

No. 26-180

In the Supreme Court of the United States

EDWARD ALLYN HUDACKO,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF CALIFORNIA,
ET AL.,
Respondents.

*On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit*

**BRIEF OF DR. LEOR SAPIR
AS AMICUS CURIAE
IN SUPPORT OF PETITIONER**

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QUESTIONS PRESENTED

1. Whether judicial decisions are the only valid source of clearly established law (the approach of the Fifth, Seventh, Ninth, Tenth, and D.C. Circuits); or whether other sources of law or non-legal materials, like professional knowledge, may also be examined (as in the First, Second, Third, Fourth, Sixth, Eighth, and Eleventh Circuits)?
2. Whether the same clearly-established-law test applies to all government officials, or whether as a threshold question courts should determine “whether immunity was historically accorded the relevant official in an analogous situation at common law,” as this Court used to ask in qualified immunity cases and still does for absolute immunity. *Baxter v. Bracey*, 590 U.S. 1011, 1014 (2020) (Thomas, J., dissenting).

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INTEREST OF *AMICUS CURIAE*¹

Leor Sapir, Ph.D., is a senior fellow at Manhattan Institute who researches the medical evidence for pediatric gender transition and its implications for public policy. His scholarship has appeared in many publications, including *Archives of Sexual Behavior*. He coauthored the U.S. Department of Health and Human Services review on pediatric gender dysphoria. *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (2025).

Dr. Sapir submits this brief to provide context on the state of the evidence for, and the ethics of, pediatric medical interventions relevant to this case, drawing on that review.

SUMMARY OF ARGUMENT

This case concerns the question of whether government-employed medical professionals are entitled to qualified immunity after performing a procedure on a minor without the parental consent required by a court order. Underlying this question, however, is one of greater significance: Are such treatments ever in a minor's best interest, and can they reasonably be considered "healthcare"? The best available evidence suggests that the answer is no.

On November 19, 2025, the U.S. Department of Health and Human Services published the final, peer-

¹ Rule 37 statement: All parties were timely notified of the filing of this brief. No part of this brief was authored by any party's counsel. No person or entity other than the Manhattan Institute (MI), which employs Dr. Sapir, funded its preparation or submission. MI, alongside the Independent Women's Law Center, previously filed a brief in this case, in which one counsel here (Shapiro) participated. Dr. Sapir had no role in that brief.

reviewed version of its review of evidence and best practices for the treatment of pediatric gender dysphoria. U.S. Dep’t of Health & Hum. Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (2025) (“HHS Final Review”). The HHS Final Review’s central conclusion—that pediatric medical transition (“PMT”) is unsupported by evidence—is neither new nor controversial. It is what health authorities in Sweden, Finland, Denmark, Norway, the United Kingdom, and other countries have concluded following multiple systematic reviews of evidence—the gold standard in evidence-based medicine. The Review underscored the extraordinarily weak evidentiary foundation for such medical interventions: “The evidence for benefit of pediatric medical transition is very uncertain, while the evidence for harm is less uncertain.” HHS Final Review at 15.

PMT cannot be defended on the ground that much of pediatric medicine rests on similarly weak evidence. Even the practice’s most committed advocates no longer seriously dispute that its benefits lack support from quality research. *See, e.g.*, Meredith McNamara & Ian D. Wolfe, *Uncertainty and Ethical Permissibility in Youth Gender Care*, JAMA Pediatrics, Aug. 3, 2026, at E1 (showing that two of the leading academic proponents of PMT admit: “Youth [gender-affirming care] is typical in involving low-certainty evidence . . .”). But unlike ordinary pediatric care, PMT is unusual in offering minors with no physical pathology interventions with an unfavorable risk-benefit profile, based on a subjective diagnosis with poor predictive validity.

Analogies to other cases of low-quality evidence pediatric medicine fail for these reasons. The uncertainty of benefit and severe side effects of treatments in those

cases are accepted because alternatives (including watchful waiting) are almost certain to result in far worse outcomes, including death. For PMT, decades of research have failed to show evidence of benefits outweighing known and anticipated risks (*e.g.*, sterility).

