No. 23-2366

IN THE

United States Court of Appeals for the Seventh Circuit

K.C., et al.,

Plaintiffs-Appellees,

v.

INDIVIDUAL MEMBERS OF THE MEDICAL LICENSING BOARD OF INDIANA, et al.,

Defendants-Appellants,

On Appeal from the United States District Court
for the Southern District of Indiana
Case No. 1:23-cv-00595-JPH-KMB
Honorable James P. Hanlon

BRIEF OF AMICUS CURIAE GOOD TROUBLE COALITION INDIANA, INC. IN SUPPORT OF APPELLEES AND AFFIRMANCE

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STATEMENT OF INTEREST OF AMICUS CURIAE[1]

This brief is filed by amicus curiae Good Trouble Coalition Indiana, Inc. ("GTC"). GTC is a grassroots non-profit advocacy group with a membership comprised of more than 1,200 Indiana healthcare stakeholders including physicians, nurses, nurse practitioners, and bioethicists. As a non-partisan organization, GTC advocates for evidence-based, patient-focused healthcare in the Hoosier State by testifying before the Indiana General Assembly, preparing advocacy letters to governing bodies, encouraging voter engagement, and publishing editorials regarding public health and the impact of legislation on healthcare practitioners and their patients.

Maintaining appropriate, evidence-based standards of care in Indiana is core to GTC's mission and the medical practices of its individual members. GTC opposes Senate Enrolled Act 480 ("S.E.A. 480"), which attempts to prohibit gender-affirming care for minors. When S.E.A. 480 was initially under consideration by the Public Health Committee of Indiana's House of Representatives, GTC members delivered to the committee chair a letter signed by hundreds of Indiana healthcare

[1] All parties have consented to the filing of this brief. Pursuant to Fed. R. App. P. 29(a)(4)(E), undersigned counsel represent that no party or party's counsel authored this brief in whole or in part; that no party or party's counsel contributed money that was intended to fund preparation or submission of this brief; and that no person other than amicus GTC and counsel identified herein contributed money that was intended to fund preparation or submission of this brief.

workers who raised data-based concerns with the proposed bill.[2] GTC and its members also testified[3] before the Indiana General Assembly regarding S.E.A. 480 and, once the bill was sent to the Governor, raised public concerns regarding the bill's impact on healthcare practitioners.[4]

As enacted, S.E.A. 480 would have an immediate and confusing impact on pediatricians, pediatric nurse practitioners, endocrinologists, child psychologists and therapists, obstetrician-gynecologists, and social workers in Indiana. This confusion would deter or outright prohibit common healthcare services entirely unrelated to gender-affirming care. And S.E.A. 480's convoluted prohibitions disregard widely accepted, evidence-based standards of medical care.

INTRODUCTION

S.E.A. 480 seeks to prohibit Indiana's youth from receiving gender-affirming healthcare and is premised on asserted governmental interests in "regulating the medical profession" and "safeguarding the physical and psychological well-being of

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[2] Lauren Chapman, *More than 200 health care workers sign letter to halt gender-affirming care ban for minors*, wyfi: Indianapolis (Mar. 20, 2023), https://www.wfyi.org/news/articles/more-than-200-health-care-workers-sign-letter-to-halt-gender-affirming-care-ban-for-minors.

[3] *Hearing on S.E.A. 480 Before the Ind. H. Comm. on Pub. Health* (Mar. 21, 2023, beginning 1:12:59) (statement of Haley A. Pritchard, MD, Secretary, GTC), https://iga.in.gov/session/2023/video/committee_public_health_1500/ ("S.E.A. 480 Ind. H. Comm. Hr'g").

[4] Jane Hartsock, *Op/Ed: Gov. Holcomb signed a bill he called 'clear as mud.' We're confused and concerned.*, IndyStar (updated Apr. 12, 2023), https://www.indystar.com/story/opinion/2023/04/12/indiana-governor-called-sb-480-clear-as-mud-but-signed-it-anyway/70103354007/.

a minor." *See* Appellants' Br. at 42-43 (quotations omitted). Those interests, however, are incompatible with the impact S.E.A. 480 would in fact have on healthcare practitioners and patients in this State.

S.E.A. 480 does not survive any level of scrutiny—including rational-basis review. The law's prohibitions on healthcare for minors are simultaneously overinclusive and underinclusive. And, of critical importance to amicus GTC's members, healthcare practitioners have no clarity on the precise scope of services banned by S.E.A. 480. The law's plain language appears to prohibit common medical services entirely unrelated to gender-affirming care, such as newborn circumcision, birth control prescriptions, and use of an intrauterine device ("IUD"). Perhaps this is what Indiana's Governor meant when he said the law's prohibitions are "clear as mud."[5]

These muddled prohibitions could have a chilling effect on *all* healthcare services provided to transgender minors in Indiana, not just gender-affirming care, leaving youth with gender dysphoria and other gender-related anxieties or depressions unable to get critical healthcare, including mental health services. This result is indisputably contrary to the public interest.

[5] Arleigh Rodgers & Tom Davies, *Indiana trans health care ban 'clear as mud,' governor says*, APnews.com (Apr. 4, 2023), https://apnews.com/article/indiana-trans-heath-care-ban-d4690b52eebc1067dc1a64f43f99ce11.

