

January 27, 2022

**Via Federal eRulemaking Portal**

Secretary Xavier Becerra  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-99L1-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: EPPC Scholars Comment Opposing Proposed Rule “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023,” RIN 0938-AU65**

Dear Secretary Becerra:

We are scholars at the Ethics & Public Policy Center (EPPC) and write in opposition to the proposed rule “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023,” 87 Fed. Reg. 584. Ryan T. Anderson is the President of EPPC and the author of *When Harry Became Sally: Responding to the Transgender Moment*, which is quoted throughout in this comment. Roger Severino is an EPPC Senior Fellow, Director of EPPC’s HHS Accountability Project, and is the former Director for the Office for Civil Rights at the Department of Health and Human Services (2017–2021). Rachel N. Morrison is an EPPC Fellow, member of the HHS Accountability Project, and former attorney at the Equal Employment Opportunity Commission. Mary Hasson is an EPPC Fellow, attorney, and co-founder of EPPC’s Person and Identity Project, an initiative that equips parents and faith-based institutions to counter gender ideology and promote the truth of the human person.

Based on our collective experience and expertise, we urge HHS not to finalize the proposed rule, specifically the proposals to add “sexual orientation and gender identity” to six nondiscrimination provisions in Patient Protection and Affordable Care Act (ACA) regulations and to add language in one of those provisions limiting which sources are considered authoritative on discriminatory benefit designs. Below we elaborate on many concerns, including: (i) why the Centers for Medicare and Medicaid Services (CMS) cannot use nondiscrimination provisions to establish a medical standard of care; (ii) the harms of medical and surgical transitioning, especially for minors; (iii) why the proposed rule is an end-run of Section 1557 and court orders, and is not required by *Bostock*; and (iv) CMS’s failure to adequately address conscience and religious freedom concerns.

The rule as proposed is arbitrary and capricious, is without legal support, contradicts long-standing scientific understandings of the human person, attempts to evade court injunctions, promotes harm to patients (especially minors), tramples religious freedom, and places ideology ahead of sound medicine.

**I. CMS cannot use nondiscrimination provisions to establish a medical “standard of care.”**

In the proposed rule, CMS is attempting to establish a medical standard of care through nondiscrimination provisions. But a nondiscrimination provision cannot establish what is “medically necessary” or good or bad medicine. Before requiring coverage, much less as an essential health benefit, CMS has the burden to prove that something is medically necessary or the standard of care. Merely repeating that certain procedures and treatments “medically necessary” or the “standard of care” do not make it so.

The proposed rule would require insurance coverage of services that are “medically necessary gender-affirming care.” 87 Fed. Reg. at 597. Excluding coverage of these and other treatments for gender dysphoria where those services are covered in the benefit plan for other reasons would be considered “presumptively discriminatory.” 87 Fed. Reg. at 666–667.

***What is medically necessary “gender-affirming care”?***

The rule specifically mentions “sex reassignment surgery” and “hormone therapy” as example of services that have not been covered, CMS does not provide a comprehensive list of what services and treatments it considers “medically necessary gender-affirming care.” 87 Fed. Reg. at 597. CMS must provide a list of such procedures to provide clarity and ensure coverage. Not doing so is capricious.

In October 2021, HHS approved Colorado’s EHB benchmark plan to require coverage for “gender affirming” services and the proposed rule cited Colorado’s EHB-benchmark plan as an example of plan that is in compliance with the updated nondiscrimination policies. 87 Fed. Reg. at 707. CMS’s press release praising Colorado’s new EHB benchmark plan claimed: “Gender-affirming care is considered a standard level of care by the American Medical Association, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Psychiatric Association.”<sup>1</sup> But what is considered “gender-affirming care”?

The Colorado EHB plan notes that “[s]urgical services and hormone therapy for medically necessary gender-affirming care are EHB under this EHB-benchmark plan,” and thus the plan design covers the following “gender-affirming” interventions, “at a minimum”:

1. Blepharoplasty (eye and lid modification)
2. Face/forehead and/or neck tightening
3. Facial bone remodeling for facial feminization
4. Genioplasty (chin width reduction)
5. Rhytidectomy (cheek, chin, and neck)
6. Cheek, chin, and nose implants
7. Lip lift/augmentation
8. Mandibular angle augmentation/creation/reduction (jaw)
9. Orbital recontouring
10. Rhinoplasty (nose reshaping)

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<sup>1</sup> Press Release, CMS, Biden-Harris Administration Greenlights Coverage of LGBTQ+ Care as an Essential Health Benefit in Colorado (Oct. 12, 2021), <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-greenlights-coverage-lgbtq-care-essential-health-benefit-colorado>.

11. Laser or electrolysis hair removal
12. Breast/chest augmentation, reduction, construction<sup>2</sup>

Colorado states that this list is the “minimum.” But are all these procedures considered “medically necessary gender-affirming care” and by whom? Will the proposed addition of “gender identity” to the various ACA nondiscrimination provisions require coverage of all twelve of these procedures or only some, and if so which ones? Are there any additional procedures or treatments that CMS will consider “medically necessary gender-affirming” care under the proposed rule?

Plan issuers, states, and the insured need to know the answers to these questions. Otherwise the CMS’s requirements are not only vague and unknown, but also arbitrary and capricious.

***There is no established standard of care for treating gender dysphoria through surgical or chemical “transition.”***

The proposed rule’s citation to the Colorado EHB benchmark plan suggests that the Colorado EHB represents the “standard of care” for the treatment of persons diagnosed with gender dysphoria.

“Gender dysphoria” (not “gender identity”) is the clinical diagnosis that requires treatment. The medical community, broadly speaking, does not hold a universal position on the best or even appropriate treatments for the clinical condition of “gender dysphoria.” In fact, the appropriate care, particularly for minors diagnosed with “gender dysphoria,” is a matter of significant debate among clinicians globally.

It is far from settled that medical and surgical interventions such as those represented by the Colorado EHB benchmark plan cited in the proposed rule represent the best or even minimally competent approach to addressing gender dysphoria. To the contrary, the evidence base supporting the medical and surgical interventions listed in the Colorado EHB benchmark plan is thin and contested for some of the interventions mentioned, and non-existent for others.

An attached meta-analysis provides examples of the disputed evidentiary basis for the interventions listed in the Colorado EHB benchmark plan.

We reject the view that the listed procedures in Colorado’s EHB benchmark plan reflect the prevailing standard of care. We further reject the claim that it is even possible to set a national “standard of care” as a matter of law, as the obligation to provide “minimally competent care” is best understood in light of the general skill required of medical practitioners within a particular specialty, the particular procedure at issue, the specific factors in a particular case, and the local law.<sup>3</sup> The standard of care is a

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<sup>2</sup> COLORADO BENEFITS FOR HEALTH CARE COVERAGE 38, <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb> (listing covered “Gender Affirming Care”).

<sup>3</sup> For example, juries in medical malpractice cases may be instructed as follows: “The mere fact that the plaintiff’s expert may use a different approach is not considered a deviation from the recognized standard of medical care. Nor is the standard violated because the expert disagrees with a defendant as to what is the best or better approach in treating a patient. Medicine is an inexact science, and generally qualified physicians may differ as to what constitutes a preferable course of treatment.” Moffett, P., & Moore, G. (2011). The Standard of Care: Legal History and Definitions: The Bad and Good News. *The Western Journal of Emergency Medicine*, 12(1), 109–112. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088386/>.

