Submitted Electronically

Federal Trade Commission 600 Pennsylvania Avenue, NW Washington, DC 20580

Re: FTC-2025-0264, Request for Public Comment Regarding "Gender-Affirming Care" for Minors

To Whom It May Concern:

We appreciate the opportunity to respond to the FTC's request for public comment regarding so-called "gender-affirming care" for minors. Do No Harm is a diverse group of over 37,000 physicians, healthcare professionals, medical students, patients, and policymakers whose goal is to protect healthcare from a radical, divisive, and discriminatory ideology. Basing its name on the ethical underpinnings of the Hippocratic Oath, Do No Harm is committed to ensuring that the practice of medicine is driven by scientific evidence rather than ideology. In recent years, the practice of biology-denying interventions, euphemistically known as "gender-affirming care," has become more common despite the serious harm caused by those medical interventions and the complete lack of reliable evidence for any benefit resulting from them. Do No Harm has developed a database demonstrating that nearly 14,000 minors were subject to biology-denying interventions in the United States between 2019 and 2023. *See* Press Release, Do No Harm, Do No Harm Launches First National Database Exposing the Child Trans Industry (Oct. 8, 2024), https://perma.cc/JW24-3J6V.

One possible explanation for these shocking numbers is the insistence that these interventions are safe and effective by people who should know better. Those statements are false or, at the very least, misleading. And they have been put forth by practitioners and proponents of biology-denying interventions for years. Do No Harm takes this opportunity to highlight five of the biggest myths surrounding these interventions: (1) "gender-affirming care reduces the risk of suicide"; (2) "gender-affirming care is proven to be effective"; (3) "gender-affirming care is safe"; (4) "puberty blockers are reversible"; and (5) "rates of regret are low." As demonstrated below, the scientific evidence wholly undermines these false or misleading assertions. Do No Harm is hopeful that this information will assist the FTC in protecting minors throughout the country from these dangerous and unproven interventions.

I. Myth No. 1: "Gender-Affirming Care Reduces the Risk of Suicide."

The "suicide myth" has been one of the most grossly irresponsible misleading assertions surrounding the use of biology-denying interventions. Some doctors blinded by gender ideology have even asked parents with minors suffering from gender dysphoria, "Would you rather have a dead daughter or a live son?" *See* Joint App. in *United States v. Skrmetti*, No. 23-477 (U.S.), p. 905 ("*Skrmetti* J.A.") (quotations omitted). Separately, medical interest groups—including the American Academy of Pediatrics, the American Medical Association, and the American Psychiatric Association—have told *courts* that denial of these interventions "materially heightens

the risk of . . . suicide." See Br. of Amici Curiae Am. Acad. of Pediatrics et al. in Supp. of Plaintiffs at 2, ECF No. 30, Brandt v. Rutledge, No. 4:21-cv-450 (E.D. Ark. June 24, 2021) ("AAP Amicus Br.").

This emotional blackmail is completely unsupported by the evidence. As admitted by a researcher for WPATH (one of the organizations that signed on to the previously cited amicus brief): "There is insufficient evidence to draw a conclusion about the effect of hormone therapy on death by suicide among transgender people." Kellan E. Baker et al., *Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review,* 5 J. ENDOCRINE SOCIETY. 1, 13 tbl.6 (2021); *id.* at 12 ("It was impossible to draw conclusions about the effects of hormone therapy on death by suicide."). And just last year, the ACLU's Co-Director of the LGBT & HIV Project made a similar admission to the Supreme Court. Transcript of Oral Argument at 88:16–18, *United States v. Skrmetti*, 145 S. Ct. 1816 (2024) (No. 23-477) ("There is no evidence . . . in the studies that this treatment reduces completed suicide."). And in what is likely the most controlled environment that is currently feasible, a researcher in the U.K. concluded that there was no evidence of a rise in suicides after the country's health service had restricted the use of puberty blockers as a treatment for gender dysphoria. See Puberty Blocker Curb Has Not Led to Suicide Rise—Review, BBC (July 20, 2024), https://perma.cc/XRX8-4953.

Thus, "[t]he evidence does not adequately support the claim that gender-affirming treatment reduces suicide risk." *United States v. Skrmetti*, 145 S. Ct. 1816, 1845 (2025) (Thomas, J., concurring) (quoting Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report*, The Cass Rev. (2024), https://perma.cc/V9HV-MFJA ("Cass Review")). Practitioners who have said otherwise have misled their patients—vulnerable young children suffering from severe psychological distress—which has resulted in devastating consequences for families around the country.

