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

JANE DOE, et al.,

Plaintiffs,

v. Case No. 4:23-cv-00114-RH-MAF

JOSEPH A. LAPADO, et al.,

Defendants.
_____/

THE STATE'S RESPONSE IN OPPOSITION TO THE PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND MEMORADUM OF LAW

The State Defendants oppose the Plaintiffs' motion for preliminary injunction for the reasons set forth in the accompanying memorandum.

Dated: August 7, 2023

Ashley Moody
ATTORNEY GENERAL

/s/ Joseph E. Hart
Joseph E. Hart (FBN 0124720)
COUNSELOR TO THE ATTORNEY GENERAL

Office of the Attorney General
The Capitol, Pl-01
Tallahassee, Florida 32399-1050
(850) 414-3300
(850) 410-2672 (fax)
Joseph.Hart@myfloridalegal.com

Counsel for the Surgeon General, the Department of Health, and State Attorney Gladson

Respectfully submitted by:

/s/ Mohammad O. Jazil
Mohammad O. Jazil (FBN 72556)
Gary V. Perko (FBN 855898)
Michael Beato (FBN 1017715)
Holtzman Vogel Baran
Torchinsky & Josefiak PLLC
119 S. Monroe St., Suite 500
Tallahassee, FL 32301
(850) 270-5938
mjazil@holtzmanvogel.com
gperko@holtzmanvogel.com
mbeato@holtzmanvogel.com

Counsel for the Surgeon General, the Department of Health, the Boards of Medicine, and the individual Board Members

CERTIFICATE OF COMPLIANCE

As required by Local Rule 7.1(F), I certify that this response in opposition to the Plaintiffs' motion for preliminary injunction contains 35 words.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF SERVICE

I certify that, on August 7, 2023, this response in opposition to the Plaintiffs' motion for preliminary injunction was filed through the Court's CM/ECF system, which will send a notice of electronic filing to all counsel of record.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

INTRODUCTION

Despite the Plaintiffs' assertions to the contrary, the informed-consent provisions they challenge do not "deny[] transgender patients medical care." ECF No. 116, at 21. They do not discriminate by "prevent[ing] transgender adults in Florida from obtaining established medical care because they are transgender." ECF No. 116, at 21. And they do not, nor were they ever intended to, "scare" patients with gender dysphoria "from getting needed care." ECF No. 116, at 9.

Instead, each provision challenged by the Plaintiffs exists to ensure that any person seeking sex-modification procedures benefits from "the doctrine of informed consent," a principle with common-law roots that imposes upon "physician[s] . . . an obligation to advise [their] patient[s] of the material risks of undergoing a medical procedure." *State v. Presidential Women's Ctr.*, 937 So. 2d 114, 116 (Fla. 2006). Florida codified the doctrine as a general matter back in the 1970s, *see* Fla. Stat. § 766.103, and—particularly relevant here—has routinely enacted more granular informed-consent provisions when a particular medical procedure has counseled in favor of doing so, *see, e.g.*, *id.* § 458.324, (breast cancer); *id.* § 458.325 (electroconvulsive and psychosurgical procedures); *id.* § 945.48 (inmates receiving psychiatric treatment).

The Constitution, moreover, authorizes Florida, not the World Professional Association for Transgender Health, the Endocrine Society, or any other medical group, to regulate medical care within its borders. *Andino v. Middleton*, 141 S. Ct. 9, 10 (2020) (Kavanaugh, J., concurral); *see also L.W. v. Skrmetti*, 73 F. 4th 408, 418 (6th Cir. 2023)

(explaining that the Constitution does not require state legislatures to agree with "the majority" of medical professionals or organizations). States, through their elected representatives accountable to the people—not "experts" or the courts—are the institutions tasked with deciding issues of health and welfare in our republic. *Skrmetti*, 73 F. 4th 408 at 420. Florida's decision to protect its citizens by requiring informed consent and creating additional guidelines for procuring and performing these procedures was well within its constitutional powers.

Even this Court has explicitly acknowledged that the "medications" at issue in this case "have attendant risks." *See* ECF No. 90, at 11. It has further reiterated (several times) that decisions to begin such treatment should be made "in consultation with properly trained practitioners," and that patients must be "fully apprised of the current state of medical knowledge and all attendant risks" before beginning sex-modification procedures. *E.g.*, ECF No. 90, at 11. Ensuring that individuals are so apprised is necessary if they are to have the "ability to evaluate the benefits and risks" of undergoing certain treatment. ECF No. 90, at 11. Simply put, the benefits and risks cannot be weighed in any sense of the word if the benefits and risks remain unknown.

That is all these provisions do. They ensure that the benefits and risks of sex-modification treatments are communicated in person by a physician—an individual with the training and credentials necessary to provide fulsome information and answer any questions that arise. In other words, they ensure that individuals seeking sex-modification procedures have the information that they need to make a fully informed

decision about treatment that has not yet been accepted universally and that carries ascertainable risks.