“reasonableness” standard, not a pre-set algorithm or one-size-fits-all “package.” In fact, clinicians and researchers in the area of gender dysphoria reject a “one-size-fits-all” approach.<sup>4</sup>

***A single standard cannot apply to treatment for children, adolescents, and adults.***

The regulation appears to apply “gender identity” anti-discrimination provisions across the board to the care of “transgender” or “gender dysphoric” minors as well as adults. This needs clarification. Even gender clinicians who promote “gender affirming care” agree that children and adolescents should not be treated as mini adults; they require standards and treatment protocols that take into account the different developmental needs of children and adolescents.<sup>5</sup>

***The proposed rule’s limitation of authoritative sources is arbitrary and capricious.***

The proposed rule would arbitrarily establish what constitutes authoritative sources in determining what is a non-discriminatory benefit plan design and which procedures have an appropriate medical basis. The proposed regulation § 156.125 would state: “A non-discriminatory benefit design that provides EHB is one that is clinically-based, incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources.” 87 Fed. Reg. at 726. The preamble states that other sources could not be used to dispute claims of a discriminatory benefit design.

While the preamble provides examples of what it considers “reputable” and “credible sources,” and which health professional associations it deems to provide relevant and credible practice guidelines, it also states that it would allow reliance on any applicable source representing current thinking and subject to the previously discussed criteria “since medicine is a constantly evolving field.” 87 Fed. Reg. at 663–665.

Apart from the specific sources identified, it is unclear which other sources would qualify and could be relied upon in determining a nondiscriminatory benefit plan design. Who would be responsible for determining whether a particular peer-reviewed journal that publishes a research article or clinical opinion is “current and relevant”? This standard is arbitrary, vague, and unknowable by those who would be bound by it.

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<sup>4</sup> Decisions about appropriate treatment for minors diagnosed with “gender dysphoria” cannot be made on a uniform basis but require a case-by-case determination. See, e.g., D’Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. Arch Sex Behav. 2021 Jan;50(1):7-16. doi: 10.1007/s10508-020-01844-2. Epub 2020 Oct 21. PMID: 33089441; PMCID: PMC7878242.

In a 2022 meta-analysis of “gender-affirming surgeries” to treat gender dysphoria, the authors note that: “surgery for transgender individuals is decidedly not ‘one size fits all.’” Oles N, Darrach H, Landford W, Garza M, Twose C, Park CS, Tran P, Schechter LS, Lau B, Coon D. Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 1: Breast/Chest, Face, and Voice). Ann Surg. 2022 Jan 1;275(1):e52-e66. doi: 10.1097/SLA.0000000000004728. PMID: 33443903.

<sup>5</sup> Edwards-Leeper, L., Leibowitz, S., & Sangganjanavanich, V. F. (2016). Affirmative practice with transgender and gender nonconforming youth: Expanding the model. *Psychology of Sexual Orientation and Gender Diversity*, 3(2), 165–172. <https://doi.org/10.1037/sgd0000167>.

Further, the use of practice guidelines is itself contested in determining standard of care, as the reasonableness of relying on particular practice guidelines depends on the evidentiary basis for the particular practice guideline, the degree to which a practice guideline reflects ideological bias or is tainted by conflicts of interest of its authors or sponsoring body, and other factors. Whether or not a particular practice guideline reflects the actual standard of care applicable to a situation is a case-by-case determination.

The current World Professional Association for Transgender Health (WPATH) “standards of care” (SOC 7)<sup>6</sup> (discussed in more detail below) are a case in point. They lack an evidentiary research base, are the product of a membership body that includes non-professionals and activists and reflect ideological bias. In fact, the WPATH “standards of care” are self-described as “flexible guidelines” (or suggestions) and clinicians practicing in the area of “transgender medicine” widely disregard the supposed standards they set. For example, a recent research article noted that the assessment criteria followed by Mount Sinai medical center diverged from the WPATH guidelines in the vast majority of cases.<sup>7</sup> A 2022 meta-analysis of “gender affirming” surgeries describing the WPATH guidelines, notes their weak evidentiary basis: “Although World Professional Association for Transgender Health policies set guideline recommendations for clinical decision-making, the evidence base remains widely scattered, with no reviews that unify gender surgery across all facets.”<sup>8</sup> Yet, the preamble to the proposed rule positively cites WPATH as a “professional society” that has “published criteria for guidelines in treating gender dysphoria and gender-affirming care for transgender people.” 87 Fed. Reg. at 667.

But just because a professional society has published “guidelines” does not mean those guidelines are the standard of care. Indeed, a New York Times article from January 13, 2022, discusses the debate among doctors whether teenagers should receive therapy before they receive hormones, further revealing that the standard of care when it comes to treating transgender persons.<sup>9</sup>

***The WPATH “Standards of Care” (SOC7) fail to provide reliable clinical guidance.***

The WPATH SOC were cited by the agency as an example of “criteria for guidelines in treating gender dysphoria and gender-affirming care for transgender people.” 87 Fed. Reg. at 667. However, WPATH “Standards of Care” (SOC7) are not recognized as true “standards of care” and clinicians routinely depart from their recommendations.

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<sup>6</sup> World Professional Assn for Transgender Health, Standards of Care Version 7 (2018), <https://www.wpath.org/publications/soc>.

<sup>7</sup> Lichtenstein, M., Stein, L., Connolly, E., Goldstein, Z. G., Martinson, T., Tiersten, L., Shin, S. J., Pang, J. H., & Safer, J. D. (2020). The Mount Sinai Patient-Centered Preoperative Criteria Meant to Optimize Outcomes Are Less of a Barrier to Care Than WPATH SOC 7 Criteria Before Transgender-Specific Surgery. *Transgender health*, 5(3), 166–172. <https://doi.org/10.1089/trgh.2019.0066>.

<sup>8</sup> Oles N, Darrach H, Landford W, Garza M, Twose C, Park CS, Tran P, Schechter LS, Lau B, Coon D. Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 1: Breast/Chest, Face, and Voice). *Ann Surg*. 2022 Jan 1;275(1):e52-e66. doi: 10.1097/SLA.0000000000004728. PMID: 33443903.

<sup>9</sup> Azeen Ghorayshi, *Doctors Debate Whether Trans Teens Need Therapy Before Hormones*, NY TIMES (Jan. 13, 2022), <https://www.nytimes.com/2022/01/13/health/transgender-teens-hormones.html>.

Unlike authentic “standards of care,” which typically set the floor—or “minimum”—level of required care, WPATH states that “The SOC are intended to be flexible.”<sup>10</sup> WPATH expressly states that “individual health professionals and programs may modify” the SOC. It recognizes that “clinical departures from the SOC” may come about for a range of reasons including the patient’s anatomy, “unique” situation, the clinician’s “evolving method,” “lack of resources,” and “harm reduction.” WPATH emphasizes that the practical purpose of its guidelines is to “help patients consider the full range of health services open to them, in accordance with their clinical needs and goals for gender expression.” Put differently, WPATH SOC mainly help patients set their personal “gender transition” goals.

