June 16, 2023

Submitted Electronically

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Director, Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 515F
Washington, DC 20201

Re: HIPAA Privacy Rule to Support Reproductive Health Care Privacy; 88 Fed. Reg. 23506 (RIN 0945–AA20) (April 17, 2023)

Dear Director Fontes Rainer:

We appreciate the opportunity to comment on HHS's proposed rule modifying the HIPAA Privacy Rule for so-called "reproductive health care." 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. Do No Harm urges the Department of Health and Human Services (HHS) to abandon this proposed rulemaking because it would unlawfully frustrate efforts to protect vulnerable children from dangerous, ideologically driven medical practices.

Tragically, an increasing number of American doctors have embraced experimental, harmful, and irreversible methods for treating pediatric gender dysphoria—the medical diagnosis for severe distress that results from an inconsistency between an individual's sex and that individual's perceived gender or sex.[1] Recently, numerous states have restricted the provision of these drugs and surgeries in an effort to provide justice to those who have come to regret these treatments and to ensure other vulnerable children will not be subjected to them in the future.

The proposed rule would potentially hinder the enforcement of these critical laws. Specifically, the proposed rule's novel and broad definition of "reproductive health care" would arguably encompass services that permanently sterilize children and adolescents through the use of puberty blockers, cross-sex hormones, and surgeries. HHS should narrow the definition of "reproductive health care" to make clear that this proposed rule does not prohibit the use or production of protected health information (PHI) for criminal, civil or administrative investigations or proceedings regarding the practice of experimental gender medicine on minors.

To the extent HHS intends for the proposed rule to cover these investigations, the rule would be both contrary to law and arbitrary and capricious. Specifically, HHS lacks statutory authority to limit a State's power to investigate public health violations under state law, such as

[1] AM. PSYCHIATRIC ASS'N, Diagnostic and Statistical Manual of Mental Disorders 451–52 (5th ed. 2013).

the practice of experimental gender medicine on minors. At the very least, such a sweeping and significant power to override State sovereignty was not hidden away in an otherwise anodyne provision of the Health Insurance Portability and Accountability Act (HIPAA). In addition, it would be arbitrary and capricious to extend HHS's analysis from the proposed rule's primary focus of abortion to the wholly separate context of experimental gender medicine for minors. The Notice of Proposed Rulemaking (NPRM) provides no analysis regarding the practice of experimental gender medicine on minors. Because the agency has entirely failed to consider this practice, the proposed rule is arbitrary and capricious to the extent it frustrates States' ability to investigate violations of laws that prohibit that sort of experimentation on children and adolescents.

We therefore write to request that HHS withdraw its proposed rule or, at the very least, make clear that the proposed rule's definition of "reproductive health care" does not encompass experimental gender medicine performed on minors.

I. The Proposed Rule Exceeds HHS's Statutory Authority To The Extent It Frustrates State Enforcement of Laws Prohibiting The Practice of Experimental Gender Medicine On Minors.

The proposed rule would, among other things, prohibit the use or disclosure of PHI when "the use or disclosure is for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive healthcare." 88 Fed. Reg. 23552. The proposed rule would further define reproductive health care as "care, services, or supplies related to the reproductive health of the individual." *Id.* at 23527. And the NPRM indicates HHS's intention to interpret this definition to include "health care related to reproductive organs, regardless of whether the health care is related to an individual's pregnancy or whether the individual is of reproductive age." *Id.*

The proposed rule would also adopt a narrowing interpretation of Congress's protection for State laws in HIPAA. Specifically, Congress guaranteed that HIPAA would not "be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 13720d-7(b). The proposed rule would construe "public health" to mean "population-level activities to prevent disease and promote health of populations," and it would expressly *exclude* from that definition investigations relating to "reproductive health care." 88 Fed. Reg. 23552.