Read as a whole (instead of in the piecemeal fashion offered by the Plaintiffs), the informed-consent forms are neither incorrect nor confusing. If an individual has questions about something in the forms, the in-person-consultation requirement facilitates the give-and-take between doctor and patient that helps ensure a fully informed decision. And if the doctor and patient decide on a course of hormonal or surgical treatment, then the doctor-as-prescriber requirement provides an additional layer of expertise and protection so that, for instance, a schedule-III controlled substance like testosterone is administered responsibly, or the full ramifications of sex-modification procedures are explained by the most knowledgeable medical professional.

All these requirements are reasonable, rational, and responsible. None discriminate based on sex or gender identity. None bar an individual experiencing gender dysphoria from seeking medical intervention. Accordingly, none should be preliminarily enjoined under the Fourteenth Amendment's Equal Protection Clause.

STATEMENT OF CASE & FACTS

I. FLORIDA LAW ENSURES THAT INDIVIDUALS EXPERIENCING GENDER DYSPHORIA ARE AS FULLY INFORMED AS THEY CAN BE.

In earlier filings in both this case and in *Dekker v. Weida*, 4:22-cv-325 (N.D. Fla. 2022) ("*Dekker* Doc."), the State set out its position regarding gender dysphoria and the

lack of medical consensus regarding the appropriate course of treatment for it. *See, e.g.*, ECF No. 55, at 3-9. Given the Court's familiarity with the issues and the State's position, the State will limit its discussion here to the regulations giving rise to the Plaintiffs' current motion for a preliminary injunction. The State does, however, incorporate by reference its previously stated assertions. *See, e.g.*, ECF No. 55, at 3-9.

The provisions of Senate Bill 254 that the Plaintiffs ask the Court to preliminary enjoin are straightforward, uncontroversial, and commonsensically in accord with other informed-consent provisions. Specifically, Florida law provides that "[i]f sex-reassignment prescriptions or procedures are prescribed for or administered or performed," then "consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine." Fla. Stat. § 456.52. Informed consent is defined as arising "only if the physician who is to prescribe or administer the pharmaceutical product or perform the procedure has, at a minimum, while physically present in the same room":

> (a) Informed the patient of the nature and risks of the prescription or procedure in order for the patient to make a prudent decision;
>
> (b) Provided the informed consent form, as adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, to the patient; and
>
> (c) Received the patient's written acknowledgment, before the prescription or procedure is prescribed, administered, or performed, that the information required to be provided under this subsection has been provided.

Id. Finally, "[s]ex-reassignment prescriptions or procedures may not be prescribed, administered, or performed except by a physician." *Id.*

On July 7, 2023, the Florida Board of Medicine complied with Senate Bill 254 by creating three standard informed-consent forms for individuals seeking treatment for gender dysphoria. One form, titled "Surgical Treatment for Adults with Gender Dysphoria," opens with the following language:

> Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.
>
> Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.
>
> Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

Exh. A. The two other forms are titled "Feminizing Medications for Patients with Gender Dysphoria" and "Masculinizing Medications for Patients with Gender Dysphoria," both of which begin with the following language.

> Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

> The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It is your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.
>
> After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.
>
> Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

Exhs. B, C.

None of the foregoing is inaccurate or misleading. Throughout the *Dekker* Trial, the Court heard testimony that the quality of the scientific data underlying the transgender standards of care remain "very low or low," even though the standards nonetheless "recommend," e.g., "hormonal treatment." *Dekker* Trial Tr. at 978 (Testimony of Dr. Stephen B. Levine). The "very low or low" categorization is based on "[t]he GRADE system," which "is a systematic way of rating the quality of evidence that is present within clinical practice guidelines." *Dekker* Trial Tr. at 154 (Testimony of Dr. Paul Hruz). "By definition, studies that are of very low[-]quality mean that it is very likely that the recommendations will change as new information becomes available." *Dekker* Trial Tr. at 154 (Testimony of Dr. Paul Hruz). Indeed, even the Court expressly

acknowledged that "[i]t seems—and that's true, I think. I think the record shows that it is low-quality evidence." *Dekker* Trial Tr. at 1035. At no point have either the Plaintiffs here or those in *Dekker* disputed this. Simply put, "the evidence-base is" indeed "low quality, and that is consistent with all of the reviews." *Dekker* Trial Tr. at 1110 (Testimony of Dr. Kristopher Kaliebe).

