EXHIBIT 12

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

AUGUST DEKKER, et al.,

Plaintiffs,

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

SIMONE MARSTILLER, et al.,

Defendants.
_____/

REDACTED DEFENDANTS' RESPONSE IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION AND INCORPORATED MEMORANDUM OF LAW

Defendants Secretary Marstiller and the Agency for Health Care Administration oppose the motion for preliminary injunction.[1]

INTRODUCTION

Eugenics, lobotomies, and opioids. These are just some of the medical trade groups' preferred treatments from the not-so-distant past. *See infra*. Fortunately, "the Constitution principally entrusts the safety and health of the people to the politically accountable officials of the State." *Andino v. Middleton*, 141 S. Ct. 9, 10 (2020) (Kavanaugh, J., concurral). Florida's politically accountable officials choose not to reimburse under Medicaid the cost of *certain* treatments for *one* medical condition—

[1] This filing refers to Generally Accepted Professional Medical Standards as "GAPMS" and includes citations to an appendix filed contemporaneously with it. "App." citations refer to the appendix.

gender dysphoria—because the State found those treatments to not be "consistent with generally accepted professional medical standards," and to otherwise be "experimental or investigational." Fla. Admin. R. 59G-1.035 (GAPMS Rule); *see also* App.43. In so doing, the State of Florida echoed the concerns expressed in Sweden, Finland, France, Australia, New Zealand, and the United Kingdom, and those begrudgingly acknowledged by the federal government. *See infra.*

"[L]ike other health and welfare laws," Florida's regulation "is entitled to a strong presumption of validity." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022) (cleaned up). The State's distinction between treatments that work and don't work is consistent with the Equal Protection Clause. And no "individual" is "subjected to discrimination" when the State makes this distinction. 42 U.S.C. § 18116(a). Because Plaintiffs provide no constitutional or statutory reason for second-guessing the State's decision, they can't satisfy the likelihood-of-success prong for a preliminary injunction.

Nor can they satisfy the other three prongs for relief. Without class certification, Plaintiffs ask for a universal injunction. Without testimony from physicians familiar with their medical records, Plaintiffs attempt to show irreparable harm to themselves. Without clear expert and factual testimony to the contrary, Plaintiffs ask to reverse the studied decision made by the State of Florida through its rule-based process, its expert analysis done during the process, and the material now attached to this response that, among other things, *does* consider the medical records of each Plaintiff. Plaintiffs ask for too much.

STATEMENT OF FACTS

I. Gender Dysphoria and the State's Science-Based Choices.

A. Gender dysphoria is a psychiatric diagnosis. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, explains that individuals with the condition (1) "have a marked incongruence" between their biological sex "and their experienced/expressed gender," and (2) experience "clinically significant distress or impairment" because of the incongruence. App.251. No laboratory tests, imaging, biopsies, or other objective tests exist to diagnose someone with gender dysphoria. *Id.*; *see also* App.770. No biological markers establish gender dysphoria as an immutable condition. *Id.* Gender identity and, by extension, gender dysphoria are psychological constructs. *Id.*

"Among prepubescent children who feel gender dysphoric, the majority cease to want to be the other gender over the course of puberty—ranging from 61-88% desistance across the large, prospective studies." App.140. "It is because of this long-established and unanimous research finding of desistance being probable but not inevitable, that the 'watchful waiting' method became the standard approach for assisting gender dysphoric children." App.141. "Watchful waiting does not mean do nothing." App.144. Rather, the approach "emphasize[s] the need for extensive mental health assessment, including clinical interviews, formal psychological testing with validated psychometric instruments, and multiple sessions with the child and the child's parents." *Id.* Focusing on mental health is particularly sensible because gender dysphoric

children have "elevated rates" of other conditions such as depression, autism, and attention-deficit hyperactivity disorder. App.152.

The manifestation of gender dysphoria in adolescents is a relatively new phenomenon. App.153. Those presenting as adolescents are "predominately biologically female." *Id.* "The majority of cases appear to occur within clusters of peers and in association with increased social media use and especially among people with autism or other neurodevelopmental or mental health issues." *Id.*

Adult-onset gender dysphoria occurs "nearly exclusively" in "biological males" who are in "their 30s or 40s." App.138. Again, the "co-occurrence of mental illness" in this group is "widely recognized and widely documented." App.139. And gender dysphoric adults "continue to show high rates of mental health issues after transition[ing]" to the other gender. *Id.*

B. Rule 59G-1.050(7)(a) states that "Florida Medicaid does not cover," as "treatment of gender dysphoria," the use of (1) "puberty blockers," (2) "hormones or hormone antagonists," (3) "sex reassignment surgeries," or (4) "other procedures that alter primary or secondary sexual characteristics." That's it. The State continues to reimburse a long list of treatments provided by clinical psychologists, child psychotherapists, psychiatrists, family therapists, and social workers. App.260.

The State's June 2022 GAPMS' Report supports the limited exclusion. GAPMS is a rule-based process that allows the Medicaid program to decide whether to reimburse certain health services. Fla. Admin. Code R. 59G-1.035. The process allows the State to

consult with "clinical or technical experts." *Id.* at 59(G)-1.035(4)(f). Here, the State consulted with several experts, five of whom provided reports attached to GAPMS.

Dr. Romina Brignardello-Petersen, together with a post-doctoral fellow, conducted a systematic review of medical studies published between 2020 and April 2022. App.59. They concluded that the evidence simply doesn't support the use of puberty blockers, cross-sex hormones, and reassignment surgeries as treatments for gender dysphoria. App.62-63. As they put it, there's "low and very low certainty evidence" to support these excluded treatments. App.63.

