October 3, 2024

Micky Tripathi, PhD.
Assistant Secretary for Technology Policy and National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services (HHS)
330 C St NW, Floor 7
Washington, DC 20201

RE: "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability" (RIN: 0955-AA06) (89 Fed. Reg. 63,498)

Dear Assistant Secretary Tripathi:

Below are the comments of Advancing American Freedom ("AAF") on the Office of the National Coordinator for Health Information Technology's Proposed "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability" Rule by the Health and Human Services Department on 10/02/2024.

Introduction

Advancing American Freedom (AAF) is a 501(c)(4) non-profit organization that advocates for conservative values and policies by developing innovative policy solutions, strategies, coalitions, and messaging that build upon the accomplishments of the last administration and expand freedom for all Americans.

AAF has many questions about this Proposed Rule and whether the Office of the National Coordinator for Health Information Technology is abandoning truth as its foundation and will needlessly confuse American medical staff. If enacted, would this Rule require doctors and hospital employees to enter false categories on medical records, to the detriment of the patient's health?[1]

The Proposed Rule Lacks Constitutional Authority

Before we ask questions about the deeply flawed substance of this Rule, we must first point out that the Department of Health and Human Services (HHS) lacks the authority to impose such confusion on medical professionals. Congress did not task it with this responsibility. The proposed Rule would not be necessary or proper even if enacted by Congress, so it is doubly unnecessary and improper here (especially post-*Chevron*). The Constitution grants Congress the

[1] This proposal, seemingly designed to introduce chaos into order, reminds us of what C.S. Lewis described as schemes "conceived and ordered (moved, seconded, carried, and minuted) in clean, carpeted, warmed and well-lighted offices, by quiet men with white collars and cut fingernails and smooth-shaven cheeks who do not need to raise their voices." *The Screwtape Letters* at viii (MacMillan Publishing Co. 1961).

power "[t]o regulate Commerce . . . among the several States."[2] In other words, it grants Congress the power "to regulate the buying and selling of goods and services trafficked across state lines," as Justice Clarence Thomas stated in his *Gonzales v. Raich* and *United States v. Lopez* opinions. This understanding of "commerce" as trade was common not only to the drafters of the Constitution but to the general public, including those who ratified it.[3] Implementation of the Proposed Rule is neither a necessary nor proper means of exercising Congress's power to regulate interstate trade. The Necessary and Proper Clause gives Congress the authority "[t]o make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States."[4] In his *McCulloch v. Maryland* opinion, Chief Justice John Marshall explained his understanding of this clause: "Let the end be legitimate, let it be within the scope of the constitution, and all means which are appropriate, which are plainly adapted to that end, which are not prohibited, but consist with the letter and spirit of the [C]onstitution, are constitutional." As Justice Thomas explained in his *United States v. Comstock* dissent, *McCulloch* created a two-part test for compliance with the Necessary and Proper Clause:

> "First, the law must be directed toward a "legitimate" end, which McCulloch defines as one "within the scope of the [C]onstitution"— that is, the powers expressly delegated to the Federal Government by some provision in the Constitution . . . Second, there must be a necessary and proper fit between the "means" (the federal law) and the "end" (the enumerated power or powers) it is designed to serve . . . The means Congress selects will be deemed "necessary" if they are "appropriate" and "plainly adapted" to the exercise of an enumerated power, and "proper" if they are not otherwise "prohibited" by the Constitution and not "[in]consistent" with its "letter and spirit."

From where does HHS claim to derive such authority? We can find no statute mandating it. Who on your staff stands behind such an aggrandizing claim? This is an example of constitutionally prohibited extra-legislative rulemaking in violation of the Vesting Clause and Separation of Powers (Section I). One would be hard pressed to postulate that the Framers, Ratifiers, or the founding-era public would have understood the Constitution to allow for novel pronoun standardization in medal records or secrecy surrounding abortion and gender transition procedures. This Rule will fail to pass judicial muster in court.

<u>The Proposed Rule Would Harm Women and Pressure Americans to Deny Reality</u>

According to District Court Judge Danny Reeves of the Eastern District of Kentucky (who recently heard the *Tennessee v. Cardona* case) and according to virtually everyone in history until very recently, "There are two sexes: male and female." A pivotal question regarding this

[2] U.S. Const. art. 1, § 8, cl. 3.
[3] Randy Barnett, *New Evidence of the Original Meaning of the Commerce Clause*, 55 Ark. L.Rev. 847, 857-862 (2003).
[4] U.S. Const. art. 1, § 8, cl. 18. I.