II. THE PLAINTIFFS' CHERRY-PICKED, OUT-OF-CONTEXT OBJECTIONS TO THE STATE'S INFORMED CONSENT REQUIREMENTS.

Despite the self-evident benefit inherent in the very notion of informed consent, the Plaintiffs nonetheless assert that the State's attempt to fully inform individuals experiencing gender dysphoria is somehow a bad thing. In addition to their objections to the in-person consent requirement, the physician-as-prescriber requirement, and the low-quality research disclaimer, the Plaintiffs pluck out the following concerns:

- "Both cross-sex hormone forms state that the use of hormones to treat gender dysphoria is considered 'off label' because they are not being used for their intended purpose." ECF No. 116, at 11.

- The forms ask the patient to affirm that he or she "know[s] that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT." ECF No. 116, at 12.

- "Both cross-sex hormone forms state that 'psychological therapy with a mental health provider' is an 'option' for patients who do not wish to start or continue hormone therapy." ECF No. 116, at 13.

- "Both cross-sex hormone forms state: 'Treatment with femininizing [or masculinizing] medications will not prevent serious psychiatric events, including suicide.'" ECF No. 116, at 13.

- "[T]he form for feminizing hormones includes information about cyproterone acetate. . . . Similarly, the form for masculinizing hormones gratuitously mentions testosterone pills, despite noting that testosterone is typically 'not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems.'" ECF No. 116, at 14.

- "[T]he form for masculinizing hormones falsely states that finasteride is a treatment for gender dysphoria in transgender men, whereas in fact is a treatment for baldness in both transgender and non-transgender men. In contrast, finasteride may be prescribed to treat gender dysphoria in transgender women." ECF No. 116, at 14.

- "[T]he form for masculinizing hormones falsely states that 'treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts,' and 'taking testosterone causes or worsens migraines.' . . . This form also states that taking testosterone may cause certain changes that 'could be permanent,' but stating that any of the listed changes could be permanent is incorrect as they are all non-permanent effects of testosterone. . . . The form for feminizing hormones states: 'My risk of breast cancer may significantly increase.'" ECF No. 116, at 15.

- "Both cross-sex hormone forms state: 'HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.'" ECF No. 116, at 16.

- "[T]he recommendation that patients may be required to undergo annual bone scans has no medical basis whatsoever. . . . [T]here is no medical reason for either transgender men or transgender women to undergo annual bone scans. Doing so is not only

> unnecessary but serves no medical purpose whatsoever." ECF No. 116, at 18.

Based on foregoing (misguided) disagreement with Florida's informed-consent requirements, the Plaintiffs have asked the Court to conclude that Florida has violated their Fourteenth Amendment Equal Protection rights by discriminating on the basis of sex. ECF Nos. 115, 116.

RELEVANT LEGAL STANDARD

The Court 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 if the Plaintiffs demonstrate that: (1) they have "a substantial likelihood for success on the merits"; (2) they 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 cannot meet any of the four prongs for a preliminary injunction. Their equal-protection challenge has no likelihood of success. None have established that they will experience irreparable harm unless the Court grants their requested injunction now, particularly since none of the informed-consent requirement provisions they challenge prohibit any treatment for gender dysphoria. And both the equities and public interest tilt decidedly in the State's favor.

I. THE PLAINTIFFS' EQUAL-PROTECTION CHALLENGE CANNOT SUCCEED.

A. The Plaintiffs are not likely to prevail on their claim that transgender status is a protected class.

The Plaintiffs assert that they are likely to succeed on their equal protection claim because the challenged regulations "single out transgender patients because of their . . . transgender status." ECF 116, at 21. "But neither the Supreme Court nor [the Eleventh Circuit] has recognized transgender status as a quasi-suspect class." *L.W. v. Skrmetti*, 73 F. 4th 408, 419 (6th Cir. 2023). "The bar for recognizing a new quasi-suspect class, moreover, is a high one." *Id.* Accordingly, the novelty of this claim, alone, precludes the Plaintiffs from establishing that they are likely to succeed on its merits. *Id.*; *see also Adams ex rel. Kasper v. St. Johns Cnty.*, 57 F.4th 801, 805 n.5 (11th Cir. 2022) ("[W]e have grave doubt that transgender persons constitute a quasi-suspect class).

B. The challenged regulations do not discriminate based on sex.

The Plaintiffs also assert that they are likely to succeed on their equal protection claim because the challenged regulations discriminate against them "because they are transgender and, therefore, because of their sex." ECF 116, at 21. The regulations, however, apply to both sexes equally—whether an individual is a biological male seeking sex-modification surgery, or a biological female seeking sex-modification surgery, the informed-consent requirements apply equally to all. Accordingly, the challenged regulations do not discriminate based upon sex. *Skrmetti*, 73 F. 4th at 419.