Dr. James Cantor, editor-in-chief of the peer-reviewed journal Sexual Abuse, a professor, and a clinician, also looked at the medical literature and drew on his own experience. App.132. He found every one of the "11 outcome studies" that tracked pre-pubescent children showed that "the majority of children" "cease to feel dysphoric by puberty," App.137, thereby making the use of puberty blockers, cross-sex hormones, and surgeries inappropriate in this population. App.141. For adolescents, the medical literature showed some improvement with medical intervention *and* psychotherapy but couldn't show whether it was the medical intervention or psychotherapy that helped. App.137, 153-55. For those with gender dysphoria, regardless of age, there was a greater likelihood of comorbidities—some other affliction—being the root cause of distress and even suicide. App.137, 151, 155-61. And Dr. Cantor concluded that the perspective of the *leadership* of medical trade groups in the United States was increasingly at odds

with the current positions of European countries with formerly permissive regimes for the treatment of gender dysphoria. App.165-80.

Dr. Quentin Van Meter, a pediatric endocrinologist who trained at Johns Hopkins, and is currently on the clinical faculties of Emory University and Morehouse College, discussed the effects of the excluded treatments on children. App.204. He cautioned against the "interruption of natural puberty," App.209, because it's puberty that "prepare[s] the body for reproduction and affects the bones, gonads, and brain." App.211. He further explained that "blocking puberty at the age of normal puberty prevents the needed accretion of calcium into the skeleton and prevents the maturation of the gonads." *Id.* This contrasts with treatments for precocious puberty—the early onset of puberty—where puberty blockers *are* carefully used and the "end of treatment is carefully timed" so that *natural* puberty resumes at the appropriate age. App.210. He also rebutted the notion that the use of puberty-blockers and cross-sex hormones is reversible, noting, for example, that there can be "permanent infertility." *Id.* And, recognizing that most of those with gender dysphoria later identify with their biological sex, he recommended against the very "permanent" surgical treatments. *Id.*

Dr. Patrick Lappert, a plastic surgeon with decades of experience, focused on the appropriateness of sex reassignment surgeries on a person's chest. App.219. He criticized the methods of those (like Dr. Olson-Kennedy) who have performed "breast removal surgery" on patients as young as thirteen, App.224, and distinguished sex reassignment surgeries from procedures like gynecomastia (an "objectively abnormal

condition" that "makes males develop female-type breast gland tissue") and breast reduction (done when women suffer from "debilitating orthopedic" pain in their neck, back, or shoulders). App.226. He concluded that "the medical necessity of transgender chest surgery is not supported by scientific evidence and appears to be firmly in the category of cosmetic surgery." App.231. Worse yet, this type of procedure poses ethical concerns for surgeons because "[n]o other cosmetic procedure is expected to produce major functional loss." *Id.*

Dr. G. Kevin Donovan, formerly the Director for the Center for Clinical Bioethics at Georgetown University School of Medicine, discussed ethical concerns associated with the excluded treatments. App.236. He found that "[v]ulnerable subjects such as children cannot legally or ethically participate in the consent process" needed for the excluded treatment "due to their age and maturity level." App.238 (citing 46 C.F.R. §§ 401-09). More broadly, he criticized the terminological wordplay used in recent years; he noted that the 2013 adoption of the phrase "gender dysphoria" to replace "gender identity disorder" in the DSM-V shifted the focus away from "correcting the underlying cause of the dysphoria" towards "transitioning to the preferred gender." App.240.

The June 2022 GAPMS Report summarized the findings of the consulting experts and concluded as follows: "the evidence shows that the [excluded] treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health

conditions, and cause infertility or sterility," and, as such, the "treatments do not conform to GAPMS and are experimental and investigational." App.43.

Comments (in writing and in a public meeting) were also provided concerning the GAPMS Report and Rule 59G-1.050(7)(a). Among those providing oral comments were two detransitioners—those who stopped and sought to reverse the effects of the excluded medical treatments. One of the detransitioners, Chloe Cole, stated:

> I was medically transitioned from ages 13 to 16. My parents took me to a therapist to affirm my male identity. The therapist did not care about causality or encourage me to learn to be comfortable in my body because of—partially due to California's conversion therapy bans. He brushed off my parents' concerns about that because he had hormones, puberty blockers, and surgeries. My parents were given a suicide threat as a reason to move me forward in my transition. My endocrinologist, after two or three appointments, put me on puberty blockers and injectable testosterone. At age 15, I asked to remove my breasts. My therapist continued to affirm my transition. . . . I went through with the surgery. Despite having therapists and attending the top surgery class, I really didn't understand all of the ramifications of any of the medical decisions I was making. I wasn't capable of understanding it, and it was downplayed consistently. My parents, on the other hand, were pressured to continue my so-called gender journey with the suicide threat. I have been forced to realize that I will never be able to breastfeed a child, despite my increasing desire to as I mature. I have blood clots in my urine. I am unable to fully empty my bladder. I do not yet know if I am capable of carrying a child to full term. In fact, even the doctors who put me on puberty blockers and testosterone do not know.

App.270-71. *See also* App.892 (Chloe Cole Declaration).

Sophia Galvin, another detransitioner, shared her history of mental illness and shared that her desire to transition "was all in an effort to escape the fear of being a woman in this society and because of traumas that" she "had been through in" her

"life." App.272. She stated that she was harmed by her gender-dysphoria treatments and that they "should not be covered under Medicaid." *Id.*

Following Chloe's and Sophia's comments, Katie Caterbury, a mother, commented on how medical professionals failed her and her family:

> At the age of 14, my once healthy and happy daughter was convinced by the Gay-Straight Alliance at school that she was my son. At the age of 16, a physician injected her with testosterone without my consent and without my knowledge. At the age of 17, Medicaid paid surgeons to perform a double mastectomy and a hysterectomy as an outpatient. At age 19, Medicaid paid for her to undergo a phalloplasty. She had and still has private insurance that was bypassed. I fought against what happened to my daughter every step of the way, but to no avail.