Read for all it is worth, HHS's interpretation would obstruct State investigations into violations of State laws that prohibit medical providers from delivering experimental drugs and surgeries to minors as a treatment for gender dysphoria. *See, e.g.*, ALA. CODE §§ 26-26-1 *et seq.*; ARK. CODE §§ 20-9-1501-04; FLA. STAT. §§ 61.5175, 456.001, 456.52, 456.074; 2023 Ind. Legis. Serv. P.L. 10-2023 (S.E.A. 480) (to be codified at IND. CODE ANN. §§ 25-1-22-1 *et seq.*); 2023 Ky. Laws Ch. 132 (SB 150) (to be codified at K.R.S. § 311.372); 2023 Mo. Legis. Serv. S.B. 49, 236 & 164 (to be codified at MO. REV. STAT. §§ 191.1720, 208.152, 217.230, and 221.120); TENN. CODE §§ 68-33-101 *et seq.* These laws generally prohibit the use of puberty blockers, cross-sex hormones, and surgeries to manipulate a minor's secondary sex characteristics to match the minor's *perceived* gender or sex. Because these medical interventions are "related to reproductive

organs," they would arguably fall within the proposed rule's definition of "reproductive health care."

We urge HHS to narrow the definition of "reproductive health care" to make clear that the definition does *not include* the practice of experimental gender medicine on minors and to make clear that the enforcement of such laws falls within Congress' recognition of State sovereignty in 42 U.S.C. § 13702d-7(b).

HHS lacks statutory authority to do otherwise. Because "an agency literally has no power to act . . . unless and until Congress confers power upon it," *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986), "an administrative agency's power to regulate . . . must always be grounded in a valid grant of authority from Congress," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). Accordingly, while an agency like HHS has authority to exercise the power delegated upon it by Congress, if it "exercises power beyond the bounds of its authority, it acts unlawfully." *DHS v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1921 (2020). Here, that means that the scope of HHS's authority to modify the Privacy Rule is limited by the statutory metes and bounds set by Congress in HIPAA and related statutes.

HIPAA does not confer authority on HHS to adopt the proposed rule. According to the NPRM, the substantive authority for the proposed rule comes from two provisions. First, the NPRM cites Congress' authorization for HHS to promulgate regulations containing "standards with respect to the privacy of individually identifiable health information" in the absence of congressional action after HIPAA's enactment. *See* 88 Fed. Reg. 23513 n.79 (citing 42 U.S.C. § 1320d-2 note). Second, the NPRM points to HHS's general rulemaking authority to "make and publish such rules and regulations" that are "necessary to the efficient administration" of HHS's functions. *See id.* at 23513 n.80 (citing 42 U.S.C. § 1302).

These two general provisions, however, "must be read in context." *See Jones v. United States*, 527 U.S. 373, 389 (1999). And "no statute pursues a single policy at all costs." *Bartenwerfer v. Buckley*, 143 S. Ct. 665, 675 (2023). Just so with HIPAA. Congress did not grant unyielding authority for HHS to "go forth and regulate." Instead, it limited HIPAA's scope and ensured that "[n]othing" in HIPAA "shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b). The upshot is that, although HHS may issue regulations to implement HIPAA, it may *not* issue regulations that frustrate States' ability to investigate violations of laws relating to public health or States' ability to intervene to punish or prevent those violations.

"It is a fundamental canon of statutory construction that words generally should be interpreted as taking their ordinary meaning at the time Congress enacted the statute." *See New Prime Inc. v. Oliveira*, 139 S. Ct. 532, 539 (2019) (cleaned up). Under the ordinary meaning of § 1320d-7(b), investigations into violations of State laws that prohibit experimental gender medicine on minors are investigations or interventions relating to "public health." Indeed, the NPRM effectively acknowledges this point. It defines "public health" to refer to "*population*-based

activities to prevent disease and promote health of *populations*." 88 Fed. Reg. 23525.[2] By their own terms, State statutes protecting minors from experimental gender medicine promote the health of one of our Nation's most important and vulnerable "populations"—children and adolescents.