By enacting these restrictions, Indiana disregarded widely accepted, evidence-based standards of medical care that provide for certain minors to obtain gender-affirming care in narrow circumstances. Indiana youth with gender dysphoria would no longer be able to access the full scope of medically necessary healthcare. Instead, S.E.A. 480 prohibits doctors from practicing medicine in line with the Shared Decision-Making Model, the prevailing evidence-based framework used to make healthcare decisions suited to an individual patient's medical situation, context, views, and preferences.

Appellants identify no abuse of discretion in the District Court's preliminary injunction order. Dkts. 67-68; *see Baja Contractors, Inc. v. City of Chicago*, 830 F.2d 667, 674 (7th Cir. 1987) (abuse-of-discretion standard applies). The District Court correctly weighed the four well-established preliminary injunction factors and none of its findings of fact are clearly erroneous. For the reasons set forth below, in addition to the arguments in Plaintiffs-Appellees' brief, this Court should affirm the District Court's order enjoining certain provisions of S.E.A. 480.

ARGUMENT

I. S.E.A. 480 WOULD SOW CONFUSION ACROSS NUMEROUS MEDICAL SPECIALTIES AND CAUSE IMMEDIATE HARM TO HEALTHCARE PRACTITIONERS AND PATIENTS.

If S.E.A. 480 goes into effect, it would cause widespread confusion among Indiana's medical community and deter or outright prohibit a number of healthcare

treatments entirely unrelated to gender-affirming care. Although Indiana claims to have a compelling interest in "regulating the medical profession" and "safeguarding the physical and psychological well-being of a minor," *see* Appellants' Br. at 42-43 (quotations omitted), S.E.A. 480 is not tailored to those interests. The broad prohibitions in S.E.A. 480 would create confusion for providers across medical specialties because they are overinclusive in certain respects, underinclusive in other respects, and would chill the provision of care since consequences for healthcare practitioners who violate its unclear terms are severe. To quote Indiana's Governor, the prohibitions in S.E.A. 480 are "clear as mud."[6] S.E.A. 480 fails any level of scrutiny—including rational-basis review.

A. S.E.A. 480's Ban on Healthcare Services Is Irrationally Expansive.

S.E.A. 480 forbids Indiana's healthcare practitioners and governmental healthcare facilities from providing minors "gender transition procedures," a term of art that includes a potentially unlimited number of medical services and procedures unrelated to gender-affirming care. "Gender transition procedures" are defined in Section 5(a) as:

> (a) any medical or surgical service, including physician's services, practitioner's services, inpatient and outpatient hospital services, or prescribed drugs related to gender transition, that seeks to:

[6] Rodgers & Davies, *supra* note 5.

> (1) alter or remove physical or anatomical characteristics or features that are typical for the individual's sex; or
> (2) instill or create physiological or anatomical characteristics that resemble a sex different from the individual's sex, including medical services that provide puberty blocking drugs, gender transition hormone therapy, or genital gender reassignment surgery or nongenital gender reassignment surgery knowingly performed for the purpose of assisting an individual with a gender transition.

S.E.A. 480 § 5(a) (to be codified at Ind. Code § 25-1-22 (effective July 1, 2023)). Section 5(b) provides six limited exceptions allowing for medical services related to, among other things, genetic chromosomal disorders, conditions of sexual development, and situations involving "imminent danger of death or impairment of major bodily function[.]" *Id.* § 5(b).

Rather than listing the specific healthcare services prohibited, the Indiana legislature instead created a catch-all definition that includes, in relevant part, "any medical or surgical service . . . that seeks to . . . alter or remove physical or anatomical characteristics or features that are typical for the individual's sex[.]" *Id.* § 5(a)(1). A parenthetical phrase explains that the defined group of services include, at a minimum, "physician's services, practitioner's services, inpatient and outpatient hospital services, or prescribed drugs related to gender transition." *Id.* § 5(a). Courts must give the words of S.E.A. 480 their plain and ordinary meaning "unless the construction is plainly repugnant to the intent of the legislature . . . [.]" Ind. Code Ann. 1-1-4-1; *see also Clark v. Hunter*, 861 N.E.2d 1202, 1210 (Ind. Ct. App. 2007).

Section 5(a)(1)'s plain and ordinary meaning would ban, for example, medical services such as (i) circumcision of a newborn male, (ii) prescription of hormonal birth control, and (iii) use of contraceptive devices or implants. Though exceedingly commonplace and safe,[7] these examples fall within the law's irrationally expansive definition because each is a medical or surgical service that seeks to "alter" or "remove" an anatomical characteristic or feature that is "typical" for a particular sex, and none fall within the limited exceptions of Section 5(b). Under S.E.A. 480, Indiana's healthcare practitioners and governmental healthcare facilities cannot provide any of these services to a minor.

Any construction that reads Section 5(a)(1) as less expansive would require the creative insertion of additional words or punctuation that the legislature did not enact. Where the legislature intended to create more restricted definitions in S.E.A. 480, it did so. For example, multiple defined terms prohibited by S.E.A. 480 only include services "knowingly performed for the purpose of assisting an individual with a gender transition." *See, e.g.*, S.E.A. 480 § 2 (defining "gender reassignment surgery"); *id.* § 8 (defining "nongenital gender reassignment surgery"); *id.* § 11

[7] *See, e.g.*, Am. Acad. of Pediatrics, *Contraception for Adolescents*, 134 Pediatrics e1244, e1245-49 (2014), *available at* https://publications.aap.org/pediatrics/article/134/4/e1244/32981/Contraception-for-Adolescents (noting "the Institute of Medicine has recommended contraception as an essential component of adolescent preventive care, and the Patient Protection and Affordable Care Act of 2010 requires coverage of preventive services for women, which includes contraception, without a copay").

