No. 22-11707

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

PAUL A. EKNES-TUCKER, et al.,
Plaintiffs-Appellees,

&

UNITED STATES OF AMERICA
Intervenor-Plaintiff-Appellee,

v.

GOVERNOR OF THE STATE OF ALABAMA, et al.,
Defendants-Appellants.

On Appeal from the United States District Court
for the Middle District of Alabama
Case No. 2:22-cv-184-LCB

BRIEF OF *AMICUS CURIAE* ETHICS AND PUBLIC POLICY CENTER IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rule 26.1-1(a)(3), 26.1-2(b), and 26.1-3, the undersigned counsel certifies that the following listed persons and parties not already included in the CIP contained in the first brief and in any other brief filed have an interest in the outcome of this case:

1. Ethics and Public Policy Center – *Amicus Curiae*;
2. Hasson, Mary Rice – Counsel for *Amicus Curiae*;
3. Morrison, Rachel N. – Counsel for *Amicus Curiae*.

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Respectfully submitted this 5th day of July 2022.

s/ Rachel Morrison
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STATEMENT OF THE ISSUES

1. Alabama banned transitioning treatments for children based on the Legislature's determination that the risks of the interventions outweigh their proven benefits. Does the Due Process Clause provide parents a fundamental right to obtain these sterilizing treatments for their children?

2. Does the Equal Protection Clause forbid States from banning transitioning treatments for all minors?

3. Did the district court abuse its discretion by entering a universal injunction?

STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The Ethics and Public Policy Center (EPPC) is a nonprofit research institution dedicated to applying the Judeo-Christian moral tradition to critical issues of public policy, law, culture, and politics. EPPC's programs cover a wide range of issues, including governmental and judicial restraint, bioethics and human flourishing, and personhood and identity. EPPC has a strong interest in ensuring the proper interpretation and application of rights guaranteed by the Constitution, promoting the Judeo-Christian vision of the human person, and responding to cultural and legal challenges to both constitutional rights and human flourishing.

[1] All parties have consented to this filing. No party's counsel authored this brief in whole or in part, and no person or entity other than *Amicus Curiae* or their counsel made a monetary contribution intended to fund the brief's preparation or submission.

Gender ideology has permeated the culture with stunning speed, influencing medical, government, and family decisions and creating an urgent need for clarity, education, and public discourse. This is particularly true in healthcare and when it comes to protecting minors, which are at issue in this case. EPPC's brief demonstrates the lack of medical consensus regarding an authoritative standard of care for the treatment of gender dysphoria and transitioning interventions, underscores the harms of transitioning treatments for minors, and points to the consequent importance of legislative efforts to protect minors from irreversible harms.

SUMMARY OF ARGUMENT

Since the first gender clinic for minors opened in the U.S. in 2007, the number of minors seeking and receiving medical transitioning treatments (puberty blockers, cross-sex hormones, and surgeries) has skyrocketed. This unprecedented surge in transitioning treatments for minors carries a high cost. These treatments are unproven, life-altering, and can lead to significant and irreversible harms, including sterilization, loss of sexual function, and serious mental health problems. Despite the poor evidence base underlying these treatments and the lack of medical consensus supporting them, gender clinicians continue to provide transitioning treatments to minors and medical associations continue to endorse them.

Alabama's legislature was rightly concerned about the reported harms to vulnerable children and acted constitutionally to weigh the risks and benefits of

transitioning treatments for minors. It determined that the state's compelling interests in protecting Alabama's children required it to prohibit these experimental medical interventions. Alabama's legislature constitutionally sought to protect Alabama's minors from lifelong medical harm when, after assessing the risks and benefits of transitioning treatments, evaluating medical evidence, weighing expert opinion, and considering witness testimony, it prohibited the transitioning treatments for minors.

Instead of deferring to the Alabama legislature's evidenced-based findings that transitioning treatments pose an unacceptable risk of harm to minors, the district court deferred to eminence-based medicine, stating multiple times that "at least twenty-two major medical associations in the United States endorse transitioning medications as well-established, evidence-based treatments for gender dysphoria in minors," DE112-1:17, 19; *see also* DE112-1:4 & n.4, 9-10, 24. The court's conclusion that Parent Plaintiffs had a "fundamental right to treat their children with transitioning medications" gave undue weight to World Professional Association for Transgender Health (WPATH) guidelines endorsed by "major medical associations." DE112-1:4, 17, 18, 19, 24.

But endorsements neither create a standard of care nor imply a fundamental right to access controversial medical treatments. Contrary to the district court's assumption, WPATH guidelines are not the standard of care. There is no national or

international medical consensus regarding an authoritative standard of care for the treatment of gender dysphoria or the use of transitioning treatments. This lack of medical consensus has been recognized by the federal government, is reflected in state action, and continues to generate controversy in the medical profession.

Under the district court's preliminary injunction, children in Alabama will continue to have access to and suffer from the harmful, irreversible, and sterilizing transitioning treatments. The Court should reverse.

ARGUMENT

I. There is no national or international medical consensus regarding an authoritative standard of care for gender dysphoria or transitioning treatments.

Instead of deferring to the Alabama legislature's *evidence-based* findings that medical transitioning treatments pose an unacceptable risk of harm to minors, the district court inexplicably deferred to Plaintiffs' healthcare *amici*, making an *eminence-based* medical judgment.[2] Despite the district court's oft-repeated statement that "at least twenty-two major medical associations in the United States endorse transitioning medications as well-established, evidence-based treatments for gender dysphoria in minors," DE112-1:19; *see also* DE112-1:17; DE112-1:4 & n.4, 9-10, 19, 24, there is no consensus within the medical profession regarding an authoritative standard of care for gender dysphoria or transitioning treatments. This lack of medical consensus is reflected historically, internationally, and in actions by the federal government and other states, and transitioning treatments continue to generate controversy among medical professionals.

