February 17, 2026

Submitted Electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

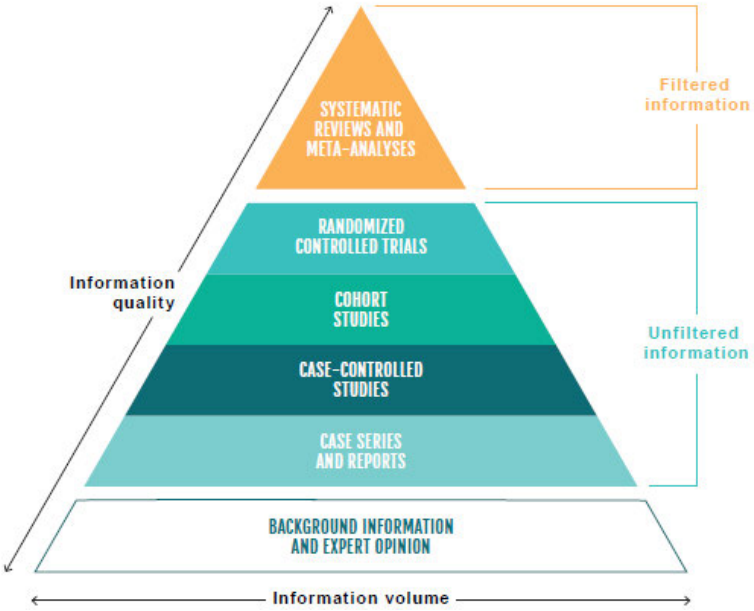
Re: Comment from Do No Harm Action re CMS-3481-P and CMS-2451-P

To Whom It May Concern:

We appreciate the opportunity to comment on CMS's proposed rules regarding the prohibition on the use of federal funds for "sex-rejecting procedures" as defined in the proposed rules. This comment is submitted in support of both CMS-2451-P, "Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children," and CMS-3481-P, "Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children." Do No Harm is a diverse group of 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 believes healthcare should be free from experimental procedures that place political agendas ahead of patient well-being. To that end, 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 availability of federal funding to support them. Do No Harm Action urges the Department of Health and Human Services (HHS) to adopt these proposed rules to ensure that federal funds are not used to support the practice of harmful and life-altering interventions on minors for which there is no reliable evidence.

I. In The Practice Of Evidence-Based Medicine, Systematic Reviews Are The Highest Form Of Medical Evidence.

Although the proper practice of medicine is driven by evidence, not all medical evidence is created equal. Researchers have thus spent decades refining the process that clinicians use to assess the medical evidence supporting a particular medical intervention. That process—often referred to as the practice of "evidence-based medicine"—outlines a hierarchy of medical evidence based on the confidence a clinician can place in a particular source of evidence. *See* Gordon Guyatt, et al., Users' Guides to the Medical Literature: Essentials of Evidence-Based Clinical Practice 15 fig. 2-3, JAMAevidence (3d ed. 2015) ("Evidence-Based Medicine User Guide"). The "pyramid of standards of evidence" reflects the hierarchy of reliability for evidence in medicine:



See Independent Review of Gender Identity Services for Children and Young People: Final Report, Nat'l Health Serv. Eng. 55 (Apr. 2024) ("Cass Review"). As the pyramid shows, "systematic reviews" are at the top of the hierarchy of medical evidence. At the bottom of the hierarchy is clinical experience—*i.e.*, "the unsystematic observations of individual clinicians." Evidence-Based Medicine User Guide at 15.

Systematic reviews provide the greatest insight into the medical evidence underpinning a particular intervention because they account for all relevant studies, assess those individual studies for areas of potential scientific bias, and thus show the *reliability* of the *entire* evidence base. *See id*. at 274-76. To assess bias in individual studies, researchers frequently use tools such as the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method. *See id.* at 16-17. In the GRADE system, researchers rate the evidence using specified criteria. "In the context of a systematic review, the ratings of the quality of evidence reflect the extent of our confidence that the estimates of the effect are correct." Howard Balshem, et al., *GRADE Guidelines: 3. Rating the Quality of Evidence*, 64 J. Clinical Epidemiology 401, 403 (2011). This resulting rating of the evidence is either "high, moderate, low, or very low." Evidence-Based Medicine Users Guide at 16. The following definitions explain what the various levels mean:

> High Quality Evidence: "We are *very confident* that the true effect lies close to that of the estimate of the effect." Balshem, *supra*, at 404 tbl. 2 (emphasis added).
>
> Moderate Quality Evidence: "We are *moderately confident* in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different." *Id.* (emphasis added).
>
> Low Quality Evidence: "Our *confidence* in the effect estimate *is limited*: The true effect may be *substantially different* from the estimate of the effect." *Id.* (emphasis added).

Very Low Quality Evidence: "We have *very little confidence* in the effect estimate: The true effect *is likely to be substantially different* from the estimate of effect." *Id.* (emphasis added).

Thus, when evidence is deemed "low" or "very low" quality, that means researchers have "limited" or "very little confidence" that the results of the study reflect the truth; indeed, the truth may or *likely* will turn out "to be substantially different" from what such studies say.