(defining "puberty blocking drugs"). The lack of such limiting language in Section 5(a)(1) is more apparent when contrasted against Section 5(a)(2), the *very next subsection*, which refers to a limited category of services that are "knowingly performed for the purpose of assisting an individual with a gender transition." *Id.* § 5(a)(2).

By defining "gender transition procedures" to sweep in numerous services and procedures unrelated to gender-affirming care, the legislature enacted a prohibition that is overinclusive relative to Indiana's asserted interests. Any potential confusion about the scope of prohibited medical services under Section 5 reinforces that the District Court did not abuse its discretion in preliminarily enjoining the provision. Appellees have a likelihood of success in their legal claims, and it would be contrary to the public interest to prohibit healthcare that could fall within Section 5's expansive definition.

B. S.E.A. 480 Ignores the Existence of Non-Binary Patients.

S.E.A. 480's omission of non-binary patients makes many of its provisions underinclusive in light of the Indiana's stated interests. The law's definitions of "gender," "sex," and "gender transition" mean that many of the law's provisions apply only to patients who identify as being "male" or "female." These narrow definitions do not include minors who identify as non-binary (neither "male" nor "female"). If the intent behind enacting S.E.A. 480 was to regulate "children

suffering with gender dysphoria,"[8] then the bill's definitional framework is irrational.

Not only do the definitions fail to accurately reflect the relevant patient population, they further complicate the confusing provisions of S.E.A. 480 for healthcare practitioners. In practice, this means Indiana's healthcare practitioners would need to closely scrutinize S.E.A. 480 in its entirety to identify what specific provisions are inapplicable to non-binary patients. Although Indiana's stated interest is "safeguarding the physical and psychological well-being of a minor," it is unclear the extent to which the law carves out non-binary minors from its convoluted prohibitions. *See* Appellants' Br. at 42-43 (quotations omitted).

C. S.E.A. 480 Bans an Undefined Category of Mental Health Services.

Because it is unclear exactly what mental health services are prohibited by S.E.A. 480, this vague prohibition would chill *all* mental health services provided to transgender minors. The law's definition of "gender transition procedures" allows for "[m]ental health or social services *other than gender transition procedures as defined in subsection (a).*" S.E.A. 480 § 5(b)(5) (emphasis added). But subsection (a) provides no clarity on what mental health services are banned. *See id.* § 5(a). This

[8] *Statement from State Sen. Tyler Johnson on SB 480*, Ind. S. Republicans (Feb. 20, 2023), https://www.indianasenaterepublicans.com/statement-from-state-sen-tyler-johnson-on-sb-480.

tautological definition leaves Indiana therapists and counselors without guidance on how to lawfully treat transgender minors.

The legislative history makes the confusion worse. S.E.A. 480's lead author opined that "this bill allows for *important* counseling and mental healthcare to continue,"[9] suggesting the intent was not to prohibit *all* counseling and mental healthcare for transgender minors. But nothing in the enacted law, floor debate, or legislative history sheds any light on what "important" mental health services are permissible under Section 5(b)(5).

This vague prohibition on mental health services would cause immediate harm to Indiana's patients, child therapists, and counselors. For instance, if a child therapist is treating a patient who happens to have gender dysphoria, it is not clear what services could be lawfully provided, including (1) whether the therapist could treat patient's panic attacks that are triggered by gender incongruence or (2) whether the therapist could support the patient's preparation to receive gender-affirming care on their eighteenth birthday. This lack of clarity would likely chill *all* mental health services provided to transgender minors since consequences for healthcare practitioners who violate S.E.A. 480's vague prohibitions are severe. Indiana child therapists would be hesitant to accept transgender patients and may choose to stop

[9] S.E.A. 480 Ind. H. Comm. Hr'g at 02:18 (statement of Senator Tyler Johnson) (emphasis added).

treating any patient who mentions gender dysphoria during their treatment.[10] That would leave the entire population of Indiana youth with gender dysphoria and other gender-related anxieties or depressions unable to get mental health services—a result that is indisputably contrary to the public interest.

II. S.E.A. 480 DEVIATES FROM EVIDENCE-BASED STANDARDS OF CARE AND OVERRIDES THE SHARED DECISION-MAKING MODEL.

Widely accepted and evidence-based standards of care provide gender-affirming care options for minors. S.E.A. 480 requires physicians to violate these standards, limiting the full scope of medically-necessary healthcare that can be provided to Indiana youth with gender dysphoria. In doing so, S.E.A. 480 also supplants the Shared Decision-Making Model, which is the prevailing evidence-based framework used to make a healthcare decision that suits an individual patient's medical situation, context, views, and preferences.

A. Evidence-Based Medical Guidelines Establish Widely Accepted Standards of Care for Adolescents Experiencing Gender Dysphoria.