A. There is no consensus within the medical profession historically.

Since the first transitioning surgeries were performed in the U.S. on adults in the mid-20th century to the present day, there has been no medical consensus

[2] Eminence-based medicine relies not on quality evidence but "on the clinical experience, advice, and opinions of our mentors…. Eminence-based decision-making has value, but it is flawed and limited." Ruth D. Williams, *Of Eminence-Based and Evidence-Based Medicine*, EyeNet

regarding the authoritative standard of care to treat gender dysphoria (previously, "gender identity disorder") in minors or to evaluate the risks and benefits of medically assisted "transitions."

Historically, there have been uneven and, at times, competing trajectories in the development of therapeutic responses to gender dysphoria; diagnostic labels, criteria, and interventions have evolved significantly over a relatively short time.[3] The American Psychiatric Association (APA) defines gender dysphoria as "clinically significant distress or impairment related to a strong desire to be of another gender, which may include desire to change primary and/or secondary sex characteristics."[4] An "inherently subjective phenomenon," gender dysphoria is variously classified as "a mental disorder" or "a condition related to sexual health."[5]

Magazine, Am. Acad. of Opthalmology (Sept. 2018), https://www.aao.org/eyenet/article/of-eminence-based-and-evidence-based-medicine.

[3] The APA's Diagnostic and Statistical Manual (DSM) changed terminology and diagnostic criteria as follows: "transsexualism" (DSM-III), "gender identity disorder" (DSM-IV), and "gender dysphoria." *Gender Dysphoria Diagnosis*, Am. Psychiatric Ass'n (2022), https://www.psychiatry.org/psychiatrists/diversity/education/transgender-and-gender-nonconforming-patients/gender-dysphoria-diagnosis.

[4] *What Is Gender Dysphoria?*, Am. Psychiatric Ass'n (Nov. 2020), https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria.

[5] The APA classifies "gender dysphoria" under mental health disorders, while the World Health Organization classifies "gender incongruence" under "sexual health." Karl Gerritse et al., *Decision-Making Approaches in Transgender Healthcare: Conceptual Analysis and Ethical Implications*, 24 Med. Health Care & Phil. 687, 688 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8557156/.

Until recently, responding to a child's gender dysphoria with "watchful waiting" or family therapy was not controversial because, in most cases, the child's gender incongruence resolved by puberty.[6] In contrast, the use of medical transitioning treatments for minors has been controversial since its inception—and remains so.

The Dutch researchers who pioneered the use of puberty suppression as a transitioning treatment for minors acknowledge persistent skepticism towards their work, including from providers concerned that gender dysphoria "can only be diagnosed with certainty in adulthood," and fearful of "disapproval of the peer group, reactions of the correctional medical boards, or litigation."[7]

Dr. Norman Spack opened the first U.S. pediatric gender clinic at Boston Children's Hospital in 2007 and used puberty suppression as a transitioning treatment for minors. With scant research available, he viewed "stopping puberty" as "a diagnostic test."[8] If it brought relief, the diagnosis was right.

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[6] Devita Singh et al., *A Follow-Up Study of Boys with Gender Identity Disorder*, Front. Psychiatry 632784 (2021), https://pubmed.ncbi.nlm.nih.gov/33854450/.

[7] Peggy Cohen-Kettenis et al., *The Treatment of Adolescent Transsexuals: Changing* Insight, J. Sexual Med. 1892, 1893 (2008), https://doi.org/10.1111/j.1743-6109.2008.00870.x.

[8] Pagan Kennedy, *Q & A with Norman Spack*, Boston.com (archives Boston Globe), (Mar. 30, 2008), http://archive.boston.com/bostonglobe/ideas/articles/2008/03/30/qa_with_norman_spack/?page=full.

No professional medical society recommended medically treating gender dysphoria in minors until 2009,[9] when the Endocrine Society's then-newly-released Clinical Practice Guidelines supported puberty suppression and cross-sex hormones for minors—despite lacking "rigorous evaluation of the effectiveness and safety of endocrine protocols."[10]

In 2012, the World Professional Association for Transgender Health (WPATH), an advocacy group and early promoter of medical transitioning for minors, noted that adoption of medical transitioning for minors "differs among countries and centers. Not all clinics offer puberty suppression…. The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings."[11] In short, no consensus.

Although a 2014 Dutch study reported positive psychological functioning for fifty-five patients who received medical transitioning treatments as adolescents

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[9] Edwards-Leeper & Norman P. Spack, *Psychological Evaluation and Medical Treatment of Transgender Youth in an Interdisciplinary "Gender Management Service" (GeMS) in a Major Pediatric Center*, 59 J. Homosexuality 321, 323 (2012), https://pubmed.ncbi.nlm.nih.gov/22455323/.

[10] Wylie C. Hembree et al., *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*, 94 J. Clinical Endocrinology & Metabolism 3132, 3134 (2009), https://pubmed.ncbi.nlm.nih.gov/19509099/.

