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

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

PLAINTIFFS' TRIAL BRIEF

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INTRODUCTION

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

STATEMENT OF FACTS

I. The Parties

A. The Plaintiffs

1. Brit Rothstein

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

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

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

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

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

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

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

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

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

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

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

2. Susan Doe

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

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

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

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

3. August Dekker

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

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

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

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

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

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

4. K.F.

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

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

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

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

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

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

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

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

B. The Defendants

1. Defendant Jason Weida

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

2. Defendant Agency for Healthcare Administration

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

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

II. The History of Discrimination Against Transgender People

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. Gender Identity & Gender Dysphoria

A. Gender Identity

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

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

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

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

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

B. Gender Dysphoria

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

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

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

C. Treatment for Gender Dysphoria

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

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

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

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

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

1. Puberty-Delaying Medications

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

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

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

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

2. Hormone Therapy

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

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

3. Gender Confirming Surgeries

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

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

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

A. History of Gender-Affirming Medical Care

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Assessment and Diagnosis of Gender Dysphoria

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

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

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

2. Criteria for Gender-Affirming Medical Interventions

Adults

Gender-affirming medical interventions may be considered for transgender

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

Adolescents

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

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

Some surgical procedures, primarily chest masculinization and breast

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

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

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

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

C. Gender-Affirming Care Is Safe and Effective

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

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

1. Puberty-delaying medications

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Hormone Therapy

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

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

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

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

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

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

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

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

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

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

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

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

3. Surgery

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Levels of Evidence

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

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

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

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

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

Rebuttal ¶¶ 23-24, 47 (ECF 175-11).)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. The Medicaid Program

A. Federal Requirements

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

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

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

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

B. Florida's Medicaid Program and the GAPMS Process

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

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

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

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

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

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

A. Florida Medicaid Coverage of Gender-Affirming Medical Care

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

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

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

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

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

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

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

B. Defendants' Promulgation of the Challenged Exclusion

1. The Lead Up to the Challenged Exclusion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. The 2022 GAPMS Review Process and Proposed Rule

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

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

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

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

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

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

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

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

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

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

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

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

3. Public Comment on the Proposed Rule

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

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

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

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

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

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

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

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

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

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

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

coverage for gender-affirming care.[22]

LEGAL ARGUMENT AND AUTHORITIES

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

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

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

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

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

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

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

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

A. Evidence-based clinical practice guidelines

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Effectiveness in improving prognosis or health outcomes

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

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

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

D. Utilization trends

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

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

E. Other coverage policies

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. The Challenged Exclusion facially discriminates based on sex.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Defendants' Challenged Exclusion Violates Equal Protection.

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

A. The Challenged Exclusion Classifies Based on Sex.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Defendants Engaged in Purposeful Discrimination.

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

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

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

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

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

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

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

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

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

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

D. The Challenged Exclusion Cannot Survive Heightened Scrutiny

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

Respectfully submitted this 28th day of April 2023.

/s/ Chelsea Dunn
Chelsea Dunn

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CERTIFICATE OF SERVICE

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

/s/ Chelsea Dunn
Counsel for Plaintiffs

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

AUGUST DEKKER, et al.,

Plaintiff,

vs.

JASON WEIDA, et al.,

Defendant.
_____/

REMOTE ZOOM-RECORDED DEPOSITION OF

AUGUST DEKKER

VOLUME 1
Pages 1 through 35

Thursday, January 26, 2023

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

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

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

Job No.: 291657

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

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

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

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

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

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

A. Yes.

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

A. Yes.

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

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

Q. By medication, are you referring to testosterone?

A. Yes.

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

A. Yes.

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

A. Yes.

Q. And what were some of those?

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

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

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

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

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

THE WITNESS: Yes.

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

THE CERTIFIED STENOGRAPHER: Okay. And --

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

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

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

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

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INDEX TO WITNESS

PLAINTIFF'S INDEX TO EXHIBITS

DEFENDANT'S INDEX TO EXHIBITS

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

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

that is on our fee schedule and it is --

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

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

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

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

THE WITNESS: Do answer or --

MR. PERKO: Do answer.

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

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

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

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

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

Q So, to your knowledge --

A No.

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

A I'm unclear how you define that.

Q Fair.

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

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

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

Q Okay. How about request from a political figure?