Widely accepted and evidence-based standards of care provide for access to gender-affirming care options for certain minors in narrow circumstances. For

[10] In other states, similar bans have already resulted in a chilling of legal healthcare services provided to transgender youth. *See, e.g.*, Jim Salter & Geoff Mulvihill, *Some providers are dropping gender-affirming care for kids even in cases where it's legal*, APnews.com (updated Sept. 23, 2023), https://apnews.com/article/genderaffirming-care-providers-treatment-parents-liability-45012ee33f078eeea7871e622a5eee1d.

transgender and gender diverse ("TGD") youth experiencing distress and unease caused by incongruence with their sex assigned at birth ("gender dysphoria"), their health and well-being is heavily dependent on healthcare practitioners providing them with medically necessary gender-affirming care consistent with evidence-based healthcare standards. These prevailing standards are primarily set forth in two clinical guidelines: (i) the World Professional Association for Transgender Health Standards of Care ("WPATH Standards") and (ii) the Endocrine Society Clinical Practice Guideline ("Endocrine Guideline").

The WPATH is an international, multidisciplinary, professional association made up of over 3,000 healthcare professionals, social scientists, and legal professionals. WPATH has established the highest standards of healthcare for TGD individuals, including adolescents (*i.e.*, from the start of puberty until age eighteen), through the best available science and expert consensus since 1979.[11] Version 8 of their Standards of Care was published online on September 15, 2022 in response to mounting scientific evidence with respect to TGD adolescents.[12] These standards provide clinical guidance to healthcare practitioners who treat TGD individuals with

[11] *See* E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 Int'l J. of Transgender Health S1 (2022), *available at* https://wpath.org/publications/soc ("WPATH Standards").

[12] *See id.*

gender dysphoria, ensuring access to safe and effective pathways that optimize their health and well-being.[13]

The Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions, comprised of more than 18,000 members in 122 countries.[14] Its Guideline establishes a methodical, conservative framework for gender-affirming care of TGD individuals, including adolescents, which includes pubertal suppression, hormones, and surgery, based upon evidence—supported by more than 260 studies[15]—that treatment of gender dysphoria/incongruence is medically necessary.[16] These standards are "designed to take a conservative approach."[17] The Endocrine Society has explained:

> When young children experience feelings that their gender identity does not match the sex recorded at birth, the first course of action is to support the child in exploring their gender identity and to provide mental health support, as needed.

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[13] *Id*. at S5.

[14] Endocrine Soc'y, *AMA strengthens its policy on protecting access to gender-affirming care*, (June 12, 2023), https://www.endocrine.org/news-and-advocacy/news-room/2023/ama-gender-affirming-care ("Endocrine Soc'y, *AMA strengthens*").

[15] *Id.*

[16] *See, e.g.*, Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. of Clinical Endocrinology & Metabolism 3869 (2017), https://doi.org/10.1210/jc.2017-01658 ("Endocrine Guideline").

[17] Endocrine Soc'y, *AMA strengthens*, *supra* note 14.

> Medical intervention is reserved for older adolescents and adults, with treatment plans tailored to the individual and designed to maximize the time teenagers and their families have to make decisions about their transitions. Major medical organizations also agree on waiting until an individual has turned 18 or reached the age of majority in their country to undergo gender-affirming genital surgery.[18]

Dozens of leading professional medical associations across the United States—including the American Medical Association, American Academy of Pediatrics, and American College of Physicians—support evidence-based gender-affirming care for minors.[19] The WPATH Standards and Endocrine Guideline are specifically endorsed and cited as authoritative for the assessment, diagnosis, and treatment of gender dysphoria by these major professional medical and mental health associations,[20] and by numerous Indiana-based medical institutions including the

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[18] *Id.*

[19] GLAAD, *Medical Association Statements in Support of Health Care for Transgender People and Youth*, (June 21, 2023), https://glaad.org/medical-association-statements-supporting-trans-youth-healthcare-and-against-discriminatory/.

[20] *See, e.g.*, WPATH & U.S. Pro. Ass'n for Transgender Health ("USPATH"), *USPATH and WPATH Confirm Gender-Affirming Health Care is Not Experimental; Condemns Legislation Asserting Otherwise*, (Mar. 22, 2023), https://www.wpath.org/media/cms/Documents/Public%20Policies/2023/USPATH_WPATH%20Response%20to%20AG%20Bailey%20Emergency%20Regulation%2003.22.2023.pdf (WPATH Standards are "the foremost evidence-based guideline for the provision of TGD healthcare" and "based on the best available science with input from over 100 global medical professionals and experts and represents best-practice guidelines for the provision of gender-affirming healthcare."); Pediatric Endocrine Soc'y, *The Pediatric Endocrine Society Opposes Bills that Harm Transgender Youth*, (Apr. 2021), https://pedsendo.org/wp-content/uploads/2021/04/The-Pediatric-Endocrine-Society-Statement-TG.pdf (Bills that threaten TGD youth health "contradict evidence-based Standards of Care recommendations from the Pediatric Endocrine Society" and "several national and international medical associations with expertise in the care of TGD youth, such as the American Academy of Pediatrics, the Endocrine Society, the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association and the World Professional

Indiana University School of Medicine, Riley Children's Health, and Eskenazi Health.[21]