States' concern regarding experimental gender medicine on this population is well founded. In recent years, there has been a dramatic increase in the number of minors in the United States who report some form of inconsistency between their sex and their perception of their gender or sex. Available data indicate that diagnoses of gender dysphoria in minors ages 6 to 17 rose by about 20% annually between 2017 and 2020, and by 80% between 2020 and 2021, for a total of 121,882 new diagnoses during this five-year period. [3] Indeed, this is likely a conservative estimate because it is based solely on insurance claims.[4] There is currently no adequate explanation for the precipitous rise in individuals presenting with gender dysphoria and the disproportionate number of young females now suffering from gender dysphoria. That recent change in the profile of the typical patient led experts in Sweden to greatly curtail the use of puberty blockers and hormonal treatments in their country.[5] Lastly, a growing body of evidence points to the emergence of detransitioners—individuals who have come to regret the irreversible physical changes made to their bodies to treat gender dysphoria.[6] There are zero reliable, long-term studies on rates of regret and detransition among the new cohort of children who are being treated according to current protocols. Startingly, one recent study suggests that the rate could be as high as 30%.[7]

The NPRM's attempt to evade the plain meaning of "public health" in the statute is unpersuasive. The NPRM states that investigations regarding "reproductive health care" do not constitute "public health investigations" because they "generally target specific persons" and because "they are not designed to address population-level health concerns." 88 Fed. Reg. 23526. How HHS wrings this distinction from the phrase "public health investigation" is a mystery. After all, it is not possible to investigate a "population" without investigating circumstances regarding the *individuals* who make up that population. Here, the relevant "population" is children and adolescents, and the enforcement of State laws prohibiting the practice of experimental gender medicine on minors is a public health investigation and intervention.[8]

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[2] And elsewhere, the NPRM recognizes that care "for individuals' health" is reflective of "public health." *See* 88 Fed. Reg. 23509; *see also id.* at 23508.

[3] Robin Respaut & Chad Terhune, *Putting Numbers on the Rise in Children Seeking Gender Care*, REUTERS (Oct. 6, 2022), https://tinyurl.com/5n6hbkvy.

[4] *Id*.

[5] *Care of Children and Adolescents with Gender Dysphoria, Summary*, SOCIALSTYRELSEN, 3 (2022), https://bit.ly/3KIEiOO.

[6] Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition who Subsequently Detransitioned: A Survey of 100 Detransitioners,* 50 ARCHIVES OF SEXUAL BEHAVIOR 3353 (Oct. 19, 2021), https://tinyurl.com/2p97uks5.

[7] 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.

[8] Moreover, the statute protects not only a State's authority to conduct a public health "investigation," but also its authority to conduct a public health "intervention." The NPRM does not appear to draw any distinction between these two terms, thus failing "to construe Congress's

HHS thus lacks the authority to frustrate States' ability to enforce their laws prohibiting the practice of experimental gender medicine on minors. Nothing in HIPAA grants HHS the power to shield this dangerous, unproven, and often irreversible practice from States' legitimate public-health laws under the euphemism of "reproductive health care." Therefore, HHS lacks statutory authority to adopt the proposed rule.

Nor can the agency contend that this immense power was stashed away in HHS's general rulemaking authority. Even if statutory provisions confer a general authority on HHS to implement HIPAA, "the history and the breadth of the authority that [HHS] has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority." *West Virginia v. EPA*, 142 S. Ct. 2587, 2608 (2022) (cleaned up). This principle—the major questions doctrine—has force where "agencies assert[] highly consequential power beyond what Congress could reasonably have understood to have granted." *Id.* at 2609.

Here, HHS reads HIPAA and similar statutes to confer authority to effectively preempt State laws protecting minors from experimental gender medicine. There is no hint that Congress intended to confer such authority. To be sure, HIPAA gives HHS authority to take steps to protect individuals' health records. "Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally." *Gonzalez v. Oregon*, 546 U.S. 243 (2006). "The silence is understandable given the structure and limitations of federalism, which allow the States 'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (cleaned up)). Through the proposed rule, HHS seeks to weaponize a *privacy* regulation into an extraordinary authority to effectively preempt State laws regulating any medical procedure that HHS favors. Nothing in HIPAA could be said to demonstrate Congress' intent to confer this power through that statute.