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

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

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

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

A Yes.

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

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

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

Q You said it was the standard process?

A It is.

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

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

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

A Not in my experience.

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

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

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

(Brief recess.)

BY MS. DeBRIERE::

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

A I did not.

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

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

A No.

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

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

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

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

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

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

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

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

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

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

Q Okay. And who currently is the Medicaid director?

A Tom Wallace.

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

A Ann Dalton.

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

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

Q Is that different from being a decision maker?

A A decision point? Yes.

Q No, a decision maker. Sorry.

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

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

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

THE WITNESS: I don't know.

BY MS. DeBRIERE::

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

A Not in my experience, no.

Q How many GAPMS reports are issued per year?

A That's kind of a loaded question.

Q I don't mean it to be.

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

medical necessity?

A I've read it before.

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

A Sure.

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

THE WITNESS: Yes.

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

BY MS. DeBRIERE::

Q Do you know what AHCA uses this definition for?

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

Q How does it relate to the GAPMS process?

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

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

notify the general public?

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

Q Would AHCA typically publish that decision on a website?

A Not that I'm aware of, no.

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

A Not that I'm aware of, no.

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

A Not in my experience, no.

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

A Not that I'm aware of, no.

Q Any other political figures, are they typically involved?

A Not that I'm aware of, no.

Q Other state agency heads?

A No.

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

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

Q If through the GAPMS process a service is

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

Q Okay. Looking at this particular GAPMS --

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

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

A Yeah.

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

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

THE WITNESS: See, this one predates me.

BY MS. DeBRIERE::

Q So what happened there?

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

from that one.

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

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

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

BY MS. DeBRIERE::

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

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

Q Do you remember what organizations those were?

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

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

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

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

Q Do you remember if one of the organizations you looked at was the American Academy of Pediatrics, or relied on?

A Almost certainly.

Q Why are you -- why are you almost certainly?

A They're kind of a name brand organization.

Q Is it one that you find trustworthy in terms of their opinion?

A I have.

Q Can you look at this document and tell me if

this is -- the reason I ask is that -- skip to the front page, to page three. Do you know if it's complete? If you see there's a page number at the corner there.

A Yeah. Yeah, there's -- there should be a page. Yeah, there's a page there.

Q You don't think it's a typo?

A No, it's -- because on the second page, it picks up with, like, mid-paragraph.

Q Okay. Thank you for that. Were you involved in anything related to the GAPMS for scleral contact lenses?

A I was not.

Q So just going over the GAPMS process generally, in summary, to determine whether a service is experimental under GAPMS, you look at professional literature. And then the most persuasive professional literature is going to be, that's peer review?

A Ideally, sure.

Q You look at whether other state Medicaid programs cover?

A Yes.

Q And you look whether health insurance in the private market covers?

A Yes.

Q And if the majority of states cover, that's

going to be in the favor of finding it not experimental?
A It's hard -- it would be -- make it harder for us to justify that it's experimental.
Q And you look at whether Medicare covers?
A Yes.
Q And, again, whether Medicaid covers favors a finding of not being experimental?
A Yes.
MR. PERKO: Object to form.
BY MS. DeBRIERE::
Q And you look at whether evidence-based clinical practice guidelines exist?
A Yes.
Q And you look at whether the service is accepted by relevant professional medical organizations?
A Yes.
Q How do you -- would the American Medical Association be considered an organization on which AHCA would rely for GAPMS?
MR. PERKO: Object to form.
THE WITNESS: Yes.
BY MS. DeBRIERE::
Q How about the American Psychological Association?
MR. PERKO: Same objection.

THE WITNESS: Yes.
BY MS. DeBRIERE::
Q The American Academy of Child and Adolescent Psychiatry?
MR. PERKO: Same objection.
THE WITNESS: I am not familiar with that organization.
BY MS. DeBRIERE::
Q The American College of Obstetricians and Gynecologists?
MR. PERKO: Same objection.
THE WITNESS: Yes.
BY MS. DeBRIERE::
Q In the past GAPMS, organizations on which you've relied include the American Academy of Pediatrics?
A Yes.
Q You undertake a cost analysis for potential cost-saving to Florida Medicaid when you're doing GAPMS?
A Yeah. I mean, if it's not budget-neutral, it's almost certainly not going to be covered.
Q You do not typically enlist outside medical experts during the GAPMS process?
A I have not.
Q You do not pay outside individuals?