Courts recognize these standards are "well-established," *Dekker v. Weida*, No. 4:22cv325-RH-MAF, 2023 WL 4102243, at *6 (N.D. Fla. June 21, 2023), reflect "best practices by the major medical and mental health professional associations in the United States," *Brandt v. Rutledge*, No. 4:21CV00450 JM, 2023 WL 4073727, at *5 (E.D. Ark. June 20, 2023), and are "widely followed by clinicians." *Id.* Indeed, "not a single reputable medical association has taken a contrary position." *Dekker*, 2023 WL 4102243, at *7; *see also Brandt v. Rutledge*, 47 F.4th 661, 671 (8th Cir. 2022) (substantial evidence supported finding that Arkansas's ban on care to

Association for Transgender Health."); Am. Ass'n of Clinical Endocrinology, *AACE Position Statement: Transgender and Gender Diverse Patients and the Endocrine Community*, (Mar. 7, 2020), https://pro.aace.com/recent-news-and-updates/aace-position-statement-transgender-and-gender-diverse-patients ("Medical treatment" for TGD adults and adolescents "includ[ing] behavioral assessment, hormone therapy, and surgery . . . are well established in the relevant established, international professional society guidelines including those from the Endocrine Society co-sponsored by the American Association of Clinical Endocrinology (AACE) and the . . . WPATH.")

[21] *See, e.g.*, Ind. Univ. Sch. of Med., *LGBTQ+ Healthcare: Guidelines*, https://iupui.libguides.com/LGBTQ/Providers (last visited Sept. 27, 2023) (WPATH "promotes the highest standards of health care for individuals through the articulation of Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People. The SOC are based on the best available science and expert professional consensus."); Eskenazi Health, *General Health Program*, https://www.eskenazihealth.edu/health-services/gender-health (last visited Sept. 27, 2023) ("Established in March 2016, the program includes many skilled team members trained in the WPATH standards of care."); Riley Childs. Health: Ind. Univ. Health, *Gender Health Program*, https://www.rileychildrens.org/departments/gender-health-program (last visited Sept. 27, 2023) (WPATH: "This professional organization teaches medical professionals about gender health issues, conducts research and helps shape the international standard of care for people with gender dysphoria.").

transgender youth "prohibits medical treatment that conforms with the recognized standards of care"); *Doe v. Ladapo*, No. 4:23cv114-RH-MAF, 2023 WL 3833848, at *10 (N.D. Fla. June 6, 2023).

Even international bodies that consider gender-affirming care to be "experimental" recommend treatment that closely mirrors the WPATH Standards. In a case similar to this one, the Eighth Circuit explained that, despite a report from the Council for Choices in Health Care in Finland concluding that "gender reassignment of minors is an experimental practice," the Finnish council "still recommends that gender-affirming care be available to minors under appropriate circumstances" and its "recommendations for treatment closely mirror the standards of care laid out by the [WPATH] and the Endocrine Society." *Brandt*, 47 F.4th at 671 (quotation omitted). For example, "[l]ike WPATH, the Finnish council concluded that puberty-suppressing hormones might be appropriate for adolescents at the onset of puberty who have exhibited persistent gender nonconformity and who are already addressing any coexisting psychological issues." *Id.* The *Brandt* court also noted that an initial decision in the United Kingdom prohibiting minors under sixteen from consenting to hormone therapies based on "limited evidence as to its efficacy" was subsequently reversed. *Id.* at 671 n.5 (quoting *Bell v. Tavistock & Portman NHS Found. Tr.*, [2020] EWHC (Admin) 3274 ¶ 134 (Eng.)). The Eighth Circuit credited the United Kingdom court's conclusion that "'[n]othing about the

nature or implications of the treatment with puberty blockers allows for a real distinction to be made' from other medical treatment an adolescent might seek." *Id.* (quoting *Bell v. Tavistock & Portman NHS Found. Tr.*, [2021] EWHC (Civ) 1363 ¶ 76 (Eng.)).

In sum, the prevailing medical standards of care for adolescents experiencing gender dysphoria provide access to gender-affirming care for a specific subset of minors in limited situations.

B. S.E.A. 480 Would Require Doctors to Deviate from the Established Standards of Care.

S.E.A. 480 explicitly bans healthcare practitioners from providing the gender-affirming care recommended by the WPATH Standards and Endocrine Guideline, including puberty blockers and hormone treatment that have been deemed "medically necessary" for certain TGD youth. Withholding such medically necessary care would put minors at risk of serious harm to their health and well-being. The fact that no reputable medical association agrees with Indiana's prohibition of medically necessary care for TGD youth underscores the lack of nexus between S.E.A. 480 and the compelling interests it purportedly furthers.

S.E.A. 480 prohibits healthcare practitioners from "knowingly provid[ing] gender transition procedures to a minor . . . [or] aid[ing] or abet[ting] another physician or practitioner in the provision of gender transition procedures to a minor." S.E.A. 480 § 13(b). As discussed, *supra* Section I.A., S.E.A. 480 defines "gender

transition procedures" to include a broad range of medical services that either (1) alter anatomical characteristics associated with an individual's sex assigned at birth or (2) create anatomical characteristics that resemble a sex different from the individual's sex assigned at birth, including by use of "puberty blocking drugs, gender transition hormone therapy, or genital gender reassignment surgery or non-genital gender reassignment surgery[22] knowingly performed for the purpose of assisting an individual with a gender transition." *Id.* § 5(a).