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 do not 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" "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)); *see also Students for Fair Admission v. Harvard Coll.*, 141 S. Ct. 2141, 2219-20 (2023) (Gorsuch, J., concurring); *Skrmetti*, 73 F. 4th at 420. 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* does not translate to the informed-consent context because Florida's informed-consent regulations are entirely gender and sex neutral. Whether a person is a transgender male seeking sex-modification procedures, or a transgender woman seeking the same, he or she must comply with Senate Bill 254's informed-consent requirements and the regulations implementing them. In other words, one *need not* "know the sex of a person to know whether or how [these] provision[s] appl[y] to the person." *Dekker* Final Order 30. So long as a person is seeking certain treatments for gender dysphoria, it matters not the sex of that individual—the informed-consent requirements apply regardless. *See Skrmetti*, 73 F. 4th at 419.

C. The Plaintiffs are not treated dissimilarly from anyone "similarly situated."

The Plaintiffs neglect to show how Florida's informed-consent requirements treat them any differently from individuals who are "similarly situated" to them. For at least three decades, the Eleventh Circuit has ascribed to the rule that "'[d]ifferent

treatment of *dissimilarly situated* persons does not violate the equal protection clause.'" *Griffin Indus. v. Irvin*, 496 F.3d 1189, 1207 (11th Cir. 2007) (citing *E & T Realty v. Strickland*, 830 F.2d 1107, 1109 (11th Cir. 1987)). "'"The reason that there is a 'similarly situated' requirement in the first place is that at their heart, equal protection claims . . . are basically claims of discrimination."' *Id.* (quoting *McDonald v. Vill. of Winnetka*, 371 F.3d 992, 1009 (7th Cir. 2004)). Indeed, "[t]o maintain this focus on discrimination, and to avoid constitutionalizing every state regulatory dispute," courts of this Circuit "are obliged to apply the 'similarly situated' requirement with rigor." *Id.*

The Plaintiffs make virtually no attempt to demonstrate how Senate Bill 254's informed-consent provisions treat them any differently than a *similarly situated* individual. And the reason is obvious: a person experiencing gender dysphoria is self-evidently *not* similarly situated to any other patient. The reasons why an individual suffering from hypogonadism would opt for hormonal therapy are not the same as a person seeking to transition from one gender to another. The risks associated with hormonal therapy between the two are quite distinct as well; with the former, the treatment seeks to bring hormone levels in line with those that are naturally occurring, while the latter far exceeds what his or her body would otherwise naturally produce. The Plaintiffs make no real attempt to reconcile this apples-to-oranges comparison, and their failure to do so dooms their Equal Protection Claim.

D. Even assuming that the Plaintiffs have shown that Florida's informed-consent requirement treats them differently than similarly situated individuals, rational-basis review applies.

The Supreme Court has recently clarified that the "regulation of a medical procedure . . . 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." *Dobbs*, 142 S. Ct. 2245-46 (cleaned up). The reason is clear—regulation of medical care (particularly informing patients of the risks and benefits of one procedure versus another) involves a number of considerations that States, and not courts, are best positioned to decide. *Skrmetti*, 73 F. 4th at 417 (noting the important role states play in regulating health and cautioning federal courts to "be vigilant not to substitute their views for those of legislatures"). And because the Plaintiffs have offered nothing other than rank conjecture to suggest that Florida's informed-consent requirements are a mere pretext to hide animus against the transgender community, *Dobbs* commands that rational-basis review applies.

E. Florida's informed-consent requirements satisfy *both* heightened scrutiny and rational-basis review.

Even if the Court disagrees and applies heightened scrutiny, Florida's informed-consent regulations are still plainly constitutional. This level of scrutiny requires the State to note (1) "important governmental objectives," and to show that its chosen regulation is (2) "substantially related to the achievement of those objectives." *Nguyen*, 533 U.S. at 61 (cleaned up). And "like other health and welfare laws," Florida's regulation "is entitled to a 'strong presumption of validity.'" *Dobbs*, 142 S. Ct. at 2284 (citations omitted).

At the outset, the Plaintiffs' constant characterizations of the challenged regulations as "deny[ing] essential medical care to transgender patients," ECF 116, at 21, or "preventing transgender patients from receiving necessary medical care," ECF 116, at 23, are flatly incorrect. At no point do the informed-consent requirements that the Plaintiffs challenge here prohibit them (or anyone else) from obtaining the procedures they desire. The challenged regulations merely provide guidelines for receiving the desired procedures, which are similar to guidelines the State provides in a myriad of other medical contexts. Furthermore, the Plaintiffs' concerns about their ability to find qualified physicians or psychologists to perform the necessary evaluations for these procedures are undermined by their unwavering insistence that these procedures are widely accepted within the medical community.

