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

JANE DOE, et al.	
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Civil No. 4:23-cv-00114-RH-MAF

Plaintiffs,

V.

JOSEPH A. LADAPO, et al.,

Defendants.

PLAINTIFFS' REPLY TO DEFENDANTS'
RESPONSE TO PLAINTIFFS' SECOND MOTION
FOR PRELIMINARY INJUNCTION

Plaintiffs reply to Defendants' Response in Opposition to Motion for Preliminary Injunction ("Response"), and state as follows:

A. <u>Like the Minor Treatment Ban, SB 254 Restrictions on Adult Care</u> Target Transgender People and thus Require Heightened Scrutiny.

Defendants offer no valid reasons for applying a different standard for assessing the constitutionality of the adult restrictions than the one already applied to the transgender adolescent ban.

SB 254 prevents "patients younger than 18 years of age" from obtaining "[s]ex-reassignment prescriptions and procedures," Fla. Stat. § 456.52(1), also known as "transition-related care" or "gender transition." In its June 6, 2023 preliminary injunction order, this Court applied heightened scrutiny to that

prohibition for at least two reasons. ECF 90 (PI Order) at 42-44. First, in order to know whether a minor may receive care, "one must know the adolescent's sex." *Id.* at 19. "This is a line drawn on the basis of sex, plain and simple." *Id.* at 20. Second, "the statute and rules at issue draw lines based on transgender status." *Id.* SB 254 prohibits the banned treatments only when needed by transgender minors, not others.

For the same reasons, the provisions of SB 254 that apply to adults also discriminate based on sex and transgender status. The same language is used to describe the treatments in the provisions of SB 254 that pertain to adults as those that pertain to minors: "sex-reassignment prescriptions or procedures." Fla. Stat. § 456.52(2). And both provisions regulate those "prescriptions and procedures" *only* when used "to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex,"—in other words only when the patient is transgender. Fla. Stat. § 456.001(9)(a). So, just as with the minor treatment ban, one must know the "sex of a person to know whether or how" SB 254 and its implementing rules apply to adults. ECF 90 at 19. And, the law and rules facially target transgender adults just as SB 254 targets transgender minors.

Defendants raise no new arguments here. They argue against heightened scrutiny, as before, because both transgender men and transgender women are targeted. The only new support they offer for this argument are citations to the Sixth Circuit's divided opinion granting an emergency stay of a district court's order

enjoining Tennessee's minor treatment ban. *L.W. v. Skrmetti*, 73 F.4th 408 (6th Cir. 2023). That opinion is not controlling here, and the Sixth Circuit panel itself acknowledged that "[i]t may be that the one week we have had to resolve this motion does not suffice to see our own mistakes." *Id.* at 422. There is no reason for this Court to reverse itself based on that panel's thin, hasty, and divided assessment.

Neither do Defendants' efforts to cabin *Glenn* and *Bostock*'s analysis to the employment context fare any better here than they did in this Court's consideration of SB 254's transgender adolescent ban. *See* ECF. 90 at 19-20.

The Defendants repackage another failed argument, contending that the informed consent forms do not discriminate based on transgender status. But as this Court already held, "[a]lthough the defendants deny it, the statute and rules at issue draw lines based on transgender status." *Id.* at 20. The mandatory consent forms, which must be executed in-person, in the presence of a physician, are requirements which apply *only* to care when provided to transgender patients and not others. This facial discrimination triggers heightened scrutiny. *Id.* at 19-25; *Glenn v. Brumby*, 663 F.3d 1312, 1315-16 (11th Cir. 2011).

Defendants also again argue that regulating medical treatments for transgender adults is not discrimination because transgender people are dissimilar to others seeking these treatments. ECF 127 at 12-13 (State's Am. Resp. Opp. Plfs.' PI Mot.) ("[A] person experiencing gender dysphoria is self-evidently *not* similarly

"not change the fact that this is differential treatment based on sex. The *reason* for sex-based differential treatment is the purported *justification* . . . the justification that must survive" heightened review. ECF 90 at 20. It is not a *reason* to avoid heightened review.

Griffin Indus. v. Irvin, 496 F.3d 1189 (11th Cir. 2007), is inapposite. Unlike here, Griffin was the "unusual civil rights case" alleging a class of one, id. at 1193, where "in the absence of class-based discrimination," id. at 1202, the court was forced to independently assess whether a chicken rendering plant was similarly situated to others. Id. at 1200-08. Here, where SB 254 draws both a sex-based and a transgender-based classification, Defendants' reasons for drawing this line become relevant only at stage two of this Court's analysis applying heightened review, not determining whether heightened scrutiny applies.