II. Myth No. 2: "Gender-Affirming Care Is Proven To Be Effective."

Major medical interest groups in the United States have repeatedly asserted that biology-denying interventions are proven to be effective. For example, medical organizations have said that a "robust body of scientific evidence supports the efficacy" of biology-denying interventions. AAP Amicus Br., *supra*, at 12. That assertion and others like it are misleading at best.

Several entities and institutions have conducted systematic reviews to assess the evidence underlying the use of puberty blockers and cross-sex hormones as a treatment for minors with gender dysphoria. "A systematic review is a summary of research that addresses a focused clinical question in a systematic, reproducible manner." GORDON GUYATT, ET AL., USERS' GUIDES TO THE MEDICAL LITERATURE 272 (3d ed. 2015). Essentially, a systematic review is a "study of studies" that provides a look at *all* the evidence on a particular question. And it is well recognized that the principles of evidence-based medicine place "systematic reviews" at the top of the hierarchy of medical evidence. *See id.* at 15; *see also Cass Review* at 55. All systematic reviews performed on this topic have concluded that the evidence underlying medical interventions for gender dysphoria in minors is weak; zero have come out the other way.

<u>Finland</u>. The first systematic review came in 2019 when Finland's Ministry of Social Affairs and Health completed its review of the medical evidence. *See Skrmetti J.A.* at 331. In light of this evidence review, Finland's healthcare authority concluded that "gender reassignment of minors is an experimental practice." *See id.* at 583-84. This conclusion was based on the fact that "[t]he reliability of the existing studies" is "highly uncertain." *Id.* at 583.

The Cass Review Interim Report. Next, in 2020, the United Kingdom's National Institute for Health and Care Excellence (NICE) completed its review of the evidence for using puberty blockers and cross-sex hormones on minors with gender dysphoria to aid the Cass Review, an independent review commissioned by the United Kingdom's National Health Service. See Id. at 364. The result was two separate systematic reviews—one for puberty blockers and one for cross-sex hormones. See id. at 364-66. The review of puberty blockers concluded that the relevant studies were "all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty." See Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria, NAT'L INST. HEALTH & CARE EXCELLENCE 13 (Oct. 2020), https://bit.ly/3NnivfV. Similarly, in the review of cross-sex hormones, the reviewers concluded that the relevant studies were "uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty." See Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria, NAT'L INST. HEALTH & CARE EXCELLENCE 13 (Oct. 2020), https://bit.ly/3YnzzZH.

The State of Florida. In 2022, researchers at McMaster University completed a systematic review at the request of the Florida Agency for Health Care Administration. *Skrmetti* J.A. at 361-62. They also found that the evidence supporting these interventions was weak. "Due to the important limitations in the body of evidence," they concluded, "there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria." *Id.* at 362 (quoting Romina Brignardello Petersen & Wojtek Wiercioch, *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence* 5 (May 16, 2022), https://bit.ly/4dE7ZM9).

Sweden. In 2023, Swedish researchers published a systematic review that was commissioned by Sweden's Agency for Health Technology and Assessment of Social Services. Skrmetti J.A. at 338. The review concluded that the "[e]vidence to assess the effects of hormone treatment" on (among other things) "mental health" in minors "with gender dysphoria is insufficient." Id. at 280-82 (providing Jonas F. Ludvigsson et al., A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and Recommendations for Research, 112 ACTA PAEDIATRICA 2279, 2280 (2023)). Specifically, it noted that "[l]ong-term effects of hormone therapy on psychosocial health are unknown," and using puberty blockers to treat gender dysphoria "should be considered experimental treatment." See id. at 283; see also id. at 338.

The Cass Review Final Report. Most recently, researchers from York University published a series of systematic reviews as part of the Cass Review. The York University researchers conducted systematic reviews of the evidence for both puberty blockers and cross-sex hormones. See generally Jo Taylor et al., Interventions To Suppress Puberty in Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review, ARCHIVES DISEASE CHILDHOOD (2024), https://bit.ly/402E7WC ("Taylor – Puberty Blockers"); Jo Taylor et al., Masculinising and

Feminising Hormone Interventions for Adolescents Experiencing Gender Dysphoria or Incongruence: Systematic Review, ARCHIVES DISEASE CHILDHOOD (2024),Ahttps://bit.ly/4dE9Pws ("Taylor – Cross-Sex Hormones"). In their review of puberty blockers, the researchers concluded that their "findings add to other systematic reviews in concluding there is insufficient and/or inconsistent evidence about the effects of puberty suppression on gender dysphoria, body satisfaction, psychological and psychosocial health, cognitive development, cardiometabolic risk and fertility." Taylor – Puberty Blockers at 12. Similarly, in their review for cross-sex hormones, the researchers concluded that their "findings add to other systematic reviews in concluding there is insufficient and/or inconsistent evidence about the risks and benefits of hormone interventions in this population." Taylor – Cross-Sex Hormones at 6.