Leading physicians who provide medical or surgical treatments for gender dysphoria seem to have few qualms about disregarding WPATH’s “flexible” clinical guidelines. The assessment criteria followed by Mount Sinai medical center diverged from the WPATH guidelines in the vast majority of cases.<sup>11</sup> A 2019 overview article by Dr. Kenneth Zucker, a gender clinician with decades of experience, notes that age guidelines set forth by WPATH are “only suggested guidelines and it is well known that some (many?) clinicians endorse these procedures at younger ages.” Zucker cites, as examples, three studies by prominent researchers in the field.<sup>12</sup>

***The proposed rule has missing calculations on cost-benefit analysis.***

To accurately determine the costs and the benefits of the proposal, CMS must clarify:

- How many issuers and plans already cover these procedures.
- How many individuals will seek insurance coverage of “gender affirming” procedures.
- The average cost of each “gender affirming” procedure.
- The increased costs to both the issuers and the insured to cover these additional procedures.

Without providing this information, CMS cannot not accurately compute the costs as required in its regulatory impact analysis, making its determination that the benefits outweigh the costs arbitrary and capricious.

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<sup>10</sup> WPATH SOC 7 at 2.

<sup>11</sup> Lichtenstein, M., Stein, L., Connolly, E., Goldstein, Z. G., Martinson, T., Tiersten, L., Shin, S. J., Pang, J. H., & Safer, J. D. (2020). The Mount Sinai Patient-Centered Preoperative Criteria Meant to Optimize Outcomes Are Less of a Barrier to Care Than WPATH SOC 7 Criteria Before Transgender-Specific Surgery. *Transgender health*, 5(3), 166–172. <https://doi.org/10.1089/trgh.2019.0066>.

<sup>12</sup> Zucker, K. J. (2019). Adolescents with gender dysphoria: Reflections on some contemporary clinical and research issues. *Archives of Sexual Behavior*, 48(7), 1983–1992. <https://link.springer.com/article/10.1007%2Fs10508-019-01518-8>. Zucker cites to Milrod, C. (2014). How young is too young: Ethical concerns in genital surgery of the transgender MTF adolescent. *Journal of Sexual Medicine*, 11, 338–346; Milrod, C., & Karasic, D. H. (2017). Age is just a number: WPATH- affiliated surgeons’ experiences and attitudes toward vaginoplasty in transgender females under 18 years of age in the United States. *Journal of Sexual Medicine*, 14, 624–634; Olson-Kennedy, J., Warus, J., Okonta, V., Belzer, M., & Clark, L. F. (2018). Chest reconstruction and chest dysphoria in transmasculine minors and young adults: Comparisons of nonsurgical and postsurgical cohorts. *JAMA Pediatrics*, 172, 431–436.

**II. The proposed rule would require coverage of transition procedures that are harmful, especially for minors.**

*The agency arbitrarily ignores that a person’s sex is defined by biology.*

Even the decision in *Bostock v. Clayton County*, on which the proposed rule heavily relies, explicitly assumed that “sex” referred “only to biological distinctions between male and female.”<sup>13</sup> It is arbitrary and capricious for the proposed rule to avoid specifying precisely what sex in medicine and science means and how it relates to medical necessity with respect to gender dysphoria treatments. The concept of gender dysphoria is meaningless without sex, just as transgender transition as a proposed medical solution is meaningless. What would a person be transitioning to and from exactly? If the agency cannot answer such a basic question with any semblance of scientific and medical rigor, it has no basis to mandate coverage of such “transition” treatments and procedures in any context, and certainly not as an essential health benefit. Moreover, not only *must* the agency answer the question what sex is in medicine, it must answer it correctly and in accordance with logic and science.

A person’s sex is defined as “male or female according to their reproductive organs and functions assigned by the chromosomal complement.”<sup>14</sup> Sex is imprinted in every cell of the person’s body and cannot change.<sup>15</sup> Even HHS’s National Institutes of Health (NIH) matter-of-factly states that “every cell has a sex”<sup>16</sup> and still requires its 80,000 research grant applicants to account for sex as a biological variable in all animal and human studies.<sup>17</sup> This is because NIH knows that a person’s immutable sexual biology explains in significant part why men and women respond differently to medication, vary in their experience and manifestation of pain, and have disparate susceptibility to illnesses, from heart disease and cancer to psychological conditions such as depression and anxiety. Sex in medicine and research cannot be replaced by subjective “gender identity.” Male and female are not part of an ever multiplying spectrum nor are they merely placeholders assigned at birth.

But the case for “transitioning” as the medical solution to gender dysphoria rests on the notion that transgender identity is innate—that a person can simply be born as “a man trapped in a woman’s body,” or vice versa. Therefore, adjusting that person’s hormone balance and restructuring the anatomy, to align the body with the inner sense of identity, should make things right. But does the agency have any biological basis to believe that a man could be born in the bodily form of a female, invisible to those who “assign” a sex at birth? Can the agency be confident that hormones and surgery can “reassign” sex? To answer these questions, we must start by examining what science tells us about the biological genesis of sex.

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<sup>13</sup> *Bostock*, 140 S. Ct. at 1739 (2020).

<sup>14</sup> Institute of Medicine 2001. *Exploring the Biological Contributions to Human Health: Does Sex Matter?*. Washington, DC: The National Academies Press, at p. 1. <https://doi.org/10.17226/10028>.

<sup>15</sup> Institute of Medicine 2001. *Exploring the Biological Contributions to Human Health: Does Sex Matter?*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/10028>.

<sup>16</sup> National Institutes of Health, Sex as a Biological Variable (March 18, 2021). <https://www.youtube.com/watch?v=oshnZrAKkiY&feature=youtu.be>.

<sup>17</sup> Consideration of Sex as a Biological Variable in NIH-funded Research, NOT-OD-15-102 (June 9, 2015). <https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html>.

The basics of sex determination are relatively clear. Sex, in terms of male or female, is identified by the organization of the organism for sexually reproductive acts. *Langman's Medical Embryology* concisely explains how the sex of a new organism is determined at fertilization: "An X-carrying sperm produces a female (XX) embryo, and a Y carrying sperm produces a male (XY) embryo. Hence, the chromosomal sex of the embryo is determined at fertilization." A new human organism of a particular sex is created at that moment. Scientists now know that "the *presence* of a Y chromosome determines maleness and its *absence* determines femaleness." This is because the Y chromosome ordinarily carries the SRY ("sex-determining region on Y") gene. The SRY gene contains a transcription factor known as the testis-determining factor (TDF), which directs the formation of the male gonads.

Sex as a status—male or female—is a recognition of the organization of a body designed for dimorphic sexual reproduction. More than simply being *identified* on the basis of such organization, sex is a *coherent concept* only on the basis of that organization. The fundamental conceptual distinction between a male and a female is the organism's organization for sexual reproduction. The conceptual distinction between male and female based on reproductive organization provides the only coherent way to classify the two sexes.

Lawrence Mayer and Paul McHugh highlighted the same truth in a recent review of the scientific literature on sexuality and gender identity:

The underlying basis of maleness and femaleness is the distinction between the reproductive roles of the sexes; in mammals such as humans, the female gestates offspring and the male impregnates the female. . . . This conceptual basis for sex roles is binary and stable, and allows us to distinguish males from females on the grounds of their reproductive systems, even when these individuals exhibit behaviors that are not typical of males or females.