[11] World Prof'l Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People Version 7 13 (2012) [hereinafter "WPATH SOC7"], https://www.wpath.org/publications/soc.

and surgery as adults,[12] subsequent studies failed to replicate those positive outcomes,[13] and many have criticized the study's methodology.[14] The Endocrine Society's 2017 guidelines rely on the Dutch study but acknowledge the overall "low" and "very low" quality of supporting evidence generally[15] and note new concerns emerging since 2009, including "effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain."[16]

In 2019, Boston Children's opened the first pediatric center for gender surgery, solely dedicated to removing minors' breasts, ovaries, testicles, and genitals as part of medicalized transition.[17] The surgery center reflects gender medicine's

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[12] Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696, 702 (2014), https://pubmed.ncbi.nlm.nih.gov/25201798/.

[13] Polly Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLoS ONE (2021), https://doi.org/10.1371/journal.pone.0243894 (failing to replicate Dutch study).

[14] Stephen B. Levine et al., *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults*, J. Sex & Marital Therapy 9 (2022), https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2046221.

[15] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clinical Endocrinology & Metabolism 3869, 3880 (2017), https://doi.org/10.1210/jc.2017-01658.

[16] *Id.* at 3874.

[17] *Center for Gender Surgery: Conditions & Procedures*, Boston Children's Hospital, https://www.childrenshospital.org/programs/center-gender-surgery-program/conditions-and-treatments.

bold extension of transitioning treatments to younger and younger adolescents—controversial decisions unsupported by consensus.[18]

In the fifteen years since U.S. gender clinicians began the controversial practice of offering transitioning treatments for minors, the number of minors seeking and receiving them has skyrocketed. So too has the number of gender clinics for minors, growing from one in 2007 to over 60 today.[19] But market expansion should not be mistaken for a medical consensus. The next chapter in treatment for gender dysphoria is still being written.

B. There is a lack of evidence supporting transitioning treatments for minors.

Gender specialists admit that "[t]ransgender medicine presents a particular challenge for the development of evidence-based guidelines" because of "limited" data, "lower-quality evidence," retrospective study design, "lack of uniform data collection," and limited research funding.[20] Many experts admit that "gender-

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[18] *See* Hembree et al., *supra* note 15, at 3872; Christine & Dan Karasic, *Age Is Just a Number: WPATH-Affiliated Surgeons' Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States*, 14 J. Sex Med. 624, 625 (2017), https://pubmed.ncbi.nlm.nih.gov/28325535/ (urging lowering of recommended age for surgeries); Elizabeth R. Boskey & Judith A. Johnson, *Ethical Issues Considered when Establishing a Pediatric Gender Surgery Center*, 143 Pediatrics 1, 2 (2019), https://pediatrics.aappublications.org/content/143/6/e20183053.figures-only.

[19] *Comprehensive Care Clinics*, Human Rights Campaign Foundation, https://www.thehrcfoundation.org/professional-resources/comprehensive-care-clinics.

[20] Madeline B. Deutsch et al., *What's in a Guideline? Developing Collaborative and Sound Research Designs that Substantiate Best Practice Recommendations for Transgender Health Care*, 18 AMA J. of Ethics 1098, 1099 (2016), https://doi.org/10.1001/journalofethics.2016.18.11.stas1-1611.

affirming" transitioning treatments for gender dysphoria rest on a "relatively slim (biomedical) evidence base."[21]

In 2021, Dutch gender clinician, Dr. Thomas Steensma, acknowledged the need for "[m]ore research on sex changes in young people under the age of 18…. Doctors who provide transgender care in [the Netherlands] say they know too little about the target group and the long-term effects."[22] Lawrence Tabak, acting director of the National Institutes of Health, told a U.S. Senate Committee in 2022 that "no long-term studies are available evaluating the effects of puberty blockers when used for gender dysphoria."[23] Diane Chen, a leading psychologist with Lurie Children's Hospital gender clinic, recently admitted that "a lot of the questions around long-term medical health outcomes we won't be able to answer until the youth who started hormones at 13, 14, 15, are in their 50s, 60s, 70s."[24]

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[21] Gerritse et al., *supra* note 5, at 687.

[22] *More Research Is Urgently Needed into Transgender Care for Young People: "Where does the Large Increase of Children Come From?"*, Voorzij (Feb. 27, 2021), https://www.voorzij.nl/more-research-is-urgently-needed-into-transgender-care-for-young-people-where-does-the-large-increase-of-children-come-from/ (English translation of Dutch newspaper, original available here: https://www.ad.nl/nijmegen/drang-meer-onderzoek-nieuwe-naar-transgenderzorg-aan-jongeren-waar-komen-de-grote-stroom-kinderen-vandaan ~aec79d00/#:~:text=There%20is%20urgent%20more%20research,put%20by%20the%20long%20waiting lists).

[23] Florida Agency for Health Care Administration, Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria 14 (June 2022) [hereinafter Florida Medicaid Report], https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf (from report, description of comments from U.S. Senate Committee on Appropriations, 2022).

[24] Frieda Klotz, *The Fractious Evolution of Pediatric Transgender Medicine*, Undark.org (Apr. 6, 2022), https://undark.org/2022/04/06/the-evolution-of-pediatric-transgender-medicine/.