Defendants also contend that *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022), means that heightened scrutiny does not apply because the consent forms regulate the provision of medical treatment. But *Dobbs* involved a law the Supreme Court viewed as facially neutral. *Id.* at 2246. In stark contrast, SB 254 facially classifies based on sex, and *Dobbs* does not reduce the level of scrutiny applied to sex discriminatory law or policy merely because they involve the regulation of healthcare.

B. SB 254 and the Mandatory Forms Restrict Care.

Defendants' argument that SB 254's adult restrictions and mandatory forms "merely provide guidelines," rather than restrictions, is specious. ECF 127 at 15. The forms themselves identify "specific *requirements* that need to be met before and during treatment." *Id.* at Exs. A, B, and C (emphasis added). This is apparent both in the "question and answer" portion ("What are the *requirements* to receive hormone replacement therapy (HRT)?") and in the provisions that set forth "specific *requirements* for you to receive and continue HRT treatment[.]" 49 Fla. Admin. Reg. 2433, 2435 (July 7, 2023) (emphasis added).

Though Defendants suggest there are other supposedly "similar" forms, they cite none. Defendants cite to Florida laws that require informed consent for specific procedures — breast cancer treatments, electroconvulsive and psychosurgical treatments, and psychiatric treatments for incarcerated people. ECF 127 at 1.¹ None of these laws require or resulted in mandatory consent forms adopted by the Boards of Medicine. To the extent Plaintiffs could find any forms relating to those treatments, none state requirements for care or continuing care (Florida Breast and Cervical Cancer Detection Program applicant agreement attached as **Exhibit A**; Florida Authorization for Electroconvulsive Treatment for Resident of a State Mental Health Facility attached as **Exhibit B**). And neither of the only two consent

¹ Citations to ECF 127 correspond to page numbers in Defendants' Memorandum, not Motion.

forms Plaintiffs could find in the Boards of Medicine rules include any requirements for care. Fla. Admin. Code R. 64B8-9.017 (providing for a mandatory informed consent form for the prescription of medical marijuana; form attached as **Exhibit C**); Fla. Admin. Code R. 64B8-9.018 (setting out a recommended consent form for cataract procedures; form attached as **Exhibit D**). In sum, unlike any other healthcare-related forms in Florida law, the challenged forms impose arbitrary and burdensome restrictions that have no medical basis and conflict with the medical standard of care. They stand in stark contrast to other examples Defendants cite and do not bear a shred of resemblance to any other Florida medical consent forms.

C. <u>Defendants Cannot Justify an In-Person Requirement Only for Transgender Patients Initiating Care.</u>

Contrary to Defendants' unsupported claim, there is no medical justification for SB 254's arbitrary "in-person" requirement, which applies only to transgender patients. This requirement has no medical basis and conflicts with the WPATH Standards of Care, Version 8 ("SOC 8"), which expressly authorize telehealth visits. *Dekker v. Weida*, Case No. 4:22cv325 (N.D. Fla.) ("*Dekker*"), Def's Trial Ex. 16, SOC 8, at S31 ("Assessments may be in person or through telehealth."). As the SOC 8 notes, telehealth services "reduce barriers and improve access." *Id.* at S8. This is especially critical for patients who do not live near a provider or who lack means to travel, as the United States Department of Health and Human Services has also confirmed. *See* HHS, Telehealth for LGBTQ+ Patients ("Telehealth appointments

are a safe, convenient way for LGBTQ+ patients to access healthcare" and "can also be a necessary lifeline for some patients who do not have LGBTQ+ affirming healthcare available nearby.") (available at Telehealth.HHS.gov).

Defendants cite Dr. Stephen Levine's testimony in an attempt to justify the in-person requirement, contending that it is necessary to provide an adequate assessment, but nothing in his testimony explains why assessments for gender dysphoria cannot be done through telehealth, which allows for more flexibility in scheduling, provider availability, and maximization of time with patients. As the WPATH SOC 8 note, what matters is not the method of care delivery, but adherence to "the principles of gender-affirming care as outlined in the SOC-8[.]" SOC 8 at S8. And if there were any doubt about the State's inability to justify the requirement, the text of SB 254 removes it. SB 254 requires only that the mandatory *consents* be executed while the patient is "physically present in the same room" as the physician, not any *assessment*. Fla. Stat. § 456.52(2).