Mayer is a scholar-in-residence in the Department of Psychiatry at Johns Hopkins University and a professor of statistics and biostatistics at Arizona State University. McHugh is a professor of psychiatry and behavioral sciences at the Johns Hopkins University School of Medicine, and for twenty-five years was the psychiatrist-in-chief at the Johns Hopkins Hospital. The editor of the *New Atlantis*, in the introductory note to their report, called McHugh "arguably the most important American psychiatrist of the last half-century."

After explaining the "binary and stable" conceptual basis for maleness and femaleness, Mayer and McHugh note that a structural difference for the purposes of reproduction is the only "widely accepted" way of classifying the two sexes:

In biology, an organism is male or female if it is structured to perform one of the respective roles in reproduction. This definition does not require any arbitrary measurable or quantifiable physical characteristics or behaviors; it requires understanding the reproductive system and the reproduction process. Different animals have different reproductive systems, but sexual reproduction occurs when the sex cells from the male and female of the species come together to form newly fertilized embryos. It is these reproductive roles that provide the conceptual basis for the differentiation of animals into the biological categories of male and female. There is no other widely accepted biological classification for the sexes.



This fundamental difference in organization is what allows scientists to distinguish male from female. When Dr. Deanna Adkins called this “an extremely outdated view of biological sex” in her declaration to a federal court in North Carolina, Dr. Mayer responded in his rebuttal declaration: “This statement is stunning. I have searched dozens of references in biology, medicine and genetics—even Wiki!—and can find no alternative scientific definition. In fact the only references to a more fluid definition of biological sex are in the social policy literature.” Just so, yet the proposed regulation adopts a wholly subjective and amorphous understanding of the person, based on gender identity, divorced from scientific realities.

Here is how one scholar put it in *Best Practice and Research: Clinical Endocrinology and Metabolism*:

Females enter puberty earlier and undergo a more rapid pubertal transition, whereas boys have a substantially longer growth period. After adjusting for dimorphism in size (height), adult males have greater total lean mass and mineral mass, and a lower fat mass than females. These whole-body differences are complemented by major differences in tissue distribution. Adult males have greater arm muscle mass, larger and stronger bones, and reduced limb fat, but a similar degree of central abdominal fat. Females have a more peripheral distribution of fat in early adulthood; however, greater parity and the menopause both induce a more android fat distribution with increasing age. Sex differences in body composition are primarily attributable to the action of sex steroid hormones, which drive the dimorphisms during pubertal development. Oestrogen is important not only in body fat distribution but also in the female pattern of bone development that predisposes to a greater female risk of osteoporosis in old age.

The result is that male and female bodies differ not only in their sex chromosomes (XX and XY) and in their organization for reproduction, but also, on average, in size, shape, bone length and density, fat distribution, musculature, and various organs including the brain. These secondary sex differences are not what define us as male or female; organization for reproduction does that. But this organization leads to other bodily differences. There are organizational differences and organism-wide differences in organs and tissues, as well as differences at the cellular and molecular levels.

### ***Innate Sex Differences Affect Our Health***

There are biological differences between men and women, and they are consequential for our health. Recognizing differences between the sexes is increasingly regarded as vitally important for good medical practice, because scientists have found that male and female bodies tend to be susceptible to certain diseases in different ways, to differing degrees, and they respond to treatments differently. For this reason, the best research protocols now require that both males and females be included in samples, and that the sex of participants be tracked so that any sex-specific results can be recorded.

The Institute of Medicine at the National Academy of Sciences published a report in 2001 titled *Exploring the Biological Contributions to Human Health: Does Sex Matter?* The executive summary answered the question in the affirmative, saying that the explosive growth of biological information “has made it increasingly apparent that many normal physiological functions—and, in many cases, pathological functions—are influenced either directly or indirectly by sex-based differences in biology.” Because genetics and physiology are among the influences on an individual’s health, the “incidence and severity of diseases vary between the sexes.” The difference between male and female is thus “an

important basic human variable that should be considered when designing and analyzing studies in all areas and at all levels of biomedical and health-related research.”

The chapter titles of the report sum up basic truths about our bodily nature: “Every Cell Has a Sex.” “Sex Begins in the Womb.” “Sex Affects Behavior and Perception.” “Sex Affects Health.” Some of the biological differences between the sexes that bear on health derive from hormone exposure, but others come more directly from our genetic material. There are “multiple, ubiquitous differences in the basic cellular biochemistries of males and females that can affect an individual’s health. Many of these differences do not necessarily arise as a result of differences in the hormonal regime to which males and females are exposed but are a direct result of the genetic differences between the two sexes.” Written into our genetic code are differences that manifest themselves at the cellular level, in ways that can affect our health. Sexual differentiation begins at conception, progresses in the womb, and continues throughout life, notably at puberty but also significantly at menopause in females. “Hormonal events occurring in puberty lay a framework for biological differences that persist through life and contribute to the variable onset and progression of disease in males and females.”

“Basic genetic and physiological differences, in combination with environmental factors, result in behavioral and cognitive differences between males and females,” says the Institute of Medicine. These biological differences seem to have consequences for mental health. An article in the *Neuroscience and Biobehavioral Review* points to well-known differences between men and women in susceptibility to mental disorders: “Examples of male-biased conditions include autism, attention deficit/hyperactivity disorder, conduct disorder, specific language impairment, Tourette syndrome, and dyslexia, and examples of female-biased conditions include depression, anxiety disorder, and anorexia nervosa.” This is not to say that these are exclusively male or female conditions, but that one sex or another experiences them with greater frequency.

A literature review in the *Journal of Cellular Physiology* tells us that “men are able to synthesize serotonin, the neurotransmitter commonly associated with pleasant moods, at a greater rate than women,” and therefore men have a lower incidence of major depression, anxiety, and multiple sclerosis, but a higher incidence of attention deficit hyperactive disorder and coronary artery disease. There are also differences in susceptibility to Alzheimer’s disease and dementia. While scientists don’t know how much of these differences are due to environment and how much to biology, they do know that “innate physiological differences between males and females may play a large role in sex differences in disease onset, susceptibility, prevalence, and treatment responses.”

Men and women also tend to respond differently to pain, which has important implications for the use of painkillers and other medicines. Men and women have “variable responses to pharmacological agents and the initiation and manifestation of diseases such as obesity, autoimmune disorders, and coronary heart disease, to name a few.” Differences in the chemistry and structure of the brain influence our response to stressful events and how we remember them. The differences between men and women in memory formation surrounding “emotionally arousing incidents” have implications for the treatment for post-traumatic stress disorder.

Acknowledging sex-based differences is vital for women’s health, as Jill Goldstein and colleagues emphasize in a paper for *Frontiers in Neuroscience*. “We now know there are significant sex differences in many chronic diseases, including brain disorders,” they write, so understanding the causes of these differences “is critical to understanding women’s mental health and healthcare needs.” They cite

studies demonstrating, for example, that “the vulnerability for sex-dependent risk for MDD [major depressive disorder] begins in fetal development” (their italics). Neuroscience must therefore “adopt a ‘sex-dependent’ and/or ‘sex-specific’ lens on investigations of the brain.”