App.273-74.

Yaacov Sheinfeld, whose declaration is attached to this response, shares Ms. Caterbury's sentiment. App.919. His daughter, who had a history of suffering from depression, began taking testosterone at age eighteen and received a double mastectomy at age nineteen. *Id.* Mr. Sheinfeld:

> [W]itnessed distressing physical and emotional changes in [my daughter]. . . . [She] gained and lost lots of weight, had pain all over her body, suffered from mood swings, could not concentrate, and described herself at times as "barely alive." At one point she was hospitalized in a psychiatric hospital for depression and suicidal thoughts. [She] was deeply depressed and taking a significant number of medications along with testosterone. It did not appear any medical professional was monitoring all these medications or even understood their possible interactions. I kept assuring her that I would do whatever I could to help her. [Her] pain became so intense that she began taking Fentanyl. [She] was found dead on August 6, 2021 with Fentanyl and alcohol in her system. She was 28. [She] had been identifying as a male and taking testosterone for ten years. Florida's Rule and similar laws to not cover services for the treatment of gender dysphoria are critically important because young people, especially those

> with mental health issues such as [my daughter], cannot make clear decisions about their future, particularly when neither they nor their parents are provided with full information about the effects of these interventions.

App.921-22.

Other detransitioners and parents have had similar experiences. *See* App.871 (C.G. Declaration); 912 (Zoe Hawes Declaration); 878 (Camille Kiefel Declaration); 885 (Carol Freitas Declaration); 900 (KathyGrace Duncan Declaration); 905 (Sydney Wright Declaration); 925 (Declaration Julie Framingham); 931 (Jeanne Crowley Declaration).

Florida finalized Rule 5G-1.050(7)(a). The rule became effective August 21, 2022.

II. International Trends and Federal Acknowledgment of Errors and Past Reliance on Low-Quality Science.

A. Florida is not alone in taking a cautious approach to the use of puberty blockers, cross-sex hormone therapies, and sex reassignment surgeries. Many European countries that previously had permissive transitioning regimes are reconsidering their positions. *See generally* App.179-83.

Sweden's National Board of Health and Welfare has determined that "the risk[s] of puberty suppression treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits." App.231. Sweden has now banned the use of puberty blockers and hormone therapy except in "exceptional cases" or strictly regulated research settings. *Id.*

Finland's Council for Choices in Healthcare has urged extreme caution when providing gender transitioning services to children. It says that "[t]he reliability of the

existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development." *Recommendation of the Council for Choices in Health Care in Finland*, PALKO/COHERE (June 11, 2022), https://bit.ly/3SV6LBV (referenced in App.787, 807).

The United Kingdom is in the process of a systemwide reevaluation of the services it provides, App.787, and the Royal Australian and New Zealand College of Psychiatrists has said that there's a "paucity of quality evidence on the outcomes of those presenting with gender dysphoria." App.228. France's Académie Nationale de Médecine agrees and says that "great medical caution" must be taken "given the vulnerability, particularly psychological, of this population [of younger people presenting with gender dysphoria] and the many undesirable effects, and even serious complications, that some of the available therapies can cause." App.173.

Sweden's experience is particularly noteworthy. Researchers looking at Sweden have access to "all persons in the Swedish medical system, from pre-natal to death," with reports on "all episodes of care and all demographic information in a uniform vocabulary." App.223. Given the data, and the history of a permissive transitioning regime, it's possible to ask questions like the following: "What is the likelihood that a fully transitioned transgender male will be hospitalized for psychiatric illness when compared to the age/sex-matched control group?" Or "[w]hat is the relative risk of suicide in transgender persons." *Id.*

Indeed, a "30-year population-based matched cohort study of all 324 sex-reassigned adult persons in Sweden" did ask some of these questions. App.541 (citing Dhejne, *et al.*, 2011). That study revealed that the "completed suicide" rate among transgender individuals was "19 times that of the general population 10 years post-transition." *Id.* The rate was "40 times higher than in the general population" when looking at female-to-male transitioners. App.224 (citing Dhejne, *et al.*, 2011).

And a 2020 study of "9.7 million Swedish residents" seemingly confirmed the findings of the earlier Swedish study; the 2020 study found "that 'neither gender-affirming hormone treatment' nor 'gender-affirming surgeries' achieved improvement in the mental health service usage and endpoints assessed." App.541 (citing Branstorm, *et al.*, 2020). There was, in fact, an increased risk of "serious suicide attempts and anxiety disorders" *after* the supposed treatment. App.224 (citing Branstorm, *et al.*, 2020).

B. In recent years, even the federal government has at least acknowledged that the science doesn't mandate States to make available puberty blockers, cross-sex hormones, and surgeries. In 2016, the Centers for Medicare and Medicaid Services ("CMS") issued a decision memorandum declining to make a determination "on gender reassignment surgery for Medicaid beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population." Decision Memorandum, *Gender Dysphoria and Gender Reassignment Surgery*, Ctrs. For Medicare & Medicaid Srvs. (Aug. 30, 2016), https://go.cms.gov/3Uqw68E. "Based on an extensive assessment of the clinical evidence," CMS, like Florida, said that "there is not enough high quality

evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." *Id.*

In 2020, the U.S. Department of Health and Human Services ("HHS") declined to "take a definitive view on any of the medical questions raised" "about treatments for gender dysphoria." Nondiscrimination in Health & Health Education Programs or Activities, 85 Fed. Reg. 37,160, 37,187 (Jun. 19, 2020). In assessing comments, HHS acknowledged the "wide variation" in the efficacy of treatments and said "that the medical community is divided" on many of these issues. *Id.* at 31,186. HHS even said that a 2016 federal rule was "erroneous" in its "assertion" that a "categorical coverage exclusion or limitation for all health services related to gender transition" was based on "outdated" and not "current standards of care." *Id.* HHS conceded that, in the 2016 rule, the federal government erred in relying "excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding." *Id.* at 37,197. Much like the State of Florida, HHS concluded in 2020 that there is a "lack of high-quality scientific evidence supporting" treatments for gender dysphoria like "sex-reassignment surgeries." *Id.* at 31,187.

