, social skills deficits, or other issues.[55]

63. Despite differences in country, culture, decade, follow-up length and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than gender discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children before the widespread adoption of the "affirming" model discussed below.[56] In 2018, for instance, studies found that 67% of children meeting the diagnostic criteria for gender dysphoria no longer had the diagnosis as adults, with an even higher rate (93%) of natural resolution of gender-related distress for the less significantly impacted

[55] See van Bentum et al., Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression, 38 Depression & Anxiety 940 (2021).
[56] T. D. Steensma et al., "Factors Associated with Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-up Study," J Am Acad Child Adolesc Psychiatry 52, no. 6 (2013); K. D. Drummond et al., "A Follow-up Study of Girls with Gender Identity Disorder," Dev Psychol 44, no. 1 (2008); M. S. Wallien and P. T. Cohen-Kettenis, "Psychosexual Outcome of Gender-Dysphoric Children," J Am Acad Child Adolesc Psychiatry 47, no. 12 (2008); K. J. Zucker and S. J. Bradley, Gender Identity Disorder and Psychosexual Problem in Children and Adolescents (New York: Guilford Press., 1995).

cases.[57] A March 2021 study, with one of the largest samples in the relevant literature, suggests that most young gender dysphoric children grow out of the condition without medical interventions.[58] Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation.

64. Decades of peer-reviewed, published scientific research, including the pioneering work of Dr. Kenneth Zucker, have supported the efficacy of the psychological approaches for the majority of patients experiencing gender dysphoria.[59] Cognitive therapy and interpersonal psychotherapy have been found to reduce suicidal ideation independent of their effect on depression.[60] Within the "watchful

[57] See, e.g., Zucker, K. J. (2018). The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-conforming children" by Temple Newhook et al. (2018). International Journal of Transgenderism, 19(2), 231–245.
[58] See Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021, Volume 12, Article 632784, www.frontiersin.org.
[59] See Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008); Bradley, S. J. & Zucker, K. J. Gender Identity Disorder: A Review of the Past 10 YearsG. Journal of the American Academy of Child & Adolescent Psychiatry 36, 872-880, doi:10.1097/00004583-199707000-00008.).
[60] van Bentum JS et al. Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression. Depress Anxiety. 9:940-949 (2021). doi: 10.1002/da.23151.; Gallagher, M. W., Phillips, C. A., D'Souza, J., Richardson, A., Long, L. J., Boswell, J. F., Farchione, T. J., & Barlow, D. H. (2020). Trajectories of change in well-being during cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety. *Psychotherapy (Chicago, Ill.)*, *57*(3), 379–390. https://doi.org/10.1037/pst0000283.

waiting" model, these data support the investigative use of modern psychotherapeutic approaches to address suicidal ideation in children with gender dysphoria.

C. Gender Affirming

65. The third, so-called "gender affirming," approach is to affirm the child's present gender identity. This affirmation may have social, medical, legal, and behavioral dimensions. Typically, the "affirming" approach encourages children to embrace transgender identity with social transitioning followed by puberty blockage and hormonal therapy (cross-sex hormones), and potential surgical interventions.[61] This approach is considered below.

66. Before analyzing this course of treatment, it is important to understand that underlying biology is not changed by altering bodily features to appear as the opposite sex, and such alterations do not change disease vulnerabilities associated with genetically defined sex. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities

[61] See Walch et al., Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective, J. Clin. Endocrinol Metab. 106(2):305-308. doi:10.1210/clinem/dgaa816 (2021).

associated with that chromosomally-defined sex.[62] For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks.[63] And their underlying biology does not change.

Puberty Blockers

67. Only in the 1990s did GnRH analogues begin being used to suppress puberty in children who identify as the opposite sex. In 1998, Peggy Cohen-Kettenis and Stephanie van Goozen, psychologists at a Dutch gender clinic, described the case of a 13-year-old female gender-dysphoria patient, on whom a GnRH analogue was used to suppress puberty before the patient received a definitive diagnosis of gender identity disorder at age 16. At age 18, the patient underwent sex-reassignment surgery.[64]

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[62] See "Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences. Exploring the Biological Contributions to Human Health: Does Sex Matter?" Wizemann TM, Pardue ML, editors. Washington (DC): National Academies Press (US); 2001. PMID: 25057540.

[63] See S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. Am. Acad Psychiatry Law 44, 236 at 238 ("Reflections").

[64] Cohen-Kettenis and van Goozen, "Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent," 246. See also Peggy T. Cohen-Kettenis, Thomas D. Steensma, and Annelou L.C. de Vries, "Treatment of Adolescents With Gender Dysphoria in the Netherlands," Child Adolescent Psychiatric Clinics of North America 20, (2011): 689–700, http://dx.doi.org/10.1016/j.chc.2011.08.001.

68. The clinic's scientists developed an influential protocol, often referred to as the "Dutch protocol," which involved puberty suppression followed by cross-sex hormones and potential surgical interventions. In many clinics that adhere to the gender affirmation model, the ages for initiating sex-discordant gender affirming sex steroid hormones has deviated substantially from the original Dutch protocol. The typical protocol is to initiate puberty blockers (GnRH analogs) as soon as puberty begins (Tanner stage 2) which can occur as early as 8 years in females and 9 years in males. While in the Dutch protocol, cross-sex hormones are started at 16 years, many programs in the United States offer these hormones earlier to coincide with the start of normal pubertal development in males (13-14 years) and females (12-13 years). Gender-affirming surgery in the Dutch model was reserved to patients 18 years or older. Again, programs in the United States have advocated for individualization of decisions on ages for surgery in minors. GnRH analogs are discontinued after gonadectomy is performed as this medication is no longer needed to suppress gonads that are no longer present. Due to the suppressive effect of exogenous sex-steroids on gonadal function, GnRH analogs are often stopped after gender affirming hormone administration has been titrated to maximal doses required to achieve the desired change in secondary sex characteristics.

69. This gender "affirming" model would make gender dysphoria unique: it would be "the only psychiatric condition to be treated by surgery, even though

no endocrine or surgical intervention package corrects any identified biological abnormality."[65]

70. These scientists, along with others, have claimed that puberty suppression is "fully reversible."[66] On this view, puberty suppression "give[s] adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved."[67]

71. This claim appears to presume that natural sex characteristics interfere with the "exploration" of gender identity, when one would expect that the development of natural sex characteristics might contribute to the natural consolidation of one's gender identity. It is based upon an untested scientific premise that interfering with the development of natural sex characteristics can allow for a more accurate diagnosis of the gender identity of the child. It seems equally plausible that the interference with normal pubertal development will influence the gender identity

[65] S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law, 44, 236 at 238 ("Reflections"), at 240.
[66] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, "Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects," European Journal of Endocrinology 155 (2006): S133, http://dx.doi.org/10.1530/eje.1.02231.
[67] Peggy T. Cohen-Kettenis, Henriette A. Delemarre-van de Waal, and Louis J.G. Gooren, "The Treatment of Adolescent Transsexuals: Changing Insights," Journal of Sexual Medicine 5, no. 8 (2008): 1894, http://dx.doi.org/10.1111/j.1743-6109.2008.00870.x.

of the child by reducing the prospects for developing a gender identity corresponding to his or her biological sex.

72. Given their potential importance in the lives of the affected children, claims about reversibility are worth careful examination. In developmental biology, it makes little sense to describe anything as "reversible." If a child does not develop certain characteristics at age 12 because of a medical intervention, then his or her developing those characteristics at age 18 is not a "reversal," since the sequence of development has already been disrupted. This is especially important since there is a complex relationship between physiological and psychosocial development during adolescence. Gender identity is shaped during puberty and adolescence as young people's bodies become more sexually differentiated and mature. Given how little we understand about gender identity and how it is formed and consolidated, we should be cautious about interfering with the normal process of sexual maturation.

73. A more relevant question is whether the physiological and psychosocial development that occurs during puberty can resume in something resembling a normal way after puberty-suppressing treatments are withdrawn. In children with precocious puberty, this does appear to be the case. Puberty-suppressing hormones are typically withdrawn around the average age for the normal onset of gonadarche, at about age 12, and normal hormone levels and pubertal development

gradually resume. For one common method of treating precocious puberty, girls reached menarche approximately a year after their hormone treatments ended, at an average age of approximately 13, essentially the same average age as the general population.[68] The evidence for the safety and efficacy of puberty suppression in boys is less robust, chiefly since precocious puberty is much rarer in boys. Although the risks are speculative and based on limited evidence, boys who undergo puberty suppression may be at greater risk for the development of testicular microcalcifications, which may be associated with an increased risk of testicular cancer, and puberty suppression in boys may also be associated with obesity.[69]

74. Unlike children affected by precocious puberty, adolescents with gender dysphoria do not have any physiological disorders of puberty that are being corrected by the puberty-suppressing drugs. The fact that children with suppressed precocious puberty between ages 8 and 12 resume puberty at age 13 does not mean that adolescents suffering from gender dysphoria whose puberty is suppressed beginning at age 12 will simply resume normal pubertal development down the road if they choose to withdraw from the puberty-suppressing treatment and choose not

[68] Marisa M. Fisher, Deborah Lemay, and Erica A. Eugster, "Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant," The Journal of Pediatrics 164, no. 4 (2014): 3, http://dx.doi.org/10.1016/j.jpeds.2013.12.009.

[69] Silvano Bertelloni and Dick Mul, "Treatment of central precocious puberty by GnRH analogs: long-term outcome in men," Asian Journal of Andrology 10, no. 4 (2008): 531, http://dx.doi.org/10.1111/j.1745-7262.2008.00409.x.

to undergo other sex-reassignment procedures. Interrupting puberty in this manner may have significant effects on final stature and bone density.[70]

75. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty.[71] Once puberty is blocked, even if eventually unblocked (and assuming signaling from the pituitary gland resumes), the person cannot "buy back" the time when the physical process of puberty has been disrupted at the time when it would normally occur with complementary psychological processes in that stage in the person's life.

76. A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation.[72]

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[70] Joseph T, Ting J, Butler G. The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: findings from a large national cohort. J Pediatr Endocrinol Metab. 32(10):1077-1081 (2019); Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015).

[71] See Hruz, Mayer, and McHugh, "Growing Pains, The New Atlantis: A Journal of Technology and Society, Spring 2017, pg 3-36; see also Vijayakumar N, Op de Macks Z, Shirtcliff EA, Pfeifer JH. Puberty and the human brain: Insights into adolescent development. Neurosci Biobehav Rev. 2018 Sep;92:417-436. doi: 10.1016/j.neubiorev.2018.06.004. Epub 2018 Jul 1. PMID: 29972766; PMCID: PMC6234123; see also Choudhury S, Culturing the adolescent brain: what can neuroscience learn from anthropology?, *Social Cognitive and Affective Neuroscience*, Volume 5, Issue 2-3, June/September 2010, Pages 159–167, https://doi.org/10.1093/scan/nsp030.

[72] See Arain, M., Haque, M., Johal, L., Mathur, P., Nel, W., Rais, A., Sandhu, R., & Sharma, S. (2013). Maturation of the adolescent brain. *Neuropsychiatric disease and treatment*, *9*, 449–461. https://doi.org/10.2147/NDT.S39776.

77. Another troubling question that has been largely uninvestigated is what psychological consequences there might be for children with gender dysphoria whose puberty has been suppressed and who later come to identify as their biological sex.

78. In addition to the reasons to suspect that puberty suppression may have side effects on physiological, psychological, and brain development, the evidence that something like normal puberty will resume for these patients after puberty-suppressing drugs are removed is very weak.