D. <u>Defendants Cannot Justify Prohibiting APRN-NPs From Providing Care Only for Transgender Patients.</u>

Defendants similarly cannot justify arbitrarily barring qualified Advanced Practice Registered Nurse – Nurse Practitioners ("APRN-NPs") from caring for transgender patients. Defendants argue that testosterone may be abused (ECF 127 at 21-22), but SB 254 leaves non-physicians free to prescribe testosterone to non-transgender persons, a far larger group. Similarly, Defendants argue that doctors are

"better trained," (*id.* at 25) but that explanation would apply equally to all forms of healthcare; it does not justify a restriction *solely* on transgender healthcare.

Nor does any such justification exist. As the WPATH SOC 8 explains, qualified non-physician healthcare providers are as competent as physicians to care for transgender patients. WPATH SOC, at S33 ("HCPs [healthcare providers] should have at a minimum a masters-level qualification in a clinical field related to transgender health or equivalent further clinical training and be statutorily regulated; examples include a mental health professional (MHP), general medical practitioner, nurse, or other qualified HCP."); *see also*, *e.g.*, *id.* at S34 ("The need to include an HCP with some expertise in mental health does not require the inclusion of a psychologist, psychiatrist, or social worker in each assessment. Instead, a general medical practitioner, nurse, or other qualified HCP could also fulfill this requirement[.]"); *id.* at S143 (primary care providers may include nurse practitioners and advanced practice nurses).

Defendants cite Dr. Levine's testimony that an unnamed nurse practitioner allegedly prescribed hormone therapy without a proper assessment. ECF 127 at 25 (*citing Dekker*, Trial Tr. at 1009:19-22)). That unsupported allegation, without more, cannot justify a *sui generis* exception to Florida's autonomous practice law, Fla. Stat. § 464.0123, only for transgender people. Dr. Levine himself acknowledged that he has no personal knowledge of how transgender healthcare is provided in Florida.

Dekker, Trial Tr. at 1011:5-8. As with the in-person requirement, the only impact of this selective restriction is to reduce care for transgender patients.

E. The Information in the Consent Forms is Misleading and, in Many Cases, Wrong.

Little else Defendants argue necessitates response, given the fulsome record before this Court. But Plaintiffs would be remiss in not flagging some of Defendants' unsupported assertions.

This Court has already found that evidence suggesting the regulated medical treatments "are ineffective is nonexistent." ECF 90 at 28. Accordingly, Defendants cannot defend the form's assertions that the regulated treatments are "purely speculative" or "based on very limited, poor-quality research." ECF 127, Ex. A. This Court has dismissed those arguments. ECF 90 at 27-30. Defendants contend that the research is "low-quality," but as the record makes clear, that is a term of art that does not mean that research showing the effectiveness of these treatments is lacking. *Dekker*, Trial Tr. 359:12-18 (Dr. Antommaria). And, in any case, the forms do not speak of "low quality" evidence, they refer to "poor-quality research," a statement with no evidentiary support. ECF 127, Ex. A.

This Court has also already rejected Defendants' argument that off-label use means these medications do "not have U.S. Food and Drug Administration (FDA) approval." Form DH5079-MQA at 1; Form DH5080-MQA at 1; Form DH5082-MQA at 1; Form DH5083-MQA at 1. *See also* 49 Fla. Admin. Reg. 2433, 2435 (July

7, 2023). "That the FDA approved these drugs at all confirms that, at least for one use, they are safe and effective." ECF 90 at 38; *see also Dekker* Trial Tr. 1016:5-1018:7.

Defendants continue to rely on Drs. Hruz, Laidlaw, and Lappert to defend false statements in the forms, but this Court has already determined that their testimony is not credible. Dr. Lappert believes gender transition care is a "lie," "a moral violation," "a huge evil," and "diabolical" (ECF 90, at 5); Dr. Hruz testified as a "deeply biased advocate, not as an expert" (*id.* at 5, n.8); and Dr. Laidlaw, who ended up not even testifying in the *Dekker* case at the merits phase, is a "person that's that far off from the accepted view, even by the State[.]" *Dekker*, ECF 62 (Trial Tr. at 88:6-19).

In sum, Defendants cannot justify the many misstatements and inaccuracies in the forms. These include the forms' statements: calling into question the efficacy of transition-related treatments; saying that there is no evidentiary support for the dosing requirements set by the Endocrine Society; and saying that psychotherapy alone is an effective treatment option – none of which are supported by any credible evidence.

F. This is Not an Informed Consent Form Like Any Other.

Defendants wrongly claim that the consent forms are like any others. For one, no other Florida mandatory consent form includes substantive requirements for

initiating care or for continued care. Second, Defendants can provide no explanation for why *only* transgender patients must be advised of side effects resulting from medications or procedures much more commonly used by non-transgender patients, and that pose the same risks to all.