Rule is whether the federal government, in this case the federal bureaucracy rather than the elected representatives of the people, can impose on the whole nation a vision of reality that rejects this basic fact. That distorted vision depends on the assumption that men and women are fundamentally interchangeable and indistinguishable. Girls and women are the first and most profound victims of this attempted reconstitution of reality, despite the fact that the ideas behind this movement arose in part from feminist authors like Shulamith Firestone. As Carl Trueman explains, "her philosophy ultimately dissolves the human being to a disembodied will limited only by the technological tools available to it. The problem with such a view is that it is ultimately dehumanizing in its rejection of any notion of natural limits, limits that it typically treats as problems to be overcome."[5]

This Rule proposes adopting the following series of pronouns: he/him/his/his/himself; she/her/her/hers/herself; they/them/their/theirs/themselves; ze/zir/zir/zirs/zirself; xie/hir ("here")/hir/hirs/hirself; co/co/cos/cos/coself, en/en/ens/ens/enself; ey/em/eir/eirs/emself; ve/vis/ver/ver/verself; [and] yo/yo/yos/yos/yoself. Was the latter developed by Tom and Donna from *Parks and Recreation*?[6] This Rule,[7] and the LOINC standards[8] it relies upon, adopts an arbitrary approach to pronoun usage. How did HHS decide upon these ten sets of pronouns? Are Facebook's 58 gender options accounted for?[9] Where is the authority for limiting the pronouns to this list and not a Pandora's Box of others? The varying pronoun applications reflect the faddish nature of this policy and how it serves as a madcap distraction for medical professionals.

The Rule at issue here risks chilling speech in an endeavor critical of the gender movement. Additionally, doctors and parents are, shockingly, using puberty blockers that prevent the natural and healthy development of their children in order to mitigate the development of those physiological symptoms. Does the Rule countenance the mutation of pronouns from one to another because of chemical or surgical intervention? These dangers lurk behind the Rule at issue. If hospitals and doctors are forced to adopt language and structures that support a falsehood, the harms to women and children will only expand.

In his dissent in *Bostock v. Clayton County*, Supreme Court Justice Samuel Alito expressed his concern that the Court's decision there would "pressure employers to suppress any statements by employees expressing disapproval of same-sex relationships and sex reassignment procedures," because those employers "will fear that allowing employees to express their religious views on these subjects may give rise to Title VII harassment claims." Of course, criticisms of many issues related to the gender debate are not necessarily religious in nature. Yet this Rule infringes upon the First Amendment freedoms of speech and religion to which Americans are entitled. How

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[5] Carl R. Trueman, *Shulamith Firestone Was a Prophet*, First Things (July 25, 2024) https://www.firstthings.com/web-exclusives/2024/07/shulamithfirestone-was-a-prophet
[6] https://www.youtube.com/watch?v=u094qvRYDA0
[7] Proposed Rule at 272.
[8] https://loinc.org/90778-2/
[9] https://abcnews.go.com/blogs/headlines/2014/02/heres-a-list-of-58-gender-options-for-facebook-users

does HHS recommend handling free speech cases as medical employees choose between exercising their rights, self-censorship, or giving in to compelled speech to avoid being harassed by co-workers or the human resources department? More broadly, claimed concern about "harm" is often used to justify efforts to silence or compel speech depending on the preferred outcome of bureaucratic diktat. Does the Rule address doctors who, for example, might face reprisals for using pronouns consistent with biology, accidentally or otherwise using a previous name for someone who is declared as transgender (so-called "deadnaming")[10], or for making statements like that of Judge Reeves, that there are only two sexes? In other words, will doctors, nurses, and other medical employees who deal with matters of life and death will be forced to pretend not to notice reality under this proposed Rule?[11]

The HHS speech restrictions and the attendant danger of violating them are reminiscent of George Orwell's *1984*. Towards the end of the story, Winston, while being tortured, is allowed to briefly see a photo before it is "memory holed." "It exists," Winston exclaims. O'Brien, his torturer, responds, "It does not exist. It never existed." Winston retorts, "But it did exist! It does exist. In memory. I remember it. You remember it." When O'Brien denies remembering the photo he had moments before destroyed, "Winston's heart sank," because it seemed to him in that moment that:

> "[I]t was perfectly possible that O'Brien had really forgotten the photograph. And if so, then already he would have forgotten his denial of remembering it, and forgotten the act of forgetting. How could one be sure that it was simple trickery? Perhaps that lunatic dislocation in the mind could really happen: that was the thought that defeated him. O'Brien asks Winston to repeat the relevant party slogan. "Who controls the past controls the future: who controls the present controls the past."

Earlier in the novel, Winston had written in his diary, "Freedom is the freedom to say that two plus two make four." O'Brien holds up four fingers and asks Winston how many. After Winston answers, O'Brien asks, "And if the party says that it is not four but five—then how many?" Winston's answer of "[f]our" earns him a shock. The torture goes on. Eventually, Winston claims to see five fingers. O'Brien chastises him for lying. Winston is not allowed relief until, being asked again, he responds, "I don't know. I don't know. You will kill me if you do that again. Four, five, six—in all honesty I don't know." As O'Brien had earlier explained, "It is not easy to become sane." It is hard to convince yourself not to believe your own eyes.

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[10] See, e.g., Samuel Spencer, *Using Elliot Page's 'Deadname' is a Problem—Here's Why*, Newsweek (Dec. 02, 2022 7:19 AM) https://www.newsweek.com/elliot-pagedeadname-birth-name-1551714. *See, also*, Jennifer Bauwens et al., *The Trans Youth Phenomenon: Critiques and Hard Questions*, CURE, available at https://downloads.frc.org/EF/EF23I36.pdf.