Cross-Sex Hormones

79. Rather than resuming biologically normal puberty, adolescents treated on the "affirming" model overwhelmingly go from suppressed puberty to medically conditioned cross-sex puberty, when they are administered cross-sex hormones. Specifically, exogenous estrogen is administered to biological men to induce gynecomastia (i.e., the enlargement of breast tissues), and testosterone is administered to biological women to induce virilization (i.e., the development of facial hair and other desired male features) and to interfere with normal ovarian function. Nearly all of the children that have been studied that have received puberty blockers go on to cross-sex hormones.[73]

[73] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(22)00254-1/fulltext

80. Along with (and often before) estrogen is administered to biological males in this treatment, spironolactone may be used as an androgen blocker. Spironolactone is primarily used for the treatment of blood pressure and heart failure. It is a mineralocorticoid antagonist. But it also has effects in blocking the action of androgens. As discussed, androgens are masculinizing hormones that lead to virilization. Testosterone is a prime androgen, but other androgens are also made in the gonads and adrenal gland. Spironolactone is sometimes used in the treatment of polycystic ovarian syndrome, in which females will undergo virilization due to excess androgen production in the ovaries. This syndrome can have adverse effects on fertility, metabolic health, and cardiovascular health.[74] The diagnosis of polycystic ovarian syndrome is a clinical diagnosis based upon the physical evidence of virilization or androgen effects, insulin resistance, and irregular periods. There are objective biological measures to assess those androgen levels, most notably elevated free testosterone levels. And there are objective measures of dysregulation of relevant signals from the pituitary gland, the LH and the FSH, to complement the clinical diagnosis by looking at the degree of virilization that is present in the patient.

[74] Hunter MH, Sterrett JJ. Polycystic ovary syndrome: it's not just infertility. Am Fam Physician. 2000 Sep 1;62(5):1079-88, 1090

81. Spironolactone would not be prescribed to male patients for an endocrinologic purpose related to androgen production. Once again, this reflects a fundamental biological difference between males and females. Though spironolactone can be used to regulate the levels of potassium and sodium in the body, such treatment would be based on objective markers of those levels.

82. Likewise, the administration of the sex steroid hormones differ by the sex of the individual. It is not identical to give testosterone to a male as it is to give it to a female, nor is it the same treatment to give estrogen to a male versus female. This difference has an established scientific basis. The differences between males and females occurs in every nucleated cell of the body, for males and females have different genetic programming. This is a process known as epigenetics, meaning that there are modifications of the DNA itself that alter the expression of genes when exposed to the same stimulus. There are over 6,000 sex-differentially expressed genes. So, if one gives testosterone to a male, the physiologic effects of that treatment, even in the measurement at which genes are turned on and turned off, will be different than if one gives testosterone to a female.[75]

83. When a patient with gender dysphoria is placed on cross-sex hormones, per the Dutch protocol, puberty-suppressing GnRH analogues continue to

[75] Gershoni M, Pietrokovski S. The landscape of sex-differential transcriptome and its consequent selection in human adults. BMC Biol. 2017 Feb 7;15(1):7

be administered until exogenous administration of cross-sex hormones (i.e. sex hormones normally produced the gonads of the opposite sex) leads to sufficient suppression of endogenous sex hormone production or the gonads are surgically removed. Sex hormones that are normally secreted by the maturing gonads are not produced. This means that adolescents undergoing cross-sex hormone treatment circumvent the most fundamental form of sexual maturation—the maturation of their reproductive organs.

84. Patients undergoing gender affirming surgery discontinue GnRH treatment after having their gonads removed, since the secretion of sex hormones that the treatment is ultimately intended to prevent will no longer be possible. These patients are then sterile, as loss or alteration of primary sexual organs leads directly to impairment of reproductive potential.

85. Although the long-term effect of exposing immature gonads to cross-sex hormones is currently unknown, it is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility, which may be irreversible.[76] Specifically, estrogen administration to males who identify as women results in impaired spermatogenesis and an absence of Leydig cells in the

[76] See Nahata, L., Tishelman, A. C., Caltabellotta, N. M. & Quinn, G. P. Low Fertility Preservation Utilization Among Transgender Youth. Journal of Adolescent Health 61, 40-44, doi:https://doi.org/10.1016/j.jadohealth.2016.12.012 (2017).

testis.[77] Exogenous testosterone administration to females who identify as men causes ovarian stromal hyperplasia and follicular atresia.[78] Recognition of these consequences is the basis for the development of new arenas of medical practice where there is an attempt to restore fertility that has been intentionally destroyed.[79]

86. Gametes (sperm and ova) require natural puberty to mature to the point that they are viable for reproduction.[80] While it is expected that the exposure of immature gonads to cross-sex hormones will lead to infertility, whether affected individuals have permanent sterility has not been established. Much of the uncertainty arises from the novelty of this intervention and the lack of long term follow up. There are limited reports of successful pregnancies after cross-sex hormones, but all of the subjects started gender affirming hormones as adults after completing

[77] Schulze C. Response of the human testis to long-term estrogen treatment: Morphology of Sertoli cells, Leydig cells and spermatogonial stem cells. Cell Tissue Res 251:31e43 (1988)..
[78] [2] Pache TD, Chadha S, Gooren LJ, et al. Ovarian morphology in long-term androgen-treated female to male transsexuals. A human model for the study of polycystic ovarian syndrome? Histopathology 19: 445e52 (1991); Ikeda K, Baba T, Noguchi H, et al. Excessive androgen exposure in female-to-male transsexual persons of reproductive age induces hyperplasia of the ovarian cortex and stroma but not polycystic ovary morphology. Hum Reprod 28:453e61 (2013).
[79] See, e.g., Ainsworth AJ, Allyse M, Khan Z. Fertility Preservation for Transgender Individuals: A Review. Mayo Clin Proc. 2020 Apr; 95(4):784-792. doi: 10.1016/j.mayocp.2019.10.040. Epub 2020 Feb 27. PMID: 32115195.
[80] Howard E. Kulin, et al., "The Onset of Sperm Production in Pubertal Boys. Relationship to Gonadotropin Excretion," American Journal of Diseases in Children 143(2), 190-193 (1989).

puberty.[81] I am not aware of any reports that show this for children who were exposed to puberty blockers before completing puberty followed by cross-sex hormones.

87. There are many other known risks to puberty suppression followed by cross-sex hormones beyond fertility concerns. As noted, emerging data show that treated patients have lower bone density, which may lead to increased fracture risk later in life.[82] Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease.[83] In addition, non-physiological levels of

[81] de Nie I, van Mello NM, Vlahakis E, Cooper C, Peri A, den Heijer M, Meißner A, Huirne J, Pang KC. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. Cell Rep Med. 2023 Jan 17;4(1):100858. doi: 10.1016/j.xcrm.2022.100858.

[82] See Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015).

[83] See Seal, L. J. A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria. Annals of Clinical Biochemistry 53, 10-20, doi:10.1177/0004563215587763 (2016); Banks, K., Kyinn, M., Leemaqz, S. Y., Sarkodie, E., Goldstein, D., & Irwig, M. S. (2021). See also, Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults. *Hypertension (Dallas, Tex.: 1979)*, HYPERTENSIONAHA12016839. Advance online publication. https://doi.org/10.1161/HYPERTENSIONAHA.120.16839; Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. *Annals of internal medicine*, *169*(4), 205–213. https://doi.org/10.7326/M17-2785; Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643.

estrogen in males has been shown to increase the risk of thromboembolic stroke above the incidence observed in females.[84]

Endocrine Society and WPATH Guidelines

88. A reasonable understanding of relative risk versus benefit for medical products or procedures is a fundamental obligation in providing appropriate clinical care. This is the bedrock standard of "evidence based medical practice." When considering clinical practice guidelines, it is essential that physicians recognize the relative risks and benefits of such documents. If done properly, they can distill large data sets into actionable clinical recommendations. However, there is a long history of clinical practice guidelines that have later been found to be deficient, resulting in wasted medical resources, have failed to achieve desired benefits, or have caused substantial harm to patients.[85]

89. As detailed throughout this report, this foundational standard of "evidence based medical practice" has never been met as to so-called gender affirming care. The field of "affirming care" is characterized by a poor quality of evidence

[84] E.g. Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. Annals of internal medicine, 169(4), 205–213. https://doi.org/10.7326/M17-2785.

[85] See Woolf et al., Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *BMJ (Clinical research ed.)*, 318(7182), 527–530, https://doi.org/10.1136/bmj.318.7182.527 (1999).

regarding safety and efficacy, as well as attempts to silence standard scientific discussion and consideration of alternative hypotheses, failures to acknowledge existing data showing persistence of suicidality after intervening, the intentional impairment and destruction of normally formed and functioning male and female sexual organs to address psychological-psychiatric distress, the manipulation of language from standard medical definitions, and widespread failures to properly report research data related to gender transitioning.

90. Because of ideological and political pressure, health providers in many fields are now not permitted to openly asks questions, properly investigate alternative diagnoses, or explore alternative hypotheses for the symptoms of gender dysphoric patients.[86] Providers are instead compelled (sometimes under fear of employment termination or legal attacks) to adopt a patient's self-diagnosis and only support "affirming" medical interventions. These providers are thus being pressured and/or compelled to commit the scientific and medical malpractice of confirmation bias—one of the most serious of all methodological diagnostic failures. As one paper explained, "physicians' desire to confirm a preliminary diagno-

[86] See https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4928.pdf and https://williamsinstitute.law.ucla.edu/publications/conversion-therapy-and-lgbt-youth/

sis while failing to seek contradictory evidence" appears to be "an important reason for wrong diagnoses."[87] Such "[d]iagnostic errors can have tremendous consequences because they can result in a fatal chain of wrong decisions."[88]

91. Despite the dangers of confirmation basis, existing guidelines base recommendations for "affirming" medical interventions on uncorroborated patient self-reports, assessed by mental health professionals with no methodology for discerning true from false patient reports, with no ability to decipher accurate from contaminated "memories," with no alternative treatments offered, and no alternative explanations (e.g., social contagion) explored. Clinicians tasked with providing GnRH analogs to suppress normally timed puberty and gender affirming cross-sex hormones to induce secondary sexual characteristics coinciding with a sex-discordant gender identity rely upon subjective criteria to establish a diagnosis of sex-gender incongruence. There is no biological test to verify the diagnosis.

[87] Mendel et. al., Confirmation bias: why psychiatrists stick to wrong preliminary diagnoses, Psychological Medicine, Oxford University Press (2011).
[88] *Id.*; see also Doherty et al., Believing in Overcoming Cognitive Biases, American Medical Association Journal of Ethics 22(9):E773-778 (2020) ("Confirmation bias is the selective gathering and interpretation of evidence consistent with current beliefs and the neglect of evidence that contradicts them."); Hershberger et al., Teaching awareness of cognitive bias in medical decision making. *Acad Med*. 70(8):661 (1995).

I. Endocrine Society

92. In 2009, the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria.[89] The recommendations include temporary suppression of pubertal development of children with GnRH agonists followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As stated in the Endocrine Society publication, "the strength of recommendations and the quality of evidence was low or very low." According to the GRADE system, low recommendations indicate that "[f]urther research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate." Very low recommendations mean that **"**any estimate of effect is very uncertain."[90]

[89] See Hembree et al., Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline, *The Journal of clinical endocrinology and metabolism*, *94*(9), 3132–3154, https://doi.org/10.1210/jc.2009-0345 (2009).
[90] Guyatt et al., GRADE: an emerging consensus on rating quality of evidence and strength of recommendations, BMJ; 336:924 doi:10.1136/bmj.39489.470347 (2008).

93. The Endocrine Society published an updated set of guidelines in September 2017.[91] Those guidelines show that all recommendations as to "affirming" treatment of adolescents are supported by low or very low quality evidence.

94. It is highly misleading to imply that the current Endocrine Society guidelines represent the opinions of the Society's 18,000 members. The committee that drafted these guidelines was composed of *less than a dozen* members. The guidelines were never submitted to the entire Endocrine Society membership for comment and approval prior to publication. They also did not undergo external review. Such methodologies are common in association "statements" and "endorsement"; they are not scientific or generally reliable.

95. The panel that drafted the Endocrine Society guidelines was heavily composed of individuals who have significant associations with WPATH. Specifically, all but one of the committee members were leaders in WPATH. Two of the authors served as WPATH's president (Walter J. Meyer and Vin Tangpricha); at least four have served, or are serving, on WPATH's Board of Directors (Peggy Cohen-Kettenis, Louis Gorren, Stephen Rosenthal, Guy T'Sjoen); and at least four (Stephen Rosenthal, Joshua Safer, Vin Tangpricha, and Guy T'Sjoen) were authors

[91] See Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of clinical endocrinology and metabolism*, *102*(11), 3869–3903, https://doi.org/10.1210/jc.2017-01658 (2017).

of WPATH SOC 8. Three (Peggy Cohen-Kettenis, Walter Meyer, and Vin Tangpricha) were authors of WPATH SOC 7.