Moreover, HHS admits that it has never proposed a rule like this before: "The Department acknowledges that the Privacy Rule has not previously conditioned uses and disclosures for certain purposes on the specific type of health care about which the disclosure relates, as it does herein with reproductive health care." 88 Fed. Reg. 23521. HHS's sudden discovery of this "unheralded" and "newfound power" in language never-before used this way further underscores the impossibility that Congress actually conferred this authority on HHS in the first place. *West Virginia v. EPA*, 142 S. Ct. at 2610. Therefore, even if HHS's statutory authority could be read so broadly as to encompass the power to effectively preempt State laws protecting minors from experimental gender medicine, the principles underlying the major questions doctrine foreclose that result.

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work so that effect is given to all provisions, so that no part will be inoperative or superfluous, void or insignificant." *Ysleta Del sur Pueblo v. Texas*, 142 S. Ct. 1929, 1939 (2022).

II. The Proposed Rule Is Arbitrary And Capricious If It Applies To State Investigations Regarding The Practice of Experimental Gender Medicine on Minors.

Agency action is unlawful and must be set aside if it is "arbitrary" and "capricious." 5 U.S.C. § 706(2)(A). "To satisfy the 'arbitrary and capricious' standard, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Bloomberg L.P. v. SEC*, 45 F.4th 462, 472 (D.C. Cir. 2022) (cleaned up). Agency action is arbitrary and capricious if, among other things, the "agency has 'entirely failed to consider an important aspect of the problem.'" *Daikin Applied Americas Inc. v. EPA*, 39 F.4th 701, 712 (D.C. Cir. 2022) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

The NPRM makes clear that the primary motivation for the proposed rule was the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). *See* 88 Fed. Reg. 23507-10. There, the Supreme Court overruled *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), and returned the regulation of abortion to the States. *Dobbs*, 142 S. Ct. at 2242-43. As the NPRM recounts, after *Dobbs*, many States have taken steps to regulate abortion. *See* 88 Fed. Reg. 23507 n.10. And these examples of State legislation are the reason HHS now deems it necessary to amend the Privacy Rule. *See id.* at 23507-08.

Whatever the merits of that decision, however, HHS has engaged in *no analysis* regarding the application of the proposed rule to State laws prohibiting the practice of experimental gender medicine on minors. And that practice raises countless issues that HHS must consider before effectively nullifying States' authority to enforce laws that prohibit its practice on minors. Thus, extending application of the proposed rule to the practice of experimental gender medicine on minors would be "arbitrary, capricious, or an abuse of discretion." 5 U.S.C. § 706(2)(a).

State level restrictions on experimental gender medicine are informed by serious concerns about the known harms, poorly understood risks, and lack of proven benefits for the associated treatments. Without the enforcement of these state prohibitions, American doctors may continue to act in contradiction to their European counterparts, greatly increasing the risks to children in the United States.

Experimental gender medicine is a process of altering a child's body to match the child's perceived sex or gender. The process generally begins with the off-label prescription of gonadotropin-releasing hormone agonists (GnRHa) to block puberty during its early stages.[9] Having halted the child's normal puberty, doctors then prescribe cross-sex hormonal treatments to

[9] Eli Coleman, et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INTERNATIONAL JOURNAL OF TRANSGENDER HEALTH S1, S50 (2022), https://tinyurl.com/yc7s4972 ("WPATH Standards of Care 8"), at S45–48, S59–66; Chad Terhune, et al., *As More Transgender Children Seek Medical Care, Families Confront Many Unknowns*, REUTERS (Oct. 6, 2022), https://tinyurl.com/2mb9h89v (discussing that puberty blockers have not been approved by the FDA for treating gender dysphoria).