Dr. Johanna Olson-Kennedy leads The Trans Youth Research Network, a collaborative, multi-million-dollar research project involving four major gender clinics. The project is necessary, Olson-Kennedy wrote in 2019, because "there is a consensus gap about the best approach to the care of youth with gender dysphoria," and "lack of consensus among professionals around timing of initiation of medical interventions, as well as optimal dosing regimens."[25] After receiving over $7.7 million in federal grants, the project's renewal application in 2022 described a "scant evidence-base currently guiding the clinical care of [transgender/gender diverse] youth."[26] A 2022 funding request by several gender clinicians to research the impact of puberty blockers in minors admits that "[t]he overall impacts of [puberty suppression] have not been systematically studied.[27] A multi-year grant application from Stanford researchers sought to study the use of cross-sex hormones "in early pubertal adolescents," because clinicians need a "foundation for understanding the

[25] Johanna Olson-Kennedy et al., *Creating the Trans Youth Research Network: A Collaborative Research Endeavor*, 4 Transgender Health 304, 305 (2019), https://liebertpub.com/doi/full/10.1089/trgh.2019.0024.

[26] 2022 Renewal, The Impact of Early Medical Treatment in Transgender Youth, NIH Project No. 5R01HD082554-07, https://reporter.nih.gov/search/RiXZr_7vAECGmmm-c_pjIw/project-details/10401756#similar-Projects (multi-year, four-center study led by Dr. Johanna Olson-Kennedy received $7,748,467 to date).

[27] Eric Nelson et al., *The Impact of Pubertal Suppression on Adolescent Neural and Mental Health Trajectories* (2022), https://reporter.nih.gov/search/Xr4WhUWe906AqRywwpsXVA/project-details/10442698.

longitudinal impact of treatments that are *already being used* in clinical settings" (emphasis added).[28]

C. WPATH and Endocrine Society guidelines are not the standard of care.

The district court's conclusion that Parent Plaintiffs have a "fundamental right to treat their children with transitioning medications" gave undue weight to guidelines formulated by WPATH and uncritically endorsed by "major medical associations." DE112-1:4, 17, 18, 19, 24. Endorsements neither create a standard of care nor imply a fundamental right to access controversial medical treatments.

Plaintiffs and their *amici*, as well as gender clinicians, cite to and promote WPATH guidelines as a dispositive summary of the "professional consensus about the psychiatric, psychological, medical, and surgical management of gender dysphoria."[29] WPATH guidelines, however, state that its recommendations do not constitute "standards of care" and are merely "flexible clinical guidelines."[30] Indeed, the Centers for Medicare & Medicaid Services (CMS) cited the "flexibility"

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[28] David S. Hong et al., *Sex Hormone Effects on Neurodevelopment: Controlled Puberty in Transgender Adolescents* (2020), https://reporter.nih.gov/search/XPR7Y2lFAEC3glQp53hqPw/project-details/9940793.

[29] *Facts About Anti-Trans Youth Bills*, Fenway Health (2022), https://fenwayhealth.org/the-fenway-institute/health-policy/transyouthmatter/; *see also* Madeline B. Deutsch, *Overview of Gender-Affirming Procedures*, Univ. Cal. San Fran. Transgender Care (June 17, 2016), https://transcare.ucsf.edu/guidelines/overview.

[30] WPATH SOC7, *supra* note 11.

of WPATH's guidelines when it declined to endorse WPATH guidelines for Medicare coverage determinations.[31]

Moreover, WPATH guidelines lack the rigor and evidence base necessary to qualify as authoritative standards of care or clinical practice guidelines (CPGs).[32] According to a 2021 first-of-its-kind systematic analysis of international CPGs for "gender minority/trans health"[33] published in the British Medical Journal (BMJ), "WPATH SOCv7 *cannot* be considered 'gold standard'" (emphasis added).[34] None of the twelve international gender medicine guidelines assessed in the BMJ review met the rigorous standard for clinical practice guidelines (or standards of care), but

[31] CMS, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery, CAG–00446N (Aug. 30, 2016) [hereinafter "CMS Decision Memo"], https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282.

[32] Deutsch et al., *supra* note 20. Trustworthy CPGs "should be based on a systematic review of the existing evidence; be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups; consider important patient subgroups and patient preferences, as appropriate; be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest; provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations." Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Clinical Practice Guidelines We Can Trust 3 (Robin Graham et al. eds., 2011), https://www.ncbi.nlm.nih.gov/books/NBK209546/ (cleaned up).

[33] Sara Dahlen et al., *International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment*, 11 BMJ Open 1, 8 (2021), https://pubmed.ncbi.nlm.nih.gov/33926984/ (describing an overall "paucity" of "high quality" clinical guidance pertaining to gender dysphoria and transitioning treatments).

[34] *Id.* at 8.

WPATH guidelines were singled out for particularly strong criticism and fell far short of an authoritative standard of care.[35]

The Endocrine Society's guidelines are similarly inadequate. Like the WPATH "standards," the Endocrine Society guidelines rely on "low" and "very low" quality evidence and include a disclaimer stating that its "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care."[36]

No current guidelines for treating gender dysphoria qualify as an authoritative CPG or standard of care, and clinicians with diverse perspectives on transitioning treatments for minors recognize that no medical consensus exists. For example, in 2015, medical "proponents and opponents of early treatment (pediatric endocrinologists, psychologists, psychiatrists, ethicists) of 17 treatment teams worldwide"[37] convened to discuss ethical concerns surrounding the WPATH and Endocrine Society recommendations supporting medical transitioning for minors. The convening identified seven areas of debate regarding the controversial treatments and concluded that "as long as debate remains on these seven themes and only limited long-term data are available, there will be no consensus on treatment."[38]

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[35] *Id*. at 8 (referencing the "incoherence" of WPATH SOCv7).

[36] Hembree et al., *supra* note 15.