II. WPATH

96. The World Professional Association for Transgender Health (WPATH) has also issued several iterations of guidelines. The first set of clinical practice guidelines was published in 1979. WPATH published its latest version of their "Standards of Care for the Health of Transgender and Gender Diverse People" (SOC 8) in September of 2022. [92] While this document has been presented as "authoritative" and "evidenced based", numerous concerns have been raised about the updated recommendations. This includes removal of age limits for initiation of cross sex hormones and gender affirming surgery, recommendations for excluding parents in the decision making process if they question or challenge medical interventions, elimination of safeguards for addressing underlying mental health illness before the start of gender affirming medical interventions, and the addition of a section on "eunuch-identified" people. [93] Many of the recommendations made reflect WPATH's acknowledged agenda as an advocacy group. In SOC8 they specifically state "Health is promoted through public policies and legal reforms that ad-

[92] ibid

[93] Coleman et al, Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644..

vance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy." Despite the claim that the SOC8 guidelines are based upon solid scientific evidence, such recommendations represent ideological positions devoid of rigorous scientific evidence. Scientific data on long-term outcomes in adolescents who are exposed to the U.S. affirmation model simply do not exist.

97. In sum, clinical guidelines or standards of care should provide practitioners with evidence-based standards by which they may reliably inform the patient of projected outcomes, and do so with a known error rate. Such data is the starting point for obtaining informed consent. This information is not provided by either WPATH or Endocrine Society's guidelines.

Informed Consent

98. The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. As discussed above, relying on clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. Using "affirming"

treatments on minors violates this essential principle by using experimental treatments on vulnerable populations without properly informing them of the actual risks and limitations of the treatments.[94]

99. It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment.[95]

100. Essential requirements for informed consent include the ability of the patient or study subject to understand the proposed procedure, full disclosure of known and potential risks and benefits, discussion of alternative treatments, and freedom to act voluntarily. This information is presented verbally and in written form with allowance of sufficient time for the patient to ask questions and for the provider to assess adequate comprehension by the patient. It is well recognized that

[94] See Jonson et al., Clinical Ethics, New York: McGraw Hill (1998).
[95] See Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998, ("Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits.") See also Katz, A., Webb, S., and Committee on Bioethics, Informed Consent in Decision-Making in Pediatric Practice, Pediatrics, August 2016, 138 (2) e20161485; DOI: https://doi.org/10.1542/peds.2016-1485 at https://pediatrics.aappublications.org/content/138/2/e20161485.

the signing of a formal consent form does not guarantee that informed consent has been obtained.

101. Several aspects of the care of individuals with gender dysphoria may substantially interfere with proper application of these foundational principles.[96] For adolescent children seeking medical gender affirmation medical, well established limitations in decision making ability raise serious concerns about their ability to consent to hormonals and surgical interventions. Adolescents have a known tendency to engage in risky behaviors, exercise poor impulse control, and show frequent failure to appreciate long-term consequences of current choices.[97]

102. For example, the ability of a child to understand implications for future fertility while still developmentally immature can pose a significant barrier to meeting the criterion of appreciating decision consequence. Children are often unlikely to be capable of giving truly informed consent, particularly when it comes to hormonal or surgical treatments that will result in lifelong sterility.[98] Adolescents' inability to adequately weigh potential short-term benefits against long-term risks

[96] Paul S. Appelbaum and Thomas Grisso, "Assessing Patients' Capacities to Consent to Treatment," New England Journal of Medicine 319, no. 25 (1988).
[97] Sarah-Jayne Blakemore and Trevor W. Robbins, "Decision-Making in the Adolescent Brain," *Nature Neuroscience* 15 (2012); Neuroscientists have found that the adolescent brain is too immature to make reliably rational decisions. B.J. Casey, Rebecca M. Jones, and Todd A. Hare, "The Adolescent Brain," Annals of the New York Academy of Sciences 1124 (2008): 111, http://dx.doi.org/10.1196/annals.1440.010.
[98] See Geier, Adolescent cognitive control and reward processing: Implications for risk taking and substance use, Hormones and Behavior 64, 333-342, doi:https://doi.org/10.1016/j.yhbeh.2013.02.008 (2013).

seems supported by the observation that few adolescents express concern over loss of fertility even when directly told of the potential sterilizing effect of medical intervention.[99]

103. Similarly, individuals with transgender identity who also have clinical depression or other serious psychiatric comorbidity may have limited capacity to objectively weight proposed clinical interventions with potentially irreversible consequences and would therefore fail to meet psychological abilities criteria.[100]

104. In addition, a study subject's underlying belief that he or she was born in the wrong body is the primary reason for seeking medical intervention. Thus any challenge to this underlying premise is seen as a threat to the affected individual. Under such conditions, an individual will find it difficult, if not impossible, to give truly informed consent.

105. A model relying on parental consent with child assenting to affirmative medical interventions does not remove concerns about the difficulty in obtaining truly informed consent. Since many of the long-term outcomes of gender affirming interventions are unknown, prospective patients are being asked to consent

[99] Leena Nahata et al., "Low Fertility Preservation Utilization among Transgender Youth," Journal of Adolescent Health 61, no. 1 (2017).
[100] H. Helmchen, "Ethics of Clinical Research with Mentally Ill Persons," Eur Arch Psychiatry Clin Neurosci 262, no. 5 (2012).

without sufficient knowledge of inherent risk versus benefit. Without understanding that nearly all adolescents who are put on puberty blockers will proceed to gender affirming hormones, with many subsequently opting for gender affirming surgeries, focus on gaining consent for this first stage of the affirmative model is difficult if not impossible.

106. Parents are often told by gender affirmation activists or providers that the failure to allow a gender dysphoric child to medically transition will result in suicide. These "threats" ignore data that challenge this biased assumption.[101]

107. While any cases of suicide are of utmost concern, suicide rates in children with sex-discordant gender identity must be put in context of overall suicidality in the pediatric population independent of gender dysphoria. When considered in this context, the rates of suicidal ideation and attempt in transgender adolescents are similar to those found in adolescents without gender dysphoria who present for psychological care (ref). Furthermore, it is necessary to critically assess, with rigorous scientific data, whether gender affirming medical interventions succeed in preventing suicides. While long-term data are not available for pediatric patients,

[101] See D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, *Arch Sex Behav* 50**,** 7–16, https://doi.org/10.1007/s10508-020-01844-2 (2021).

the adult literature consistently reports continued elevated suicidality after undergoing gender affirming medical interventions.[102]

108. Researchers have noted that in the "affirming" context, "the informed consent process rarely adequately discloses" either "the uncertain permanence of a child's or an adolescent's gender identity" or "the uncertain long-term physical and psychological health outcomes of gender transition."[103] Levine et al. recently noted the following major deficiencies in the informed consent process under existing "affirming" guidelines and approaches:

- "High rate of desistance/natural resolution of gender dysphoria in children is not disclosed";
- "Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained"; and,
- "The question of suicide is inappropriately handled".[104]

As discussed above, the informed consent process for "affirming" treatments is further "limited by" "erroneous professional assumptions" and "poor quality of the initial evaluations."[105]

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[102] Adams N, Hitomi M, Moody C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health. 2017 Apr 1;2(1):60-75. doi: 10.1089/trgh.2016.0036; Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011).
[103] Levine et al., Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, *Journal of sex & marital therapy*, 1–22, https://doi.org/10.1080/0092623X.2022.2046221 (2022).
[104] *Id.*
[105] *Id.*

109. Using experimental procedures on uninformed, vulnerable patients is unethical and improper. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science—such is the case with the gender transition industry. The infamous Tuskegee studies, Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia[106]), recovered memory therapy-multiple personality disorders, rebirthing therapy,[107] coercive holding therapy,[108] and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions.

Existing Literature and Its Limitations

110. Before turning to the existing literature on gender dysphoria and its treatments, it is important to understand the varying types of studies conducted in this and other medical fields, as well as the general approach to scientific testing.

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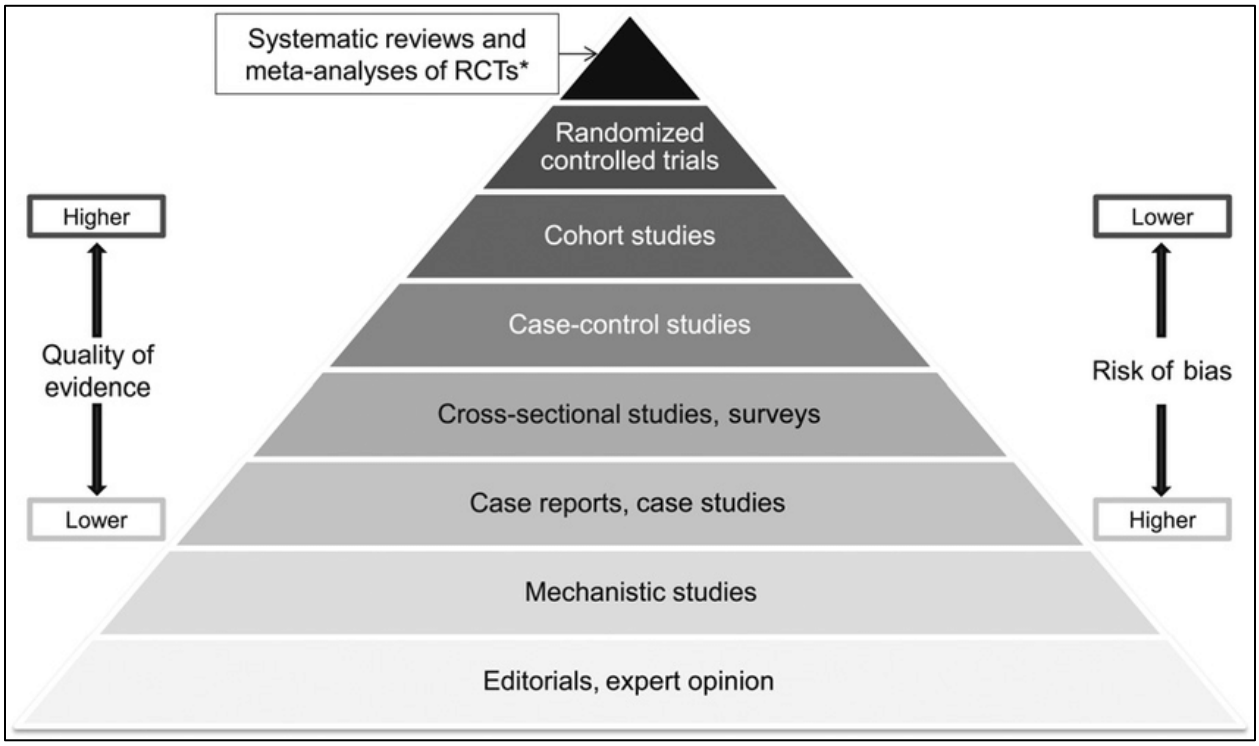
[106] See https://www.nobelprize.org/prizes/medicine/1949/moniz/article.
[107] See, e.g., Janofsky, M. Girl's Death Brings Ban on Kind of 'Therapy'. New York Times. April 18, 2001; see also Peggy Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, April 21, 2001.
[108] See, Hyde, J. "Holding therapy appears finished, State orders the last practitioner of holding therapy to end controversial method" Deseret News, Feb 13, 2005.

Appropriate testing of medical and other scientific hypothesis requires proper study design. First, the research formulates a hypothesis as to whether there is a difference—a cause and effect relationship—from the studied intervention. The study starts by assuming the "null hypothesis"—there is no difference—and then one looks for evidence sufficient to disprove the null hypothesis. When conducting the study, statistical significance is of central importance, for it states the likelihood that the observation would exist if the null hypothesis were true. Only if there is a very small likelihood that the null hypothesis is true is it generally appropriate to treat a study as providing evidence that the null hypothesis is, in fact, false. Accordingly, if a study finding does not reach statistical significance, it would be improper to use the finding as a rejection of the null hypothesis.