A I don't.
Q You don't ask outside individuals to write a report?
A No.
MR. PERKO: Asked and answered, counsel.
BY MS. DeBRIERE::
Q You do not typically codify your conclusions reached during the GAPMS process into rule?
A I don't believe so.
Q You do not typically develop a website and slogan to advertise a GAPMS conclusion?
A I have not.
Q Generally, other agency heads or political figures not involved in the initiation -- are not involved in the initiation of the GAPMS process?
A Not in my experience.
Q In disseminating its conclusion?
A No.
(Whereupon, Exhibit No. 10 was marked for identification.)
BY MS. DeBRIERE::
Q Let's go to Exhibit 10, is the 2016 GAPMS memo, and this is going to be DEF_000288776 to DEF_00028 8785. Are you familiar with this document, Mr. English?
A I am not.

imagine this is a very large agency. Have you been involved in any conversation around AHCA's coverage of cross-sex hormone therapy?

A I am not.

Q Okay. Do you have any idea as to why, even though you were the GAPMS guy during these dates, that you would not be involved in these decisions?

MR. PERKO: Object to form.

THE WITNESS: I do. What I was explained by Jesse, my supervisor, his version of how -- and I don't know if the same person that wrote the gender dysphoria GAPMS wrote this -- Jesse's explanation for how that author was chosen, he said that it was a meeting between he and Jason and Ann, and Jason had come and asked who they might recommend to write the report, and when my name was brought up, Jesse said no, that he -- I guess he didn't want me working on that. And Ann offered up the actual author, eventual author, and Jesse concurred.

BY MS. DeBRIERE::

Q How do you know that this meeting happened?

A He told me.

Q Jesse told you?

A Uh-huh.

Q Why did Jesse say no? Did he say to you?

A Yes. He -- I believe his perception of it was that it was -- he said that he didn't want me involved with it. He didn't want to be supervising the person who was, and he didn't think that it was something that I would have been willing to do.

Q Was he right?

A Yes.

Q Why?

A Because my perception was that that particular GAPMS was a conclusion in search of an argument.

Q Did Jesse agree with you?

A You'd have to ask him.

Q Why don't you think Jesse wanted to supervise the project?

A We're all sitting here right now.

Q Fair.

A And on top of that, I mean, he was pretty new in his position, too. He had been promoted after Christina left.

Q How long had he been in that position?

A Not super, super long. I mean, God, I think Christina was -- actually, I don't know. She left -- one of the December's during the pandemic, but I don't remember. She went out on maternity leave and never came back, and then he ended up filling her position.

Could have been 2021, or it could have been 2022. I don't honestly recall.

Q Who was the author of the report you're referring to?

A Matt Brackett.

Q Do you know why Mr. Brackett was chosen?

MR. PERKO: Object to form.

THE WITNESS: Jesse told me that he -- he told Jason that Matt would do any assignment that he was given.

BY MS. DeBRIERE::

Q Had Mr. Brackett ever done a GAPMS memo before?

A He had. He was -- he wrote GAPMS prior to my arrival.

Q Why didn't they keep Mr. Brackett in that position? Why did they hire someone new?

MR. PERKO: Object to form.

THE WITNESS: When I arrived, Matt was over the -- I believe he was over durable medical equipment. And I think, just based on conversations he and I had had, there's a kind of a bit of frustration built into the GAPMS position because it's not a priority, you know, outside of a pandemic, even it's just not a priority. And so he

was -- you know, he would tell me, you know, look, I didn't get a lot, you know, through either -- it's kind of a thankless job, but it's important, you know, that kind of thing. So it -- I think he wanted to go do -- he's been here -- you know, I don't know how much longer though, at least a little bit, or maybe more than that longer than me, and I think he just wanted to go do something else.

BY MS. DeBRIERE::

Q Okay. Why do you think it mattered to Mr. Boucher that you not be a part of the gender dysphoria GAPMS?

MR. PERKO: Object to form.

THE WITNESS: My belief is that he didn't see -- he didn't believe that it would be something that I would -- I would be willing to do and he, I believe, was possibly trying to save himself, a hassle as well.