induce secondary sex characteristics commonly associated with the opposite sex.[10] For example, a male might take estrogen to develop breasts, or a female might take testosterone to develop more body hair and greater muscle mass. Finally, children are subjected to surgeries during which healthy body parts are removed and are sometimes replaced with artificial body parts that approximate the appearance of the opposite sex.[11]

Each step of this process inflicts permanent harm and carries significant risks. Puberty blockers have been linked to weight gain, insulin resistance, decreased bone density, cognitive impairment, metabolic syndrome, polycystic ovarian syndrome, increased risk of infertility, and potential for diminished adult sexual function.[12] Moreover, it remains unknown the extent to which puberty blockers impact brain development and cognition, and some have raised concerns that their use may *contribute* to suicidal ideation and behavior.[13] The side effects of cross-sex hormones are numerous and, for males, include blood clots, heart attacks, tumors, strikes, cancer, and irreversibility infertility.[14] For females, hormones are associated with severe liver dysfunction, heart attacks, depression, hypertension, infertility, and cancer.[15] Those who undergo surgeries are at risk of fistulas, chronic infection, stenosis, necrosis, prolapse, complete loss of sexual sensation, need for various follow-up procedures and maintenance, and even death.[16]

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[10] WPATH Standards of Care 8, *supra* n.9, at S46–48, S64–66.

[11] *Id*. at S48, S64–66.

[12] See Natalie J. Nokoff, et al., *Body Composition and Markers of Cardiometabolic Health in Transgender Youth on Gonadotropin-Releasing Hormone Agonists*, 6 TRANSGENDER HEALTH 111 (Apr. 16, 2021), https://tinyurl.com/mww7xu5t; 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; Sarah C.J. Jorgensen, et al., *Puberty blockers for gender dysphoric youth: A lack of sound science*, 5 J. OF THE AM. COLLEGE OF CLINICAL PHARM. 1005, (Sept. 15, 2022), https://bit.ly/3Mkz253; Philip J. Cheng, et al., *Fertility concerns of the transgender patient*, 8 TRANSLATIONAL ANDROLOGY AND UROLOGY 209 (June 2019), https://bit.ly/3nW2K6p; David Larson, *Duke Health Emerges as Southern Hub for Youth Gender Transition*, THE CAROLINA J. (Aug. 31, 2022), https://tinyurl.com/44rd939t (Current WPATH President Marci Bowers "seemed to acknowledge … that 'really about zero' biological males who block puberty at the typical Tanner 2 Stage of puberty (around 11 years old) will go on to ever achieve an orgasm[.]").

[13] Diane Chen, et al., *Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth*, 5 TRANSGENDER HEALTH 246 (2020), https://tinyurl.com/m6vzyru7 (expressing concern that puberty blockers "may prevent key aspects of development during a sensitive period of brain organization," and did not know whether a patient would "catch-up" to otherwise normal brain functioning); *Board of Directors: The Tavistock and Portman*, NHS ENGLAND 53 (June 23, 2015), https://bit.ly/3UdrNh3 (noting a statistically significant increase in self-harm after a year of puberty suppression).

[14] WPATH Standards of Care 8, *supra* n.9, at S43.

[15] *Id.* at S254.

[16] Wouter B. van der Sluis, et al., *Clinical Characteristics and Management of Neovaginal Fistulas After Vaginoplasty in Transgender Women*, OBSTETRICS AND GYNECOLOGY (June 2016), https://tinyurl.com/4cw9nxzp; Jing J. Zhao, *Surgical Site Infections in Genital Reconstruction Surgery for Gender Reassignment, Detroit: 1984–2008*, SURGICAL INFECTIONS (Apr. 2014), https://tinyurl.com/yua6zwtm; Oscar J. Manrique, et al., *Complications and Patient-Reported*

Crucially, the sequential nature of these treatments means that the harms and risks of the later treatments (like surgery) cannot be dissociated from the earlier treatments (like puberty blockers). As some experts have noted, puberty blockers may have an iatrogenic effect that makes it more likely that a child continues to hormones and surgeries.[17] Indeed, research shows that the vast majority of children (96%-98%) who start puberty blockers continue on to use cross-sex hormones.[18]