111. Case reports or experts' opinions are recognized as the lowest level of evidence. Those are based upon general experiences, not scientific testing. They can be useful for generating a novel hypotheses, which can then be tested through experimental testing to establish if there are cause/effect relationships. Next up on the pyramid of quality of evidence would be, for example, cross-sectional studies that are done where one looks at a condition at one point in time. One can merely infer associations from these types of studies. Randomized longitudinal studies can permit, to some extent, the elimination of unrecognized variables that may distort the results. The highest part of the evidence-based pyramid (for individual studies)

is randomized controlled trials, in which the investigator attempts to control all aspects of the study with the exception of the independent variable that is being tested. When done properly, this type of study can provide strong evidence of causation. The following illustrates this pyramid:[109]



112. Since the "affirming" model of treating transgender children, as summarized by the World Professional Association for Transgender Health (WPATH) and Endocrine Society guidelines discussed below, are relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions

[109] https://www.researchgate.net/figure/Hierarchy-of-evidence-pyramid-The-pyramidal-shape-qualitatively-integrates-the-amount-of_fig1_311504831

in psychological distress following social transition in a "gender affirming" environment remains inconclusive. Multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design.[110] No randomized control trials have been performed, and the existing longitudinal studies have serious limitations—most significantly, that they follow cohorts of patients in a non-controlled, unrandomized manner. This design severely limits any conclusions that can be drawn.

113. Moreover, many studies find no improvement—or negative effects—from "affirming" care. For instance, a 2020 British study (Carmichael et al.[111]) found "no evidence of change (no improvement) in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm." Puberty blockers used to treat children aged 12 to 15 who had severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image. However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age

[110] See Hruz, P. W. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q* 87, 34-42, doi:10.1177/0024363919873762 (2020).
[111] Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653.

16. As Oxford's Professor Michael Biggs summarized the study's findings, "After a year on GnRHa [puberty blockers] children reported greater self-harm, and girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body—so puberty blockers actually exacerbated gender dysphoria."[112]

114. The widely respected Cochrane Review examined hormonal treatment outcomes for male-to-female transitioners over 16 years.[113] They found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." Thus, decades after the first transitioned male-to-female patient, quality evidence for the benefit of transitioning remains lacking.

115. Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have undergone social transition with or without surgical modification of external genitalia

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[112] https://www.transgendertrend.com/tavistock-experiment-puberty-blockers/; Dyer, C. Puberty blockers: children under 16 should not be referred without court order, says NHS England. BMJ2020;371:m4717.doi:10.1136/bmj.m4717 pmid:33268453. See, Dyer, C., Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study, BMJ 2021;372:n356 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021); see also Dyer, C. Puberty blockers do not alleviate [suicidal] negative thoughts in children with gender dysphoria, finds study. BMJ 372, n356, doi:10.1136/bmj.n356 (2021). https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1; BBC summary: https://www.bbc.com/news/uk-55282113

[113] See Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020 and https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013138.pub2/full.

continue to have rates of depression, anxiety, substance abuse and suicide far above the background population.[114]

A. Change in Patient Population

116. One important (and contentious) issue requiring more study is the recent trend of adolescent female to male gender discordant patients. In the United Kingdom, where centralized medical care provides data to track health care phenomenon, the number of adolescent girls seeking sex transitioning exploded over 4,000% in the last decade. Similarly, in the United States, where we lack the same kinds of centralized health care data, it has been reported that in 2018, 2% of high school students identified on surveys as "transgender"—this is 200 times greater response, a 20,000% increase—over reports during past decades which showed a rate of only .01 percent.[115]

117. Along with this increase in transgender patients and identifiers has come a radical and recent transformation of the patient population from early onset males to rapid onset adolescent girls. Currently the majority of new patients with

[114] See Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); see also Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011).

[115] See Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017. MMWR Morb Mortal Wkly Rep 2019; 68:67–71.

sex-gender discordance are not males with a long, stable history of gender dysphoria since early childhood—as they were for decades, and under the Dutch protocols—but instead adolescent females with no documented long-term history of gender dysphoria. One might say, as Dr. Lisa Littman has theorized, [116] that these females experienced "rapid onset" transgender identification.

118. This recent change in the typical patient raises questions about our understanding of the origins of transgender identity. For instance, a genetics or "immutable" theory of transgender identity cannot explain the rapid expansion of new GD cases (a 4,000% to 20,000% increase), given that our genome is simply not changing that fast. Nor can that theory explain the explosion of adolescent females presented with GD. A "brain structures" theory has only weak medical evidence, and it also cannot explain the rapid expansion of new gender dysphoria cases. As for the theory that increased social acceptance of the transgender lifestyle is leading many people who were transgender all along to come out. Yet this theory fails to explain why males and older women are not also coming out in the same large numbers and not coming out in "social peer group clusters," as adolescent females are reportedly doing.

[116] See Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

B. Methodological Problems with "Affirming" Literature

119. The published literature relied on to advocate for the use of puberty blockers, cross-sex hormones and gender affirming surgeries in minors consists almost entirely of studies with major methodological limitations.[117] As detailed next, these include:

- Significant recruitment biases, including internet-based convenience sampling;
- Relatively small sample sizes for addressing a condition that is likely to be multifactorial;
- Short term follow-up;
- Lack of randomization to different treatment arms;
- Failure to consider alternate hypotheses;
- Failure to include proper control groups;
- Reliance on cross sectional sampling that may identify associations, but cannot establish causal relationships between intervention and outcome;
- A high rate of patients lost to follow up in longitudinal analyses, which is relevant to questions of regret, desistance and completed suicide;
- Biased interpretation of study findings with a goal of validating *a priori* conclusions rather than seeking evidence to disprove the null hypothesis; and
- Ignoring starkly contradictory research documenting the lack of effectiveness of "transitioning" procedures, the low quality of research in this area, and the ongoing contentions and disagreements over this highly controversial, experimental medical field.

[117] See generally Hruz, Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, Linacre Q 87(1), 34-42, doi:10.1177/0024363919873762 (2020).

120. Some or all of these methodological and statistical flaws are present in the following studies, which are commonly relied on by advocates of "affirming" treatments.

The Branstrom Long-Term Treatment Outcome Study: The historic Branstrom study is a long-term treatment (10+ years) outcome research investigation testing the effects of hormonal and surgical "transitioning" treatments on patients. This historic research found no reliable benefits from these treatments, as well as evidence suggesting *increased* suicide attempts and anxiety disorders following the "gender transitioning" treatments. In addition, detailed methodological critiques discovered significant research errors by the authors that appear to support the investigative theory that the authors had initially attempted to manipulate and misreport the findings of the study. The authors ultimately recanted their initial misreporting and agreed that their study produced *no reliable evidence* of benefits for gender reassignment hormone and surgical treatments. This historic investigation has helped to generate a profound collapse of support for these experimental procedures across Europe.[118]

[118] See SEGM, *Correction of a Key Study: No Evidence of "Gender-Affirming" Surgeries Improving Mental Health*, https://segm.org/ajp_correction_2020 (Aug. 30, 2020); Van Mol et al., *Gender-Affirmation Surgery Conclusion Lacks Evidence.* Am. J. Of Psych., 177(8), 765-766 (2020).

A 2011 Dutch study by de Vries et al.[119] is often cited to support longitudinal evidence of benefit from pubertal blockade. Although the study found slight improvements in mood improved and the risk of behavioral disorders with pubertal blockade over baseline, the study included no control group, and all 70 participants received ongoing psychological support. Thus, the authors were unable to determine the basis of the limited observed improvement. The authors acknowledge that psychological support or other reasons may have contributed to (or wholly caused) this observation. By the very nature of the trial, at best the study can provide a rationale for doing further studies that could show whether "affirming" interventions provide a benefit. The study does not (and cannot) answer the central question: whether the administration of puberty blockers is the solution to the problem and whether alternative approaches that do not carry the same risks relative to purported benefits (i.e., psychological interventions) may have the same or superior benefits.

Moreover, there remain questions about the extent to which the protocol used in these early Dutch studies may be relevant to the patient population presenting today. For decades transgender patients were mostly older adults or very young boys. As noted, over the last few years, a tsunami of teenaged girls has

[119] de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. *J Sex Med*. 8(8):2276-2283 (2011).

flipped the demographics of transgender patients—now up to 7 to 1 teen girls. The newly presenting cases are vastly overrepresented by adolescent females, the majority of whom also have significant mental health problems and neurocognitive comorbidities such as autism-spectrum disorder or ADHD.[120] Furthermore, estimates of gender dysphoria-transgenderism are rocketing upwards from 1 in 10,000 to "the number of U.S. transgender-identified youth may be as high as 9%."[121] This unexplained, radical transformation of patient demographics raises questions about the applicability even of the limited existing literature on this issue, particularly as to the Dutch protocol. Dr. Thomas Steensma, a prominent investigator of the Dutch protocol—the original model for transitioning treatments—has recently noted that "[w]e don't know whether studies we have done in the past can still be applied to this time," specifically because of the unexplained surge in female adolescents reporting gender dysphoria. "Many more children are registering, but also of a different type… Suddenly there are many more girls applying who feel like a boy." He concluded with the warning that "[w]e conduct structural

[120] See de Graaf, Nastasja M., and Polly Carmichael. "Reflections on Emerging Trends in Clinical Work with Gender Diverse Children and Adolescents." Clinical Child Psychology and Psychiatry, vol. 24, no. 2, Apr. 2019, pp. 353–64.
[121] See Kidd, Kacie M., et al. "Prevalence of Gender-Diverse Youth in an Urban School District." Pediatrics, vol. 147, no. 6, June 2021, p. e2020049823.

research in the Netherlands. But the rest of the world is blindly adopting our research."[122]

A 2014 follow-up study by de Vries et al.[123] encompassed 55 of the original 70 patients; 15 were lost to follow-up or not included. It has the same limitations that was present in assessing the original 2011 study, including a carefully selected patient population that is not representative of the broader population, especially now. Having a longer study does not obviate the limitations of the study design in making a conclusion that can be applied to the gender clinics that are operating in the United States.

In addition to the concerns of the Dutch studies already exposed, "[t]he linchpin result of the Dutch studies is the reported resolution of gender dysphoria, as measured by the Utrecht Gender Dysphoria Scale (UGDS)." Yet, as several researchers recently explained, the observed "drop was an artifact of switching the scale from 'female' to 'male' versions (and vice versa) before and after treatment, prompting a problematic reversal in the scoring."[124] "The same gender dysphoric

[122] See https://www.voorzij.nl/more-research-is-urgently-needed-into-transgender-care-for-young-people-where-does-the-large-increase-of-children-come-from/.
[123] de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics. 2014 Oct;134(4):696-704. doi: 10.1542/peds.2013-2958
[124] Abbruzzese E, Levine SB, Mason JW. The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies-and research that has followed. J Sex Marital Ther. 2023 Jan 2:1-27. doi: 10.1080/0092623X.2022.2150346.

individual, effectively answering the same question (albeit linguistically inverted)"—e.g., "Every time someone treats me like a girl [or boy] I feel hurt"—"results in either the maximum or the minimum 'gender dysphoria' score—depending on which sexed version of the scale was used." Thus, because researches used different scales of the UGDS before and after treatment, "it is impossible to determine if [the result shows] a real difference in gender dysphoria between groups or if this is an artifact of measurement error." Indeed, if anything, "[t]he fact that after gender reassignment, the UGDS scores were low on the opposite-sex scale indicates that the subjects would have scored high on the natal sex scale, which corresponds to a *persistence in transgender identity*." This, of course, is the opposite result purportedly reached by the study.