[37] Lieke Josephina Jeanne Johanna Vrouenraets et al., *Early Medical Treatment of Children and Adolescents with Gender Dysphoria: An Empirical Ethical Study*, 57 J. Adolesc. Health 367 (2015), https://pubmed.ncbi.nlm.nih.gov/26119518/.

[38] *Id.*

A 2020 study from the Mount Sinai Center for Transgender Medicine and Surgery, a leading center for transgender medical care, notes that WPATH guidelines "are often considered the standard of care for [transgender] people throughout the world," but characterizes them as a "barrier to care," "impractical," unclear, and detrimental to patient wellbeing.[39] Indeed, Mount Sinai eventually developed its own criteria for transitioning treatments—criteria that diverged significantly from WPATH guidelines, with less than ten percent of Mount Sinai patients meeting criteria for both WPATH and Mount Sinai assessments.[40]

Several circuit courts have recognized that WPATH guidelines do not reflect medical consensus. *See Gibson v. Collier*, 920 F.3d 212, 223 (5th Cir. 2019) (finding "WPATH Standards of Care do not reflect medical consensus"); *Doe v. Snyder*, 28 F.4th 103, 112 (9th Cir. 2022) (affirming district court's reliance on "expert testimony that WPATH's Standards of Care are not universally endorsed"); *Kosilek v. Spencer*, 774 F.3d 63, 88 (1st Cir. 2014) (en banc) (holding "[p]rudent medical professionals ... do reasonably differ in their opinions regarding [WPATH's] requirements"); *cf. Keohane v. Fla. Dep't of Corr. Sec'y*, 952 F.3d 1257, 1296 (11th Cir. 2020) (acknowledging district court and others have found

[39] Max Lichtenstein et al., *The Mount Sinai Patient-Centered Preoperative Criteria Meant to Optimize Outcomes Are Less of a Barrier to Care than WPATH SOC 7 Criteria Before Transgender-Specific Surgery*, 5 Transgender Health 166, 170 (2020), https://doi.org/10.1089/trgh.2019.0066.

[40] *Id.* at 170.

WPATH standards "authoritative for treating gender dysphoria in prison," without evaluating merits of WPATH standards); *Edmo v. Corizon, Inc*., 935 F.3d 757, 787, 788 & n.16 (9th Cir. 2019) (per curiam) (holding WPATH standards are the "established standards" for evaluations of the necessity of transitioning surgery and the "undisputed starting point in determining the appropriate treatment for gender dysphoric individuals"), *rehearing en banc denied*, 949 F.3d 489, 497 (9th Cir. 2020) (O'Scannlain, J., joined by Callahan, Bea, Ikuta, R. Nelson, Bade, Bress, Bumatay, and Vandyke, JJ., respecting denial of rehearing en banc) (rejecting panel's characterization because "WPATH Standards are merely criteria promulgated by a controversial private organization with a declared point of view").

Plaintiffs' *amici* fail to mention the shortcomings of WPATH and Endocrine Society guidelines and overstate the clinical impact of WPATH's guidelines, particularly the recommendation that a mental health provider diagnose the minor's gender dysphoria. In practice, the role of mental health providers varies widely, depending on the clinic. Seattle Children's Gender Clinic, for example, offers "brief mental health support" but no ongoing mental health therapy,[41] while other clinics, such as Boston Children's, conduct "comprehensive psychological and medical

[41] *Services We Provide: Brief Mental Health Support*, Seattle Children's Gender Clinic, https://www.seattlechildrens.org/clinics/gender-clinic/.

assessments."[42] Two veteran gender clinicians, Dr Erica Anderson and Dr. Laura Edwards-Leeper, have warned that some adolescents receive "sloppy care" from clinicians who start them on transitioning treatments with minimal psychological assessments.[43]

D. There is a suppression of evidence-based research and discourse.

Scientific inquiry is stunted when activists, clinicians, or medical associations attempt to silence or punish those who question medicalized transition, produce research that does not align with favored conclusions, or caution against rushing children into transitioning treatments without adequate psychological assessments. For example, Dr. Kenneth Zucker, a highly regarded researcher, clinician, and journal editor was de-platformed at several national transgender health conferences after activists denounced his caution regarding transitioning treatments for minors as "transphobic."[44] Zucker's emphasis on psychotherapy for minors was demonized as "conversion therapy" and his gender clinic shuttered.[45] (Zucker later

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[42] *Overview*, Gender Multispecialty Clinic (GeMS), Boston Children's Hospital, https://www.childrenshospital.org/programs/gender-multispecialty-service/your-visit.

[43] Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, Real Clear Politics, (Oct. 5, 2021), https://www.realclearpolitics.com/2021/10/05/top_trans_doctors_blow_the_whistle_on_sloppy_care_553290.html.

[44] Jesse Singal, *How the Fight Over Transgender Kids Got a Leading Sex Researcher Fired*, The Cut, *New York Magazine* (Feb. 7, 2016), https://www.thecut.com/2016/02/fight-over-trans-kids-got-a-researcher-fired.html.

[45] *Id.*

prevailed in a defamation claim against his former employer.[46]) Similarly, when Brown University physician-researcher Lisa Littman published a study describing how peers and social media might influence the onset of gender dysphoria in adolescent females (a phenomenon dubbed "rapid onset gender dysphoria"), activists sought to silence her and discredit her work. Her published study was withdrawn and subject to additional scrutiny before being republished; her research contract was not renewed.[47]

A recent *New York Times* article highlights growing divisions among gender clinicians over the appropriate care for adolescents seeking transitioning treatments.[48] Drs. Anderson and Edwards-Leeper are applauded by colleagues who share their concerns, but other clinicians deride their emphasis on pre-transition psychological assessments as "discriminatory" and "reek[ing] of some old kind of conversion-therapy-type things."[49]

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[46] *Id.*

[47] Jonathan Kay, *An Interview with Lisa Littman Who Coined the Term "Rapid Onset Gender Dysphoria,"* Quillette (Mar. 19, 2019), https://quillette.com/2019/03/19/an-interview-with-lisa-littman-who-coined-the-term-rapid-onset-gender-dysphoria/.