Florida, of course, has a *compelling* interest in ensuring that its residents are fully informed and validly consent to any medical procedure. Indeed, the Florida Supreme Court has emphasized that "[u]nless a person knows the risks and dangers of such a procedure, 'a 'consent' does not represent a choice and is ineffectual.'" *Presidential Women's Ctr.*, 937 So. 2d at 116 (quoting *Bowers v. Talmage*, 159 So. 2d 888, 889 (Fla. 3d DCA 1963)). Simply put, "[t]he doctrine of informed consent is well recognized, has a long history, and is grounded in the common law and based in the concepts of bodily integrity and patient autonomy." *Id.* The State's interest in protecting it is one of the highest order, let alone "important." Each provision challenged by the Plaintiffs is also "substantially related to the achievement of [its] objective[]," *Nguyen*, 533 U.S. at 61—

i.e., ensuring that individuals experiencing gender dysphoria are fully apprised of the risks, and that they provide valid consent to such procedures irrespective of those risks.

In the Plaintiffs' telling, some of the information could cause confusion. Setting aside that their objections say *nothing* about the sort of disparate treatment that could support an equal-protection challenge, they're simply wrong that there is anything in Florida's informed-consent rules that are misleading, arbitrary, or gratuitous. Indeed, unrebutted testimony elicited during, and the Court's conclusions after, the *Dekker* Trial establish these points beyond any reasonable dispute.

The physical presence requirement. The first objection that the Plaintiffs lodge is to the requirement that a physician be "physically present in the same room" when a patient provides his or her informed consent to undergo gender-affirming care. Fla. Stat. § 456.52. In their view, "[a] physical presence requirement needlessly prevents the use of telehealth and serves as an insurmountable barrier for patients who do not live in proximity to their provider or who lack access to transportation." ECF No. 116, at 10. But testimony from the *Dekker* Trial reveals that the physical-presence requirement serves a profoundly important function.

Specifically, a telehealth appointment is not adequate to assess the complexity that goes into determining whether an individual is an appropriate candidate for sex-modification treatment. According to Dr. Aron Janssen, "[t]he primary components of an assessment" include "a full diagnostic evaluation," since physicians "want to understand . . . that the presence, the diagnosis of gender dysphoria has been persistent,

and that the diagnostic criteria are met." *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen). Critically, "[t]his diagnosis is made not just with an interview with the patient themselves but also looking at other criteria, other informants." *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen). Providers will also want to assess "any co-occurring mental health and psychiatric disorders, how they may or may not influence the diagnosis of gender dysphoria." *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen). Then, the provider is in a better position to "make sure" that everyone has "a very clear understanding . . . of the specific risks, benefits, and alternatives, which include both the known and unknown risks of whatever that intervention is." *Dekker* Trial Tr. at 84 (Testimony of Dr. Aron Janssen).

This sort of in-depth process cannot occur as productively over a video link. This is particularly true given that "adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population," which "is true before and after transition, hormones, and surgery." Expert Report of Dr. Stephen B. Levine, at 11. An in-person informed-consent requirement ensures that a physician can assess non-verbal indications of comorbidities that he or she might miss over a video link. And given the stakes attendant to sex-modification procedures—including possible irreversible loss of bodily organs/functionality, sterility, and hormonal changes—the sort of open, trusting, give-and-take informational exchange that occurs more naturally in person than over a

telehealth session is a critical part of ensuring full understanding and valid consent to these sorts of medical procedures.

The State's decision to require in-person informed consent is both abundantly rational and more than substantially related to the compelling interest it has in assuring that those seeking treatment for gender dysphoria understand the costs and benefits of their course of treatment. It should not be enjoined.

The information in the informed-consent forms. Next, the Plaintiffs take issue with several of the disclaimers listed in the informed-consent forms. In their view, the forms are "likely to cause confusion, to overwhelm a patient with irrelevant information, prevent a patient from understanding the individualized risks and benefits of the medication that is being recommended or prescribed, and generally make it more difficult for the patient to focus on the information relevant to their health." ECF No. 116, at 13. Rather than acquiescing to the Plaintiffs' exaggeration, the State invites the Court to read the three forms (which the State attaches as Exhibits A, B, and C) and to assess for itself whether they are confusing, ambiguous, or likely to cause *less* of an understanding regarding the costs and benefits of sex modification procedures. And the State would be remiss if it didn't note that the in-person informed-consent requirement exists so that a patient can have all of his or her questions answered regarding the forms.

In any event, the information on the informed-consent forms is neither false nor misleading. As noted above, *supra*, the scientific data underlying the standards of care

for gender dysphoria remain "very low or low," even though the standards nonetheless "recommend," e.g., "hormonal treatment." *Dekker* Trial Tr. at 978 (Testimony of Dr. Stephen B. Levine). Indeed, this Court expressly acknowledged that "[i]t seems—and that's true, I think. I think the record shows that it is low-quality evidence." *Dekker* Trial Tr. at 1035. This is information that a person seeking gender-affirming treatment is entitled to have if he or she is going to be fully informed and provide valid consent to that treatment.