This past May, the National Institutes of Health's ("NIH") Acting Director told the U.S. Senate that the long-term effects of puberty blockers for gender transition are unclear, and that the NIH has only funded observational studies in the area. *See* A Review of the President's FY 2023 Funding Request and Budget Justification for the

National Institutes of Health, Sen. Comm. on Appropriations (May 17, 2022), https://bit.ly/3QTkaJD (1:12:49 - 1:14:55); *cf.* Juliana Bunim, *First U.S. Study of Transgender Youth Funded by NIH*, Univ. of Cal. S.F. (Aug. 17, 2015), https://bit.ly/3BuTj0F (funding the first U.S. study in 2015 "to evaluate the long-term outcomes of medical treatment for transgender youth").

C. Finally, the emerging international consensus and the federal government's new stance highlight another fact: medical trade groups don't always get things right. In fact, medical history is littered with such groups and prominent physicians getting things wrong, often with disastrous consequences.

Take eugenics. "The most important elite advocating eugenic sterilization was the medical establishment." Adam Cohen, *Imbeciles: The Supreme Court, American Eugenics, and the Sterilization of Carrie Buck* 66 (2016). "[E]very article on the subject of eugenic sterilization published in a medical journal between 1899 and 1912 endorsed the practice." *Id.*; *see also Eugenics and Public Health in American History*, 87 Am. J. Pub. Health 1767, 1769 (1997), https://bit.ly/3fxIoMe. The study of eugenics was even encouraged to be part of medical school curricula, and the Assistant Surgeon General of the U.S. Public Health Service went so far to say that "[e]ugenics is a science. It is a fact, not a fad." Paul Lombardo, *Taking Eugenics Seriously: Three Generations of ??? Are Enough?*, 30 Fla. St. L. Rev. 191, 210, 214 (2003).

Consider lobotomies. So taken was the medical community with lobotomies that the 1949 Nobel Prize in Medicine was awarded to the world's leading lobotomist. *See*

Ann Jane Tierney, *Egas Moniz and the Origins of Psychosurgery: A Review Commemorating the 50th Anniversary of Moniz's Nobel Prize*, 9 J. Hist. Neurosciences 22 (2000). Lobotomies were billed as "simple operation[s]," "always safe," and effective tools to treat mental illnesses. *Id.* at 31. Even President Kennedy's sister was subject to the treatment, only to be rendered "permanently mentally deficient" because of it. App.639

Opioids are another example of the medical community erring. Since the 1890s, medical trade groups and doctors provided the public with incorrect information about opioids. And both the "1890s and 1990s" were "characterized by unopposed amplification of the benefits of opioids" and "the transformation of physicians into unabashed cheerleaders." Haider J. Warraich, *What an 1890s Opioid Epidemic Can Teach Us About Ending Addiction Today*, STAT (Feb. 11, 2020), https://bit.ly/3E2fgXT. Opioids were claimed to be non-"hypnotic" and to "rare[ly]" lead to addiction. *Id.* States disagreed, and then intervened to protect their citizens from the medical trade groups' "overreliance on opioids." David W. Baker, *The Joint Commission's Pain Standards: Origins and Evolution* 4 (May 5, 2017), https://bit.ly/3BWd6Gr.

The list goes on. *E.g.*, App.564 (explaining the fraught history of treating stomach ulcers with surgery rather than medication). Doctors even prescribed cigarettes to relieve throat irritation. *See Big Tobacco Led Throat Doctors to Blow Smoke*, Stanford Med. News Ctr. (Jan. 23, 2012), https://stan.md/3dSbFB9. But States held tobacco companies accountable.

III. Plaintiffs' Request for a Preliminary Injunction.

On September 7, 2022, Plaintiffs sued the Florida Agency for Health Care Administration and its Secretary for the Agency's decision not to reimburse under Medicaid certain unproven (and potentially harmful) treatments for gender dysphoria. Doc.1. While not representatives for a putative class, the four Plaintiffs with gender dysphoria seek "preliminary and permanent injunctions prohibiting" the State from implementing Rule 59G-1.050(7)(a).

The separate motion for preliminary injunction also seeks relief beyond that necessary for the named Plaintiffs. Doc.11 at 1, 37. The only two bases for this broad, class-like request are the Equal Protection Clause, and the Affordable Care Act's non-discrimination provision. 42 U.S.C. § 18116(a). Doc.11 at 2.

RELEVANT LEGAL STANDARD

District courts may grant the "extraordinary and drastic remedy" of a preliminary injunction, *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998), only when the movant shows: "(1) it has a substantial likelihood of success on the merits;" (2) it will suffer irreparable injury "unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (*en banc*). The non-moving party doesn't have "the burden of coming forward and presenting its case against a preliminary injunction." *Ala. v. U.S. Army Corps of Eng'rs*, 424 F.3d 1117, 1136 (11th Cir.