Of course, male and female bodies are alike in many ways, but there are notable differences in average male and average female bodies beyond our different organizations for reproduction. In other words, there is a fundamental, essential difference, and there are subsidiary, average differences. There is also wide variation among males and among females, and considerable overlap between them, even in the areas just discussed. While environmental factors are likely to influence many of these differences, there’s no denying the role of biology.<sup>18</sup>

As cited in HHS’s 2020 Rule on Section 1557, in an actual case from 2019, a person who was admitted to an emergency room with severe abdominal pain was tracked according to a preferred male gender identity. Unbeknownst to the triage staff, the patient was actually a woman in late-stage labor. The result was the stillbirth of a very real human child who possibly could have been saved but for gender identity politics distorting the truth of the situation. According to HHS, “this case is not based on speculation. Rather, it involved the actual death of an unborn child and attendant trauma and anguish for those involved, all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex. Given that life-and-death decisions are frequently made in healthcare settings and often in urgent circumstances, this story serves as an example of the consequences that could result from the confusion caused by the . . . . mandate to treat individuals ‘consistent with’ stated gender identity.”<sup>19</sup> HHS also found that using non-discrimination rationales to impose a gender identity rule “risked masking clinically relevant, and sometimes vitally important, information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity.”<sup>20</sup>

When science is supplanted by ideological concerns, real people suffer, yet the proposed rule ignores the science and attempts to impose a national standard of care and coverage without answering any of the necessary predicate medical and scientific questions.

***“Transition” treatment for children and adolescents is a novel approach with little longitudinal evidence of benefit.***

For decades, gender dysphoria in children was addressed successfully through “watchful waiting” or with psychotherapy for the child and family. In most (up to 88%) of these situations, the child’s gender dysphoria (identity distress) resolved by puberty.<sup>21</sup>

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<sup>18</sup> RYAN T. ANDERSON, WHEN HARRY BECAME SALLY: RESPONDING TO THE TRANSGENDER MOMENT 77–88 (2018) (internal citations omitted).

<sup>19</sup> 85 FR 37190.

<sup>20</sup> *Id.*

<sup>21</sup> Singh, D., Bradley, S. J., & Zucker, K. J. (2021). A Follow-Up Study of Boys With Gender Identity Disorder. *Frontiers in psychiatry*, 12, 632784. [doi.org/10.3389/fpsy.2021.632784](https://doi.org/10.3389/fpsy.2021.632784); <https://www.frontiersin.org/articles/10.3389/fpsy.2021.632784/full>; Steensma TD, Biemond R, de Boer F, Cohen-Kettenis PT. Desisting and persisting gender dysphoria after childhood: a qualitative follow-up study. *Clin Child Psychol Psychiatry*. 2011 Oct;16(4):499-516. doi: 10.1177/1359104510378303. Epub 2011 Jan 7. PMID: 21216800; Steensma TD, McGuire JK, Kreukels BP, Beekman AJ, Cohen-Kettenis PT. Factors associated with desistence and

The “gender-affirming” approach initiated by the Dutch in the 1990s introduced “biomedical aspects of sex/gender transition in early to mid-adolescence, rather than waiting for the legal age of adulthood. Adolescents deemed appropriate for such treatment are prescribed hormonal medication (GnRH agonists) to delay or suppress somatic puberty (prior to the age of 16 years). If the gender dysphoria persists, then cross-hormonal therapy is offered at the age of 16 years, and, if the adolescent so desires, surgical sex change procedures are offered at a lower bound age of 18 years.”<sup>22</sup>

The first full-spectrum youth transgender clinic in the U.S. opened less than 15 years ago, in 2007. A decade later, only a “single group of scholars... has described a gender-affirmative treatment model for TGNC [transgender and non-conforming] children and adolescents.”<sup>23</sup> Leading gender clinicians acknowledged, as recently as 2016, that social and medical transition was but one of many possible clinical approaches and that, “[g]iven the lack of evidence-based treatment guidelines and the limitations in the scientific research on gender development, it is misguided to universally employ” a singular approach to all children who experience gender dysphoria, “as doing so fails to take into consideration the wide variability and potential complexity present for each child.”<sup>24</sup> The model supporting rejection of one’s biological sex departs from decades of practice to reject “therapeutic approaches that encourage individuals to accept their given body and assigned gender,” contending that alternative approaches “may inadvertently cause psychological harm.”<sup>25</sup> Despite the “absence of empirical data” to support these theories, the gender affirming model and transgender surgical interventions have been heavily promoted by transgender activists, allied clinicians, and several establishment medical organizations, which erroneously present such approaches as universally accepted and well-supported by the evidence.<sup>26</sup> The numbers of transgender-identified adolescents continue to increase, spurred by cultural change and other factors, resulting in reported increases in gender affirming interventions. But as more adolescents and young adults continue to seek irreversible “transgender” body

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persistence of childhood gender dysphoria: a quantitative follow-up study. *J Am Acad Child Adolesc Psychiatry*. 2013 Jun;52(6):582-90. doi: 10.1016/j.jaac.2013.03.016. Epub 2013 May 3. PMID: 23702447.

<sup>22</sup> Zucker, K. J. (2019). Adolescents with gender dysphoria: Reflections on some contemporary clinical and research issues. *Archives of Sexual Behavior*, 48(7), 1983–1992. <https://link.springer.com/article/10.1007%2Fs10508-019-01518-8>.

The Dutch protocol was described in de Vries, A. L. C., & Cohen-Kettenis, P. T. (2012). Clinical management of gender dysphoria in children and adolescents: The Dutch approach. *Journal of Homosexuality*, 59, 301–320. <http://dx.doi.org/10.1080/00918369.2012.653300>.

<sup>23</sup> Edwards-Leeper, L., Leibowitz, S., & Sangganjanavanich, V. F. (2016). Affirmative practice with transgender and gender nonconforming youth: Expanding the model. *Psychology of Sexual Orientation and Gender Diversity*, 3(2), 165–172. <https://doi.org/10.1037/sgd0000167>, citing Hidalgo, M. A., Ehrensaft, D., Tishelman, A. C., Clark, L. F., Garofalo, R., Rosenthal, S. M., . . . Olson, J. (2013). The gender affirmative model: What we know and what we aim to learn. *Human Development*, 56, 285–290. <http://dx.doi.org/10.1159/000355235>.

<sup>24</sup> Edwards-Leeper, L., Leibowitz, S., & Sangganjanavanich, V. F. (2016). Affirmative practice with transgender and gender nonconforming youth: Expanding the model. *Psychology of Sexual Orientation and Gender Diversity*, 3(2), 165–172. <https://doi.org/10.1037/sgd0000167>.