[11] "I am not a critic of the West. I am a critic of the weakness of the West. I am a critic of a fact which we can't comprehend: how one can lose one's spiritual strength, one's will power and, possessing freedom, not value it, not be willing to make sacrifices for it." *An Interview with Aleksandr Solzhenitsyn*, Carnegie Council in Ethics and International Affairs, https://www.carnegiecouncil.org/media/series/100- for-100/an-interview-with-aleksandr-solzhenitsyn (last visited Aug. 29, 2024).

A pattern of disregarding reality can lead to loss of life. An example of this is the government's treatment of abortion, another issue mentioned in this Rule.[12] The deaths of young mothers like Amber Thurman[13] and Alyona Dixon[14] are among the tragic consequences of the FDA's reckless approval of chemical abortion drugs.[15] The danger those drugs pose to women's health was clear at the time of their approval by the FDA and has not abated in the intervening decades, even as the agency has repeatedly reduced the restrictions it had once implemented as a way of mitigating some of the risk.

The FDA knew about the significant negative health consequences of mifepristone before approving it for abortifacient use in the United States. Despite the continued danger of chemical abortion since its approval, the FDA has simultaneously removed protective limitations on the prescription of chemical abortion drugs and weakened the reporting requirements for adverse events caused by those drugs, casting doubt on its claims about the safety of mifepristone. In 2024, adverse events are widely underreported because the FDA only requires prescribers to report deaths, not other less-than-lethal adverse events associated with mifepristone. In 2000, the FDA approved mifepristone with certain safeguards and requirements to decrease the dangers mifepristone could pose to women, consistent with Subpart H.[16] Although compliance with those requirements was insufficient to prevent adverse events, they were much more stringent than the requirements imposed today. Among those requirements in 2000, prescribers were obligated to report[17] non-fatal but serious adverse events to the drug manufacturer. Beginning in 2016, prescribers need only report deaths[18] associated with the drug, not other serious adverse events.[19] The FDA's intentional blinding of itself and the public along with its claims that chemical abortion is safe because there are so few reports of adverse events is a through-the-looking-glass approach to public health that intentionally obscures the true dangers of mifepristone. Such reckless disregard of data collection on women's well-being is politics, not science. The FDA's inexplicable removal of most adverse event reporting requirements forces researchers to look overseas for data on mifepristone's harm to women. Even recent experience with mifepristone bears out the fact that it continues to be more dangerous than surgical abortion, contrary to the requirements of Subpart H. As British researcher and medical doctor Calum Miller explains:

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[12] Proposed Rule at 125.
[13] Kavitha Surana, *Abortion Bans Have Delayed Emergency Medical Care. In Georgia, Experts Say This Mother's Death Was Preventable*, ProPublica (Sept. 16, 2024) https://www.propublica.org/article/georgia-abortion-banamber-thurman-death.
[14] Carole Novielli, *Woman's Death from 'Septic Abortion' Days After Obtaining Abortion Pill Sparks Lawsuit*, Live Action (September 25, 2023) https://www.liveaction.org/news/womans-death-septic-abortion-pill-lawsuit/
[15] See https://advancingamericanfreedom.com/aaf-the-truth-about-the-georgia-abortion-death/
[16] See 21 C.F.R. § 314.520.
[17] Food and Drug Administration, Approved Labeling Text for Mifeprex (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm
[18] Food and Drug Administration, Risk Evaluation and Mitigation Strategy (March 2016), https://www.fda.gov/media/164649/download
[19] Food and Drug Administration, Risk Evaluation and Management Strategy (May 2021), https://www.fda.gov/media/164651/download

> "During the COVID-19 pandemic, a small minority of countries permitted abortion providers to send abortion pills—usually mifepristone and misoprostol—by post to women after a remote consultation by video or telephone (hereafter, "telemedicine" refers to either)—that is, without any in-person contact throughout the process. This was an unprecedented move since full telemedicine had not been studied in legal, experimental conditions prior to this… In the United Kingdom… ambulance calls and responses relating to medical abortion also increased dramatically between 2018 and 2021, following the introduction of [chemical abortion] at home and then full telemedicine."

Further, according to British researchers:

> "Data obtained from five NHS Ambulance Trusts in England, show that emergency ambulance responses for complications arising after a medical abortion are three times higher for women using pills-by-post at home, compared to those who have their medical abortion in a clinic.""

Not only did the FDA remove the adverse event reporting requirement; it also removed the in-person doctor assessment that had previously been required. At the time of the FDA's initial approval, a woman seeking a chemical abortion was required to visit the doctor three times to receive a chemical abortion prescription. In 2016, that number of visits dropped to one.[20] Then in 2021 the FDA removed the in-person visit requirement altogether,[21] meaning that a woman can obtain mifepristone through the mail without in-person examination, sonogram, or laboratory analysis. Prescribing chemical abortion drugs via telemedicine exposes women to several risks, one of the most significant of which is a ruptured ectopic pregnancy. Ultrasounds, which require an in-person assessment, are critical in identifying gestational age and ruling out ectopic pregnancies. Chemical abortion is ineffective in cases of ectopic pregnancy, yet "there is simply no requirement that any procedure is done to rule out an ectopic pregnancy—which is a serious and life-threatening situation." The current REMS require only that the prescriber have the "ability to diagnose ectopic pregnancies," not that a doctor actually assess whether the patient has one. [22] Finally, telemedicine may not allow for a thorough discussion of the patient's medical history or assessment of her needs, potentially missing important details that could impact the procedure's safety. Telemedicine also leads to uncertainty and the inability to confirm that a woman is not being coerced into performing an abortion against their will. Further, "We can expect that 1-in-17 women using the abortion pills at home, will subsequently need hospital treatment for complications arising from the medical abortion treatment failure, presenting with