2005) (quoting *Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Trust Drivers Local No. 70*, 415 U.S. 423, 442 (1974)). And because courts adjudicate only the case or controversy before them, absent class certification, "injunctive relief should be limited in scope to the extent necessary to protect the interests of the *parties*." *Ga. Advoc. Off. v. Jackson*, 4 F.4th 1200, 1209 (11th Cir. 2021) (cleaned up) (emphasis added).

ARGUMENT

Plaintiffs can't meet any of the four prongs for a preliminary injunction. There is no likelihood of success on equal protection or statutory grounds. The four Plaintiffs with gender dysphoria can't establish irreparable harm. And the equities and public interest tilt decidedly in the State's favor.

I. Likelihood of Success: Equal Protection Clause.

A. Rule 59G-1.050(7)(a) makes a distinction between treatments for those with gender dysphoria; the State will pay for some treatments but not others. In *Dobbs*, the U.S. Supreme Court held that the "regulation of a medical procedure," even one that "only one sex can undergo," "does not trigger heightened constitutional scrutiny unless the regulation is mere pretext designed to effect an invidious discrimination against members of one sex or the other." 142 S. Ct. at 2245-46 (cleaned up). Without adequately pleading invidious discrimination in their complaint, without attempting to prove it anywhere in their preliminary injunction motion, and without even mentioning the *Arlington Heights* factors, Plaintiffs must contend with the rational basis standard

when challenging the State's exclusion of certain medical treatments for one medical diagnosis.[2]

Under the applicable standard, the State's choices are subject to a "strong presumption of validity" and "must be sustained if there is a rational basis on which" the government "could have thought it would serve legitimate state interests." *Id.* at 2284 (cleaned up). Florida has a legitimate and compelling interest in protecting its citizens from unnecessary and experimental treatments that (in the State's estimation) are grounded in low-quality evidence and threaten to cause permanent harm like sterilization and infertility. *See supra*. Rational basis is more than satisfied here. *See Dobbs*, 142 S. Ct. at 2268 ("courts [generally] defer to the judgments of legislatures in areas fraught with medical and scientific uncertainties") (cleaned up)); *Otto v. City of Boca Raton*, 981 F.3d 854, 868 (11th Cir. 2020) ("It is indisputable 'that a State's interest in safeguarding the physical and psychological well-being of a minor is compelling.'" (quoting *New York v. Ferber*, 458 U.S. 747, 756-57 (1982))); *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) (recognizing the use of police powers to pass health-related laws).

[2] Nor could they establish intentional discrimination. Other than bald assertions of pretext, Plaintiffs offer no factual allegations (supported by evidence) that the State's rule is motivated by anything other than genuine concern for the health and safety of its people, including persons suffering from gender dysphoria. And in the absence of any such evidence, the State is entitled to the presumption of good faith. *League of Women Voters of Fla., Inc. v. Fla. Sec'y of State*, 32 F.4th 1363, 1373 (11th Cir. 2022) (citing *Abbott v. Perez*, 138 S. Ct. 2305, 2324 (2018)). Any unsupported attempt to cast a disagreement over the appropriate treatment for gender dysphoria, as well as the strength of the evidence for so-called "gender-affirming care," as evidence of discriminatory animus should be rejected.

B. Even if *Dobbs* doesn't control, which it does, Plaintiffs are still wrong in alleging that the State's rule is subject to heightened scrutiny. Plaintiffs' thesis is this: *any* distinction concerning the treatment of gender dysphoria affects only *transgender* individuals, and this *facial* distinction is one based on *sex* or, at the very least, their *protected* status as transgender individuals. The problems here are threefold.

First, facially discriminatory laws divide similarly situated individuals based on some protected classification. In *United States v. Virginia*, for example, a state school divided applicants based on their sex and admitted only male applicants. 518 U.S. 515, 523 (1996). And in *Nguyen v. INS*, an immigration statute "impose[d] different requirements for a child's acquisition of citizenship depending upon whether the citizen parent" was "the mother or father." 553 U.S. 53, 56-57 (2001). That's not this case.

This case is like *Geduldig v. Aiello*, where the Supreme Court held that a state insurance program that excluded coverage based on pregnancy did *not* classify on the basis of sex. 417 U.S. 484, 485 (1974). "While it is true that only women can become pregnant," the Supreme Court explained that "it does not follow that every legislative classification concerning pregnancy is a sex-based classification." *Id.* at 496 n.20. There were "pregnant women," on the one hand, and "nonpregnant persons," on the other. *Id.* The "first group" was "exclusively female," but "the second include[d] members of both sexes." *Id.* This revealed a "lack of identity" between pregnancy and sex. *Id.*

So too here. Florida's rule excludes certain treatments for gender dysphoria. Two groups are relevant to the analysis: (1) transgender individuals with gender dysphoria,

and (2) non-transgender individuals and transgender individuals without gender dysphoria. Just as in *Geduldig* then, there's a "lack of identity" between gender dysphoria and transgender status. *Id.* Even if such status is the equivalent of sex or can be elevated to a suspect class, there still isn't any distinction that triggers heightened scrutiny. *Id.*

Plaintiffs' arguments to the contrary are unavailing. They baldly state that "[p]regnancy is not the defining characteristic of a woman," but "[l]iving in accord with one's gender identity rather than birth-assigned sex is the defining characteristic of a transgender person." Doc.11 at 29 n.25 And so, Plaintiffs argue, excluding certain treatments for gender dysphoria is tantamount to discrimination based on sex or transgender status. Not true. Plaintiffs have not and cannot show that all or even most transgender individuals undergo the excluded treatments at issue in this case. After all, not all transgender individuals have gender dysphoria and, in turn, not all transgender individuals seek these treatments. Plaintiffs thus ignore *Geduldig*'s core holding.[3]