The 2018 paper by Wiepjies, et al.[125] is a retrospective review of records from all patients of the Center of Expertise on Gender Dysphoria gender clinic in Amsterdam from 1972-2015. While the study appears to report on the regret rates among a large cohort of adolescents (812) and children (548), regret is only reported for children and adolescents who had undergone gonadectomy once over 18 years of age. Of the adolescents, 41% started puberty suppression. Of those who started GnRH agonists, only 2% stopped this intervention (meaning that 98% of

[125] Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, *The Journal of Sexual Medicine*, *15*(4), 582–590 (2018).

those who started puberty suppression progressed to cross-sex hormone therapy). An additional 32%, having already completed puberty, started cross-sex hormone therapy without use of a GnRH agonist. Classification of regret was very stringent, requiring physician documentation of patient verbalized regret after gonadectomy and start of sex-concordant hormones to treat the iatrogenic hypogonadism. This means there are significant limitations to the conclusions that can be drawn from this paper. There is no discussion in the paper regarding adolescent regret of use of puberty blockers, cross-sex hormones or mastectomies. Importantly, 36% of patients were lost to follow up. This is notable given that gonadectomy iatrogenically induces the pathologic state of primary hypogonadism. Affected patients have a lifelong dependency for exogenously administered sex-steroid hormones, and thus an acute need for ongoing follow-up. Their failure to return to the physicians who provided gender affirming interventions raises serious questions about their outcome. It is reasonable to hypothesize that some may have experienced regret or completed suicide. Yet due to missing data, their fate remains unknown. It is also significant that the average time to regret was 130 months. The authors themselves acknowledge that it may be too early to predict regret in patients who started hormone therapy in the past 10 years.

The 2018 Olson-Kennedy et al. paper[126] presents the results of a survey of biologically female patients with male gender identity at the lead author's institution using a novel rating system for "chest dysphoria" created by the study authors. There were an equal number (68) of nonsurgical and post-surgical subjects surveyed. Those who had undergone bilateral mastectomies were reported to have less chest dysphoria than those who did not receive this intervention. Limitations of this study include convenience sampling of nonsurgical study subjects with high potential for selection bias, cross-sectional design, lack of validation of the primary outcome measure, and short follow-up time (about 2 years). Test validation is particularly relevant in assessing adolescent questionnaires due to a variety of cognitive and situational factors in this population.[127] Rigorous validation methods have been previously used in several other established questionnaires addressing adolescent self-perception.[128] As previously noted, this study cannot provide information about a causal relationship between the intervention and outcomes observed.

[126] Olson-Kennedy et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts, *JAMA Pediatr.* 172(5):431–436 (2018).
[127] See Brener et al., Assessment of Factors Affecting the Validity of Self-Reported Health-Risk Behavior among Adolescents: Evidence from the Scientific Literature, *Journal of Adolescent Health* 33 (6): 436–57 (2003).
[128] See Palenzuela-Luis et al., Questionnaires Assessing Adolescents' Self-Concept, Self-Perception, Physical Activity and Lifestyle: A Systematic Review, *Children (Basel, Switzerland)*, *9*(1), 91 (2022).

A 2019 study by Allen et al.[129] considered suicidality after cross-sex hormones. It was limited by a very small patient population (47), had no control group, had a short follow-up period (mean < 1 year), and again ignored that patients receiving the interventions also received psychological support.

A 2020 study by Turban et al.[130] is often cited as proof that pubertal blockade prevents suicide in transgender youth. However, this study used an unreliable, biased sampling methodology. As stated in the paper, the authors considered "a cross-sectional online survey of 20,619 transgender adults aged 18 to 36 years" from the 2015 U.S. Transgender Survey. This was an online survey of transgender and "genderqueer" adults recruited from trans-friendly websites. Among the many problems with this sampling methodology, there is no evidence of study subject identities, no way to assess for potential false subjects, and no medical diagnosis for entry. No causation can be determined from this retrospective, cross-sectional design. Furthermore, the study failed to even assess individuals who may have desisted or regretted transitions. Turban claimed that desisters and regretters would "not be likely" in this study group, which also only included

[129] Allen, L. R., Watson, L. B., Egan, A. M., & Moser, C. N. (2019). Well-being and suicidality among transgender youth after gender-affirming hormones. Clinical Practice in Pediatric Psychology, 7(3), 302–311. https://doi.org/10.1037/cpp0000288

[130] Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, *145*(2), e20191725 (2020).

adults. Thus, the study "does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender."

Turban's misleading claim of lower suicidal ideation for treated patients is based upon "lifetime suicidality". It fails to recognize or acknowledge that the decision to grant the wish to provide puberty blockers was likely influenced by the mental health of the subjects at the time of presentation. Specifically, the most seriously mentally ill patients would have been denied affirmation treatment. Those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2– 0.6). In Table 3 of the paper, under "Suicidality (past 12 months)" reductions for suppressed group versus non-suppressed were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%). However, it is important to note that differences in suicidal "ideation with plan and suicide attempt" and "attempt resulting for inpatient care" did not reach statistical significance. This was ignored by the authors. It would be reasonable to be concerned from an observation of over 40% attempted suicide in the treated group that the intervention was unsuccessful in improving health.[131]

[131] See generally Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Archives of Sexual Behavior, DOI: 10.1007/s10508-020-01743-6 (2020) and the multiple Letters to the Editor that criticized the multiple methodological errors in this study,

A 2020 study by van der Miesen, et al.[132] was a cross-sectional Dutch study that measured some patients who received puberty blockers and some who did not. The study had three populations of subjects: One was patients presenting to the gender clinic who had not received any intervention. The second was patients who had received puberty blockers. The third was adolescents from the general population. Because of this study's cross-sectional nature, it cannot establish a causal relationship between intervention and effect. It also represents a non-probability sample with potential for significant biases in subject recruitment. In addition, the subjects assessed before and after treatment are difference populations. Among the differences between these groups is patient age (mean of 14.5 and 16.8 years before and after treatment, respectively). This two year age difference is important as developmental progress during adolescence is known to influence psychological well-being.[133] There was also the same limitation noted in the 2011 de Vries study, that the treated population also received psychological support.

https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation.

[132] van der Miesen AIR, Steensma TD, de Vries ALC, Bos H, Popma A. Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers. J Adolesc Health. 2020 Jun;66(6):699-704. doi: 10.1016/j.jadohealth.2019.12.018

[133] He J, Sun S, Zickgraf HF, Lin Z, Fan X. Meta-analysis of gender differences in body appreciation. Body Image. 2020 Jun;33:90-100. doi: 10.1016/j.bodyim.2020.02.011.

A 2021 study by Bustos, et al.[134] attempts to provide a systematic review of 27 observational or interventional studies that report on regret or detransition following gender-transition surgeries. A total of 7,928 subjects were included in their meta analysis. The authors concluded that only 1% or less of those who had gender-transition surgeries expressed regret. It is important to understand the serious methodological limitations and high risk of bias contained within this study's analysis.[135] This includes failure to include major relevant studies addressing this question,[136] inaccurate analysis within one of the studies considered,[137] and the general lack of controlled studies, incomplete and generally short-term follow-up, large numbers of lost subjects, and lack of valid assessment measures in the published literature addressing this question. As noted by Expósito-Campos and D'Angelo (2021), moderate to high risk of bias was present in 23 of the 27 studies included in the analysis. Furthermore, 97% of subjects analyzed were found

[134] Bustos et al., Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery. Global open*, *9*(3), e3477 (2021).
[135] See Expósito-Campos, P., & D'Angelo, R. (2021). Letter to the Editor: Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery. Global open*, *9*(11), e3951.
[136] E.g. Dhejne, C., Öberg, K., Arver, S., & Landén, M. (2014). An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. *Archives of sexual behavior*, *43*(8), 1535–1545.
[137] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med 2018; 15: 582–590.

within studies deemed to be of fair to poor scientific quality. Thus, this study cannot be used as strong support for the contention that regret is rare.

The 2021 study by Narayan et al.[138] examines anonymous survey results from 154 surgeons affiliated with WPATH. The response rate for this survey was 30%. Of the respondents, 57% had encountered patients with surgical regret. It is important to recognize that this study was specifically directed toward patients who had undergone surgical transition. Acknowledged biases of this study include selection bias, recall bias, and response bias. This type of study cannot accurately identify the prevalence in the transgender population as a whole, and is particularly limited in the ability to assess potential for regret in the pediatric population.

The 2021 Almazan study[139] attempts to address mental health outcomes in relation to gender-transition surgery. This study relies upon data from the 2015 US Transgender Survey. Limitations and weaknesses of this survey tool includes convenience sampling, recruitment of patients through transgender advocacy organizations, demand bias (i.e., the good subject effect[140]), a high number of respondents

[138] Narayan et al., Guiding the conversation-types of regret after gender-affirming surgery and their associated etiologies, *Annals of translational medicine*, *9*(7), 605 (2021).
[139] Almazan et al., Association Between Gender-Affirming Surgeries and Mental Health Outcomes. *JAMA Surgery, 156*(7): 611–618 (2021).
[140] Nichols AL, Maner JK. The good-subject effect: investigating participant demand characteristics. J Gen Psychol. 2008 Apr;135(2):151-65. doi: 10.3200/GENP.135.2.151-166. PMID: 18507315.

who reported having not transitioned medically or surgically (and reported no desire to do so in the future), and several data irregularities. One notable data irregularity was that a high number of respondents reported that their age was exactly 18 years. As noted by D'Angelo and colleagues, these irregularities raise serious questions about the reliability of the USTS data and therefore the reliability of conclusions based on that data.[141]

The **2022 van der Loos** study[142] is a Dutch cohort study that investigates the continuation rate of gender affirming interventions in people who began puberty blockers and gender affirming hormones during adolescence. The authors claim that the study provides evidence against desistance after receiving gender affirming hormones. While the paper gives the impression that subjects represent a period of study extending from 1972 to 2018, the majority of subjects recently started hormone interventions. The length of time for follow-up (mean of 3.5 years for males and 2.3 years for females) and the average age at follow-up (20.2 years for males and 19.3 years for females) are inadequate to support the authors' claim. Notably,

[141] D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, *Archives of sexual behavior*, *50*(1): 7–16. https://doi.org/10.1007/s10508-020-01844-2 (2021).

[142] van der Loos MATC, Hannema SE, Klink DT, den Heijer M, Wiepjes CM. Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: a cohort study in the Netherlands. Lancet Child Adolesc Health. 2022 Dec;6(12):869-875. doi: 10.1016/S2352-4642(22)00254-1.

research from these same investigators has suggested that the average time to de-transition is over 10 years.[143] Thus, it would be necessary for the study to assess patients at least a decade after starting gender affirming hormones to make any meaningful conclusions on desistance. Furthermore, as a retrospective cohort study without a control group, the study design cannot determine the effect of gender affirming therapy on whether or not the intervention influences the rate of desistance that would have occurred without the provision of gender affirming hormones.

The **2022 Nos** study[144] is a retrospective cohort study that reports on the likelihood of starting on gender affirming hormones (GAH) based upon whether or not subjects were treated with puberty blockers. While the title and abstract give the impression that puberty blocker use is not linked to subsequent GAH, the data fail to support this conclusion. Since nearly all of the patients in this study who did not receive GnRHa were given GAH, it is not possible to determine whether GnRHa could increase this outcome. The comparison groups differed by age at time of initial presentation (age 10-13 years versus 14-17 years). GnRHa use was higher among the younger patients owing to the fact that they had not completed

[143] Wiepjes CM, Nota NM, de Blok CJM, Klaver M, de Vries ALC, Wensing-Kruger SA, de Jongh RT, Bouman MB, Steensma TD, Cohen-Kettenis P, Gooren LJG, Kreukels BPC, den Heijer M. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med. 2018 Apr;15(4):582-590. doi: 10.1016/j.jsxm.2018.01.016.
[144] Nos AL, Klein DA, Adirim TA, Schvey NA, Hisle-Gorman E, Susi A, Roberts CM. Association of Gonadotropin-Releasing Hormone Analogue Use With Subsequent Use of Gender-Affirming Hormones Among Transgender Adolescents. JAMA Netw Open. 2022 Nov 1;5(11):e2239758. doi: 10.1001/jamanetworkopen.2022.39758.

puberty at the time of first visit. A lag in progression to GAH use in this group is heavily influenced by the difference in age at time of initial presentation. The older group was eligible to start GAH at the time of study entry while those in the younger group were not. When adjusted for age, the rates of progression to GAH use is nearly identical. Importantly, among the patients who received GnRHa, **94% (64 out of 70)** went on to take gender affirming hormones. Thus, the study further confirms that rather than serving as a "pause button" for gender dysphoric adolescents, it is an intervention that will lead to progression to gender affirming hormones.