The Plaintiffs' other objections fare no better. Prescribing hormones for gender-affirming treatment is indeed an "off-label" use of those pharmaceuticals. This means, quite literally, that the drugs were "originally approved for some other purpose." *Dekker* Trial Tr. at 1017 (Testimony of Dr. Stephen B. Levine). This is precisely the message that the informed-consent forms provide.

It is similarly true that there are no "*controlled* research studies that support the timing, dosing, and type of administration of HRT," Exhs. B, C, and that the judgment of the prescribing physician controls. Throughout the *Dekker* Trial, experts testified that there was a lack of *controlled* research studies pinning down the correct ways in which to administer cross-sex hormones for purposes of bringing a person's gender identity in line with their biological sex. *See generally, e.g.*, *Dekker* Trial Tr. at 228 (Testimony of Dr. Paul Hruz); *Dekker* Trial Tr. at 1069 (Testimony of Dr. Patrick Lappert); Expert Report of Dr. Michael K. Laidlaw ¶ 308; Expert Report of Dr. Kristopher Kaliebe ¶ 162. And "psychological therapy" does indeed remain an option for individuals who

might not want to start hormonal therapy or undergo surgery. Gender dysphoria is a psychological diagnosis that manifests by "marked incongruence between one's experienced/expressed gender and assigned gender" of at least six months duration. Diagnostic and Statistical Manual of Mental Disorders, Ed. 5. (DSM-V). It follows, then, that psychological therapy remains a potential route. Indeed, even the Plaintiffs note that "psychotherapy can be beneficial for many people, including transgender people." ECF No. 116, at 12.

Informing a person with gender dysphoria that "[t]reatment with femininizing [or masculinizing] medications will not prevent serious psychiatric events, including suicide," is entirely true. Exhs. B, C. Contrary to the Plaintiffs' suggestion, this sentence does not "suggest[] that hormone therapy" has *no* "positive impact on a transgender patient's mental health." ECF No. 116, at 13. That said, "adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population. *This is true before and after transition, hormones, and surgery.*" Expert Report of Dr. Stephen B. Levine at 11 (emphasis added). It remains accurate that the suicide rate among those receiving cross-sex hormones to treat gender dysphoria remains frighteningly high, and even the Plaintiffs admit that "no treatment can provide an absolute guarantee against 'psychiatric events, including suicide.'" ECF No. 116, at 13. This warning, then, is part of the information that someone struggling with gender dysphoria *and* other

comorbidities *should* understand before beginning hormonal treatment that they might expect to improve their well-being in all aspects of their lives.

Relatedly, anyone embarking on hormonal treatment should be made aware of the physical and mental effects such treatment can inflict. "Testosterone is an anabolic steroid," and one "of high potency." Expert Report of Dr. Michael K. Laidlaw ¶ 114. It is hazardous enough to be "classified as a Schedule 3 controlled substance by the DEA," which means abuse of it "may lead to moderate or low physical dependence or *high psychological dependence*." Expert Report of Dr. Michael K. Laidlaw ¶ 114 (emphasis added). For this reason, "[a] licensed physician with a valid DEA registration is required to prescribe testosterone," and dose "must be carefully considered and monitored to avoid excess levels in the male as there are a number of serious concerns when prescribing testosterone." Expert Report of Dr. Michael K. Laidlaw ¶¶ 114, 115. The labeling itself states that:

> Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication . . . . Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions . . . . Abuse and misuse of testosterone are seen in female adults and adolescents . . . . There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice. (Actavis Pharma, 2018)

Expert Report of Dr. Michael K. Laidlaw ¶ 116 (underscore in original). "Adverse events with respect to the nervous system include: 'Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia,'" while "[p]rolonged use of

high doses of androgens . . . has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture]—all potentially life-threatening complications." Expert Report of Dr. Michael K. Laidlaw ¶¶ 117, 122. And "[a]ccording to research[,] anabolic steroid abuse has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders," with "[t]he 'most prominent psychiatric features'" including "manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior," as well as "acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states." Expert Report of Dr. Michael K. Laidlaw ¶ 140. This, then, is more than ample support for the requirement that "you must be under the care of a licensed mental health care professional while undergoing treatment.'" Exh. B, C.

Research demonstrating these potential side effects typically examine male use of testosterone. "The use of high dose testosterone in females is experimental." Dr. Michael K. Laidlaw ¶ 115. "[T]here are," however, "greater attendant risks when you give testosterone to a female above and beyond that which you would see in giving that same hormone to a male." *Dekker* Trial Tr. at 151 (Testimony of Dr. Paul Hruz). Similarly, "[t]he effects that actually have been shown to occur in males that are given estrogen as part of a gender affirmation can increase risk of a thromboembolic stroke three to fivefold." *Dekker* Trial Tr. at 152 (Testimony of Dr. Paul Hruz).