[3] *See supra* (DSM-V definition of gender dysphoria); Expert Q&A: Gender Dysphoria, Am. Psychiatric Ass'n, https://bit.ly/3EdwfGU (last visited Oct. 2, 2022) ("Not all transgender people suffer from gender dysphoria and that distinction is important to keep in mind."); Maya Kailas *et al.*, *Prevalence and Types of Gender-Affirming Surgery Among a Sample of Transgender Endocrinology Patients Prior to State Expansion of Insurance Coverage*, 23 Am. Ass'n of Clinical Endocrinology Endocrine Practice 780 (2017) (noting that thirty-five percent of transgender individuals studied received at least one gender-affirming surgery); Understanding the Transgender Community, Human Rights Campaign, https://bit.ly/3Sx1IIb (last visited Oct. 1, 2022) ("The trans community is incredibly diverse. Some trans people identify as trans men or trans women, while others may describe themselves as non-binary, genderqueer, gender non-conforming, agender, bigender or other identities that reflect their personal experience. Some of us take hormones or have surgery as part of our transition, while others may change our pronouns or appearance.").

Second, even if Rule 59G-1.050's distinction *is* based on transgender status, Plaintiffs still can't point to any binding precedent that equates such a distinction to a sex-based distinction and then applies heightened scrutiny. True, Plaintiffs cite out-of-circuit cases as support for the proposition. Doc.11 at 24. But there are also out-of-circuit cases that apply rational basis to such a classification. *E.g.*, *Druley v. Patton,* 601 F. App'x 632, 635 (10th Cir. 2015); *Johnston v. Univ. of Pittsburgh,* 97 F. Supp. 3d 657, 668 (W.D. Pa. 2015).

While the Eleventh Circuit may decide the issue in one of two pending cases,[4] the State maintains that rational basis is the more appropriate test for classifications based on transgender status. As even Plaintiffs concede, any test for recognition of transgender status as a suspect class requires some showing that transgender individuals have immutable characteristics. Doc.11 at 24. The Supreme Court, for instance, has long grounded its sex-discrimination jurisprudence in reproductive biology. *See, e.g.*, *Nguyen*, 533 U.S. at 73; *Geduldig*, 417 U.S. at 496 n.20; *Virginia*, 518 U.S. at 533.

Yet Plaintiffs can't establish the necessary, immutable characteristics. As Dr. Laidlaw explains, there are no biological markers that show whether someone has a male brain in a female body or a female brain in a male body. App.770. There are also no objective tests—imaging, biopsies, or laboratory bloodwork—that can establish the immutable characteristics of transgender status. *Id.* And testimony from *de*transitioners,

[4] *See Adams v. School Board of St. Johns County*, Case No. 18-13592, and *Eknes-Tucker v. Governor of the State of Alabama*, Case No. 22-11707.

see App.269, makes clear that transgender status, unlike sex, is not "an immutable characteristic determined solely by the accident of birth." *Frontiero v. Richardson*, 411 U.S. 677, 689 (1973). One can cease to identify as transgender.

Third, neither *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), nor *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir. 2011), requires this Court to apply heightened scrutiny. Both cases are limited in scope and don't control in a medical context where the sexes are *not* similarly situated. *See Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985) ("The Equal Protection Clause" "is essentially a direction that all persons *similarly situated* should be treated alike" (emphasis added)).

Bostock construed "discriminate against" "because of" "sex" in a workplace discrimination law and not under the Equal Protection Clause. *Bostock*, 140 S. Ct. at 1739 (quoting 42 U.S.C. § 2000e-2.(a)(1)). It read the statute to mean that "[a]n individual's homosexuality or transgender status is not relevant to employment decisions." *Id.* at 1741. Its reasoning was that an employer who "penalizes a person identified as female at birth" discriminates based on sex under the statute because those persons are "similarly situated" for employment purposes. *Id.* at 1740-41. And it expressly reserved answering "[w]hether other policies and practices might or might not qualify as unlawful discrimination." *Id.* at 1753.

Glenn, too, was a workplace discrimination case. There, the Eleventh Circuit subjected to intermediate scrutiny certain governmental employment decisions made "based upon gender stereotypes," explaining that "we are beyond the day when an

employer could evaluate employees by assuming or insisting that they matched the stereotypes associated with their group." *Glenn*, 663 F.3d at 1320 (cleaned up).

The reasoning in *Bostock* and *Glenn* doesn't translate to the medical context where the sexes are *not* similarly situated. Even Plaintiffs' preferred trade group, WPATH, recognizes this fact. WPATH has stated that "[f]or puberty suppression, adolescents with *male* genitalia should be treated with GnRH analogues, which stop luteinizing hormone secretion and therefore testosterone secretion." WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* 18 (2012 7th ed.) (emphasis added). Conversely, "[a]dolescents with *female* genitalia should be treated with GnRH analogues, which stop the production of estrogens and progesterone." *Id.* at 18-19 (emphasis added). Clearly, sex-based distinctions play a role in medical care, unlike in the workplace where "[a]n individual's homosexuality or transgender status is not relevant to employment decisions." *Bostock*, 140 S. Ct. at 1741.

In sum, context matters when reading *Bostock* and *Glenn*. As Justice Thurgood Marshall observed, "[a] sign that says 'men only' looks very different on a bathroom door than a courthouse door." *Cleburne*, 473 U.S. at 468-69 (Marshall, J., concurring in the judgment in part and dissenting in part). The same is true when reading the words "sex" or "gender" in the employment context and when reading those words in the medical context.

C. Finally, if subjected to heightened scrutiny because of sex or transgender status, the State's rule-based exclusion satisfies that test as well. This level of scrutiny

requires the State to note (1) "important governmental objectives," and show that its chosen regulation is (2) "substantially related to the achievement of those objectives." *Nguyen*, 533 U.S. at 61 (cleaned up).