The established standards of care are clear: "Medically necessary gender-affirming interventions . . . include but are not limited to . . . puberty blocking medication and gender-affirming hormones . . . as appropriate for the patient and based on a review of the patient's individual circumstances and needs."[23] "Medical intervention for transgender youth and adults (including puberty suppression, hormone therapy and medically indicated surgery) is effective, relatively safe (when appropriately monitored), and has been established as the standard of care."[24] Yet, S.E.A. 480's prohibition of "medical services that provide puberty blocking drugs"

[22] This amicus brief does not discuss genital reassignment surgery or non-genital gender reassignment surgery, or how S.E.A. 480's ban on such medical procedures is inconsistent with the WPATH Standards and Endocrine Guideline, because the parties have stipulated that "[n]o Indiana provider performs gender transition surgery on persons under the age of 18." Dkt. 51 at 4.

[23] WPATH Standards, *supra* note 11 at S18.

[24] Endocrine Soc'y, *Transgender Health: Pediatric Endocrine Society Position Statement*, (Dec. 2020), https://www.endocrine.org/-/media/endocrine/files/advocacy/position-statement/position_statement_transgender_health_pes.pdf (citing Endocrine Guideline, *supra* note 16) ("Endocrine Soc'y, Position Statement").

and "gender transition hormone therapy" are directly in conflict with these standards and would deny medically necessary care for TGD youth.

Upon meeting the necessary criteria,[25] the established standards advise that healthcare practitioners provide gender-affirming care with pubertal hormone suppression after a TGD youth first exhibits the physical changes of puberty. This advice is designed to prevent the "irreversible development of undesirable secondary sex characteristics" corresponding to the sex designated at birth.[26] The medically-necessary treatment for eligible TGD youth includes using gonadotropin releasing hormone agonists ("GnRHa"), or progestin formulations (if GnRHa are not available or cost prohibitive), to suppress sex hormones that are not in alignment with the TGD youth's gender identity.[27] For example, GnRHa should be prescribed for eligible TGD adolescents "with a uterus to reduce dysphoria caused by their

[25] The established standards clarify that gender-affirming medical care for TGD youth, diagnosed with gender dysphoria, should only be recommended when certain criteria are met, including: when the adolescent meets the diagnostic criteria of gender dysphoria, as confirmed by a qualified mental health professional; when the experience of gender dysphoria is marked and sustained over time; when gender dysphoria worsens with the onset of puberty; when the adolescent demonstrates the emotional and cognitive maturity required to provide informed consent; when the adolescent's other mental health concerns (if any) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; and when the adolescent has been informed of any risks. *See* WPATH Standards, *supra* note 11 at S59-66; Endocrine Guideline, *supra* note 16 at 3878.

[26] Endocrine Guideline, *supra* note 16 at 3880-81; *see also* WPATH Standards, *supra* note 11 at S112.

[27] *Id*. at S113-14; Endocrine Guideline, *supra* note 16 at 3881.

menstrual cycle" (i.e., menstrual suppression).[28] GnRHa treatment provides an extended time for adolescents to explore their gender identity and often results "in a vast reduction in the level of distress stemming from physical changes" occurring from puberty.[29]

S.E.A. 480, however, prohibits healthcare practitioners from providing "any puberty blocking drugs" to minors, including GnRHa, "when used for the purpose of assisting an individual with a gender transition." S.E.A. 480 § 11. This sweeping ban targets all transgender youth experiencing gender dysphoria or seeking to align themselves physically with their gender identity that is inconsistent with their sex assigned at birth. Such a ban plainly prohibits healthcare practitioners in Indiana from adhering to the established medical standards which identify puberty suppression hormones as "medically necessary" under specific circumstances. Critically, it poses serious health risks to TGD youth. Studies have found "a decrease in the odds of lifetime suicidal ideation in adolescents who required pubertal suppression and had access to this treatment compared with those with a similar desire with no such access."[30]

[28] WPATH Standards, *supra* note 11 at S116.

[29] *Id.* at S112.

[30] *Id.* at S126 (citation omitted); *see also* Endocrine Soc'y, Position Statement, *supra* note 24 at 2.

S.E.A. 480 also denies healthcare practitioners in Indiana the ability to provide, for example, gender-affirming hormone treatment ("GAHT") for TGD youth, even when this medical intervention is "effective," "safe," and "established as the standard of care."[31] Specifically, the law bans "gender transition hormone therapy," including "testosterone[,]" "estrogen[,]" or "progesterone" if "given to an individual in an amount greater than would normally be produced endogenously in a healthy individual of that individual's age and sex." S.E.A. 480 § 4. This is directly contrary to the established medical standards, which authorize "prescrib[ing] sex hormone treatment regimes as part of gender-affirming treatment," starting at age sixteen including administering those hormones prohibited by S.E.A. 480 (as appropriate) after a multidisciplinary team of medical health practitioners has confirmed persistent gender incongruence and informed consent is established.[32]

"The overwhelming weight of medical authority supports treatment of transgender patients with GnRH agonists and cross-sex hormones in appropriate circumstances." *Dekker*, 2023 WL 4102243, at *7. "Youth who are able to access

[31] Endocrine Soc'y, Position Statement, *supra* note 24 at 2.