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[20] Information on Mifeprex Changes and Ongoing Monitoring Efforts, Government Accountability Office at 7 (Mar. 2018) https://www.gao.gov/assets/gao-18-292.pdf

[21] Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, U.S. Food and Drug Administration (Mar. 2023) https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation

[22] Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200MG, Food and Drug Administration at 1 https://www.fda.gov/media/164651/download?attachment

retained products of conception and/or hemorrhage."[23] Thus, the FDA's loosening of standards puts women at greater risk harm without a counterbalancing interest to justify that increased risk. By 2006, the dangers of chemical abortion had become even more evident than they were when the FDA approved the drugs for that use in 2000.

In her testimony in a Congressional Hearing in May of 2006, Dr. Donna Harrison said,

> "In my experience as an ob-gyn, the volume of blood loss seen in the life-threatening cases is comparable to that observed in major surgical trauma cases like motor-vehicle accidents. This volume of blood loss is rarely seen in early surgical abortion without perforation of the uterus, and it is rarely seen in spontaneous abortion."

Dr. Harrison added that no risk factors predicted such hemorrhage, and that it was life threatening for women without access to immediate medical care. Such dangers have been ignored by the FDA in its effort to push mifepristone over the past 23 years. Information that has become available since the publication of the Congressional Report in 2006 is no more encouraging. Several studies have shown the medical risk associated with the use of chemical abortion. One study found that ten percent (10%) of women, after use of chemical abortion, require follow-up medical treatment for failed or incomplete abortion,[24] and twenty percent (20%) of women who use mifepristone to induce abortions will have an adverse event, including hemorrhaging and infections.[25] This rate of adverse events is four times greater than the adverse event rate of surgical abortion. *Id.* Abortion, including chemical abortion, also risks harm to the woman's mental health. A comprehensive review of the literature on abortion and mental health found that at least some women experienced negative mental health outcomes as a result of their abortions and that "[t]he ability to identify women who are at greater risk of negative reactions has resulted in numerous recommendations for abortion providers to screen for these risk factors in order to provide additional counseling both before an abortion, including decision-making counseling, and after an abortion."[26] The dangers to women posed by chemical abortion are many. Yet the FDA, despite consistent evidence of these dangers, has repeatedly reduced the safety measures it had initially put in place to protect against those harms.

Thurman was nine weeks pregnant when she began an abortion pill regimen, the second (and fatal) stage of which she took at home. For over 15 years after the FDA's 2000 approval of the abortion pill *mifepristone*, the regimen was limited to pregnancies of no more than seven weeks and required a follow-up appointment. A qualified physician had to administer the chemicals to

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[23] FOI Investigation into Medical Abortion Treatment Failure, Percuity at 4 (Oct. 2021) https://percuity.blog/wp-content/uploads/2021/10/foi-ma-treatment-failure-211027.pdf

[24] Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BMJ, April 20, 2011, at 4.

[25] Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009).

[26] David C. Reardon, *The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable recommendations, and research opportunities*, 6 Sage Open Medicine 1, https://journals.sagepub.com/doi/10.1177/2050312118807624

the patient in person. Over time, Democratic administrations have used the Food and Drug Administration (FDA) to methodically eliminate safeguards regarding mifepristone's use in their quest to expand abortion access at all costs. Barack Obama's FDA greenlit the pill for pregnancies as late as 10 weeks in 2016, even as it eliminated the follow-up requirement, diluted the provider standard, and no longer required providers to report significant adverse events aside from deaths. After suppressing the gathering of adverse event data, the Biden-Harris FDA got rid of the in-person prescriber requirement altogether in 2021. In 2023, it created a process for mail-order distribution, meaning a pregnant woman might never see a doctor until it was too late.[27] Concerns that removing these safeguards would endanger women were dismissed by progressive administrations. And yet, Thurman died of a sepsis infection from fetal remains that failed to pass after she took the abortion pill regimen, exactly the kind of complication that all these safeguards once existed to prevent.