Despite claims to the contrary, there are no known benefits that justify undertaking these harms and risks. There is no support for the conclusion that these treatments result in long-term improvements, and studies that purport to show short-term benefits are riddled with methodological weaknesses, such as the failure to control for the confounding effects of psychotherapy and the presence of placebo effects.[19] Proponents of these treatments also push the sensational, and unfounded, claim that untreated children are at imminent risk of suicide. There is no quality evidence to support these claims, and they often rely on misleading distortions of research.[20] Even the claim that gender-dysphoric children are at a heightened risk of suicidality deserves qualification. Because gender-dysphoric children also suffer from high rates of other mental health conditions that are associated with suicidality, a simple comparison between gender-dysphoric and non-dysphoric children cannot show whether a child's gender dysphoria, as opposed to other mental health conditions, increases the risk of suicidality.[21] In fact, when a recent study

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Outcomes in Male-to-Female Vaginoplasty-Where We Are Today: A Systematic Review and Meta-Analysis, ANNALS OF PLASTIC SURGERY (Jun. 2018), https://tinyurl.com/5akm9mwv; Valeria P. Bustos, et al., *Regret After Gender-Affirmation Surgery: A Systematic Review and Meta-Analysis of Prevalence*, PLASTIC AND RECONSTRUCTIVE SURGERY GLOBAL OPEN (Mar. 19, 2021), https://tinyurl.com/29ubdtap; Vera L. Negenborn, et al., *Lethal Necrotizing Cellulitis Caused by ESBL-Producing E. Coli After Laparoscopic Intestinal Vaginoplasty*, JOURNAL OF PEDIATRIC AND ADOLESCENT GYNECOLOGY (Feb. 2017), https://tinyurl.com/yey5p5ep.

[17] 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.

[18] Biggs, *The Dutch Protocol*, *supra* n.12.

[19] Leor Sapir, *Trust the Experts' Is Not Enough: U.S. Medical Groups Get the Science Wrong on Pediatric 'Gender Affirming' Care*, MANHATTAN INST., 5 (2022), https://tinyurl.com/4eyp7mna; Alison Clayton, *Gender-Affirming Treatment of Gender Dysphoria in Youth: A Perfect Storm Environment for the Placebo Effect—The Implications for Research and Clinical Practice*, 52 ARCHIVES OF SEXUAL BEHAVIOR (2022), https://tinyurl.com/2p87mmen.

[20] Leor Sapir, *The Distortions in Jack Turban's Psychology Today Article on 'Gender Affirming Care,'* REALITY'S LAST STAND (Oct. 7, 2022), https://tinyurl.com/2s4dd3yy.

[21] Michael Biggs, *Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom*, 51 ARCHIVES OF SEXUAL BEHAVIOR 685, 687–88 (Jan. 18, 2022), https://bit.ly/3Kk3ARL.

controlled for mental health comorbidities, the differences in suicidality rates between gender-dysphoric and non-dysphoric children were either miniscule or non-existent.[22]

Given the unproven benefits and myriad risks of these treatments, it is no wonder that several European countries and many U.S. states have arrived at the conclusion that these treatments are experimental and unjustified. Just last year, Sweden's public-health body barred puberty blockers for adolescents in all but "exceptional cases" because "the efficacy and safety, benefits and risks of treatments are not proven."[23] Likewise, health authorities in Finland have implemented almost identical restrictions, labeling gender transitions for youth as "an experimental practice."[24] The United Kingdom's new restrictions are similarly motivated.[25] Norway looks poised to join these countries given the recent statement by one of its preeminent health officials that puberty blockers and cross-sex hormones to treat gender dysphoria are "treatments under trial."[26] Even more recently, one of Australia's largest medical malpractice insurers dropped coverage for pediatric gender transitions over concerns about those who will ultimately wish they had not transitioned, with the president of the company telling the media, "We don't think we can accurately and fairly price the risk of regret."[27] Lawmakers in the U.S. have followed suit. Unjustifiably, the proposed regulation could stand in the way of these scientific and safety-driven efforts to protect children.