Nor can consent make up for these shortcomings. Pediatric candidates for these interventions are too young to grasp their potentially lifelong consequences. Even proponents acknowledge that minors cannot meaningfully deliberate about future fertility, for example. Clinicians, moreover, often understate the uncertainty of the evidence while overstating the risks of forgoing medical treatment.

At base, the question consent becomes relevant only after an intervention is shown to be ethically permissible, meaning that its benefits justify its risks for a given condition. Patient autonomy is the right to refuse treatment, not the right to demand nonbeneficial interventions based on personal preferences. This principle applies with greater force in pediatrics.

Where harms are serious and potentially irreversible, the natural course of the condition is poorly understood, and less invasive alternatives exist, medical ethics require a cautionary approach. That conclusion should inform the judicial application of qualified immunity, so this case deserves the Court’s review.

ARGUMENT

I. THE BEST AVAILABLE EVIDENCE DOES NOT SHOW THAT “GENDER-AFFIRMING” MEDICAL TREATMENTS ARE IN A MINOR’S BEST INTERESTS

In *United States v. Skrametti*, this Court acknowledged “fierce scientific and policy debates about the

safety, efficacy, and propriety of medical treatments in an evolving field.” 605 U.S. at 525. It noted that “health authorities in a number of European countries have raised significant concerns regarding the potential harms associated with using puberty blockers and hormones to treat transgender minors,” *id.* at 505, and that “leading voices in this area have relied on questionable evidence, and have allowed ideology to influence their medical guidance,” *id.* at 530.

Crucially, the World Professional Association for Transgender Health (WPATH), whose recommendations (called “standards of care”) have been widely adopted in U.S. healthcare settings, advocates for patient-led “gender-affirming” approach. WPATH recently changed its legal posture, however, accepting this Court’s description of the science as unsettled. To wit, WPATH now characterizes its own recommendations as “opinions about subjects on which there is ‘medical and scientific uncertainty.’” Defendant’s Memorandum in Support of Its Motion to Dismiss at 1, *FTC v. World Prof’l Ass’n for Transgender Health, Inc.*, No. 4:26-cv-00748-O (N.D. Tex. July 28, 2026) (quoting *Skrmetti*, 605 U.S. at 524).

The HHS Final Review (which *amicus* co-authored) addresses critical gaps in nationally commissioned reviews on medical treatments for pediatric gender dysphoria, including harms, medical ethics, and psychotherapeutic alternatives. It discusses clinical realities, focusing on the systematic dismantling of medical safeguards in this area, and it highlights problems of scientific validity related to core concepts of the field.

A. An “Umbrella” Review of Reviews

Decision-making in medicine should be based on “the best available evidence, which ideally will come from systematic summaries of that evidence.” HHS Final Review at 82. Systematic reviews (“SRs”) sit at the top of evidence-based medicine’s hierarchy of evidence because they critically evaluate all available evidence for outcomes of interest using a transparent and reproducible methodology. Numerous systematic reviews had already been done on pediatric medical transition. For this reason, the authors of the HHS Final Review conducted an “umbrella review,” a review that “applies the methodology of SRs to SRs themselves, making the SRs the unit of analysis, rather than individual primary studies.” *Id.* at 83.

The umbrella review identified 17 systematic reviews dealing with puberty blockers, cross-sex hormones, surgeries, social transition, and psychotherapy for individuals up to age 26. Applying the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology, the review distinguished the lower quality systematic reviews from the higher quality ones and confirmed that “the quality of evidence for outcomes such as GD [gender dysphoria], mental health, quality of life, and regret remains very low across all intervention types.” *Id.* at 95.

B. The Limitations of Systematic Reviews Regarding Harms

Systematic reviews have limitations. One is that they are better at assessing evidence for benefits than for harm. In pediatric medical transition (“PMT”), three additional factors hamper harm-detection through systematic reviews.

First, PMT is a relatively new practice. Most minors who received PMT did so in the last ten years or so, limiting the ability to conduct longitudinal studies that can detect harms.