BY MS. DeBRIERE::

Q Let's turn back to the email between you and Mr. Cogle, which is Exhibit 5. On the second page, you have a paragraph that starts, if you will, excuse me, I feel obligated to include this information.

A Yes.

Q Are you familiar with what you wrote there?

A I am.

Q Would you say that's a reason why you didn't want to be involved in the gender dysphoria GAPMS process?

A Yes and no, indifferent all at the same time. I mean, part of why this paragraph was written was out of frustration. Again, I was -- you know, my co-worker's, it was the -- you know, we joked I was the GAPMS guy. That report came out. I read the report. It was not something I felt like I would have produced and because there were a lot of people around inside the agency and my personal life that thought that I wrote the report, because it said, GAPMS, you know. So I had grown tired of -- you know, and at the same time, it's like, you know, my friends are seeing reports about it on television and things like that, or in the newspaper or whatever, it was a news story, a prominent news story with, you know, debate and politics and all these things, and I was a bit frustrated that that was occurring. And combined with the fact that Dr. Cogle was someone I respect, and I kind of in response to the emotion I'd received in his initial email, I wanted to assure him that that wasn't me.

Q I just want to make the record clear by entering in Exhibit 14. And this exhibit is entitled

Florida Medicaid generally accepted professional medical standards determination on the treatment of gender dysphoria. It's dated June 2022.

(Whereupon, Exhibit No. 14 was marked for identification.)

BY MS. DeBRIERE::

Q Is the report we've been talking about that Mr. Brackett authored?

A Yes.

Q And this is the report that Jesse said you would not author, is that correct?

A Correct.

Q And it's the report that you did not want to author?

A Correct. I mean, keep in mind, I found out about it after the project already started. And then I went and asked Jesse about it. I was like, you know, and I wasn't like, you know, who's doing the GAPMS. I was just like, hey, what's going on, you know. And he explained, you know, how Matt was chosen and why I was not, and I was thankful for that and went from there.

Q And you said in your response to my questions about your email to Dr. Cogle that this report did not reflect the level of work that you would do, is that correct?

A Well, that's a -- that's a loaded question. I mean, it's a 45-page report, which is very different from the -- what I was dealing with, which was the push for the trend for tighter cleaner, smaller reports that took less time to read. What was the --

Q Yeah. Why isn't this GAPMS report on gender dysphoria reflective of your work?

A It veers a bit from process.

Q In what ways?

A Well, in terms of the quality of the studies included, the dismissal, the professional organizations and experts that we had frequently cited before, the length of the report, where it originated from.

Q Where did it originate from?

A I would say the executive. Came from they said, you know, Secretary Marstiller, she's part of the executive.

Q Anybody else in the executive?

A Oh, sure. Governor. Yeah.

Q I cut you off.

MR. PERKO: I meant to object to form on that last question.

BY MS. DeBRIERE::

Q You said it dismissed the opinions of professional organizations, where it was initiated was

off, the length of the report was off. Anything else?

A Keep in mind that the people who prepared the report, or Matt and a guy Ni -- I don't remember Ni's last name -- they were not discreet about what they were working on or why, and it seemed to be impacting morale a little bit among some co-workers, and it was kind of an immature sort of approach or attitude or something to it that was off-putting a bit, I suppose, for folks.

Q Are folks in the agency generally aware of things that GAPMS is working on?

A Frankly, most people don't really care or pay attention. You know, everyone has -- just the way everything's set up here, you, you know, everyone has their own little corner of the piece of the puzzle of Medicaid, and it's a big learning curve for everything, and so you want to focus on your little piece of the puzzle and try and grow your puzzle into, you know, understanding how it fits into the main thing. Certain topics sometimes, I had to do one on transanal irrigation, and I caught a lot of grief from some of my co-workers on that one, you know, silly stuff, you know, office banter, that kind of thing, but that one was -- it was just kind of altogether a different thing.

Q You described it as immature.

A Well, certain behavior was.

Q What?

A There was a -- I don't remember the person's name. I was told that they were a trans person. I knew him as this guy who had an office nearby Matt and I, and it was after the report had come out, I believe, and they were, like, kind of whooping it up, yelling back and forth across the hallway, because about -- like the number of views it was getting on Twitter and things like that. And so that employee had to get up and go over and tell them, you know, look, it's -- you know, congratulations on your report, but I feel like you're being somewhat insensitive. And, you know, that was awkward.