Finally, the informed-consent forms' discussion of cyproterone acetate, finasteride, and the potential for bone scans cannot conceivably cause the sort of confusion that rises to the level of a constitutional violation. If an individual is not prescribed either cyproterone acetate or finasteride as part of his or her sex-modification procedure, it beggars belief to think that listing these substances in the informed-consent forms will somehow confuse, dissuade, or prevent him or her from receiving that treatment. If he or she experiences confusion, the physical-presence requirement provides the opportunity to alleviate it with the prescribing physician.

* * *

According to the Court, it is crucial to take into account "[t]he risk of all of these medicines," and then "make a benefit analysis." *Dekker* Trial Tr. at 234. "Risks attend many kinds of medical treatment, perhaps most," and "it is the patient, in consultation with the doctor, who weighs the risks and benefits and chooses a course of treatment." *Dekker* Final Order at 43. "If a medicalized approach with hormones such as testosterone or medications to stop menstruation is being considered then a clear description of the risks and benefits needs to be conveyed to the patient," and "[i]t needs to be verified that they fully understand these risks." Expert Report of Dr. Michael K. Laidlaw ¶ 228.d. Similarly, "[i]f surgical procedures such as mastectomy, hysterectomy, ovariectomy, orchiectomy, or vaginoplasty are being considered then clear descriptions of the risks and benefits need to be conveyed to the patient." Expert Report of Dr. Michael K. Laidlaw ¶ 228.e.

The informed-consent forms exist to make sure that patients answer "the key question";—i.e., "whether the risk that is assumed relative is acceptable to the purported benefit." *Dekker* Trial Tr. at 234. The forms do so accurately and effectively. Accordingly, they do not violate the Equal Protection Clause.

The recurring mental-health evaluation. The Plaintiffs also take issue with the fact that "[b]oth cross-sex hormone forms require transgender patients to 'undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist' before beginning hormone therapy and 'every two years thereafter.'" ECF No. 116, at 15-16. Their protestations that "[t]here is no medical basis for these requirements," ECF No. 116, at 16, ignores that "[g]ender dysphoria is a psychiatric diagnosis" that is identified "purely by psychological methods of behavioral observation and questioning." Expert Report of Dr. Michael K. Laidlaw ¶ 23.

It also ignores that "co-occurrence of mental illness" in this group is "widely recognized and widely documented." *Dekker* Doc. ECF No. 49, at 4 (quoting App. 139). Indeed, gender dysphoric adults "continue to show high rates of mental health issues after transition" to the other gender. *Dekker* Doc. ECF No. 49, at 4 (quoting App. 139). And "[i]n working with this population," doctors "treat the whole gamut of co-occurring psychiatric disorders." *Dekker* Trial Tr. at 68 (Testimony of Dr. Aron Janssen). And as noted above, hormonal treatments (particularly, testosterone) are documented to cause or aggravate certain mental disorders. *Supra*. This

requirement, then, is abundantly rational and more than substantially related to the compelling interest the State has in assuring that those seeking gender-affirming care continue to understand the costs and benefits of their course of treatment.

The physician-as-prescriber requirement. Finally, the Plaintiffs object to Florida's requirement that "[s]ex-reassignment prescriptions or procedures may not be prescribed, administered, or performed except by a physician," Fla. Stat. § 456.52, which means that autonomous-practice certified Advanced Practice Registered Nurses can no longer do the same, *see* ECF No. 116, at 18. Contrary to their assertion that "[t]here is no medically valid basis or rationale for" limiting the provision of this treatment to physicians, *see* ECF No. 116, at 18-20, the record is replete with reasons establishing why the State's decision to create this limitation serves its compelling interest.

Simply put, physicians are better trained to deal with the complexities inherent in treating gender dysphoria. At the *Dekker* Trial, there was testimony about an individual who "went to a nurse practitioner, and in 45 minutes at the first visit to the nurse practitioner got an estrogen prescription." *Dekker* Trial Tr. at 1009 (Testimony of Dr. Stephen B. Levine). This apparently "is very common." *Dekker* Trial Tr. at 1009 (Testimony of Dr. Stephen B. Levine). So too, "the risk of over-diagnosis." Expert Report of Kristopher Kaliebe ¶ 57. Given the stakes inherent in gender-affirming treatment and the State's compelling interest in ensuring that those seeking such care are fully informed of the costs and benefits of their choices, the State's decision to

restrict prescribing authority to those with the greatest training and credentials plainly and substantially supports this goal.

II. NOT ONE OF THE PLAINTIFFS WILL SUFFER IRREPARABLE HARM IN THE ABSENCE OF A PRELIMINARY INJUNCTION.

None of the Plaintiffs have, or can, establish the requisite irreparable harm. We address each in turn.