The 2022 Green at al. study[145] purported to measure suicide attempts and access to cross-sex hormones. Though this study had a large cohort of patients, it suffered many biases in patient recruitment—which was done over the Internet and provided a cross-sectional analysis which can, at best, demonstrate correlation but not causation. Similar to other studies, it not assess the effect of psychiatric medications or psychotherapy on outcomes. It also failed to include variables to assess at what age youth began puberty blockers or the duration which they had received gender affirming hormones.

[145] Green AE, DeChants JP, Price MN, Davis CK. Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. J Adolesc Health. 2022 Apr;70(4):643-649.

The 2022 Turban et al. study[146] is retrospective cross-sectional investigation to assess whether there is an association between adolescent access to gender affirming hormones and mental health. The authors claim that there is an association between getting gender affirming hormones and favorable mental health outcomes compared to those who desired but did not receive this intervention. The methodology used is similar to the author's 2020 study on the effects of access to puberty blockers on lifetime suicidality already discussed above. Specifically, it used the same 2015 U.S. Transgender Survey (USTS), with all of the associated limitations and biases.[147] Participants in the USTS were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. Thus, there are serious concerns of selection bias.[148] It also suffers from recall bias[149] and an inability to verify the veracity of the claims of treatments given to the study respondents. Even if one dis-

[146] Tordoff DM, Wanta JW, Collin A, Stepney C, Inwards-Breland DJ, Ahrens K. Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. JAMA Netw Open. 2022 Feb 1;5(2):e220978. doi: 10.1001/jamanetworkopen.2022.0978. Erratum in: JAMA Netw Open. 2022 Jul 1;5(7):e2229031.

[147] D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* **50**, 7–16 (2021). https://doi.org/10.1007/s10508-020-01844-2

[148] Tyrer S, Heyman B. Sampling in epidemiological research: issues, hazards and pitfalls. BJPsych Bull. 2016 Apr;40(2):57-60. doi: 10.1192/pb.bp.114.050203. PMID: 27087985; PMCID: PMC4817645.

[149] Coughlin SS. Recall bias in epidemiologic studies. J Clin Epidemiol. 1990;43(1):87-91. doi: 10.1016/0895-4356(90)90060-3. PMID: 2319285.

misses these concerns, by design, the study is not able to make any conclusions regarding a causal relationship between GAH access and mental health. Review of the data contained within the paper leads to conclusions that are far different than those stated by the study authors regarding mental health of the study participants. While the odds ratio for past year suicidal ideation was statistically different between those who did and those who did not get GAH, there was no difference in those who had a suicide plan, actually attempted suicide, or were hospitalized for a suicide attempt. This is important since the rationale for accepting the attendant risks of gender affirming hormones is to prevent suicide. Those with a suicide plan or attempt are far more likely to succumb to suicide than those who merely contemplated suicide. As pointed out by Michael Biggs in a commentary of this article,[150] the data presented in this study negate the purported significance of effects of puberty blocker access on mental health as reported in Turban's 2020 Pediatric article.

The 2022 Tordoff study is a prospective observational cohort study that assessed the mental health of patients presenting to the Seattle Children's gender clinic over a one year period of follow up. The authors claimed that access to gender affirming care had significantly improved mental health with lower odds ratios

[150] https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6

of depression and suicidality. This purported finding was widely publicized by the University of Washington and was featured on several news media sites. A detailed critique of the paper's data and flawed conclusions have been posted online.[151] Contrary to the claims, data contained in the paper did not show improvement in mental health over the one year study period. At entry into the study, 59% of the subjects had moderate to severe depression. At the end of the study, 56% had moderate to severe depression. Self-harm or suicidal thoughts were 45% and 37% at baseline and 12 months, respectively. These are alarmingly high numbers for an intervention that is touted to be lifesaving. The reported statistical difference in odds ratios were comparisons between those who started on puberty blockers and cross-sex hormones and those who did not receive hormones. Importantly, there was a marked difference in the number of dropout subjects in the treated and non-treated groups (17.5% versus 80%, respectively). It is reasonable to speculate that the small number of subjects who remained in the study but did not receive hormones had significant co-morbidities that prevented them from accessing this intervention. In any event, the actual data from this study demonstrates that access to puberty blockers and gender affirming hormones did not improve mental health over the first year of treatment. This is drastically different from what the authors and the media claimed.

[151] See https://jessesingal.substack.com/p/researchers-found-puberty-blockers?s=r

The 2022 Chen study[152] is a longitudinal observational study of patients receiving care at four gender centers in the United States. The primary conclusion made by the authors is that "GAH improved appearance congruence and psychosocial functioning." However, there are major limitations and weaknesses in the data that limit the conclusions that can be made. A revealing critique of the paper by de Vries and Hannema that was published alongside this article exposes some of these concerns.[153] The most glaring problem is that the study was observational and did not include a control group. Thus, there is no ability to draw causal conclusions. At best, the authors can find associations. Akin to many of the other papers in this field, there is no way to determine whether any of the changes were contributed by or due solely to psychiatric interventions. It is also notable that even though the study was designed to recruit only subjects in with good mental health at baseline, 48 of the 307 study subjects (15.6%) were described as having severe depression at this time point. At the end of the two year follow up, 30 of the 219 remaining subjects (13.7%) were reported to have major depression. Furthermore, two patients committed suicide during the time of observation. This is an outcome that in most

[152] Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297.
[153] de Vries ALC, Hannema SE. Growing Evidence and Remaining Questions in Adolescent Transgender Care. N Engl J Med. 2023 Jan 19;388(3):275-277. doi: 10.1056/NEJMe2216191

other situations would lead to a halt in study and detailed inquiry by an institutional review board.[154] The paper claims to present two year follow up data in this cohort. However, only half of the study participants were assessed at each study time point and 30% did not have 24 month data collected. Even if one accepted the follow up period, this is likely not long enough to make firm conclusions about long-term efficacy. Most of the measures are based upon subjective experience. There is no inclusion of more robust measures of psychological well-being such as the number on antidepressants and other psychotropic medications. The study effects for many of the measured parameters was very modest at best and, while statistically significant, do not have any meaningful clinical significance. For example, the depression scores, showed little change over two years in the highest severity group. There is also significant heterogeneity in responses with some subjects showing improvement, some no change, and others worsening. Despite the spin provided by the authors and media, these data do not alleviate the serious concerns raised regarding the safety and efficacy of gender affirming medical interventions.

121. Many conclusions in the above studies are drawn or characterized in fundamentally unscientific ways without apparent regard to the scientific process of disproving a null hypothesis. Instead, these studies suggest that the authors began with a conclusion and then looked for data to support that conclusion. That is

[154] https://grants.nih.gov/grants/guide/notice-files/NOT99-107.html

a vastly unsound way of doing science, and patients will not be aware of these methodological limitations and distortions when informed of these purported conclusions.

122. There remains a significant and unmet need to improve our understand of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals, as well as the long-term effects of "affirming" interventions.[155] In particular, there is a concerning lack of randomized controlled trials or adequately controlled longitudinal studies comparing outcomes of youth with gender dysphoria who received psychological support, were encouraged to socially transition, or were put on medical interventions, and how these differential treatments affect the usual and natural progression to resolution of gender dysphoria and other variables. Such studies can be ethically designed and executed with provisions for other dignity affirming measures to all treatment groups.[156] But they have not been performed in the existing literature, leaving that literature in a state insufficient to enable sound conclusions about the efficacy of "affirming" treatments.

[155] Olson-Kennedy, J. et al. Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Current Opinion in Endocrinology, Diabetes and Obesity 23, 172-179, (2016).
[156] See Sugarman J. Ethics in the design and conduct of clinical trials. Epidemiol Rev. 2002;24(1):54-8. doi: 10.1093/epirev/24.1.54. PMID: 12119856; And https://clinicalcenter.nih.gov/recruit/ethics.html.

International Responses

123. Recognizing the paucity of evidence supporting "affirming" treatments, along with the proven risks of those treatments, other countries are increasingly limiting use of those treatments.

124. **Finland**: The National Science Review in Finland carefully examined all relevant science and suspended transition treatments for minors under age 16.[157] The review determined that "[t]he first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders." According to the review, "[c]ross-sex identification in childhood, even in extreme cases, generally disappears during puberty." The review also found: "Potential risks of GnRH therapy include disruption in bone mineralization and the as yet unknown effects on the central nervous system"; "there are no medical treatments (for transitioning) that can be considered evidence-based"; and, "[t]he reliability of the existing studies with no control groups is highly uncertain." Thus, "because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development," and "[n]o gender confirmation surgeries are performed on

[157] See 2020 Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors.

minors." "Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options. For children and adolescents, these factors are key reasons for postponing any interventions until adulthood…. In light of available evidence, gender reassignment of minors is an experimental practice."

125. **Sweden**: The world-renowned Karolinska Hospital reviewed the current research and suspended pediatric gender transitions for patients under 16 outside of experimental, monitored clinical trials settings as of May 2021. Treatment will focus on psychotherapy and assessment[158]. The "Dutch protocol" for treating gender dysphoric minors has been discontinued over concerns of medical harm and uncertain benefits.

Moreover, in a national policy review, a report commissioned by the Swedish government concluded that:

- We have not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria.

[158] See Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies. https://segm.org/Sweden_ends_use_of_Dutch_protocol. See also, Karolinska Policy Change K2021-3343 March 2021 (in English).pdf; Karolinska Hospital Ends the Use of Puberty Blockers for patients under 16: New policy statement from the Karolinska Hospital.

- We have not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria. There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium…
- No relevant randomized controlled trials in children and adolescents were found.[159]

From these findings, the Swedish National Board of Heath in December of 2022 issued updated guidelines for the care of adolescents and children with gender dysphoria.[160] This medical board concluded that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatment". Noting that there is uncertainty about the cause for the rapid rise in number of people being diagnosed with gender dysphoria, documented evidence of detransitioning young adults with uncertainty regarding the prevalence of this outcome, and lack of uniformity in experience-based knowledge among providers, GnRH analogues, gender affirming hormones and mastectomy should be provided only in exceptional cases and ideally as part of an experimental trial.

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[159] See Sweden Policy Review, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 (https://www.sbu.se/307e).
[160] https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf

126. **United Kingdom**: The British official medical review office (National Institute of Health and Care Excellence, NICE) published reports on the use of both puberty blockers and hormones for transitioning purposes. The assessment of the evidence into the drugs was commissioned by NHS England. The review found that the evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low certainty."[161] The review found that "all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly."

NICE also reviewed the evidence base for cross-sex hormones.[162] The review found the evidence of clinical effectiveness and safety of cross-sex hormones was also of "very low" quality. The review concluded: "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria."

[161] https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf
[162] https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf

A recent independent review of gender identity services in the United Kingdom, by Dr. Hillary Case, concluded that "Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally."[163] Dr. Cass notes that "[t]here is lack of consensus and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response."

Citing concerns from the Cass report that the Tavistok model of care placed affected youth at considerable risk of poor mental health, and is therefore "not a safe or viable long-term option," this clinic is being shut down. It will be replaced by a new regional hospital-based service where related services for mental health and autism can be provided by clinicians who have expertise in safeguarding, supporting looked-after children and children who have experienced trauma. Thus, gender-related distress will be addressed "within a broader child and adolescent health context."

This new model is in sharp contrast to recommendations made by WPATH in their "standards of care" (SOC8). Differences in approach include the prioritization of parent versus child expectations for care, recommendations against social

[163] https://cass.independent-review.uk/wp-content/uploads/2022/03/Cass-Review-Interim-Report-Final-Web-Accessible.pdf

affirmation of pre-pubertal youth, the provision of puberty blockers within the experimental setting, initial focus on exploration and treatment of mental health problems, and use of psychological support as a primary intervention.