<sup>25</sup> Edwards-Leeper, at 166, citing Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth, Substance Abuse and Mental Health Services Administration (2015). [https://store.samhsa.gov/product/Ending-Conversion-Therapy-Supporting-and-Affirming-LGBTQ](https://store.samhsa.gov/product/Ending-Conversion-Therapy-Supporting-and-Affirming-LGBTQ%2C%20Youth/SMA15-4928), Youth/SMA15-4928

<sup>26</sup> Edwards-Leeper, L., Leibowitz, S., & Sangganjanavanich, V. F. (2016). Affirmative practice with transgender and gender nonconforming youth: Expanding the model. *Psychology of Sexual Orientation and Gender Diversity*, 3(2), 165–172. <https://doi.org/10.1037/sgd0000167>.

modifications, the associated medical, psychological, and financial costs are rising as well, resulting in regret and growing ranks of detransitioners.<sup>27</sup>

Advocates of social and medical transition claim not only that it represents the standard of care for treating minors diagnosed with gender dysphoria, but also that “anything other than ‘affirmative’ psychotherapy for gender dysphoria (GD) is harmful and should be banned.” Doctors and scientists have described this position as seriously “misguided.”<sup>28</sup> Studies purporting to show better mental health outcomes from social and medical transition while framing alternative psychotherapeutic approaches as *per se* harmful are seriously flawed.<sup>29</sup> Relying on data from the 2015 U.S. Transgender Survey, these studies are “compromised by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects’ baseline mental health status.”<sup>30</sup>

Research on detransitioners makes clear that cross-sex medical and surgical interventions result in significant regret for a significant number of adolescents and young adults. Regret is real, underreported, and likely to increase in a clinical environment where minors bear the weight of self-diagnosis, and professionals must rely on adolescent claims of certainty and consent.<sup>31</sup>

***“Gender-affirmation” approaches ignore other co-morbidities.***

Although the specific causes of gender dysphoria are often unclear, it is well-documented that children and adolescents experiencing gender dysphoria generally present with multiple co-morbidities,

<sup>27</sup> Littman, L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav* **50**, 3353–3369 (2021).

<https://doi.org/10.1007/s10508-021-02163-w>; <https://link.springer.com/article/10.1007/s10508-021-02163-w>.

<sup>28</sup> D’Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. 2021 Jan;50(1):7-16. doi: 10.1007/s10508-020-01844-2. Epub 2020 Oct 21. PMID: 33089441; PMCID: PMC7878242.

<sup>29</sup> Turban, J. L., Beekwith, N., Reisner, S. L., & Keuroghlian, A. S. (2020). Association between recalled exposure to gender identity conversion efforts and psychological distress and suicide attempts among transgender adults. *JAMA Psychiatry*, *77*(1), 68–76. <https://doi.org/10.1001/jamapsychiatry.2019.2285>.

<sup>30</sup> D’Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. 2021 Jan;50(1):7-16. doi: 10.1007/s10508-020-01844-2. Epub 2020 Oct 21. PMID: 33089441; PMCID: PMC7878242.

<sup>31</sup> See the “detransition” studies by Dr. Lisa Littman. Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. 2021 Nov;50(8):3353-3369. doi: 10.1007/s10508-021-02163-w. Epub 2021 Oct 19. PMID: 34665380; PMCID: PMC8604821; Littman L. The Use of Methodologies in Littman (2018) Is Consistent with the Use of Methodologies in Other Studies Contributing to the Field of Gender Dysphoria Research: Response to Restar (2019). *Arch Sex Behav*. 2020 Jan;49(1):67-77. doi: 10.1007/s10508-020-01631-z. Epub 2020 Jan 17. PMID: 31953699; Littman L (2019) Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PLOS ONE* *14*(3): e0214157. <https://doi.org/10.1371/journal.pone.0214157>; Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PLoS One*. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: *PLoS One*. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

such as depression or anxiety.<sup>32</sup> Many also have suffered from adversity or traumatic childhood events. A recent study of children and adolescents seeking care for gender dysphoria found that “[akin] to children with other forms of psychological distress, children with gender dysphoria” have “multiple interacting risk factors that include at-risk attachment, unresolved loss/trauma, family conflict and loss of family cohesion, and exposure to multiple ACEs [adverse childhood experiences].”<sup>33</sup> In light of the complicated histories of transgender-identified persons, writes Dr. Lisa Littman, the minimum level of “adequate” psychotherapy ought to explore “factors that could be misinterpreted as non-temporary gender dysphoria as well as factors that could be underlying causes for gender dysphoria.”<sup>34</sup>

The focus on “gender affirmation” to the exclusion of appropriate psychotherapy creates additional psychological risks. Presuming that a minor’s dissociative feelings are healthy or indicative of a newly emergent, fixed identity is “dangerous,” according to Anna Hutchinson, a veteran NHS gender clinician. It ignores other possible causes, including “autistic-spectrum disorders, depression, trauma or a history of sexual abuse.” Foreclosing psychotherapy that explores alternative explanations “goes against what therapy is,” says Dr. Hutchinson.<sup>35</sup>

Gender therapists Laura Edwards-Leeper and Erica Anderson warn that transgender-identified minors are receiving “sloppy, dangerous,” and “substandard” care” from mental health professionals who practice “gender-affirmative care,” because “gender affirming” providers “affirm without question” an adolescent’s asserted identity and “assume that a person with gender dysphoria who declares they are transgender is transgender and needs medical interventions immediately.”<sup>36</sup>

Requiring insurers and health plans to provide transition counseling, to be followed by hormones and medical procedures, as a one-size-fits-all “solution” to gender dysphoria is arbitrary, capricious, and unsupported by the evidence. Worse, promoting abandonment of one’s biological sex to impressionable young people causes significant known harms and obscures underlying causes.

<sup>32</sup> A recent study, for example, reported that 87.7% of children and adolescents diagnosed with gender dysphoria had comorbid psychiatric diagnoses, and many had a “history of self-harm, suicidal ideation, or symptoms of distress.” Kozłowska K, Chudleigh C, McClure G, Maguire AM, Ambler GR. Attachment Patterns in Children and Adolescents With Gender Dysphoria. *Front Psychol*. 2021 Jan 12;11:582688. doi: 10.3389/fpsyg.2020.582688. PMID: 33510668; PMCID: PMC7835132; See also, Newcomb, M.E., Hill, R., Buehler, K. *et al*. High Burden of Mental Health Problems, Substance Use, Violence, and Related Psychosocial Factors in Transgender, Non-Binary, and Gender Diverse Youth and Young Adults. *Arch Sex Behav* 49, 645–659 (2020). <https://doi.org/10.1007/s10508-019-01533-9>. <https://link.springer.com/article/10.1007/s10508-019-01533-9>.

<sup>33</sup> Kozłowska K, Chudleigh C, McClure G, Maguire AM, Ambler GR. Attachment Patterns in Children and Adolescents With Gender Dysphoria. *Front Psychol*. 2021 Jan 12;11:582688. doi: 10.3389/fpsyg.2020.582688. PMID: 33510668; PMCID: PMC7835132.

<sup>34</sup> Littman, L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav* 50, 3353–3369 (2021). <https://doi.org/10.1007/s10508-021-02163-w>, <https://link.springer.com/article/10.1007/s10508-021-02163-w>.

<sup>35</sup> Missing the Mark, “A proposed bill on conversion therapy could do more harm than good, *The Economist*, Dec. 4, 2021, <https://www.economist.com/britain/2021/12/04/a-proposed-bill-on-conversion-therapy-could-do-more-harm-than-good>.

<sup>36</sup> Abigail Shrier, “Top Trans Doctors Blow the Whistle on ‘Sloppy Care,’” *Common Sense*, October 4, 2021. <https://bariweiss.substack.com/p/top-trans-doctors-blow-the-whistle>.