What could possibly justify this reckless pattern, which goes back years, if not decades, where HHS and FDA, held captive[28] by ideologues, thinks nothing of suppressing references to objective reality? For example, the FDA has repeatedly displayed a disturbing tendency of non-transparency related to its mifepristone approval process, in which HHS was implicated. Advancing American Freedom filed a FOIA request seeking such documents on May 31, 2024.[29] No response has been received to date. This ideological weaponization of data implicating people's health has rendered HHS and FDA unworthy to be trusted with their authority over Americans' medical records and treatment. [30]

The Rule Endangers Patient Health

No health outcomes are determined by pronouns, but they can confound medical professionals. This will play mind games with medical professionals with large caseloads. Men and women have different heart attack warning signs and symptoms,[31] and if a patient's gender identity differs from his/her/their/zir/hir/cos/ens/eir/ver/yos[32] biological sex, the gender identity reflected in the medical records database may mislead the doctor regarding how to treat him/her/them/zir/hir/co/en/em/vis/yo. Additionally, a pregnant woman who identified as a man was treated for ordinary lower abdomen pain instead of pregnancy complications due to her male gender identity and delivered a stillborn baby.[33] In situations where seconds matter, such disastrous confusion is

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[27] For more information about this series of changes, see https://advancingamericanfreedom.com/wp-content/uploads/2024/02/2024-02-28-Mifepristone-Fact-Sheet-Final.pdf.

[28] George Stigler developed the theory of regulatory capture, where regulated industries capture a regulatory agency in order to generate regulations for its own benefit. See generally, George Stigler, The Theory of Economic Regulation (Bell J Econ Manag Sci 2(1):3–21, 1971).

[29] See https://advancingamericanfreedom.com/foia-request-for-fda-records-on-mifepristone/.

[30] For more information on the dangers of mifepristone, see https://advancingamericanfreedom.com/aafs-testimony-in-the-senate-finance-committee-hearing-on-abortion/.

[31] https://www.heart.org/en/health-topics/house-calls/women-vs-men-heart-attack-symptoms

[32] Our use of these pronouns is meant to display the absurdity of the Rule's pronoun system.

[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7395710/#:~:text=Sam%2C%20a%2032%2Dyear%2D,d%20lost%20his%20insurance%20coverage.

unacceptable. Additionally, males who identify as women or another gender may not receive necessary prostate checks if they are not classified as men in medical records.

This denial of reality will also fill emergency rooms with further sports injuries. For example, Payton McNabb, a high school volleyball player in North Carolina, was partially paralyzed[34] by a boy playing high school girls' volleyball. She also suffered "severe head and neck injuries resulting in long-term concussion symptoms," "impaired vision, …headaches, anxiety, and depression." Female-only sports provide women with opportunities they would not otherwise have. The biological differences between men and women are real and have significant consequences for athletic performance. If women and girls are to have the opportunity to compete and excel in fair competition, males must be excluded from women's and girls' sports. In many sports, measuring the differences between the two sexes would be difficult, and this proposed rule adds to the confusion. In sports that are measured in time, however, the comparison of men and women is revealing. The data is presented below to be remembered before it is taken down and memory-holed.

Martia Koch of East Germany set the women's 400-meter world record in 1985, running the single-lap race in 47.60 seconds.[35] 3,867 different men have run the 400 meters in 46.50 seconds or faster, over a second faster than the women's world record. Counting every time a man has run a particular time, men have run the 400 meter as fast or faster than 45.50, more than two seconds faster than the women's record, at least 8,808 times. The American high school boys' record in the 400 meters is 44.59 seconds, and the 10 fastest high school boy's 400-meter times are all faster than the women's 400-meter world record. Similarly, Gudaf Tsegay of Ethiopia set the women's outdoor track 5,000-meter record in 2023, covering the distance in 14:00.21. Her time has likely been exceeded by more than 6,000 different men. Further, men have run the 5,000 meters in 13:30 or less at least 9,233 times. The American high school boys' record for the 5,000 meters is 13:25.86, and at least the top 10 high school boys' times exceed the women's world record.

Virtually every swimming National Age Group (NAG) 13–14-year-old boys' long course meters ("LCM") record is faster than the women's world records in the same events. United States age group swimming is split into five age group categories: 10 and under, 11-12, 13-14, 15-16, and 17-18. Each age group has its own records for each swimming event, including short course yards ("SCY") and LCM. In the 13-14 age group, every LCM age group record is faster than the women's overall world record. In the 50 meter-freestyle, Thomas Heilman's boy's 13-14 NAG record is 22.95, set in 2021. The women's world record in the same event was set by Sarah Sjostrom's in 2023 at 23.61. In the 200-meter individual medley, a race in which the athlete swims 50 meters of each stroke (butterfly, backstroke, breaststroke and freestyle), Shareef

[34] https://wlos.com/news/local/volleyball-player-injured-after-transgender-opponent-spiked-ball-at-her-speaks-out
[35] For citations regarding this record and the following records, see the attached brief: https://advancingamericanfreedom.com/tennessee-v-cardona/.