[48] Emily Bazelon, *The Battle Over Gender Therapy*, N.Y. Times Mag. (June 15, 2022), https://www.nytimes.com/2022/06/15/magazine/gender-therapy.html.

[49] *Id.* (quoting psychologist and physician Colt St. Amand).

The toxic climate that seeks to impose a false medical consensus regarding the appropriate standard of care for gender dysphoria or transitioning treatments impedes quality research and undermines sound clinical practice.

E. The lack of medical consensus is reflected internationally.

Many countries that initially embraced transitioning treatments, including for minors, are now reconsidering. For example, Sweden's National Board of Health and Welfare commissioned an extensive evidence review and concluded in 2022 "that the risks of anti-puberty and sex-confirming hormone treatment for those under 18 currently outweigh the possible benefits."[50] Finland likewise has reversed course. Following an extensive literature review, the Finish Health Authority issued new guidelines that prioritize psychotherapy as the first-line treatment for gender dysphoric minors.[51]

In the United Kingdom, whistleblower complaints exposed the inadequate psychological care for gender dysphoric minors at the National Health Service's

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[50] Support, Investigation and Hormone Treatment for Gender Incongruence in Children and Adolescents - Partial Update of Knowledge Support (2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf; *see also* Lisa Nainggolan, *Hormonal Tx of Youth with Gender Dysphoria Stops in Sweden*, Medscape (2021), https://www.medscape.com/viewarticle/950964.

[51] Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors (2020), *available at* https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf. COHERE Finland works in conjunction with the Ministry of Social Affairs and Health.

(NHS) gender clinic.[52] A landmark case against the NHS in 2020 by "de-transitioner" Keira Bell found that minors lacked capacity to consent to transitioning treatments that cause sterility and impair sexual function. The NHS initially suspended the use of puberty blockers and instituted new procedures to ensure better psychological care.[53] (The decision was later reversed on procedural grounds.)

Two separate evidence reviews assessing the impact of puberty suppressing drugs and cross-sex hormones to treat gender dysphoria were published in 2021 by the UK's National Institute for Health and Care Excellence (NICE). The NICE evidence review found little evidence of benefit and substantial risk of harm from "gender affirming" treatment in minors.[54] A 2022 independent review commissioned by NHS England (the "Cass report"), found that "[a]t present the professional community does not have a shared understanding about the meaning of gender dysphoria in young people," its cause, or best treatment approaches.[55] The

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[52] Lauren Lewis, *NHS's Only Gender Service for Children Believes All Girls Who Don't Like 'Pink Ribbons and Dollies' Must Be Transgender, Whistleblower Claims*, Daily Mail (Nov. 22, 2021), https://www.dailymail.co.uk/news/article-10231507/NHSs-gender-service-children-believes-girls-dont-like-pink-transgender.html.

[53] Becky McCall, *NHS Makes Child Gender Identity Service Changes After High Court Ruling*, Medscape (Dec. 4, 2020), https://www.medscape.com/viewarticle/941781.

[54] Nat'l Inst. for Health & Care Excellence, Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria (2021); Nat'l Inst. for Health & Care Excellence, Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria (2021) [hereinafter "NICE Evidence Review" collectively].

[55] Hilary Cass, *Review of Gender Identity Services for Children and Young People*, BMJ 376 (2022), https://www.bmj.com/content/376/bmj.o629.

report notes that "[m]uch of the research base is observational," with little "longer term follow up data," resulting in a "weak evidence base."[56]

Psychotherapists in Australia and New Zealand recently issued a new policy statement emphasizing mental health treatment for gender dysphoric minors, rather than "gender affirmation." They stressed the importance of assessing the "psychological state and context in which gender dysphoria has arisen," before any treatment decisions are made.[57] In February 2022, France's National Academy of Medicine warned medical professionals that the increase in young people seeking transitioning treatments may be due to social contagion and urged "great medical caution."[58]

F. The federal government has recognized the lack of medical consensus.

Despite the efforts under the current administration to push transitioning treatments for minors, the federal government has never formally determined that such treatments are the appropriate standard of care.

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[56] *Id*.

[57] Position Statement, The Royal Australian and New Zealand College of Psychiatrists, *Recognising and Addressing the Mental Health Needs of People Experiencing Gender Dysphoria/Gender Incongruence* (Aug. 2021), https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/gender-dysphoria.

[58] Press Release, French National Academy of Medicine, Medicine and Gender Transidentity in Children and Adolescents (Feb. 25, 2022), https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en.

As recently as June 2020, Department of Health and Human Services (HHS) regulations acknowledged that "there is no medical consensus to support one or another form of treatment for gender dysphoria." 85 Fed. Reg. 37160, 37198. The Department explained that prior HHS regulations regarding gender-transition surgeries "relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding," such as the CMS factfinding for its most recent National Coverage Determination. *Id*. After its factfinding, CMS declined to issue a National Coverage Determination on gender-transition surgeries for Medicare beneficiaries with gender dysphoria ''because the clinical evidence is inconclusive.''[59] ''Based on an extensive assessment of the clinical evidence,'' CMS determined that ''there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries [which include non-seniors] with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.''[60]

Similarly, a 2018 Department of Defense (DOD) report on gender dysphoria found that there is "considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related

[59] CMS Decision Memo, *supra* note 31.