As noted above, Florida has a compelling interest in protecting its citizens from unnecessary and experimental treatments that are grounded in low-quality evidence and threaten to cause permanent harm like sterilization and infertility. The State's GAPMS Report, its attachments, and the expert material provided with this filing support the State's interests. These materials underscore that excluding certain treatments from Medicaid reimbursement would protect vulnerable citizens, including children. Put bluntly, based on the State's review, the science isn't there to support the use of puberty blockers, cross-sex hormones, or reassignment surgeries for the treatment of gender dysphoria. And the State doesn't want to use its Medicaid program to experiment.

The State's interests are thus important and even compelling: they stem from careful study and not "overbroad generalizations," and are pursued in a measured way that makes a panoply of behavioral health services available to all those with gender dysphoria. *Virginia*, 518 U.S. at 533. Heightened scrutiny is satisfied.

II. Likelihood of Success: Affordable Care Act.

A. Separately, Plaintiffs say that the State's decision not to reimburse a handful of unproven services violates section 1557 of the ACA. That section prohibits the States from "subject[ing] to discrimination" any "individual" "on the basis of sex." 42 U.S.C.

§ 18116(a) (incorporating 20 U.S.C. § 1681(a)). As discussed in the equal protection section above, there's been no sex-based discrimination.

In addition, Plaintiffs have the burden of establishing the likelihood of success on this argument. They cite no binding Eleventh Circuit case to support the notion that they are entitled to relief. Nor do they note that the *en banc* Eleventh Circuit is poised to address whether Title IX—on which the relevant ACA provision relies— prohibits discrimination based on transgender status. *See Adams v. Sch. Bd. of St. Johns Cnty.*, Case No. 18-13592. And they ignore the federal government's 2020 statements concerning the requirements under the ACA. *See supra.*

Nor is it unlawful discrimination, as Plaintiffs suggest, to deny the use of medical procedures approved in one circumstance for use in a completely different circumstance. Indeed, to conclude otherwise would allow crude legal analogies to override the medical judgment of the appropriate state regulatory bodies and thereby create a very dangerous precedent for the regulation of the medical profession. To be sure, the State continues reimbursing for mastectomies to treat women with breast cancer but no longer reimburses for mastectomies to treat women with gender dysphoria. But that is because those with breast cancer and gender dysphoria are not similarly situated. The two are entirely different medical conditions that bear no relation to one another. As Dr. Lappert explained, a mastectomy to treat the former is a life-saving procedure that removes diseased breasts (or breasts likely to become diseased) while a mastectomy to treat the latter is a cosmetic procedure that removes healthy

breasts to treat a psychological condition. *See supra.* The efficacy of mastectomies to treat breast cancer says absolutely nothing about the efficacy of mastectomies to treat gender dysphoria. And as Dr. Laidlaw explains in his expert declaration, accepting a false equivalency between a treatment approved for a specific malady and gender dysphoria would run roughshod over warnings from the Food and Drug Administration, among others, on off-label use of medication. App.799-800.

Indeed, material attached to Plaintiffs' motion supports the State's position on the issue. In a 2022 peer-reviewed paper on the use of puberty blockers, academics from Australia, Idaho, Oregon, and California criticized other researchers for "mislead[ing] clinicians unfamiliar with the literature into prescribing puberty blockers to [gender dysphoric] youth with confidence, when the only clinical stance supported by the evidence is that of extreme caution." Doc.11-1 at 115 (Clayton, *et al.*, 2022). The authors said that "research in this field is rapidly evolving," *id.*, with unscrupulous researchers "trumpet[ing]" "positive outcomes of medical interventions in abstracts" but hiding "their profound limitations" "behind the paywall." *Id.* at 117. It follows that off-label use of drugs like puberty blockers should be closely scrutinized in this "rapidly evolving" field. *Id.* at 115.

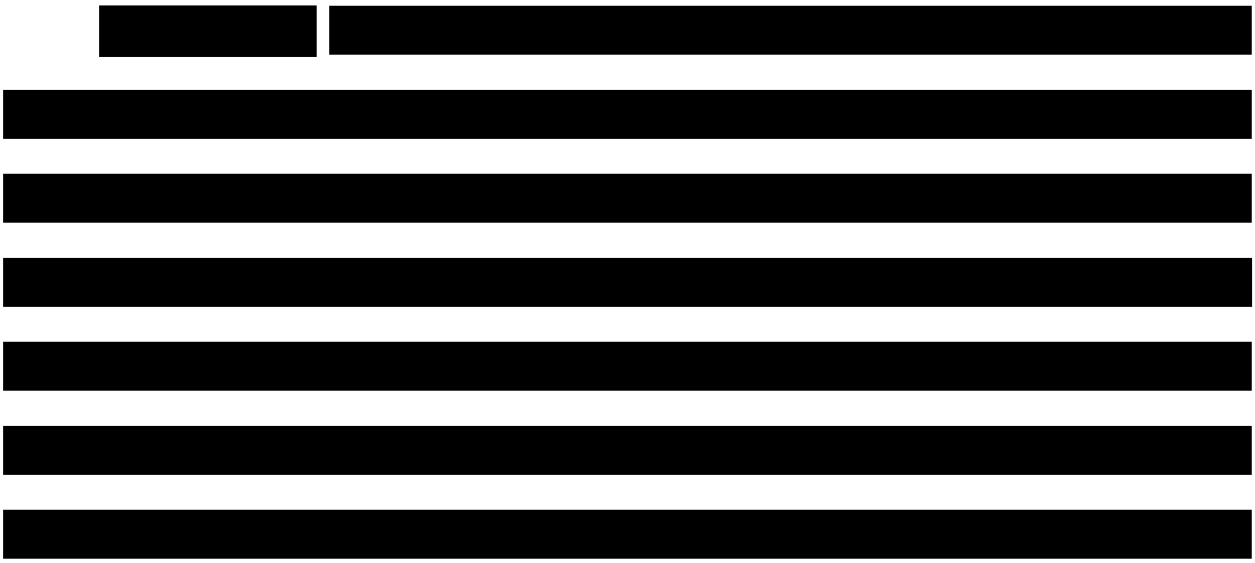
III. Irreparable Harm, the Equities, and the Public Interest: Re-focusing on the Patients and the Science.