Second, and related, the body of primary research consists exclusively of low-quality observational studies, typically with short-term follow-up. Especially in the United States, these studies are largely conducted by gender clinicians who believe in the practice and may have intellectual or other conflicts of interest. Unsurprisingly, there has been a strong emphasis on studying benefits while harms are rarely studied or fully reported.

Third, the field of PMT research is affected by publication bias. This refers to the phenomenon in which studies with null or negative findings (especially when they weaken the original hypothesis) go unpublished. Publication bias in gender medicine is well documented. For instance, the lead investigator of the best-funded research on PMT in the United States told the *New York Times* that she refused to publish disappointing findings on mental health outcomes from pubertal suppression because she was afraid the results might be “weaponized” by critics. Azeen Ghorayshi, *U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says*, N.Y. Times, Oct. 23, 2024, <https://bit.ly/3ZpLCFv>.

Perhaps related to the lack of interest in researching the harms of PMT is the common assertion that the safety profile of puberty blockers is already known based on decades of their use as a treatment for central precocious puberty (“CPP”). Such claims are specious, however, as CPP is a different indication with a different—and better-understood—risk-benefit profile. *See*,

e.g., HHS Final Review at 115–17. Puberty blockers are used in CPP to delay abnormally timed puberty to its developmentally appropriate time, not to block normal puberty and try to simulate it with exogenous hormone regimens. *Id.*

The lack of evidence for harms in systematic reviews thus creates a mistaken impression that there may be none. But absence of evidence is not evidence of absence. Evidence-based medicine calls for the judicious use of the best *available* evidence in clinical decision-making. *See id.* at 113. Ideally, this evidence comes from systematic reviews, but the scenario described above demands a more careful analysis of expected or plausible harms. To that end, the HHS Final Review draws on evidence from basic science, human development, and pharmacology.

1. Puberty and Its Suppression

Puberty is the time during which sexual maturation occurs. For males in particular, arresting puberty in accordance with the Dutch Protocol (Tanner stage 2) is assumed to result in permanent infertility as gonadal maturation and spermatogenesis will not have occurred. Michael Biggs, *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, 49 J. Sex & Marital Therapy 348, 351–53 (2023). Impacts on females are less certain, but long-term fertility risks are possible. Sexual dysfunction (impaired desire, arousal, and orgasm) is another expected harm. HHS Final Review at 121–22. In 2021, Marci Bowers, then president-elect of WPATH, reported that boys whose puberty was blocked at Tanner stage 2 (which starts as early as age 9) and who subsequently received cross-sex hormones were anorgasmic. *Id.* at 122.

It goes without saying that children at this age cannot possibly grasp the implications of forgoing fertility and sexual function for their overall well-being. As a WPATH physician observed, “it’s always a good theory that you talk about fertility preservation with a 14-year-old, but I know I’m talking to a blank wall . . . they’d be like, ew, kids, babies, gross.” *Id.* at 164–65.

Puberty is also responsible for other critical aspects of human development. Because sex steroid hormones are necessary for bone density accrual, puberty suppression increases the risk of osteopenia, osteoporosis, and fractures of the spine and hip. *Id.* at 117–18. These can lead, in turn, to increased risks of morbidity and mortality. Most children who receive puberty blockers for gender dysphoria go on to cross-sex hormones, which, research suggests, compensate for some, but not all, of the loss of bone density accrual. *Id.* at 118. There are no studies on bone health that follow PMT patients into mature adulthood. *Id.*

2. Cross-Sex Hormones

Cross-sex hormones are used in PMT to induce sex characteristics typical of the opposite sex (*e.g.*, facial hair and thickening of vocal cords in females, breast tissue growth and fat redistribution in males). *Id.* at 123. Hormones are typically administered at supraphysiologic doses to achieve desired cosmetic goals. *Id.* at 124. For example, a guideline by the Endocrine Society recommends administering testosterone to females at six to 100 times the normal reference range for their sex, resulting in hyperandrogenism (high levels of male sex hormones), and estrogen to males at three to 25 times the normal reference range for males, resulting in hyperestrogenemia (high levels of female sex hormones). *Id.* at 124–25.