[32] WPATH Standards, *supra* note 11 at S114-116; Endocrine Guideline, *supra* note 16 at 3883-84; *see also* Julia C. Sorbara et al., *Mental Health and Timing of Gender-Affirming Care*, 146 Pediatrics 1, 7 (2020), https://publications.aap.org/pediatrics/article/146/4/e20193600/79683/Mental-Health-and-Timing-of-Gender-Affirming-Care?autologincheck=redirected (concluding that late pubertal stage and older age TGD youth may be particularly vulnerable and in need of medically necessary care).

gender-affirming care, including pubertal suppression, hormones and surgery based on conservative medical guidelines and consultation from medical and mental health experts, experience significantly improved mental health outcomes over time, similar to their cis-gender peers."[33] But even if a TGD youth is eligible under the established standards for puberty suppression treatment and/or hormone therapy, they would be denied such care under S.E.A. 480. In fact, there is no situation, under S.E.A. 480, where a TGD youth can be provided such treatment if they are struggling with gender dysphoria. Thus, the law's sweeping prohibition of medically necessary gender-affirming care for TGD youth would force healthcare practitioners in Indiana to deviate from the established standards of care, which contravenes both of the compelling governmental interests offered by Indiana.

C. S.E.A. 480 Is Inconsistent with the Medical Licensing Board of Indiana's Standards of Professional Conduct.

Medical practitioners in Indiana must comply with the Standards of Professional Conduct and Competent Practice of Medicine or risk discipline for failing to do so. *See* 844 Ind. Admin. Code 5-1-3 (2022). These standards, announced by the Medical Licensing Board of Indiana, require that "[a] practitioner shall exercise reasonable care and diligence in the treatment of patients based upon

[33] Endocrine Soc'y, Position Statement, *supra* note 24 at 2.

generally accepted scientific principles, methods, treatments, and current professional theory and practice." *Id.* at 5-2-5.

Medical practitioners in Indiana are put in an impossible bind: they cannot comply with *both* the governing "reasonable care and diligence" standard set out in the Standard of Professional Conduct and Competent Practice of Medicine *and* with S.E.A. 480. This is because S.E.A. 480's ban on gender-affirming care, including puberty suppression and hormone therapy, deviates from the established medical standards of care. *See, e.g.*, *supra* Section II.B.

The WPATH Standards and Endocrine Guideline provide for medically necessary treatment of TGD youth under a particular set of circumstances. The determination of when treatment is necessary is "based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, designated Medical Specialty Societies and/or legitimate Medical Colleges' recommendations, and the views of physicians and/or HCPs [healthcare providers] practicing in relevant clinical areas."[34] The WPATH Standards explain:

> There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, . . . properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people in need of these treatments. . . . Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience

[34] WPATH's Standards of Care, *supra* note 11 at S17.

> of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria. . . . Consequently, WPATH urges health care systems to provide these medically necessary treatments . . . [including] puberty blocking medication and gender-affirming hormones . . . as appropriate for the patient and based on a review of the patient's individual circumstance and needs."[35]

There can be no doubt then that the "reasonable care and diligence" required to be exercised by Indiana practitioners under 844 Ind. Admin. Code 5-2-5 when providing healthcare to TGD youth must be consistent with the WPATH Standards and Endocrine Guideline, which are considered "generally accepted scientific principles, methods, treatments, and current professional theory and practice." 844 Ind. Admin. Code 5-2-5. As described, *supra* Section II.B, S.E.A. 480 forces practitioners to act contrary to the established medical standards of care, putting them at risk of violating the Board's Standards of Professional Conduct. A law that is contrary to peer-reviewed, widely accepted medical standards of care and inconsistent with Indiana's own Standards of Professional Conduct cannot serve a compelling government interest.

D. S.E.A. 480 Supplants the Shared Decision-Making Model, Which Is the Prevailing Evidence-Based Decision Framework Used By Today's Healthcare Practitioners.

Shared Decision Making ("SDM") is the process by which patients and healthcare practitioners collaborate to make a healthcare decision tailored to an

[35] *Id*. at S18.

individual patient's medical situation, context, views, and preferences.[36] SDM is the decision-making model preferred by healthcare practitioners, patients, and policy makers.[37] S.E.A. 480 undermines modern healthcare ethics generally and SDM specifically by (i) erasing patient autonomy and promoting paternalistic healthcare through the elimination of medically reasonable healthcare options, which are core to the SDM dialogue between healthcare practitioners and patients; and (ii) redundantly mandating blanket state intervention when SDM already contemplates such intervention in cases where patients seek potentially harmful treatments.

Patient autonomy—or self-governance—is the core ethical consideration of SDM. Self-governance is more than just a traditional American value; it is one of the four pillars of medical ethics.[38] Prioritizing autonomy also has a proven practical import in the context of modern medicine. Mounting evidence confirms that patients who are more actively involved in decision making are (i) more satisfied with the decision-making process and the decision itself; (ii) more likely to adhere to

[36] *See, e.*g., Ellen M. Driever et al., *Why do medical residents prefer paternalistic decision making? An interview study*, 22 BMC Med. Educ. 22, 1-2 (2022), *available at* https://doi.org/10.1186/s12909-022-03203-2.

[37] *Id.* at 2.