A. As this Court is well-aware, the State is irreparably harmed "when it cannot effectuate its laws," particularly those intended to protect its citizens. *Maryland v. King*,

567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers). Yet it's unclear what, if any, harm Plaintiffs will suffer.

Broadly speaking, most of those with gender dysphoria revert to their birth sex. Many suffer co-morbidities that must be disentangled from the condition at issue (gender dysphoria). Plaintiffs, however, seek a broad, statewide injunction. That's contrary to this Court's duty to carefully and narrowly craft injunctive relief. *See generally Ga. Advoc. Off.*, 4 F.4th at 1209.

Plaintiffs also provide no medical records for examination. And Plaintiffs provide no evidence—none—from treating physicians for any of the four individuals who now sue. *See Doe v. Snyder*, 28 F.4th 103, 112 (9th Cir. 2022) ("Relatedly, and significantly, [the plaintiff] failed to provide a declaration from any psychiatrist or medical doctor who is treating him that attested to the necessity and suitability of the surgery in his particular case."). Dr. Laidlaw has, however, reviewed the Medicaid file for each of the four Plaintiffs.



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B. Just as Plaintiffs' declarations in support of the individual Plaintiffs miss the mark, so too do the broader points in their expert declarations. Although the attached declarations go into greater detail, the State submits the following points:

- Dr. Kaliebe rebuts the notion that high-quality science supports Plaintiffs' position. App.843. Like Dr. Romina Brignardello-Petersen and her post-doctoral fellow, Dr. Kaliebe concludes that the evidence supporting the use of puberty blockers, hormone therapies, and surgeries is based on low-quality literature. *Id.*

- Dr. Cantor responds to Dr. Karasic's and Dr. Olson-Kennedy's declarations, which, according to Dr. Cantor, "fail to provide any meaningfully full accounting of the science" and "instead cit[e] and address[] only selective pieces, with language insinuating the presence of evidence that does not exist." App.383. In particular, Dr. Cantor rebuts Dr. Karasic's representations of mental health improvement for transitioners, and rebuts Dr. Olson-Kennedy's claim that affirmation does not increase the probability of unnecessary transition and unnecessary medical risks. App.379-80.

- Dr. Donovan responds to Dr. Karasic's statement that the State's actions amount to forced detransitioning. Dr. Donovan criticizes Dr. Karasic for "fail[ing] to see that those pathways upon which he has set patients for 'gender affirming care' should have included protocols for the 'detransitioning' that patients are already voluntarily seeking in increasing numbers." App.639.

- Dr. Nangia, a pediatric psychiatrist who has "treated over a thousand patients with gender dysphoria," states that "children under the age of eighteen should not receive" "puberty blockers, hormone and hormone antagonists, and sex reassignment surgeries" because of their inability "to make very serious medical choices that" will "affect their overall health and self concept for the rest of their lives." App.614, 632.

- Dr. Zanga and Dr. Kaliebe show that the medical trade groups don't speak for all physicians struggling to treat patients with gender dysphoria. Dr. Zanga, a fellow at the American Academy of Pediatrics, describes the "undemocratic[]" process by which the organization adopts a policy position. App.744-45. He bluntly states that "[t]here is no review or vote by the remainder of the AAP membership," and thus the AAP's policies don't reflect the views of its members. *Id.* Dr. Kaliebe states that the medical community "has become more tribal, moralizing[,] and more likely to attempt to silence divergent opinions," which has led to a "suppression of research data, publication bias, and penalizing of divergent viewpoints." App.843-46.

- Dr. Lappert, Dr. Laidlaw, and Dr. Van Mol state that WPATH's and the Endocrine Society's standards of care and guidelines do not reflect

professional consensus and are grounded on biased and low-quality evidence. App.544-45, 566-69, 571-72, 796-801.

- Dr. Laidlaw and Dr. Van Mol state that hormone therapies and surgeries for gender dysphoria can lead to cardiovascular disease, cancer, bone density deficiencies, brain development issues, harms to sexual function, infertility, and permanent sterility. App.527, 823.

In sum, Rule 59G-1.050(7)(a) serves the public interest. From the perspective of the State, which is charged with safeguarding the public's welfare, the rule better accords with the admonition to first do no harm.

IV. Conclusion.

This Court should deny the motion for preliminary injunction. The kind of "extraordinary" and "drastic" relief that Plaintiffs seek is simply not warranted here. *McDonald's Corp.*, 147 F.3d at 1306. The State of Florida has made a measured decision to exclude reimbursement under Medicaid for certain treatments for one medical condition because those treatments threaten to do more harm than good. Neither the law nor the facts provide a basis to undo that decision entrusted to the State.

Respectfully submitted,

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Dated: October 3, 2022

LOCAL RULE CERTIFICATIONS

The undersigned certifies that this memorandum contains 7,989 words, excluding the case style and certifications.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF SERVICE

I hereby certify that on October 3, 2022, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared. I hereby certify that a non-redacted response in opposition has been emailed to counsel for Plaintiffs.

/s/ Mohammad O. Jazil
Mohammad O. Jazil