Kai Pope, a 51-year old transgender man, argues that he was supposed to have "genital surgery" on "September 14, 2023," but "on July 13, 2023, he was informed by his surgeon during a phone call that his surgery was cancelled because of SB 254." Mr. Pope does not explain how or why the informed-consent provisions he is challenging caused the cancellation of his surgery, nor has he argued how enjoining the informed-consent provisions will result in it being rescheduled. Moreover, he has failed to explain why he will experience irreparable harm by waiting for this case to proceed to final judgment, given that he "was diagnosed with gender dysphoria many years ago," which means he waited "many years" to schedule his genital surgery.

Lucien Hamel, 27-year old transgender man, argues that he can no longer "get[] his hormone therapy" from "an autonomous-practice certified Advanced Practice Registered Nurse—Nurse Practitioner." By the Plaintiffs' own telling, however, there are nearly 100,000 doctors in the State who can prescribe sex-modification surgery. *See* ECF No. 116, at 19. Mr. Hamel's role as a CVS manager, moreover, strongly suggests

that it is far from impossible that he will be able to reestablish his hormonal therapy absent a preliminary injunction from this Court.

Olivia Noel, a transgender woman, has also reported difficulty in finding a physician to continue prescribing the estrogen she was prescribed by a nurse practitioner at Planned Parenthood. She reports, however, that she has a prescription refill. And with roughly 100,000 doctors in State who can continue to prescribe her the medicine she requires for her treatment, *see* ECF No. 116, at 19, she has not established the irreparable injury necessary to justify preliminary injunctive relief.

Rebecca Cruz Evia, a transgender woman, was scheduled to have a vaginoplasty surgery on August 15, 2023. Her surgeon informed her that Senate Bill 254 forced a cancellation of her surgery. Like Mr. Pope, however, Ms. Evia has not explained how or why the informed-consent provisions she is challenging caused the cancellation of her surgery, nor has she argued how enjoining the informed-consent provisions will result in it being rescheduled.

III. BALANCE OF THE EQUITIES.

The remaining preliminary-injunction factors weigh against granting a preliminary injunction. The public benefits from the State ensuring that robust informed consent will remain the policy of the State, especially in the context of inherently risky medical treatment. *See Presidential Women's Ctr.*, 937 So. 2d at116; *see also Dobbs*, 142 S. Ct. at 2282 (noting the State's strong role in making health, safety, and welfare decisions). The public is also served when the State gets to enforce its laws, and

the State is harmed when it's prevented from doing so. *See Hand v. Scott*, 888 F.3d 1206, 1214 (11th Cir. 2018) (The State is "harmed" when it can't "apply its own laws."); *see also Maryland v. King*, 567 U.S. 1301, 1301 (2012) (Roberts, C.J., in chambers) ("Any time a State is enjoined by a court from effectuating" its laws, "it suffers a form of irreparable harm." (cleaned up)).

Because the Plaintiffs haven't established a constitutional violation, haven't shown irreparable harm, and haven't shown that the balance of the equities and the public interest favor enjoining the State's informed-consent requirements, these factors tilt decidedly in the State's favor.

CONCLUSION

The Plaintiffs themselves acknowledge that "transition-related medication and surgeries have attendant risks." ECF No. 116, at 8. The provisions they challenge do no more than ensure that individuals seeking sex-modification treatment are fully informed of these risks. They do not violate the Equal Protection Clause, and for that reason (along with all the foregoing reasons), the Court should deny Plaintiffs' motion for a preliminary injunction.

Dated: August 7, 2023

Ashley Moody
ATTORNEY GENERAL

/s/ Joseph E. Hart
Joseph E. Hart (FBN 0124720)
COUNSELOR TO THE ATTORNEY GENERAL

Office of the Attorney General
The Capitol, Pl-01
Tallahassee, Florida 32399-1050
(850) 414-3300
(850) 410-2672 (fax)
Joseph.Hart@myfloridalegal.com

Counsel for the Surgeon General, the Department of Health, and State Attorney Gladson

Respectfully submitted by:

/s/ Mohammad O. Jazil
Mohammad O. Jazil (FBN 72556)
Gary V. Perko (FBN 855898)
Michael Beato (FBN 1017715)
Holtzman Vogel Baran
Torchinsky & Josefiak PLLC
119 S. Monroe St., Suite 500
Tallahassee, FL 32301
(850) 270-5938
mjazil@holtzmanvogel.com
gperko@holtzmanvogel.com
mbeato@holtzmanvogel.com

Counsel for the Surgeon General, the Department of Health, the Boards of Medicine, and the individual Board Members

CERTIFICATE OF COMPLIANCE

As required by Local Rule 7.1(F), I certify that this memorandum of law contains 7,116 words.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF SERVICE

I certify that, on August 7, 2023, this memorandum of law was filed through the Court's CM/ECF system, which will send a notice of electronic filing to all counsel of record.

/s/ Mohammad O. Jazil
Mohammad O. Jazil