Q Yeah. You mentioned that Mr. Brackett was not in -- Mr. Chen -- Dr. Chen?

A He's -- I think he's pharmacist, yeah.

Q Mr. Brackett and Mr. Chen were not discreet about it, what they were working on. How did they characterize what they were working on?

A Just what the topic was. It was actually -- Ni's the one that told me that -- he's who told me that it was -- I was wholly unaware of the assignment, and Ni's the one that told me about the assignment.

Q Is this the first time you've ever been -- since being the GAPMS guy, was the first time you'd ever

been excluded from the GAPMS process?

A Well, I mean, this other one here predates the publication of that one, but --

Q And that --

A -- in April, and this one probably began in April or March or something like that. So, yeah, whichever. The chicken or the egg, whichever one came first. I was unaware of both of those.

Q The title that you were just referencing that is Exhibit 13, I think? Is that right?

A Yes.

Q And do you think that report was a precursor to the Exhibit 14?

MR. PERKO: Object to form.

THE WITNESS: I wouldn't know.

BY MS. DeBRIERE::

Q How many Medicaid services does this GAPMS memo Exhibit 14 analyze, do you know?

A Maybe three.

Q Is that typical?

A No. Well -- I mean, no, I've looked at GAPMS where it was two devices, two different devices at the same time, but never like two different treatments, same time.

Q Do you know why AHCA used that approach here?

A I do not.
Q Would you recommend that approach in a GAPMS process?
A I can't outright say I would or would not. It would depend on the circumstance and how closely related I perceive the procedures or services to be.
Q Do you know if this is supposed to apply to children or adults or both?
A My understanding is both, or to children and -- most of the discussion has been around children. Children.
Q So you don't -- having reviewed this, you can't say?
A I don't recall. I mean, I read it back in, like, June.
Q Okay?
MR. PERKO: About ready for a break, counsel?
MS. DeBRIERE: Mr. English, do you think you can do like 10 more minutes?
THE WITNESS: I can do whatever's good for the order.
MS. DeBRIERE: Is that okay, Gary?
MR. PERKO: Yeah.
BY MS. DeBRIERE::
Q Do you know if AHCA enlisted outside medical

experts to do a literature review for this report?
A That's my understanding.
Q Is that typical for GAPMS?
A Not in my experience.
Q Do you know if they paid these professionals to do the report?
A My understanding is they did.
Q Is that typical?
A Not in my experience.
Q Do you know why AHCA used that approach here?
A I do not.
Q Have you ever -- I'm sorry. Did they attach the expert reports to the final GAPMS report? Did AHCA attach the expert reports to the final GAPMS report?
A I don't know if I saw, like, a copy with attachments or if it's -- I don't recall if it was referenced or included in their report like -- but I remember seeing those when I was looking at it, you know?
Q Is that typical?
A Well, no, I mean, I've never had outside reports to attach to it, were included with the GAPMS.
Q When you mentioned that -- one issue you took with the report is they dismissed professional organizations' opinions. Would those professional

organizations include the Endocrine Society's position?

MR. PERKO: Object to form.

BY MS. DeBRIERE::

Q If you don't remember, that's okay.

A I know who the Endocrine -- who they are. I would be hard-pressed to envision a scenario where I would second-guess them -- and without, you know, really, really good cause.

Q What about the American Academy of Pediatrics?

MR. PERKO: Object to form.

THE WITNESS: No.

BY MS. DeBRIERE::

Q No, you --

A I would be deferential to their recommendations.

Q Are you aware of the coverage of the treatment for gender dysphoria under other Medicaid programs?

A I want to say that things could have changed because I haven't really looked at some of that stuff since last year.

Q Why were you looking at it last year?

A When I --

Q Go ahead.

A If I recall, it's somewhere between maybe 30 and 40 states or something that provide coverage for it.

Q When you undertake GAPMS, how would that factor into your ultimate conclusion?

A If it were 30 states, that would -- it could be a factor. If it were 40 states or more, it would be -- it'd be harder to dismiss. It's something that my supervisor would have been making an inquiry about if I were recommending against coverage.

Q Because that many states covering indicates that it's not experimental?