In sum, all these systematic reviews concluded the same thing: There is no reliable evidence suggesting that biology-denying interventions are effective. Accordingly, "public health authorities in different countries have concluded that these sex-transition treatments are experimental in practice, and that the evidence supporting their use is of 'very low certainty,' 'insufficient,' and 'inconclusive.'" *Skrmetti*, 145 S. Ct. at 1844 (Thomas, J., concurring) (internal quotations omitted). Therefore, when medical providers say that "gender-affirming care" is proven to be effective, they are misleading their patients.

III. Myth No. 3: "Gender-Affirming Care Is Safe."

Proponents of biology-denying interventions also frequently assert "that puberty-delaying medication and hormone therapy for adolescents with gender dysphoria are safe[.]" Br. of Resp. in Supp. of Pet. at 2, *United States v. Skrmetti*, 145 S. Ct. 1816 (2025) (No. 23-477) ("ACLU Br."). Again, the evidence demonstrates that this statement is false and misleading.

To start, hormones developed during a person's natural (or "endogenous") puberty "drive important stages of neural development." *Skrmetti* J.A. at 430. There has been very limited research on the long-term effect of puberty blockers on neurodevelopment. *Id.* at 431-32. Thus, there is "concern" that suppressing the natural hormones that "trigger the opening of a critical period" for the "rewiring of neural circuits underlying executive function" could stunt "maturation of the part of the brain concerned with planning, decision making and judgment." *Id.* at 430-31 (internal quotation marks omitted). Pubertal suppression also leads to diminished growth in bone density. *Id.* at 433-34. And the "long-term effects of the deficient bone growth of people who undergo hormonal interventions at puberty remain unstudied." *Id.* at 434. In sum, the "use of drugs to suppress normal puberty has multiple organ system effects whose long-term consequences have not been investigated." *Skrmetti*, 145 S. Ct. at 1842 (Thomas, J., concurring) (internal quotations omitted).

The use of cross-sex hormones implicates "increased cardiovascular risk, osteoporosis, and hormone-dependent cancers." *Skrmetti* J.A. at 436 (internal quotations omitted). More specifically, giving testosterone to a girl as part of a gender transition leads to "increase[d] risk of heart disease and diabetes." *Id.* at 500-01; *see also* STANLEY GOLDFARB, DOING GREAT HARM 190-91 (2025) (noting studies showing increased risk of "pelvic floor dysfunction" and "urinary incontinence"); *Skrmetti*, 145 S. Ct. at 1842 (Thomas, J., concurring) (noting that testosterone "can cause increased cardiovascular risk, irreversible changes to the vocal cords, clitoromegaly and atrophy of the lining

of the uterus and vagina, as well as ovarian and breast cancer" (internal quotations omitted)). And giving estrogen to a boy as part of a gender transition includes risk of "stroke, elevated blood pressure, and changes to bone development." *Skrmetti* J.A. at 501; *see also Skrmetti*, 145 S. Ct. at 1842-43 (Thomas, J., concurring) (noting that estrogen "can produce similarly severe side effects [as testosterone] including, among other things, increased cardiovascular risk, breast cancer, and sexual dysfunction" (internal quotations omitted)).

Finally, adolescents who proceed from pubertal suppression to cross-sex hormones will be infertile. "The decision to undergo medicalized transition" thus "also represents the decision never to have biological children of one's own." *Id.* at 429. A drug that sterilizes a child cannot reasonably be called "safe." Thus, the evidence shows that the assertion that biology-denying interventions are "safe" is also false or misleading.

IV. Myth No. 4: "Puberty Blockers Are Reversible."

The next myth is that "the effects of puberty-delaying medication . . . are reversible." ACLU Br. at 44. This assertion also comes in the form of suggesting that pubertal suppression is like "a pause button." *Skrmetti* J.A. at 437. This, too, is false or misleading.