[60] *Id.*

treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria."[61] Indeed, none of the drugs used to block puberty and induce cross-sex masculine or feminine features are approved as safe or effective for such uses by the U.S. Food and Drug Administration, and the National Institutes of Health only began investigating the long-tern outcomes of transitioning treatments for youth in 2015.[62]

G. State action reflects the lack of medical consensus.

State actions reflect the lack of medical consensus for the appropriate standard of care for gender dysphoria and transitioning interventions, especially for minors. For instance, several states in addition to Alabama have passed laws that prohibit providing minor children with transitioning treatments.[63] Other states have and are considering similar bills.

State executives also have weighed in on the issue. For example, in February 2022, the Texas Attorney General issued an opinion letter stating that sterilizing treatments and other permanent "sex-change procedures," including puberty

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[61] Dep't of Defense, Report and Recommendations on Military Service by Transgender Persons 5 (Feb. 22, 2018).

[62] *See* Juliana Bunim, First U.S. Study of Transgender Youth Funded by NIH, U.C. San Francisco (Aug. 17, 2015), https://perma.cc/URA6-CERX.

[63] *See, e.g.*, Ariz. S.B. 1138 (2022); Ark. H.B. 1570 (2021); Tenn. H.B. 0578 (2021).

suppression, cross-sex hormones, and various surgeries, "can constitute child abuse when performed on minor children."[64] Texas's governor subsequently directed the Texas Department of Family and Protective Services to "conduct a prompt and thorough investigation of any reported instances of these abusive procedures in the State of Texas."[65]

More recently, Florida's Department of Health issued guidelines in response to an HHS document promoting "gender-affirming care" for young people. Florida's DOH clarified that the treatment of gender dysphoria for children and adolescents should *not* include social gender transition, puberty blockers, cross-sex hormones, or transitioning surgeries because of "the lack of conclusive evidence, and the potential for long-term, irreversible effects."[66] The state Secretary of the Agency for Health Care Administration subsequently requested that the Florida Medicaid program review whether such treatments are "consistent with generally

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[64] Tex. Att'y Gen. Op. Letter No. KP-0401, from Ken Paxton, Attorney General, to Matt Krause, Chair, House Committee on General Investigating, Texas House of Representatives 1-2 (Feb. 18, 2022), https://www.texasattorneygeneral.gov/sites/default/files/opinion-files/opinion/2022/kp-0401.pdf.

[65] Letter from Greg Abbott, Governor, State of Texas, to Jaime Masters, Commissioner, Texas Department of Family and Protective Services (Feb. 22, 2022), https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf.

[66] Office of the State Surgeon Gen., Fla. Dep't of Health, Treatment of Gender Dysphoria for Children and Adolescents (Apr. 20, 2022), https://www.floridahealth.gov/_documents/newsroom/press-releases/2022/04/20220420-gender-dysphoria-guidance.pdf; *cf. Setting the Record Straight*, Florida Agency for Health Care Administration (2022), https://ahca.myflorida.com/LetKidsBeKids/page3.shtml ("detailing the lack of conclusive evidence in recent directives and 'fact sheets' issued by the US Department of Health and Human Services for the coverage of 'gender affirming' care, for children and adolescents").

accepted professional medical standards."[67] The report, published on June 2, 2022, found that transitioning interventions for the treatment of gender dysphoria "are not consistent with widely accepted professional medical standards and are experimental and investigational with the potential for harmful long term affects [sic]."[68]

II. Transitioning treatments can lead to serious harm, especially in minors.

The Alabama Legislature found, and both Plaintiffs and the district court acknowledged, that transitioning treatments can cause significant harms, "include[ing] loss of fertility and sexual function." DE112-1:3. Long-term outcomes for individuals who undergo transitioning treatments are not promising. Those who have had genital surgery are nineteen times more likely than the general population to die by suicide,[69] and studies show that transitioning treatments fail to reduce suicide risks and mental health issues in the long-term.[70]

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[67] Florida Medicaid Report, *supra* note 23, at 2.

[68] *Report Overview*, Florida Agency for Health Care Administration (2022), https://ahca.myflorida.com/letkidsbekids/.

[69] Cecilia Dhejne et al., *Long-term Follow-up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLoS ONE e16885 (2011), https://pubmed.ncbi.nlm.nih.gov/21364939/.

[70] Roberto D'Angelo et al., *One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria*, 50 Archives Sexual Behav. 7 (2020), https://doi.org/10.1007/s10508-020-01844-2; Chantel M. Wiepjes et al., *Trends in Suicide Death Risk in Transgender People: Results from the Amsterdam Cohort of Gender Dysphoria Study (1972-2017)*, 141 Acta Psychiatrica Scandinavica 486 (2020), https://doi.org/10.1111/acps.13164; *Correction to Bränström and Pachankis*, 177 Am. J. Psychiatry 734 (2020) (correcting Richard Bränström & John E. Pachankis, *Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study*, 177 Am. J. Psychiatry 727 (2020)).