Nothing in the NPRM mentions—let alone engages with—any of this evidence (or lack thereof). The NPRM does not even acknowledge that the exceedingly broad definition of "reproductive health care" in the proposed rule would sweep in the practice of experimental gender medicine on minors. Therefore, the NPRM provides no analysis of how the proposed rule would affect State laws prohibiting that practice and whether the rule is justified in that context.

Moreover, if the proposed rule applies to laws prohibiting the practice of experimental gender medicine on minors, it potentially confers a duty on medical providers to make real-time judgments based on complex principles of constitutional law. For example, the proposed rule would prohibit disclosure of PHI related to "reproductive health care" when that form of "health care" is "protected, required, or authorized by Federal law," regardless of whether the health care is outlawed in the relevant State. *See* Fed. Reg. 23552. If "Federal law" includes the Constitution, then this proposed rule would require *medical providers* to make judgments about whether a State's law is constitutional when determining whether the medical provider has a duty to produce

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[22] Nastasja M. de Graaf, et al., *Suicidality in clinic-referred transgender adolescents*, 31 EUROPEAN CHILD & ADOLESCENT PSYCHIATRY 67 (2022), https://tinyurl.com/3d9886cw.

[23] SOCIALSTYRELSEN, *Summary*, *supra* n.5, at 3.

[24] *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*, PALVELUVALIKOIMA, 8 (2020), https://tinyurl.com/24pp8edj.

[25] Azeen Ghorayshi, *England Limits Use of Puberty-Blocking Drugs to Research Only*, N.Y. TIMES (Jun. 9, 2023), https://nyti.ms/3X8dr2W.

[26] Jennifer Block, *Norway's guidance on paediatric gender treatment is unsafe, says review*, BMJ, 1 (Mar. 23, 2023), https://tinyurl.com/54x88u82.

[27] Angus Thompson, *'What's the real risk?' Gender transition insurance cover cut for GPs*, THE SYDNEY MORNING HERALD (May 29, 2023), https://tinyurl.com/3mpu5589.

the requested PHI. That determination may be simple in the context of artificial contraception that the NPRM uses as an example. *See* Fed. Reg. 23531 (citing *Griswold v. Connecticut*, 381 U.S. 479 (1965); *but see* Michael Stokes Paulsen, *The Irrepressible Myth of* Marbury, 101 Mich. L. Rev. 2706, 2733 & n.77 (2003) ("The Constitution is paramount law and must take precedence (so to speak) over precedents that depart from it."). But it could be decidedly *complex* in the context of the Constitution's application to the practice of experimental gender medicine on minors, which is currently being litigated around the country.[28] Asking medical providers to make these types of constitutional judgments on the fly is wholly unreasonable, and the NPRM entirely fails to consider this problem.

In sum, the proposed rule is arbitrary and capricious if it applies to investigations concerning the practice of experimental gender medicine on minors. The NPRM provides no analysis regarding this distinct issue and does not even appear to understand that the broad definition of "reproductive health care" would encompass that practice. This failure "to consider an important aspect of the problem" demonstrates that the proposed rule is arbitrary and capricious. *Daikin*, 39 F.4th at 712 (cleaned up).

We therefore ask HHS to withdraw its proposed rule or, alternatively, to make clear that the proposed rule's definition of "reproductive health care" does not encompass experimental gender medicine performed on minors.

Sincerely,

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[28] Of course, Do No Harm believes the answer to that question is straightforward: States are clearly permitted to prohibit the practice of experimental gender medicine on minors. *See, e.g.*, Brief for Do No Harm as Amicus Curiae Supporting Defendants, *Dekker v. Weida*, No. 4:22-cv-325, Doc. 131-1 (N.D. Fla. Apr. 7, 2023).