Risks of gender transition-related testosterone use in females include reproductive-tract cancer, cardiovascular and metabolic disease (including heart attacks and strokes), chronic endometriosis (sometimes “treated” with hysterectomy), vaginal atrophy, pelvic pain, and pelvic floor dysfunction. *Id.* at 125–26. One reported case involved an adolescent female on testosterone who suffered serious bleeding due to vaginal tearing following sexual intercourse. *Id.* at 125 n.64. The patient’s profuse bleeding required emergency surgery. Estrogen use in males is linked to increased risk of cardiovascular and metabolic harms (venous thromboembolism and stroke), thyroid and breast cancers, and sexual dysfunction. *Id.* at 126. More research is needed to understand these risks.

II. PEDIATRIC MEDICAL TRANSITION IS INCONSISTENT WITH WIDELY ACCEPTED PRINCIPLES OF MEDICAL ETHICS

The fact that the benefits of PMT are unsupported by quality research is no longer seriously in dispute; even its most committed medical advocates have accepted this finding. *See, e.g., id.* at 79. Advocates have instead shifted to another argument: “most pediatric healthcare is guided by evidence of similar quality and strength.” G. Nic Rider et al., *Scientific Integrity and Pediatric Gender Healthcare: Disputing the HHS Review*, Sexuality Rsch. & Soc. Pol’y 1, 3 (2025). This argument, too, is false. *See, e.g.,* HHS Final Review at 113–19 (Appendix 4). But PMT remains a unique medical practice in that it offers vulnerable minors with no physical pathology medical interventions with an unfavorable risk-benefit profile based on a subjective diagnosis with poor predictive validity and despite the existence of safer alternatives.

Proponents of PMT argue that adolescents and their parents routinely consent to risky medical interventions that carry foreseeable, life-altering consequences. *Id.* at 221. Adolescents and their parents, for example, may consent to aggressive chemotherapy for cancer, despite severe side effects, or to the amputation of a diseased limb. *Id.* In such cases, consent is granted because the intervention is necessary to preserve the patient's overall health, even if it carries serious adverse effects.

Moreover, clinicians often fail to disclose the uncertainty of the evidence supporting medical benefit, while overstating the harms of non-medicalization. They frequently use euphemistic and morally loaded language that may mislead or unduly influence patients and parents. *Id.* at 221–22. Such circumstances cast doubt on the possibility of genuine informed consent even if a consent-based framework is deemed appropriate. Before consent becomes relevant, a proposed intervention must be ethically permissible, insofar as it offers benefits sufficient to justify the risks, given the condition being treated. *Id.* at 222. Accordingly, the ethical probity of an intervention necessarily precedes consent.

Respect for patient autonomy means the right of patients to refuse treatment. It does not authorize medical professionals to offer unnecessary or harmful interventions when patients request such interventions. *Id.* Indeed, clinicians bear a fundamental ethical obligation to promote patient well-being. *Id.* at 222–23. Autonomy is one ethical principle among four—the others being non-maleficence, beneficence, and justice. *Id.* at 223–24.

That principle applies with greater force in pediatrics, given children's lack of full decision-making capacity. Pediatric clinicians have legal and ethical duties to provide care that promotes the child's well-being, and parents or other legal caregivers are guided by the same standard. *Id.* at 225.

Clinicians' obligation to avoid serious, irreversible harm justifies a precautionary approach, particularly where the natural course of the condition is poorly understood and less invasive alternatives exist. *Id.* at 230–31. Unlike many off-label uses in pediatrics, medical transition lacks a favorable risk-benefit profile and reliable evidence of benefit, and involves interventions that carry foreseeable and potentially irreversible harms. *Id.* at 231. Thus, any justification for PMT must rest on a credible showing that the intervention offers benefits sufficient to justify its known and anticipated risks. For the reasons stated above, PMT has failed to make this showing. *See also* HHS Final Review at 226–31.

CONCLUSION

This case raises important issues of how courts should treat scientific evidence with respect to qualified immunity. The petition should be granted.

Respectfully submitted,

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