Conclusions

127. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

128. There are no long-term, peer-reviewed published, reliable, and valid research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological or other objective assessment of gender identity or gender dysphoria.

129. A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

130. A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

131. A currently unknown percentage and number of patients reporting gender dysphoria may be manipulated by a social contagion and social pressure

processes, including peer group, social media, YouTube role modeling, and parental pressures.

132. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

133. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

134. "Affirming" treatments have no known, peer reviewed and published error rates.

135. The gender affirming approach has limited, very weak scientific support for short-term alleviation of dysphoria and no long-term outcomes data demonstrating superiority over the other approaches.

136. Because of the major methodological limitations and weaknesses of the extent published literature in the field of gender dysphoria, one cannot make a conclusion that "affirming" treatments are justified as a safe and effective long-term solution to gender dysphoria in consideration of the significant risks and unsubstantiated long-term benefits.

137. With the limited and poor-quality data currently available about the purported efficacy of blocking normally timed puberty, administering cross-sex

hormones, and gender affirming surgeries in alleviating psychological morbidity for youth who experience sex-discordant gender identity and the associated serious medical risks associated with these interventions, it cannot be concluded that this approach is "medically necessary." Use of such medical interventions remains a largely experimental approach.

138. Experimentation on gender discordant youths is especially likely to cause harm to patients from historically marginalized communities. That is because children in such communities are disproportionally affected by gender discordance. These include:

- children with a history of psychiatric illness;[164]
- children of color;[165]
- children with mental developmental disabilities;[166]
- children on the autistic spectrum;[167] and,

[164] See, e.g., Kaltiala-Heino, R., Sumia, M., Työläjärvi, M., & Lindberg, N. (2015). Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child and adolescent psychiatry and mental health*, *9*, 9. https://doi.org/10.1186/s13034-015-0042-y.

[165] See, e.g., G. Rider et al. (2018), Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study, Pediatrics at 4, DOI: 10.1542/peds.2017-1683.

[166] See, e.g., Bedard, C., Zhang, H.L. & Zucker, K.J. Gender Identity and Sexual Orientation in People with Developmental Disabilities. *Sex Disabil* 28**,** 165–175 (2010). https://doi.org/10.1007/s11195-010-9155-7.

[167] See, e.g., de Vries, A. L., Noens, I. L., Cohen-Kettenis, P. T., van Berckelaer-Onnes, I. A. & Doreleijers, T. A. Autism spectrum disorders in gender dysphoric children and adolescents. *J Autism Dev Disord* 40, 930-936, doi:10.1007/s10803-010-0935-9 (2010).

- children residing in foster care homes and adopted children.[168]

139. Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable, valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

140. The treatment protocols and recommendations of politically influenced, non-science associations like WPATH and the American Academy of Pediatrics that engage in consensus-seeking methodologies by vote rather than science are not based on competent, credible, methodologically sound science, and have no known or published error rate.

141. Administering hormones to a child whose gender dysphoria is highly likely to resolve is risky, unscientific, and unethical. Iatrogenic damages from these interventions, including infertility, stunted growth, increased heart attack risk, and many more, are often irreversible.

142. Because of these concerns about the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not personally engaged in the delivery of gender affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the

[168] See, e.g., See e.g., D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, Transgender Health Vol. 2(1).

well-documented risks and harms of "transitioning" children, I decline to participate in such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures.

143. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if left untreated, grow out of the problem — a natural coping-developmental process — and willingly accept their biological sex. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 15, 2023.

Paul W Hruz

Paul W. Hruz, M.D., Ph.D.

Exhibit "A"

Curriculum Vitae

Date: 2/15/2023
Name: Paul W. Hruz, M.D., Ph.D.

Contact Information

Office:	Phone: 314-286-2797 Fax: 314-286-2892
Mail:	Washington University in St. Louis School of Medicine Department of Pediatrics Endocrinology and Diabetes 660 South Euclid Avenue St Louis MO 63110
Email:	Office: hruz_p@wustl.edu

Present Position

Associate Professor of Pediatrics, Endocrinology and Diabetes
Associate Professor of Pediatrics, Cell Biology & Physiology

Education

1987	BS, Chemistry, Marquette University, Milwaukee, WI
1993	PhD, Biochemistry, Medical College of Wisconsin, Milwaukee, WI Elucidation of Structural, Mechanistic, and Regulatory Elements in 3-Hydroxy-3-Methlyglutaryl-Coenzyme A Lyase, Henry Miziorko
1994	MD, Medicine, Medical College of Wisconsin, Milwaukee, WI
1994 - 1997	Pediatric Residency, University of Washington, Seattle, Washington
1997 - 2000	Pediatric Endocrinology Fellowship, Washington University, Saint Louis, MO
2017	Certification in Healthcare Ethics, National Catholic Bioethics Center, Philadelphia, PA

Academic Positions / Employment

1996 - 1997	Locum Tenens Physician, Group Health of Puget Sound Eastside Hospital, Group Health of Puget Sound Eastside Hospital, Seattle , WA
2000 - 2003	Instructor in Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2003 - 2011	Assistant Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2004 - 2011	Assistant Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO
2011 - Pres	Associate Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO

2011 - Pres	Associate Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2012 - 2017	Division Chief, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO

Clinical Title and Responsibilities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 3-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

Teaching Title and Responsibilities

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

University, School of Medicine and Hospital Appointments and Committees

University

2012 - 2020	Disorders of Sexual Development Multidisciplinary Care Program

School of Medicine

2013 - 2020	Molecular Cell Biology Graduate Student Admissions Committee
2014 - Pres	Research Consultant, ICTS Research Forum - Child Health

Hospital

2000 - Pres	Attending Physician, St. Louis Children's Hospital

Medical Licensure and Certifications

1997 - Pres	Board Certified in General Pediatrics
2000 - Pres	MO Stae License #2000155004
2001 - Pres	Board Certified in Pediatric Endocrinology & Metabolism

Honors and Awards

1987	National Institute of Chemists Research and Recognition Award
1987	Phi Beta Kappa
1987	Phi Lambda Upsilon (Honorary Chemical Society)
1988	American Heart Association Predoctoral Fellowship Award
1994	Alpha Omega Alpha
1994	Armond J. Quick Award for Excellence in Biochemistry

1994	NIDDK/Diabetes Branch Most Outstanding Resident
1998	Pfizer Postdoctoral Fellowship Award
2002	Scholar, Child Health Research Center of Excellence in Developmental Biology at Washington University
2013	Julio V Santiago, M.D. Scholar in Pediatrics
2017	Redemptor Hominis Award for Outstanding Contributions to the Study of Bioethics
2018	Eli Lilly Outstanding Contribution to Drug Discovery: Emerging Biology Award
2018	Scholar-Innovator Award, Harrington Discovery Institute
2021	Linacre Award

Editorial Responsibilities

Editorial Ad Hoc Reviews

	AIDS
	AIDS Research and Human Retroviruses
	American Journal of Pathology
	American Journal of Physiology
	British Journal of Pharmacology
	Circulation Research
	Clinical Pharmacology & Therapeutics
	Comparative Biochemistry and Physiology
	Diabetes
	Experimental Biology and Medicine
	Future Virology
	Journal of Antimicrobial Chemotherapy
	Journal of Clinical Endocrinology & Metabolism
	Journal of Molecular and Cellular Cardiology
	Obesity Research
2000 - Pres	Journal of Biological Chemistry
2013 - Pres	PlosOne
2016 - Pres	Scientific Reports
2018 - Pres	Nutrients

Editorial Boards

2014 - 2015	Endocrinology and Metabolism Clinics of North America

National Panels, Committees

2017 - Pres	Consultant, Catholic Health Association
2021 - Pres	Consulting Fellow, National Catholic Bioethics Center

National Boards

2020 - Pres	WU ICTS Clinical and Translational Research Funding Program (CTRFP) Review Committee

Community Service Contributions

Professional Societies and Organizations

American Diabetes Association
Endocrine Society
Pediatric Endocrine Society

Major Invited Professorships and Lectures

2002	Pediatric Grand Rounds, St. Louis Children's Hospital, St Louis, MO
2004	National Disease Research Interchange, Human Islet Cell Research Conference, Philadelphia, PA
2004	NIDA-NIH Sponsored National Meeting on Hormones, Drug Abuse and Infections, Bethesda, MD
2005	Endocrine Grand Rounds, University of Indiana, Indianapolis, IN
2005	The Collaborative Institute of Virology, Complications Committee Meeting, Boston, MA
2006	Metabolic Syndrome Advisory Board Meeting, Bristol-Meyers Squibb, Pennington, NJ
2007	American Heart Association and American Academy of HIV Medicine State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, Chicago, IL
2007	Minority Access to Research Careers Seminar, University of Arizona, Tucson, AZ
2007	MSTP Annual Visiting Alumnus Lecture, Medical College of Wisconsin , Milwaukee, WI
2007	Pediatric Grand Rounds, St Louis Children's Hospital, St Louis, MO
2008	Division of Endocrinology, Diabetes and Nutrition Grand Rounds, Boston University, Boston, MA
2009	Pediatric Grand Rounds, St Louis Children's Hospital, St. Louis, MO
2010	American Diabetes Association Scientific Sessions, Symposium Lecture Orlando, FL
2010	School of Biological Sciences Conference Series, University of Missouri Kansas City, Kansas City, MO
2011	Life Cycle Management Advisory Board Meeting, Bristol-Myers Squibb,, Chicago, IL
2013	Pediatric Grand Rounds, St Louis Children's Hospital, ST LOUIS, MO
2013	Clinical Practice Update Lecture, St Louis Children's Hospital, St Louis, MO
2014	Pediatric Academic Societies Meeting,, Vancouver, Canada
2014	American Diabetes Association 74th Scientific Sessions, , San Francisco, CA
2017	Division of Pediatric Endocrinology Metabolism Rounds, University of Michigan, Ann Arbor, MI
2017	Catholic Medical Association National Conference, Denver, CO
2018	Obstetrics, Gynecology & Women's Health Grand Rounds, Saint Louis University, St. Louis, MO
2018	Medical Grand Rounds, Sindicato Médico del Uruguay, Montevideo, Uraquay
2018	Internal Medicine Grand Rounds, Texas Tech , Lubbock, TX
2019	Veritas Center for Ethics in Public Life Conference, Franciscan University, Steubenville, OH
2019	MaterCare International Conference, Rome, Italy
2019	Child Health Policy Forum, Notre Dame University, South Bend , IN

2021	Obstetrics & Gynecology Grand Rounds, University of Tennessee, Knoxville , TN
2022	The World Federation of Catholic Medical Associations (*FIAMC*), Rome, Italy

Consulting Relationships and Board Memberships

1996 - 2012	Consultant, Bristol Myers Squibb
1997 - 2012	Consultant, Gilead Sciences

Research Support

Completed Governmental Support

2001 - 2006	K-08 A149747, NIH Mechanism of GLUT4 Inhibition by HIV Protease Inhibitors Role: Principal Investigator
2007 - 2012	R01 Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $800,000.00
2009 - 2011	R01 Student Supp Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $25,128.00
2009 - 2014	R01 Direct Effects of Antiretroviral Therapy on Cardiac Energy Homeostasis Role: Principal Investigator Total cost: $1,250,000.00
2017 - 2019	R-21 1R21AI130584 , National Institutes of Health SELECTIVE INHIBITION OF THE P. FALCIPARUM GLUCOSE TRANSPORTER PFHT Role: Principal Investigator Total cost: $228,750.00

Completed Non-Governmental Support

2015	Novel HIV Protease Inhibitors and GLUT4 Role: Principal Investigator
2008 - 2011	II Insulin Resistance and Myocardial Glucose Metabolism in Pediatric Heart Failure Role: Co-Investigator PI: Hruz Total cost: $249,999.00
2009 - 2012	Research Program Regulation of GLUT4 Intrinsic Activity Role: Principal Investigator Total cost: $268,262.00
2010 - 2011	Protective Effect of Saxagliptin on a Progressive Deterioration of Cardiovascular Function Role: Principal Investigator
2012 - 2015	II Solution-State NMR Structure and Dynamics of Facilitative Glucose Transport Proteins Role: Principal Investigator Total cost: $375,000.00