Elaydi's boy's 13-14 NAG 200 meter-individual-medley record is 2:03.73. Katinka 'Iron Lady' Hosszú's women's world record in this event is 2:06.12, set at the World Championships in 2015. Katie Ledecky, widely considered the greatest women's swimmer of all time, has two world records: the 800 meter freestyle and the 1,500 meter freestyle. Luka Mijatovic's boy's 13-14 NAG 800-meter freestyle record is 7:59.64, compared to Ledecky's 8:04.97 in the same event. Ledecky's 1,500-meter freestyle world record is the one exception to the rule that the 13-14 boys exceed the women's world record times. Nonetheless, Ledecky's world record of 15:20.48 is slower than the 15-16 boy's record. Further, Mijatovic's 1,500-meter freestyle 13-14 record of 15:26.73 is faster than any woman's time except Ledecky's. By the time male swimmers have reached physical maturity, a mediocre male swimmer can make himself highly competitive by swimming against women. Such a situation is not hypothetical. In the 2021 season for National Collegiate Athletic Association (NCAA) swimming, University of Pennsylvania swimmer Will Thomas was ranked 554th in the NCAA, all divisions, in the men's 200-meter freestyle. The next year, Lia Thomas (the same person, now swimming in women's races) finished 5th in the nation in the women's 200-meter freestyle, famously being given the nod by the NCAA over Riley Gaines, with whom he tied in that race. Somewhat less dramatically, but even more tragically for the women he competed against, Thomas was ranked 65th nationally in the 500-meter freestyle when swimming against men, but "won" the NCAA women's title in 2022 at that same distance, depriving Emma Weyant of the University of Virginia, the fastest woman in that race and now two-time Olympian, of the top trophy. In every sport, both men's and women's records are broken as training techniques and other technologies improve. But the disparity between men's and women's times remains. Gretchen Walsh's 50-meter freestyle NCAA record from March 21, 2024, would have been the Men's NCAA record in 1970. In 1970, the men's 50-meter freestyle NCAA record for collegiate swimming was clocked at 20.5 seconds by David Edgar, one of the greatest short course swimmers of the 1970s. As of March 2024, Gretchen Walsh holds the women's 50-meter freestyle NCAA Division I record of 20.37 seconds, which was also an American record. Walsh is also the only woman to ever break 20 seconds in the 50-meter freestyle, which she did at the 2024 ACC Championship swim meet when she swam a 19.95 second split in a relay. Although she is the fastest woman in sprinting history, her current NCAA record of 20.37 seconds would only exceed the men's record from over 50 years ago. Where the measurements are objective and men's and women's performances can easily be compared like swimming and running, the physical advantage men enjoy is relevant in every athletic competition. Does anyone consider this fair?

Causing children physical harm is an evil that has, no doubt, existed in every society throughout human history. Even more tragically, different forms of harm have been considered socially acceptable and even obligatory in many societies at different times in history. In America, such harm is, rightly, nearly universally criminalized. However, one form of such harm, the chemical or surgical manipulation of children in response to alleged gender dysphoria, is accepted by many. That children in this country are being subjected to this sort of bodily mutilation based on their self-impression is an outrage. Here we are, with a department that exists to promote the

health of the American people, embracing a harmful ideology that is most visible in the aberrant pronouns it imposes, implying that troubled individuals who undergo chemical castration or bodily mutilation can wear these pronouns as some sort of campaign medal. How does this make sense?

Puberty blockers have been approved by the FDA for treating precocious puberty, the condition in which children begin puberty earlier than is normal or healthy. They are used in such cases to delay puberty until the normal age at which puberty should begin. However, they are being prescribed to arrest the natural pubertal process not because that process has begun too early or to address some other physical malady, but to address gender dysphoria in young people.

As is explained in the Cass Review,[36] a review of gender medicine conducted in Great Britain by Dr. Hilary Cass, the safety of puberty blockers as a temporary fix for gender dysphoria cannot be extrapolated from their safety as a treatment for precocious puberty. When used to delay natural puberty, puberty blockers "are blocking the normal rise in hormones that should be occurring into teenage years, and which is essential for psychosexual and other developmental processes." The administration of puberty blockers may alter "the trajectory of development of sexual and gender identity."[37] Sadly, puberty blockers may well prevent a natural resolution of young people's gender identity issues. By preventing the natural pubertal process, young people may well be locked into their mental state rather than developing out of it. Further, even if used as intended, cross-sex hormones may lead to sexual disfunction and, by biological necessity, to sterility.[38] It is increasingly clear that starting kids on puberty blockers constitutes not a singular intervention, but rather starting them down an unproven path with a high risk of harm. Second, puberty blockers may well hinder neurocognitive development. As the Cass Review explains:

"[A]dolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying executive function (i.e. maturation of the part of the brain concerned with planning, decision making and judgement). If this is the case, *brain*

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[36] Dr. Hillary Cass, *Independent Review of Gender Identity Services for Children and Young People* 174. The full report is available for download at https://cass.independent-review.uk/home/publications/final-report/. The evidence that the science behind "trans medicine" is unreliable has continued to come in. *Research Into Trans Medicine has Been Manipulated*, The Economist (July 27, 2024) https://tinyurl.com/46esdsr6. Yet the Federal Government may be acting to cover up the data that would expose that lack of evidence in America. As Leor Sapir explains, the Department of Justice (DOJ) may be trying "to halt release of more information in the Alabama case, as that material could further expose [the World Professional Association for Transgender Health (WPATH)] and shed more light on how HHS and other executive-branch officials misled the American public about youth gender transition." Leor Sapir, *What Does the DOJ Not Want Americans to Know?*, City Journal (July 12, 2024) https://www.city-journal.org/article/what-doesthe-doj-not-want-americans-to-know.