*Medical risks of transition treatments.*

Although customary medical competency standards exist through centralized accreditation and testing organizations,<sup>37</sup> there is no formal national medical licensing regime in the United States and medical licensing and discipline remain primarily an exercise of state police power. However, with respect to drugs and biologics, the federal government licenses and approves specific medical uses after the FDA establishes their safety and efficacy under the Food, Drug, and Cosmetic Act.<sup>38</sup> Additionally, the FDA may require certain particularly risky medications to be administered by physicians under tighter protocols called a Risk Evaluation and Mitigation Strategy (REMS).<sup>39</sup> Federal law does not prohibit physicians from administering drugs “off-label,” that is, for medical or treatment purposes not approved by the FDA, when done in accord with medical judgment and with no illegal purpose.<sup>40</sup>

Drugs currently being used “off-label” to block puberty or to further or induce cross-sex transition for gender identity purposes include Histrelin Acetate, Leuprolide Acetate (puberty blockers); Estradiol, Premarin (estrogen); Androderm, Testosterone Enanthate or Cypionate, Axiron, Testopel, Striant (testosterone); Goserelin Acetate (LHRH antagonists); Depo-Provera, Provera, Prometrium (progestins).

The side effects and harms of these drugs include:

- Permanent infertility
- Serious mental health effects
- Venous thrombosis/thromboembolism
- Increased risk of cardiovascular disease
- Weight gain
- Decreased libido
- Hypertriglyceridemia
- Elevated blood pressure
- Decreased glucose tolerance
- Gallbladder disease
- Benign pituitary prolactinoma
- Lower HDL and elevated triglycerides
- Increased homocysteine levels
- Hepatotoxicity
- Polycythemia
- Sleep apnea

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<sup>37</sup> For *e.g.*, accreditation by the Council for Graduate Medical Education and the Liaison Committee on Medical Education, the Centers for Medicare & Medicaid Services’ (CMS) Graduate Medical Education standards, and widespread use of the United States Medical Licensure Examinations or the Comprehensive Osteopathic Medical Licensing Examination.

<sup>38</sup> 21 U.S.C. § 301 *et seq.*

<sup>39</sup> See <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>.

<sup>40</sup> There are however strict limits on promotion of off-label uses of drugs by physicians. See Syed, Dixon, Constantino and Regan, *The Law and Practice of Off-Label Prescribing and Physician Promotion*, Journal of the American Academy of Psychiatry and the Law (November 2020).  
<http://jaapl.org/content/early/2020/11/24/JAAPL.200049-20>.

- Insulin resistance
- Chronic pelvic pain
- Increased cancer and stroke risk.<sup>41</sup>

The side effects of surgical interventions for gender affirming purposes such as hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, vaginoplasty, and mastectomy are serious and include some of the above as well as many others associated with major surgery including increased risk of death.

In terms of any potentially offsetting mental health benefits of medical gender transition interventions, such as greater psychic well-being and reduced suicide rates, there is insufficient rigorous data to recommend such interventions as a federally-recognized standard of care. On August 30, 2016, the Centers for Medicare & Medicaid Services (CMS) declined to issue a National Coverage Determination on sex-reassignment surgery for Medicare beneficiaries with gender dysphoria “because the clinical evidence is inconclusive.”<sup>42</sup> CMS determined, “[b]ased on an extensive assessment of the clinical evidence,” that “there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries [which include non-seniors] with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.”

Similarly, in a 2018 Department of Defense (DOD) report on the diagnosis of gender dysphoria, which included input from both transgender individuals and medical professionals with experience in the care and treatment of individuals with gender dysphoria, DOD found that there is “considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.”<sup>43</sup>

In 2020 the Office for Civil Rights at the U.S. Department of Health and Human Services (HHS), addressed whether Section 1557 of the Affordable Care Act required health insurers to cover transgender procedures and treatments and doctors to perform and administer them.<sup>44</sup> HHS again concluded that there is no federally-recognized or required standard of medical necessity for transgender procedures undertaken to ameliorate symptoms of gender dysphoria.<sup>45</sup>

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<sup>41</sup> Timothy Cavanaugh, M.D., *Cross-Sex Hormone Therapy*, FENWAY HEALTH (2015).

<https://www.lgbtqihealtheducation.org/wp-content/uploads/Cross-Sex-Hormone-Therapy1.pdf>.

<sup>42</sup> CMS, “Decision Memo for Gender Dysphoria and Gender Reassignment Surgery” (CAG-00446N) (Aug. 30, 2016), <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=282>.

<sup>43</sup> Department of Defense, “Report and Recommendations on Military Service by Transgender Persons” (Feb. 22, 2018), 5.

<sup>44</sup> 42 U.S.C. § 18116.

<sup>45</sup> HHS found “there is no medical consensus to support one or another form of treatment for gender dysphoria” and that a prior HHS regulating coverage and performance of sex-reassignment surgeries “relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding—such as the factfinding that CMS undertook in deciding to not issue a National Coverage Determination with respect to sex reassignment surgeries (as discussed above) due to insufficient proof of medical necessity.” 85 F.R. 37187.



Off-label prescription of FDA-approved drugs, while a fairly common practice, does put medical practitioners at significantly greater risk of liability for any resultant harms, especially where there has not been a standard of care established for such off-label usage.<sup>46</sup> Transgender drugs and surgeries resulting in permanent and dramatic physical, psychological, and behavioral changes should still be considered experimental given the paucity of long-term studies on their effects with respect to adults and given the mixed results of the studies that do exist. These deficiencies are doubly magnified with respect to children.<sup>47</sup>

***Medical risks of transition treatments for children and adolescents.***

It is well known that symptoms of gender dysphoria in children naturally resolve with little to no intervention in 61-98% of cases and that once a child is placed on transition, including through medical intervention, the odds of persistence skyrocket.<sup>48</sup> Because up to 98% of gender dysphoric children are better off physically and psychologically *without* medical intervention towards transition, the burden lies squarely on the agency to justify how off label use of drugs and hormones and experimental surgeries on minors must now be mandated as an essential health benefit. It cannot possibly meet that burden. Yet the proposed rule does not even acknowledge the unique risks and vulnerabilities faced by children who are being recklessly pushed into transition treatments that will scar them, literally and physically, for life. Instead it proposed to mandate coverage for such treatments as an essential health benefit, without any distinction based on age or maturity.

Medical and surgical “transition” interventions are controversial, not well-supported by evidence, and expose children and adolescents to lifelong harm. The number of children and adolescents diagnosed with gender dysphoria or identifying as “transgender” has risen dramatically over the past decade, becoming “an international phenomenon, observed all across North America, Europe, Scandinavia, and elsewhere.”<sup>49</sup> The typical patient profile also has changed markedly: until recently, patients seeking treatment for gender dysphoria were usually either adult males or very young children, mostly boys. Today, the typical patient is an adolescent, usually female.<sup>50</sup> Alongside the explosive growth in gender-dysphoric or transgender-identified children and adolescents, the worlds of psychology and medicine

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<sup>46</sup> See e.g., James B. Riley, Jr. • P. Aaron Basilius, “Physicians’ liability for off-label prescriptions,” *Hematology & Oncology News & Issues*, May/June 2007. [https://www.mcguirewoods.com/news-resources/publications/health\\_care/off\\_label.pdf](https://www.mcguirewoods.com/news-resources/publications/health_care/off_label.pdf).

<sup>47</sup> *New Systematic Reviews of Puberty Blockers and Cross-Sex Hormones Published by NICE*, Society for Evidence Based Gender Medicine (March 31, 2021). [https://segm.org/NICE\\_gender\\_medicine\\_systematic\\_review\\_finds\\_poor\\_quality\\_evidence](https://segm.org/NICE_gender_medicine_systematic_review_finds_poor_quality_evidence).