2017 - 2020 Prevention And Treatment Of Hepatic Steatosis Through Selective Targeting Of GLUT8
Role: Co-Principal Investigator
PI: DeBosch
Total cost: $450,000.00

2017 - 2021 Matching Micro Grant
Novel Treatment of Fatty Liver Disease (CDD/LEAP)
Role: Principal Investigator
Total cost: $68,500.00

2018 - 2021 LEAP Innovator Challenge
Novel Treatment of Fatty Liver Disease
Role: Principal Investigator
Total cost: $68,500.00

2019 - 2021 Scholar-Innovator Award HDI2019-SI-4555 , Harrington Foundation
Novel Treatment of Non-Alcoholic Fatty Liver Disease
Role: Principal Investigator
Total cost: $379,000.00

Current Governmental Support

2021 - 2025 R-01 DK126622 (Co-investigator), 8/25/2021-7/31/2025, NIH-NIDDK, , NIH
Leveraging glucose transport and the adaptive fasting response to modulate hepatic metabolism
Role: Co-Investigator
PI: DeBosch

Trainee/Mentee/Sponsorship Record

2002 - 2002 Nishant Raj- Undergraduate Student, Other
Study area: Researcher

2002 - 2010 Joseph Koster, PhD, Postdoctoral Fellow
Study area: Researcher

2003 - 2004 Johann Hertel, Medical Student
Study area: Research
Present position: Assistant Professor, University of North Carolina, Chapel Hill, NC

2003 - 2003 John Paul Shen, Medical Student
Study area: Research

2004 - 2005 Carl Cassel- High School Student, Other
Study area: Research

2004 - 2004 Christopher Hawkins- Undergraduate Student, Other
Study area: Researcher

2004 - 2004 Kaiming Wu- High School Student, Other
Study area: Research

2005 - 2005 Helena Johnson, Graduate Student

2005 - 2005 Jeremy Etzkorn, Medical Student
Study area: Researcher

2005 - 2005 Dominic Doran, DSc, Postdoctoral Fellow
Study area: HIV Protease Inhibitor Effects on Exercize Tolerance

2006 - 2006 Ramon Jin, Graduate Student
Study area: Research

2006 - 2006 Taekyung Kim, Graduate Student
Study area: Research

2007 - 2007 Jan Freiss- Undergraduate Student, Other
Study area: Researcher

2007 - 2008 Kai-Chien Yang, Graduate Student
Study area: Research
Present position: Postdoctoral Research Associate, University of Chicago

2007 - 2007 Paul Buske, Graduate Student
Study area: Research

2007 - 2007 Randy Colvin, Medical Student
Study area: Researcher

2008 - 2011 Arpita Vyas, MD, Clinical Fellow
Study area: Research
Present position: Assistant Professor, Michigan State University, Lansing MI

2008 - 2009 Candace Reno, Graduate Student
Study area: Research
Present position: Research Associate, University of Utah

2008 - 2012 Dennis Woo- Undergraduate Student, Other
Study area: Researcher
Present position: MSTP Student, USC, Los Angeles CA

2008 - 2008 Temitope Aiyejorun, Graduate Student
Study area: Research

2009 - 2009 Anne-Sophie Stolle- Undergraduate Student, Other
Study area: Research

2009 - 2009 Matthew Hruz- High School Student, Other
Study area: Research
Present position: Computer Programmer, Consumer Affairs, Tulsa OK

2009 - 2009 Stephanie Scherer, Graduate Student
Study area: Research

2010 - 2014 Lauren Flessner, PhD, Postdoctoral Fellow
Present position: Instructor, Syracuse University

2010 - 2010 Constance Haufe- Undergraduate Student, Other
Study area: Researcher

2010 - 2011 Corinna Wilde- Undergraduate Student, Other
Study area: Researcher

2010 - 2010 Samuel Lite- High School Student, Other
Study area: Research

2011 - 2016 Thomas Kraft, Graduate Student
Study area: Glucose transporter structure/function
Present position: Postdoctoral Fellow, Roche, Penzberg, Germany

2011 - 2011 Amanda Koenig- High School Student, Other
Study area: Research

2011 - 2012 Lisa Becker- Undergraduate Student, Other

2011 - 2011 Melissa Al-Jaoude- High School Students, Other

2019 Ava Suda, Other, Pre-med

Bibliography

A. Journal Articles

1. Hruz PW, Narasimhan C, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase: affinity labeling of the Pseudomonas mevalonii enzyme and assignment of cysteine-237 to the active site. *Biochemistry*. 1992;31(29):6842-7. PMID:1637819
2. Hruz PW, Miziorko HM. Avian 3-hydroxy-3-methylglutaryl-CoA lyase: sensitivity of enzyme activity to thiol/disulfide exchange and identification of proximal reactive cysteines. *Protein Sci*. 1992;1(9):1144-53. doi:10.1002/pro.5560010908 PMCID:PMC2142181 PMID:1304393
3. Mitchell GA, Robert MF, Hruz PW, Wang S, Fontaine G, Behnke CE, Mende-Mueller LM, Schappert K, Lee C, Gibson KM, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase (HL). Cloning of human and chicken liver HL cDNAs and characterization of a mutation causing human HL deficiency. *J Biol Chem*. 1993;268(6):4376-81. PMID:8440722
4. Hruz PW, Anderson VE, Miziorko HM. 3-Hydroxy-3-methylglutaryldithio-CoA: utility of an alternative substrate in elucidation of a role for HMG-CoA lyase's cation activator. *Biochim Biophys Acta*. 1993;1162(1-2):149-54. PMID:8095409
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7. Murata H, Hruz PW, Mueckler M. The mechanism of insulin resistance caused by HIV protease inhibitor therapy. *J Biol Chem*. 2000;275(27):20251-4. doi:10.1074/jbc.C000228200 PMID:10806189
8. Hruz PW, Mueckler MM. Cysteine-scanning mutagenesis of transmembrane segment 11 of the GLUT1 facilitative glucose transporter. *Biochemistry*. 2000;39(31):9367-72. PMID:10924131
9. Hruz PW, Mueckler MM. Structural analysis of the GLUT1 facilitative glucose transporter (review). *Mol Membr Biol*. 2001;18(3):183-93. PMID:11681785
10. Murata H, Hruz PW, Mueckler M. Investigating the cellular targets of HIV protease inhibitors: implications for metabolic disorders and improvements in drug therapy. *Curr Drug Targets Infect Disord*. 2002;2(1):1-8. PMID:12462148
11. Hruz PW, Murata H, Qiu H, Mueckler M. Indinavir induces acute and reversible peripheral insulin resistance in rats. *Diabetes*. 2002;51(4):937-42. PMID:11916910
12. Murata H, Hruz PW, Mueckler M. Indinavir inhibits the glucose transporter isoform Glut4 at physiologic concentrations. *AIDS*. 2002;16(6):859-63. PMID:11919487
13. Koster JC, Remedi MS, Qiu H, Nichols CG, Hruz PW. HIV protease inhibitors acutely impair glucose-stimulated insulin release. *Diabetes*. 2003;52(7):1695-700. PMCID:PMC1403824 PMID:12829635
14. Liao Y, Shikapwashya ON, Shteyer E, Dieckgraefe BK, Hruz PW, Rudnick DA. Delayed hepatocellular mitotic progression and impaired liver regeneration in early growth response-1-deficient mice. *J Biol Chem*. 2004;279(41):43107-16. doi:10.1074/jbc.M407969200 PMID:15265859
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18. Hruz PW. Molecular Mechanisms for Altered Glucose Homeostasis in HIV Infection. *Am J Infect Dis*. 2006;2(3):187-192. PMCID:PMC1716153 PMID:17186064
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21. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. doi:10.1097/COH.0b013e3283139134 PMCID:PMC2680222 PMID:19373039
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48. Hruz PW. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q*. 2020;87(1):34-42. PMCID:PMC7016442 PMID:32431446
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51. McMillin SL, Evans PL, Taylor WM, Weyrauch LA, Sermersheim TJ, Welc SS, Heitmeier MR, Hresko RC, Hruz PW, Koumanov F, Holman GD, Abel ED, Witczak CA. Muscle-Specific Ablation of Glucose Transporter 1 (GLUT1) Does Not Impair Basal or Overload-Stimulated Skeletal Muscle Glucose Uptake. *Biomolecules*. 2022;12(12):1734. PMID: 36551162; PMCID: PMC9776291.

C2. Chapters

1. Henderson KE, Baranski TJ, Bickel PE, Clutter PE, Clutter WE, McGill JB. Endocrine Disorders in HIV/AIDS. In: *The Washington Manual Endocrinology Subspecialty Consult* Philadelphia, PA; 2008:321-328.
2. Paul W Hruz. Medical Approaches to Alleviating Gender Dysphoria In: Edward J Furton, eds. *Transgender Issues in Catholic Health Care* Philadelphia PA; 2021:1-42.
3. Cara Buskmiller and Paul Hruz. A Biological Understanding of Man and Woman In: John Finley, eds. *Sexual Identity: The Harmony of Philosophy, Science, and Revelation* Steubenville OH; 2022:Chapter 2, pp 65-103.

C4. Invited Publications

1. Grunfeld C, Kotler DP, Arnett DK, Falutz JM, Haffner SM, Hruz P, Masur H, Meigs JB, Mulligan K, Reiss P, Samaras K, Working Group 1. Contribution of metabolic and anthropometric abnormalities to cardiovascular disease risk factors. *Circulation*. 2008;118(2):e20-8. PMCID: PMC3170411 PMID: 18566314
2. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. PMCID: PMC2680222 PMID: 19373039
3. Hruz PW. Molecular mechanisms for insulin resistance in treated HIV-infection. *Best Pract Res Clin Endocrinol Metab*. 2011;25(3):459-68. PMCID: PMC3115529 PMID: 21663839
4. Hruz PW. HIV and endocrine disorders. *Endocrinol Metab Clin North Am*. 2014;43(3): xvii–xviii. PMID: 25169571
5. Hruz PW. Commentary. *Clin Chem*. 2015;61(12):1444. PMID: 26614228

6. Hruz PW, Mayer LS, and McHugh PR. Growing Pains: Problems with Pubertal Suppression in Treating Gender Dysphoria *The New Atlantis*. 2017;52:3-36.
7. Hruz, PW. The Use of Cross-Sex Steroids in Treating Gender Dysphoria *Natl Cathol Bioeth Q*. 2018;17(4):1-11.
8. Hruz, PW. Experimental Approaches to Alleviating Gender Dysphoria in Children *Nat Cathol Bioeth Q*. 2019;19(1):89-104.

Expert Witness Testimony

2009 Rosas v. Astrazeneca

2012 O'Connor v. Stamford

2016 Carcaño et al. v. Patrick McCrory (United States District Court, M.D. North Carolina)

2016 Jane Doe v. Board of Education of the Highland School District (United States District Court For the Southern District of Ohio Eastern Division, Case No. 2:16-CV-, 524)

2017 Ward v. Janssen (Circuit Court of St Louis, Division 16, MO, Case No. 1522-CC00213-01)

2017 Adams v. St John's School Board (United States District Court For the Middle District of Florida, FL Civil Action No. 3:17-cv-00739-TJCJBT)

2017 Ashton Whitaker v. Kenosha Unified School District (United States District Court Eastern District of Wisconsin, Civ. Action No. 2:16-cv-00943)

2018 Terri Bruce v. State of South Dakota (The United States District Court District of South Dakota Western Division, Case No. 17-5080)

2019 Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children

2021 Kadel vs. Falwell (The United States District Court For The Middle District Of North Carolina, Case No.: 1:19-cv-272-LCB-LPA)

2022 Brandt v Rutledge (The United States District Court Eastern District of Arkansas Central Division, Case No. 4:21-CV-00450-JM)

2022 Eknes-Tucker vs Ivey (United States District Court Middle District of Alabama Northern Division, Case 2:22-cv-00184-LCB-SRW)

2022 D.H. et al. v. Snyder (United States District Court For the District Court of Arizona, Case No. 4:20-cv-00335-SHR)