Relatedly, Defendants argue that because gender dysphoria is a mental health diagnosis, ECF 127 at 24, the State can justify ongoing and recurring mental health assessments ("[b]efore beginning HRT and every two years thereafter[,]" *id.*, Ex. A) as requisites for continued care. But these ongoing mental health assessments have no medical basis and conflict with the standard of care. ECF 115-5 (Declaration of Dr. Karasic) at ¶¶ 37-38. And, despite the fact that there are myriad other mental health diagnoses, Defendants offer no explanation for why only transgender people with a mental health diagnosis must comply with these requirements.

G. The Challenged Restrictions Fail Under Any Standard of Review.

Defendants have not identified any legitimate reason to single out transgender people for these arbitrary restrictions which serve only to keep patients from getting needed care and undermine, rather than advance, patient safety and education.

Even under rational basis review, a law "must find some footing in the realities of the subject addressed by the legislation." *Heller v. Doe*, 509 U.S. 312, 320 (1993). No such footing is evident here, much less the evidence required under heightened scrutiny.

H. Plaintiffs Are Experiencing Irreparable Harm Because of SB 254.

The adult Plaintiffs have experienced irreparable harms that will be alleviated by this Court's injunction against enforcement of SB 254 and its implementing rules.

Plaintiffs Dr. Kai Pope and Rebecca Cruz Evia had surgeries cancelled, which they were informed by their surgeons was because of SB 254. No other reasons were given for the cancellation of their surgeries and Defendants offer no evidence to suggest that if the law is enjoined their surgeries would not be rescheduled. Defendants also offer no evidence to question the urgency of Dr. Pope's or Ms. Cruz's medical needs. The fact that Dr. Pope was diagnosed "years ago[,]" ECF 127 at 26, with gender dysphoria and only scheduled his now-cancelled surgery in the last year is a reflection of what this Court has heard – a determination of medical need for treatments is individualized and based on careful assessments that take into account a patient's response to staged and ongoing care. The date of a patient's gender dysphoria diagnosis has no bearing on the time-sensitivity of their need for surgery.

Similarly, Defendants offer no evidence to rebut the harms asserted by Lucien Hamel and Olivia Noel. Mr. Hamel has been without testosterone for nearly a month and a half, missing four doses of his medication. His role as a CVS manager does not help him get medication otherwise legally barred for him. If this Court enjoins SB 254, his APRN-NP at Spektrum Health will write him a prescription. If it does

not, his provider cannot without "commit[ting] a misdemeanor of the first degree, punishable as provided" by statute. Fla Stat. §456.52(5)(c). Similarly, Defendants do not dispute that Ms. Noel cannot continue receiving treatment from the physician's assistant ("PA") from whom she had been receiving care. And although she has a refill, she is unable to get it filled because it was written by her PA before the effective date of SB 254.

Both Mr. Hamel and Ms. Noel will continue going without care for gender dysphoria unless and until they can establish care with a physician, obtain and attend an in-person appointment with that physician, and meet the requirements for care listed in the mandatory consent forms including getting a new "thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist," despite no medical justification for such a requirement. Mr. Hamel and Ms. Noel have alleged, and Defendants do not dispute, that for financial and other reasons, they are unable to meet those requirements.

In the meantime, every day Mr. Lucien is without needed hormone therapy, he continues to suffer irreparable harm. And although Ms. Noel has not yet run out of the hormones she regularly takes, she will soon. Both have had ongoing care relationships disrupted and are suffering.

An injunction issued by this Court would remedy these harms.

Respectfully submitted this 11th day of August, 2023
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/s/ Jennifer Levi
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CERTIFICATE OF WORD COUNT

Pursuant to Local Rule 7.1(F), the undersigned counsel certifies that, according to Microsoft Word, the word-processing system used to prepare this Reply, there are 3,013 total words contained within the Reply.

/s/ Simone Chriss

CERTIFICATE OF SATISFATION OF ATTORNEY CONFERENCE REQUIREMENT

Pursuant to Local Rule 7.1(B), counsel for the Plaintiffs conferred with counsel for the Defendants on August 9, 2023. Counsel for Defendants indicated that Defendants do not oppose the filing of this Reply.

/s/ Simone Chriss

CERTIFICATE OF SERVICE

I hereby certify that, on August 11, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

<u>/s/ Simone Chriss</u> **Counsel for Plaintiffs**