[37] E. Abbruzzese, Stephen B. Levine, Julia W. Mason, *The Myth of "Reliable Research" in Pediatric Gender Medicine: A Critical Evaluation of the Dutch Studies—and Research That Has Followed*, 49 Journal of Sex and Marital Therapy 673 (2023).

[38] And, as Dr. Marci Bowers, president of the WPATH said, the administration of puberty blockers before a certain stage of pubertal development leads to sexual dysfunction. Hannah Grossman, *Influential Trans Care Doctor Once Warned Puberty Blockers Could Cause Permanent Sexual Dysfunction*, Fox News (May 23, 2022 4:24 AM) https://www.foxnews.com/media/infleuntial-trans-care-doctoronce-warned-puberty-blockers-could-cause-permanent-sexual-dysfunction.

maturation may be temporarily or permanently disrupted by the use of puberty blockers, which could have a significant impact on the young person's ability to make complex risk-laden decisions, as well as having possible longer-term neuropsychological consequences."[39]

One study mentioned in the Cass Review found no cognitive difference between those adolescents given puberty blockers for less than a year and those not given puberty blockers at all, "but found worse executive functioning in those treated for more than one year compared to those not treated."[40]

Common sense suggests that delaying puberty, one of the most important physiological and psychological developmental milestones in a person's life, would have lifelong impacts. Next, the Cass Review argues that, "[i]f puberty suppression is started too early in birth-registered males it can make subsequent vaginoplasty (creation of a vagina and vulva) more difficult due to *inadequate penile development*."[41] Puberty blockers can prevent a child's sexual development such that, as an adult, he/she/they/ze/xie/co/en ey/ve/yo will not have properly developed genitalia.[42] Such destruction of young bodies is not unlike those mutilations discussed above of young boys' and girls' bodies now rightly seen as barbaric relics. Why would a health agency promote them?

By legitimizing false conceptions of gender, the Rule at issue here makes the aforementioned harms more likely. America needs this proposal like a fish needs a bicycle. Why would anyone enable such experimentation on children who do not understand the implications of what they are doing?

<u>This Rule Politicizes Medicine</u>

The Rule follows the trend of the Biden-Harris Administration and its allies to politicize medicine (especially through hot-button social issues like abortion and transgenderism) and expand the power of the executive branch beyond its constitutional bounds. Where Congress is unwilling to act on one of the President's policy priorities, the administrative state opportunistically steps in to fill the gap. The Supreme Court has already struck down two notorious examples of this overreach. The first is the Occupational Safety and Health Administration's (OSHA) workplace vaccine mandate which the Supreme Court struck down in 2022 because it exceeded the agency's statutory authority. The second, the Biden-Harris Administration's effort to unilaterally cancel student loan debt, was struck down in 2023 for exceeding the Department of Education's statutory authority. This Rule is no different.

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[39] Cass at 178, emphasis added.
[40] *Id.*
[41] Emphasis added.
[42] That these interventions could permanently close doors the importance of which the child or adolescent in question could not possibly understand at his/her/their/zir/hir/cos/ens/eir/ver/yos age is not the exercise of autonomy, but its destruction. See, generally, Moti Gorin, *What is the Aim of Pediatric "Gender-Affirming" Care?*, 54 Hastings Center Report 15 (2024).

The Rule's stated intent to "advance equity" is, to use a favorite term of DEI advocates, problematic. Medical professionals should treat the needs of every patient regardless of his/her/their/zir/hir/cos/ens/eir/ver/yos demographic characteristics. Why should one receive an inferior level of care than anyone else solely because of his/her/their/zir/hir/cos/ens/eir/ver/yos race, gender, etc.?

The Rule's explicit opposition[43] to the Supreme Court's decision in *Dobbs* v. *Jackson Women's Health Organization* indicates a clear intent to subvert states and hinder their constitutional ability to enforce their state laws protecting the right to life. Abortion destroys the right to life of the unborn, and thus destroys that person's ability ever to exercise any of his/her/their/zir/hir/cos/ens/eir/ver/yos other rights. Where the federal government has sought to promote, aid, and abet the destruction of Americans' rights, states have an obligation to step in and protect those rights. Just as northern states during the era of American slavery sought to protect the rights of escaped slaves through laws that prevented their removal, 20 American states[44] seek to prevent the violation of the rights of the unborn. This Rule would thwart that effort and allow the continued destruction of unborn life. The Rule's affirmation[45] of a previous HHS rule's redefinition of "reproductive health care" includes gender transitions[46] (the evils of which have been covered) and obstructs state efforts to enforce pro-life laws by complicating the disclosure of any medical records related to "reproductive health care."[47] Accordingly, law enforcement would be hindered from investigating illegal abortions or gender transitions performed on minors.