As an initial matter, as discussed above, the effect of pubertal suppression on neurodevelopment is wholly unknown. That fact alone forecloses any contention that the effects of pubertal suppression "are reversible." Given the "lack of knowledge" regarding this issue and others, it is "irresponsible to assert that this use of puberty blockers is 'fully reversible' and 'just a pause." *Skrmetti* J.A. at 438.

Moreover, evidence suggests that puberty blockers may have an iatrogenic effect that makes it more likely that a child continues to hormones and surgeries. Hillary Cass, *Letter to John Stewart: Independent Review of Gender Identity Services for Children and Young People—Further Advice*, NHS ENGLAND: THE CASS REVIEW (Jul. 19, 2022), https://tinyurl.com/mszjbrm7; *see also* Leor Sapir, *The School-to-Clinic Pipeline*, CITY J. (2022), https://tinyurl.com/y2hakf4z. Indeed, research shows that the vast majority of children (96%-98%) who start puberty blockers continue on to use cross-sex hormones. Michael Biggs, *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, J. Of Sex & Marital Therapy 1, 11-12 (Sept. 19, 2022), https://bit.ly/3Kgax6p; *see also Skrmetti*, 145 S. Ct. at 1842 n.4 (Thomas, J. concurring). And "given that the vast majority of young people started on puberty blockers proceed from puberty blockers to masculinizing/feminizing hormones," there is reason to think puberty blockers "may change the trajectory of psychosexual and gender identity development." Cass Review at 32. For example, children who undergo pubertal suppression "have lost the opportunity and experience of developing with their peers and must instead do so alone." *Skrmetti* J.A. at 439. This can worsen a child's gender dysphoria.

Thus, far from a reversible "pause" button, "puberty blockers appear to act as a psychosocial 'switch,' decisively shifting many children to a persistent transgender identity." *Id.* at 660. In addition, "despite widespread assertions that puberty blockers are 'fully reversible,' it is unclear whether patients ever develop normal levels of fertility if puberty blockers are terminated after a prolonged delay of puberty." *Skrmetti*, 145 S. Ct. at 1842 (Thomas, J., concurring) (cleaned

up). It is thus grossly misleading to tell parents and adolescents that puberty blockers are "reversible."

V. Myth No. 5: "Rates of Regret Are Low."

Finally, another common myth is that "[r]ates of . . . regret following gender-affirming care among adolescents are extremely low." AAP Amicus Br. at 13 n.50. This myth is used in an attempt to downplay or minimize the existence of detransitioners—those who have undergone biology-denying interventions only to later regret receiving these drugs or surgeries and thus resume identifying as their natal sex. *See Skrmetti*, 145 S. Ct. at 1846 (Thomas, J. concurring). The suggestion that rates of regret or detransition are "low" is misleading.

Indeed, one study startlingly suggests that the rate could be as high as 30%. See Christina M. Roberts, et al., Continuation of Gender-affirming Hormones Among Transgender Adolescents and Adults, 107 The Journal Of Clinical Endocrinology & Metabolism e3937 (Apr. 22, 2022), https://tinyurl.com/3f7j5hbm. And even this statistic might be low because "those who abandon a transition are likely to stop talking to their doctors" and thus "disappear from the figures." Skrmetti, 145 S. Ct. at 1847 n.7 (Thomas, J., concurring) (internal quotations omitted). Thus, as the Cass Review explained, "the percentage of people treated with hormones who subsequently detransition remains unknown due to the lack of long-term follow-up studies." Cass Review at 33. And England's experts have observed that "there is suggestion that numbers are increasing." Id. at 33. Moreover, given "the increasingly large number of children seeking these treatments," one can expect the number of detransitioners to rise. Skrmetti, 145 S. Ct. at 1847 n.7 (Thomas, J., concurring). Therefore, providers are misleading patients if they say that the rates of regret or detransition are low. "It is dangerous, destructive, and grossly irresponsible to let children, whose minds are still developing, make such life-altering decisions at such young ages especially since 90 percent of children who believe they are a different sex no longer hold that view as adults if they are left to develop on their own, without medical interventions." GOLDFARB, *supra*, at 173.

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At Do No Harm, we fight to protect children, assert truth, and defend science, which is why we stand firmly against the false and misleading claims of the radical advocates of so-called "gender-affirming care" for minors—treatments that are ruining the lives of families across the country. Do No Harm outlines these five myths in the hope that this comment will assist the FTC in protecting minors from these dangerous and unproven medical interventions and achieving justice for those who have already been harmed.

Sincerely,

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