MR. PERKO: Form.

THE WITNESS: It indicates that there is existing widespread coverage for it.

BY MS. DeBRIERE::

Q How does that factor into whether the service is experimental?

MR. PERKO: Form.

THE WITNESS: It makes an argument for coverage for something easier to make, assuming that they meet the threshold on all the other categories, you know, then that's, you know --

BY MS. DeBRIERE::

Q Do you know if they did a decision tree checklist for the services listed in the June 2022 memo?

A I do not.

Q Do you know if AHCA undertook an Analysis

of -- to determine how excluding coverage of treatment for gender dysphoria would affect the Florida Medicaid budget?

A I do not.

Q Does anything else stand out to you about this memo that we haven't discussed?

MR. PERKO: Object to form.

THE WITNESS: It's frankly unlike anything I've experienced in the process, but I mean, just the sort of -- you know, we're all sitting here, the publicity about it, everything that sort of comes with it. It's unusual, in my limited time here.

BY MS. DeBRIERE::

Q Do you agree with the conclusion?

MR. PERKO: Object to form.

THE WITNESS: I think it's two different issues.

BY MS. DeBRIERE::

Q Yeah.

A I'm not sure that it matters what I believe about the question of whether or not Florida Medicaid should pay for transgender services. I view it as a process issue, and I believe that everyone should have the same -- the same opportunity for review and a consistent process.

Q Was this consistent with the other opportunities people have had for review of a Medicaid service?

A I do not -- I do not believe it was.

Q Do you know how AHCA implemented the conclusions found in this memo?

A I do not. I know they had to write a rule, and I know they had a hearing. That's all I know.

Q Have they talked to you about implementation regarding state amendment at all?

A They have not.

Q Throughout this deposition, I got the sense that you were really good at your job, as the GAPMS guy.

A It's not for me to say. I feel like I put forth some effort.

Q Yeah, and you got a certificate for doing one in eight hours.

A Just a couple of friends, but I think my performance is reflected in my performance reviews.

Q Yeah. And why do you think they moved you from GAPMS to the state plan?

A I asked to be moved.

Q Okay. Why did you ask to be moved?

A Because I felt like the GAPMS process had lost some integrity and I didn't want to be associated with

it. I didn't want the blowback from the requesters out there who were going to wonder why their report wasn't -- I mean, every month it got harder and harder and harder to justify those reports not moving. And I was just, you know, kind of burned out. If you're in a position where you're working on something and they tell you, you know, slow down and stop, you know, then let's go learn something else. And, honestly, I thought leaving would protect me from some of this.

Q You had mentioned that they had to adopt a rule to implement this decision. Is that typical of a conclusion reached through the GAPMS process?

A Not that I'm aware of.

Q The same question with having a hearing. Is that something typically related to a conclusion in the GAPMS process?

A Not that I'm aware of.

Q Has it ever been done, that you're aware of, for any GAPMS conclusions?

A I was never asked to attend a rule hearing or anything related to any of the GAPMS I worked on. So, not that I'm aware of.

MS. DeBRIERE: Are you okay with taking like a 10 minute break?

THE WITNESS: Sure.

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

AUGUST DEKKER, et al.	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	NO. 4:22-CV-00325-RH-MAF
	)	
	)	
JASON WEIDA, et al.,	)	
	)	
Defendants.	)	

VIDEOCONFERENCE DEPOSITION OF
G. KEVIN DONOVAN, M.D., M.A.
LOCATED IN SAND SPRINGS, OKLAHOMA
TAKEN ON BEHALF OF THE PLAINTIFFS
ON MARCH 22, 2023

REPORTED BY: JANA C. HAZELBAKER, CSR

web page of the Catholic Medical Association?

A I don't think so.

Q So the website states that, "The following are resolutions accepted as positions at the Catholic Medical Association."

And we're going to jump to the resolutions that are listed in the topic of "Family and Sexual Education." Specifically I'm going to look at Resolution 8-12, which is a resolution on transgender treatments.

Resolution 8-12 reads that, "The Catholic Medical Association does not support the use of any hormones, hormone-blocking agents, or surgery in all human persons for the treatment of gender dysphoria."

Were you aware of this resolution of the Catholic Medical Association?

A No. As I've mentioned, I'm not a member of the Catholic Medical Association.