Equally troubling, the number of children and adolescents diagnosed with gender dysphoria or identifying as "transgender" has risen dramatically over the past decade, becoming "an international phenomenon, observed across North America, Europe, Scandinavia, and elsewhere."[71] The typical patient profile has changed markedly. In the past, patients seeking treatment for gender dysphoria were usually either adult males or very young children, mostly male. Today, the typical patient is an adolescent, usually female.[72]

For years, gender dysphoria in children was addressed through "watchful waiting" or family therapy. About eighty-eight percent of the time, the child's gender dysphoria resolved naturally by puberty without transitioning interventions.[73] The "gender-affirming" approach changed that pattern dramatically, as most children affirmed in their transgender beliefs persist in those beliefs and are likely to pursue transitioning treatments that irreversibly modify their bodies—and lead to regret.[74]

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[71] Kenneth J. Zucker, *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*, 48 Archives Sexual Behav. 1983 (2019), https://pubmed.ncbi.nlm.nih.gov/31321594/.

[72] *Id*.

[73] Singh et al., *supra* note 6.

[74] Carmichael et al., *supra* note 13 (study by Tavistock and Portman NHS Gender Identity Development Service (UK) finding ninety-eight percent of adolescents who underwent puberty suppression continued on to cross-sex hormones); *see also* Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 Archives Sexual Behav. 3353 (2021), https://pubmed.ncbi.nlm.nih.gov/34665380/.

Clinical concerns over the outcomes of transitioning treatments have escalated.[75] Puberty blockers, originally described as safe and fully reversible, are known to have negative effects on bone density, social and emotional maturation, and other aspects of neuro-development.[76] They generally fail to lessen the child's gender dysphoria, and deliver mixed results for mental health.[77] Long term effects remain unknown.[78]

Nearly all children who begin puberty blockers go on to receive cross-sex hormones, the next step in transitioning, with life-altering consequences.[79] Blocking a child's natural puberty prevents maturation of genitals and reproductive organs; subsequently introducing cross-sex hormones renders the child permanently sterile.[80] Gender clinicians also admit that puberty suppression may impair the child's later sexual functioning as an adult.[81] These losses cannot be fully comprehended by a child, precluding the possibility of informed consent.

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[75] William Malone, *Puberty Blockers for Gender Dysphoria: The Science is Far from Settled*, 5 Lancet Child & Adolescent Health 33 (2021), https://pubmed.ncbi.nlm.nih.gov/34418372/.

[76] NICE Evidence Review, *supra* note 54.

[77] Carmichael et al., *supra* note 13.

[78] Diane Chen et al., *Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth*, 5 Transgender Health 246 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7759272/.

[79] *Id.*

[80] Stephen B. Levine, *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, 44 J. Sex & Marital Therapy 29 (2018), https://pubmed.ncbi.nlm.nih.gov/28332936/.

[81] Shrier, *supra* note 43.

Cross-sex hormones carry numerous health risks and cause significant irreversible changes in adolescents' bodies, including genital or vaginal atrophy, hair loss (or gain), voice changes, and impaired fertility.[82] They increase cardiovascular risks and cause liver and metabolic changes,[83] The flood of opposite sex hormones has variable emotional and psychological effects as well. Females taking testosterone experience an increase in gender dysphoria, particularly regarding their breasts, which heightens the likelihood they will undergo double mastectomies—as young as thirteen.[84] Far from an evidence-based standard of care, transitioning treatments for gender dysphoria amount to unethical human experimentation—on *children*. One Swedish teen who underwent medical transition, suffered serious bodily harm, and then de-transitioned describes gender-transitioning treatments for gender dysphoria in stark terms: "They're experimenting on young people ... we're

[82] Levine et al., *supra* note 14

[83] *Gender-Affirming Hormone in Children and Adolescents*, BJM EBM Spotlight (Feb. 25, 2019), https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/.

[84] Johanna Olson-Kennedy et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 431 (2018), https://pubmed.ncbi.nlm.nih.gov/29507933/ (Figure: Age at Chest Surgery in the Post-surgical Cohort).

guinea pigs."[85] Or, as psychotherapist Alison Clayton warns, this is nothing less than "dangerous medicine."[86]

* * *

The Alabama legislature's evidence-based findings determined that transitioning treatments are harmful to minors and unsupported by medical consensus, and that the risks outweigh any proven benefits. In order to protect Alabama's compelling interest in protecting minors from harm, the legislature prohibited transitioning treatments for minors. The district court's injunction, which disregards the legislature's findings in favor of the eminence-based "standard of care" preferred by plaintiffs, unconstitutionally prevents Alabama from acting on its compelling interest to protect children.

Without reversal, Alabama is unable to protect children from dangerous, unproven treatments that threaten permanent bodily harm and sterilization.

CONCLUSION

The Court should reverse the district court's preliminary injunction.

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[85] Video, Mission: Investigate: Trans Children ("Trans Train 4") (Nov. 26, 2021), https://www.svtplay.se/video/33358590/uppdrag-granskning/mission-investigate-trans-children-avsnitt-1.

[86] Alison Clayton, *The Gender Affirmative Treatment Model for Youth with Gender Dysphoria: A Medical Advance or Dangerous Medicine?*, 51 Archives Sexual Behav. 691 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8888500/.

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CERTIFICATE OF COMPLIANCE

1. I certify that this brief complies with the type-volume limitations set forth in Fed. R. App. P. 29(a)(5). This brief contains 6,377 words, including all headings, footnotes, and quotations, and excluding the parts of the response exempted under Fed. R. App. P. 32(f) and 11 Cir. Rule 32-4.

2. In addition, this response complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Mac version 16.61 in 14-point Times New Roman font.

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I certify that on July 5, 2022, I electronically filed this document using the Court's CM/ECF system, which will serve all counsel of record.

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