The right to life, and the recognition that the unborn possess that right, are deeply rooted in American and English law. As noted above, the Declaration of Independence enumerates the right to life as one of the fundamental inalienable rights governments exist to secure. For centuries, American and English law recognized that the right to life of the unborn deserved legal protection. For example, English treatises said that abortion was a crime, and "English cases dating all the way back to the 13th century corroborate the treatises' statements that abortion was a crime."[48] In America, according to the Supreme Court in *Dobbs*, "the historical record is similar." Evidence from the colonies shows that abortion was a crime. In one 1652 case, the court said that a man "Murtherously endeavoured to destroy or Murther the Child by him

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[43] Proposed Rule at 125.
[44] https://www.kff.org/womens-health-policy/dashboard/abortion-in-the-u-s-dashboard/
[45] Proposed Rule at 125.
[46] HHS' "HIPAA Privacy Rule To Support Reproductive Health Care Privacy" defines "*reproductive health care" as* "health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes."
[47] For more information, see https://eppc.org/news/eppc-scholars-and-others-submit-comments-opposing-hipaa-privacy-reproductive-health-care-privacy-rule/; https://www.texasattorneygeneral.gov/sites/default/files/images/press/HHS%20HIPAA%20Rule%20Complaint%20Filed.pdf ; and https://thefederalist.com/2024/04/23/biden-admin-threatens-to-jail-doctors-who-assist-law-enforcement-investigating-abortions/.
[48] J. Dellapenna, *Dispelling the Myths of Abortion History* 126 and n. 16, 134-52, 188-94, and nn. 84-86 (2006); J. Keown, *Abortion, Doctors and the Law*, 3-12 (1988)).

begotten in the womb." Further, "by the 19th century, courts frequently explained that the common law made abortion of a quick child a crime." That description was consistent with the law of the States at the time, "the vast majority of [which] enacted statutes criminalizing abortion at all stages of pregnancy." "By 1868, the year of the Fourteenth Amendment's ratification, three-quarters of the States, 28 out of 37, had enacted statutes making abortion a crime even if it was performed before quickening." The territories were similarly restrictive. "By the end of the 1950s . . . statutes in all but four States and the District of Columbia prohibited abortion 'however and whenever performed, unless done to save or preserve the life of the mother.'"

Throughout most of American history in most American jurisdictions, the law has recognized the inherent value of the unborn child. That is understandable. An abortion prevents all the joy and beauty of life for the aborted child, and not for him/her/them/zir/ hir/co/en/em/vis/yo only, but for all the countless children and grandchildren of whom he/she/they/ze/xie/co/en/ey/ve/yo may have been the father or mother, grandfather or grandmother. Any attempt to draw the line of life later than conception requires making arbitrary distinctions.[49] In passing pro-life laws, American states sought to fulfill the foundational responsibility of government, the protection of rights, in an area where the federal government has failed to do so. Federal statutes should not be interpreted to interfere with this fundamental exercise of state authority without a clear statement of intent to do so from Congress.

As Judge Ho of the Fifth Circuit has noted, the Federal Government has shifted its position on whether conscience protections shield doctors from being forced to provide abortions. In the lower courts in both *United States v. Idaho* and *Alliance for Hippocratic Medicine v. U.S. Food & Drug Administration*, the Government claimed that the conscience protections would not apply in this case. Then, in both cases, the Government reversed itself before the Supreme Court in a bid to avoid review on the merits, arguing there that conscience protections would apply. At the same time, legislation currently before the Senate (the Women's Health Protection Act of 2023) would likely remove any conscience protections for doctors. With the government's inconsistency on this question and the possibility of federal legislation that would intentionally destroy conscience protections for pro-life doctors, we are skeptical about any claim that doctors with conscience objections will be protected under the law. We are similarly skeptical that this Rule will respect state pro-life laws. Encouraging secrecy as part of an abortion-at-all-costs policy scheme only incentives haphazard literal and figurative "back-alley abortions" that leftists use as a rhetorical weapon.

Conclusion

[49] While some abortion laws before the 19th century limited their application to after quickening, as the Court explains, this may well have been a practical limitation rather than a philosophical distinction. *Dobbs*, 142 S. Ct. at 2251-52. Today, medical technology allows doctors to observe signs of life in the womb very early on in the pregnancy.

This forced denial of reality has implications for every sphere of life. Athletic opportunities are being taken from women[50] by men whose physical advantage renders competition unfair and flouts the very reason of existence for single-sex sports. Confused youth who are not old enough to make life-altering decisions are being pressured into mutilating their bodies.[51] Some jurisdictions are removing custody[52] of children from parents who disagree with a child's self-identification as a member of the opposite sex. Private women-only spaces are being violated and giving people the opportunity to inflict grievous harm[53] upon women. In the fundamental interest of operation upon a foundation of truth in the medical field and the right to life of the unborn, Advancing American Freedom demands that the Department of Health and Human Services withdraw the Proposed Rule and reassign staff who worked on it to more suitable positions, where they are not a danger to public health.

Paul Teller

Executive Vice President

Advancing American Freedom

Vice President Mike Pence, Founder

[50] https://advancingamericanfreedom.com/bradley-little-governor-of-idaho-v-lindsay-hecox/
[51] https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/
[52] https://advancingamericanfreedom.com/m-c-and-j-c-v-indiana-department-of-child-services/
[53] https://apnews.com/article/loudoun-virginia-lawsuit-transgender-bathroom-sexual-assault-a26168568cc20c2aa6cec9bef50e7c3f