Finally, after analyzing all relevant studies, the researchers will "summarize the results." Evidence-Based Medicine User Guide at 275. This process can include a quantitative synthesis or "meta-analysis" of data that provides an overview to clinicians. *See id.* at 275-76. The end result is a study of studies—a comprehensive look at the evidence on a given question that accounts for the reliability of the studies forming the evidence base.

In short, systematic reviews are the most reliable form of medical evidence. And for several reasons, they are substantially more reliable than narrative reviews (such as a clinician's experiences recounted in a declaration or expert-witness report). First, unlike systematic reviews, narrative reviews "have no explicit criteria for selecting the included studies." *Id.* at 273. Therefore, narrative reviews can cherry-pick examples and individual studies—discussing only those that support their conclusions and ignoring those that do not. Systematic reviews do not suffer from this flaw.

Second, narrative reviews "do not include systematic assessments of the risk of bias associated with primary studies." *Id.* (emphasis omitted). Thus, narrative reviews may stress that several studies all support the same conclusion, but "[c]onsistent results are less compelling if they come from studies with a high risk of bias than if they come from studies with a low risk of bias." *Id.* at 283. Systematic reviews account for this principle; narrative reviews do not. For these reasons (among others), systematic reviews represent the highest form of medical evidence, and "optimally effective evidence-based practice dictates bypassing the critical assessment of primary studies and, if they are available, moving straight to the evaluation of rigorous systematic reviews." *Id.* at 4 (emphasis omitted).

II. Every Systematic Review Of Medical And Surgical Interventions For Minors With Gender Dysphoria Has Concluded The Evidence Is Weak.

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. All have concluded that the evidence underlying medical interventions for gender dysphoria in minors is weak; zero have come out the other way.

1. Finland. The first systematic review came in 2019 when Finland's Ministry of Social Affairs and Health completed its review of the medical evidence. In light of this evidence review, Finland's healthcare authority concluded that "gender reassignment of minors is an experimental practice." *See 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* at 8, Palveluvalikoima (Nov. 6, 2020) (unofficial translation by the Society

for Evidence Based Gender Medicine (SEGM)), https://perma.cc/PF72-H654. This conclusion was based on the fact that "[t]he reliability of the existing studies" is "highly uncertain." *Id*. at 7.

2. 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 NICE Evidence Reviews*, The Cass Rev., https://perma.cc/APZ2-W8MS (last visited July 30, 2025). The result was two separate systematic reviews—one for puberty blockers and one for cross-sex hormones. *Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria*, Nat'l Inst. for Health & Care Excellence (Oct. 2020), https://perma.cc/F9FF-ZPFR ("NICE – Review of Puberty Blockers"); *Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria*, Nat'l Inst. for Health & Care Excellence (Oct. 2020), https://perma.cc/U49T-JLGJ ("NICE – Review of Cross-Sex Hormones"). 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 using [a] modified GRADE" methodology. NICE – Review of Puberty Blockers at 13. Similarly, in the review of cross-sex hormones, NICE concluded that the relevant studies were "uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using [a] modified GRADE" methodology. NICE – Review of Cross-Sex Hormones at 13.

3. The State of Florida. In 2022, researchers at Canada's McMaster University—a world-renowned institution in evidence-based medicine—completed a systematic review at the request of the Florida Agency for Health Care Administration. *See* 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://perma.cc/S4A3-NKDY. They too 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*.

4. Sweden. In 2023, Swedish researchers published a systematic review that was commissioned by Sweden's Agency for Health Technology and Assessment of Social Services. *See* Jonas F. Ludvigsson, et al., *A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and Recommendations for Research*, 112 Acta Paediatrica 2279 (2023), https://perma.cc/E7S9-7CLB. 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 2280. 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.*

5. 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* Jo Taylor et al., *Interventions To Suppress Puberty in Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, Archives Disease Childhood 1 (2024),

https://bit.ly/402E7WC ("Taylor – Puberty Blockers"); Jo Taylor et al., *Masculinising and Feminising Hormone Interventions for Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, Archives Disease Childhood 1 (2024), https://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.

To summarize, all these systematic reviews concluded the same thing: there is no reliable evidence to justify the use of puberty blockers and cross-sex hormones as a treatment for gender dysphoria in minors. And this conclusion comports with the findings of the experts in evidence-based medicine hired by the medical interest group WPATH (which the district court invoked, *see* 769 F. Supp. 3d at 448), a research team at Johns Hopkins University, who reported that they "found 'little to no evidence about children and adolescents'" for these interventions. *See Trans Health Group Fought Study Analyzing 'Gender Affirming Care' for Children, Docs Show*, Do No Harm (May 17, 2024), https://bit.ly/41yv1RS (citation omitted).

III. The Myths Regarding "Gender-Affirming Care" Have Been Thoroughly Debunked.

Proponents of these interventions insist that they are safe and effective. Those statements are false or, at the very least, misleading. 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.

A. 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 less than two years ago, 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.

B. 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. To be sure, these interventions are effective in *changing an individual's body*. But as explained above, every systematic review has concluded there is no reliable evidence suggesting that biology-denying interventions are effective in *reducing the psychological distress* associated with gender dysphoria. 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.

C. 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.

D. 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."

E. 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. We applaud HHS for issuing these proposed rules that will ensure federal funding will not be used for that purpose, and we urge that these proposed rules be finalized.

Sincerely,

Dr. Stanley Goldfarb
DO NO HARM ACTION