Q And if you --

A I wasn't aware of this.

Q You weren't aware of this?

A No.

Q If you had been aware of this, would it have changed your decision to publish in the Catholic Medical Association's official journal?

A Well, I -- I imagine that I would probably be pleased if anybody agrees with me.

Q So are your beliefs aligned with this resolution?

A I don't know because I haven't seen the full text of it. I just see a title there.

Q So this is the full text of the resolution. The title is "8-12: Resolution on Transgender Treatments." And then it says "Be it resolved."

A Well, then, that does sound reasonable.

Q Okay. And then if we move down to Resolution 8-13, which is the "Resolution on Gender Dysphoria," it reads, "Be it resolved that the Catholic Medical Association and its members reject all policies that condition all persons with gender dysphoria to accept as normal a life of chemical and surgical impersonation of the opposite sex. Further, that the use of puberty-blocking hormones and cross-sex hormones and surgical reassignment surgery be rejected."

Were you aware of this resolution of the Catholic Medical Association?

A No. Like I said, I've never seen this page before and I don't know if any of these were ever adopted.

Q These are on the website of the Catholic Medical Association as adopted resolutions.

A Okay.

Q I'll represent that to you. And so if you had been aware of this resolution, would it have impacted your decision to publish in The Linacre Quarterly, the Catholic Medical Association's official publication?

A No.

Q And are your beliefs around the treatment of gender dysphoria aligned with this Resolution 8-13?

A I would not have used this language, but I don't have severe disagreements with it.

Q Okay. At this point we're going to turn back to what has been marked as Plaintiffs' Exhibit 1. And that is your report, which is not on my screen anymore, so I'm going to have to stop that share again.

(Document is displayed).

This, we already identified, as the expert declaration that was provided, written by you and provided to plaintiffs by the defendants in the lawsuit that brings us here today, Dekker versus Weida.

by your terminology. So you say that you "have studied issues surrounding transgender patients." Specifically, what issues related to transgender patients have you studied?

A Well, I think that the things that I have read about and been concerned about exactly parallel those that you see in the younger patients, as well, in terms of the concept, the diagnosis and the treatment and the results.

Q So can you estimate how many times you've been consulted on issues specific to transgender patients?

A No. I mean, these are not formal consultations, these are discussions.

Q I'm sorry. So going back to your role providing ethical consultations, either -- I guess at Georgetown would have been primarily the period of time we're talking about. Can you estimate how many of those ethical consults would have related to transgender patients?

A None of the hospital consults related to transgender patients as transgender patients.

Q So you've not given an ethical consult with regard to patient care for a patient that was transgender?

A Not for an individual patient, no.
Q And that extends to both children and adults?
A Correct.
Q Moving on to Paragraph 11 where you say, "For ethical as well as medical reasons, I have never prescribed medications nor referred for surgery any patients that consider themselves transgender."
These medical reasons you reference -- going back to your specialty, you're a pediatric gastroenterologist. We've established that. That's right, right? Is that right?
A Yes.
Q Did any of your pediatric gastroenterology patients identify as transgender, to your knowledge?
A No --
Q To your knowledge --
A -- not to my knowledge.
Q Oh, I'm sorry, I cut you off again. I apologize.
What were you saying?
A I just said "not to my knowledge."
Q To your knowledge, have any of your pediatric gastroenterology patients been diagnosed with gender dysphoria?

A Not to my knowledge.
Q Have you ever prescribed a medication to a patient in your role as a bioethicist?
A That's not the role of a bioethicist.
Q Okay. I just wanted to confirm that.
Do bioethicists treat medical conditions with surgical referrals?
A That's not the role of the bioethicist.
Q Okay. When you -- so turning back to Paragraph 11, when you refer to ethical reasons that you don't prescribe medications, is that because your activities as a bioethicist are informed by your Catholic faith?
A No, it's because I think that it's unethical.
Q Do you think that it's unethical because it's not consistent with the ERDs that we talked about as Plaintiffs' Exhibit 4?
A No, I think it's unethical on the face of it. I don't think you have to be Catholic, Muslim, Jewish, or none of the above to come to the same conclusions.
Q In Paragraph 12 you say that, "None of your opinions are biased by professional income."
The entirety of your career in medicine