[38] *See, e.g.*, Basil Varkey, *Principles of Clinical Ethics and Their Application to Practice*, 30 Med. Principles & Practice 17, 18 (2021), *available at* https://karger.com/mpp/article/30/1/17/204816/Principles-of-Clinical-Ethics-and-Their. Asserting autonomy, beneficence, nonmaleficence, and justice comprise the four principals of medical ethics.

treatment recommendations; and (iii) more likely to achieve positive health outcomes.[39] It is clear then, both ethically and empirically, that patients should have an active role in making informed choices concerning their healthcare. Yet, S.E.A. 480 mandates those choices through the removal of key steps in the common SDM model: (i) a healthcare practitioner's ability to define and recommend medically reasonable options (*e.g.*, treatments recommended by WPATH); (ii) the opportunity for the patient and healthcare practitioner to discuss those options; and (iii) the healthcare practitioner's duty to honor the patient's medically reasonable decision (*e.g.*, gender-affirming care). In other words, S.E.A. 480 *governs* both patients and healthcare practitioners to their detriment.

Because every patient has a unique blend of personality, character, experiences, and condition- or disease-specific circumstances, each patient also has different needs for best supporting their autonomy. Autonomy demands, and SDM supports, that a patient be appropriately informed that the evidence for any given treatment—or any *omitted* treatment such as gender-affirming care—may be lacking, of poor quality, or inconclusive, or may reveal widely varying outcomes for

[39] Driever, *supra* note 36 at 2 (citing E.A.G. Joosten et al., *Systematic Review of the Effects of Shared Decision-Making on Patient Satisfaction, Treatment Adherence and Health Status*, 77 Psychotherapy & Psychosomatics 219, 219-26 (2008)); *see also generally* Stacey D. Légaré et al., *Decision aids for people facing health treatment or screening decisions*, 4 Cochrane Database of Systematic Reviews 1 (2017), *available at* https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001431.pub5/full.

different patients. SDM does not paint with a broad brush like S.E.A. 480; instead, it avails patients of the positive and negative aspects of their medically reasonable options and then allows them to self-govern.

SDM's respect for patient autonomy aligns with modern codes of medical ethics and can be contrasted with paternalistic healthcare decision-making models of the past.[40] Paternalistic models involve healthcare practitioners first recommending a diagnostic or treatment action which the healthcare practitioner (not the patient) considers the best choice, and then asking for patient consent.[41] This unilateral process more closely resembles a narrow offer and acceptance than an informed dialogue of treatment options a patient can choose from. S.E.A. 480 is paternalistic, attempting to control medical outcomes for minor patients by eliminating gender-affirming care as an otherwise medically reasonable treatment option. Doing so discards the prevailing model for patient care in SDM.

Moreover, courts accept SDM as persuasive evidence of acceptable standards of care. *See, e.g.*, *Cooper v. United States*, No. CV-15-2140-PHX-MHB, 2017 WL 2376598, at *3 (D. Ariz. 2017); *Baum v. Astrazeneca*, 605 F. Supp. 2d 669, 680

[40] *See, e.g.*, Am. Med. Ass'n, *AMA Code of Medical Ethics*, *available at* https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent (last visited Sept. 27, 2023); Gen. Med. Council, *Good medical practice*, (updated Apr. 29, 2019), https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice.

[41] *See* Ezekial J. Emanual, *Four Models of the Physician-Patient Relationship*, 267 JAMA 2221, 2224 (1992), https://ksumsc.com/download_center/Archive/4th/434/PHC/B1/emanuel1992.pdf.

(W.D. Pa. 2009). A court even found SDM as persuasive evidence that gender-confirming surgery and related hormone therapy are a generally accepted form of medical treatment for gender dysphoria. *See Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1014 (W.D. Wis. 2019) (citing the American Medical Association and the Endocrine Society and concluding that "[t]he larger medical community considers these [gender-affirming] treatments to be acceptable").

SDM models already recommend governmental intervention if the minor patient and parent(s) (i) decline all medically reasonable options (in which case, a healthcare practitioner can seek state intervention to compel the adolescent to undergo the recommended therapy); or (ii) request potentially nonbeneficial or harmful treatments (in which case, a healthcare practitioner should consider seeking state intervention to protect the patient if the family elects to pursue a harmful treatment).[42] Indiana minors and parents do not require a wide-sweeping law that ignores nuance in complex healthcare issues and the expertise of the same healthcare practitioners Hoosiers trust to keep their families alive and well. If a healthcare practitioner implementing SDM concludes that gender-affirming care will be nonbeneficial or harmful to a minor patient, but the patient/parents still wish to proceed with gender-affirming care, Indiana can intervene at the direction of the

[42] *See, e.g.*, Kimberly Sawyer & Abby R. Rosenberg, *How Should Adolescent Health Decision-Making Authority Be Shared?* 22 AMA J. Ethics 372, 374-77 (2020), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2020-04/cscm4-2005.pdf.

healthcare practitioner. Thus, Indiana does not lose anything if S.E.A. 480 is enjoined, and can assert its interest on behalf of a minor patient where it is warranted in important and narrow circumstances.

CONCLUSION

For the foregoing reasons, as well as those set forth in Appellees' brief, the District Court's preliminary injunction order should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The foregoing brief complies with the type-volume limitations in Fed. R. App. P. 29(a)(5) and 32(a)(7) because it contains 6,454 words, excluding those parts exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because the brief was produced in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

/s/ Gil McDonald
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I certify that on September 27, 2023, the foregoing was electronically filed with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. All counsel of record are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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