<sup>48</sup> Thomas D. Steensma, Ph.D., Jenifer K. McGuire, Ph.D. M.P.H., *et al.* “Factors Associated With Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study,” 52(6) *Journal of the American Academy of Child & Adolescent Psychiatry* 582–90 (2013).

<sup>49</sup> Zucker, K. J. (2019). Adolescents with gender dysphoria: Reflections on some contemporary clinical and research issues. *Archives of Sexual Behavior*, 48(7), 1983–1992. <https://link.springer.com/article/10.1007%2Fs10508-019-01518-8>.

<sup>50</sup> Zucker, K. J. (2019). Adolescents with gender dysphoria: Reflections on some contemporary clinical and research issues. *Archives of Sexual Behavior*, 48(7), 1983–1992. <https://link.springer.com/article/10.1007%2Fs10508-019-01518-8>.

have witnessed a sea change in the dominant clinical approach towards these issues—changes which raise serious ethical questions.<sup>51</sup>

The use of puberty blockers (GnRHa) in children, popularized by the Dutch protocol, initially was represented as “safe and fully reversible, but there is now emerging evidence of their adverse effects.”<sup>52</sup> Below we identify many of these adverse effects of puberty blockers.

- Studies show puberty blockers affect adolescent bone growth and bone density.<sup>53</sup>
- Puberty suppression in early puberty (as opposed to mid or late puberty), followed by cross-sex hormones, causes measurable changes to the adolescent’s hip bone geometry.<sup>54</sup>
- At least one study indicates puberty blockers affect cognition and brain maturation.<sup>55</sup>
- Other risks associated with puberty blockers include “altered adult height, and impaired special memory.”<sup>56</sup>
- Studies show that nearly all (98-100%) of children who undergo “gender-affirming” puberty suppression continue on to cross-sex hormones and persist in transgender identification.<sup>57</sup>

<sup>51</sup> Robles M. The Bioethical Dilemma of Gender-Affirming Therapy in Children and Adolescents. *The Linacre Quarterly*. 2021;88(3):259-271. doi:10.1177/0024363921989475, <https://doi.org/10.1177/0024363921989475>;

Griffin, L., Clyde, K., Byng, R., & Bewley, S. (2021). Sex, gender and gender identity: A re-evaluation of the evidence. *BJPsych Bulletin*, 45(5), 291-299. doi:10.1192/bjb.2020.73, <https://pubmed.ncbi.nlm.nih.gov/32690121/>.

<sup>52</sup> D’Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. 2021 Jan;50(1):7-16. doi: 10.1007/s10508-020-01844-2. Epub 2020 Oct 21. PMID: 33089441; PMCID: PMC7878242.

<sup>53</sup> Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M., & Rotteveel, J. (2015). Bone mass in young adulthood following gonadotropin- releasing hormone analog treatment and cross-sex hormone treatment in adolescents with gender dysphoria. *Journal of Clinical Endocrinology & Metabolism*, 100(2), E270–E275. <https://doi.org/10.1210/jc.2014-2439>;

Joseph, T., Ting, J., & Butler, G. (2019). The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: Findings from a large national cohort. *Journal of Pediatric Endocrinology and Metabolism*, 32(10), 1077–1081. <https://doi.org/10.1515/jpem-2019-0046>.

<sup>54</sup> van der Loos MA, Hellinga I, Vlot MC, et al. Development of Hip Bone Geometry During Gender-Affirming Hormone Therapy in Transgender Adolescents Resembles That of the Experienced Gender When Pubertal Suspension Is Started in Early Puberty. *Journal of Bone and Mineral Research : the Official Journal of the American Society for Bone and Mineral Research*. 2021 May;36(5):931-941. DOI: 10.1002/jbmr.4262. PMID: 33507568; PMCID: PMC8247856.

<sup>55</sup> Schneider, M. A., Spritzer, P. M., Soll, B., Fontanari, A., Carneiro, M., Tovar-Moll, F., Costa, A. B., da Silva, D. C., Schwarz, K., Anes, M., Tramontina, S., & Lobato, M. (2017). Brain Maturation, Cognition and Voice Pattern in a Gender Dysphoria Case under Pubertal Suppression. *Frontiers in human neuroscience*, 11, 528. <https://doi.org/10.3389/fnhum.2017.00528>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5694455/>

<sup>56</sup> Hruz, P. W. (2020). Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *The Linacre Quarterly*, 7(1), 34–42. <https://doi.org/10.1177/0024363919873762>.

<sup>57</sup> See, for example, this study from the Tavistock and Portman NHS Gender Identity Development Service (UK), which found 98% of adolescents who underwent puberty suppression continued on to cross-sex hormones. Carmichael, P., Butler, G., Masic, U., Cole, T. J., De Stavola, B. L., Davidson, S., Skageberg, E. M., Khadr, S., & Viner, R. M. (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PloS one*, 16(2), e0243894. <https://doi.org/10.1371/journal.pone.0243894>.

Similarly, Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones. Brik T, Vrouwenraets LJJJ, de Vries MC, Hannema SE.

- This high persistence rate stands in stark contrast to the outcomes for children who are allowed to progress through natural puberty, which resolves their gender dysphoria in the majority of cases.<sup>58</sup>
- Puberty suppression appears to consolidate a child’s cross-sex identification, prevent the resolution of gender dysphoria, and lead towards a lifelong dependency on cross-sex hormones and other medical interventions.<sup>59</sup>
- Even if puberty suppression is discontinued, the child’s development (cognitive, emotional, and social, as well as physical) is affected, as “the interruption of a normal developmental process, which is time-dependent, cannot be ‘reversed.’”<sup>60</sup>
- Further, puberty blockers generally fail to lessen the child’s gender dysphoria and results are mixed in terms of effects on mental health.<sup>61</sup>
- When puberty blockers are initiated before sexual maturation of genitals and reproductive organs is complete, introducing cross-sex hormones renders the child permanently sterile.<sup>62</sup>

Trajectories of Adolescents Treated with Gonadotropin-Releasing Hormone Analogues for Gender Dysphoria. *Arch Sex Behav.* 2020 Oct;49(7):2611-2618. doi: 10.1007/s10508-020-01660-8. Epub 2020 Mar 9. PMID: 32152785; PMCID: PMC7497424.

<sup>58</sup> Kenneth J. Zucker (2018): The myth of persistence: Response to “A critical commentary on follow-up studies and ‘desistance’ theories about transgender and gender non-conforming children” by Temple Newhook et al. (2018), *International Journal of Transgenderism*, DOI: 10.1080/15532739.2018.1468293; Singh Devita, Bradley Susan J., Zucker Kenneth J. (2021) A Follow-Up Study of Boys With Gender Identity Disorder, *Front. Psychiatry*, 29 March 2021, <https://doi.org/10.3389/fpsy.2021.632784>; see also Steensma, T. D., R. Biemond, F. de Boer, and P. T. Cohen-Kettenis 2011. “Desisting and Persisting Gender Dysphoria after Childhood: A Qualitative Follow-Up Study.” *Clinical Child Psychology and Psychiatry* 16: 499–516. doi: 10.1177/1359104510378303. Steensma, T. D., J. K. McGuire, B. P. Kreukels, A. J. Beekman, and P. T. Cohen-Kettenis 2013. “Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study.” *Journal of the American Academy of Child and Adolescent Psychiatry* 52:582–90. doi: 10.1016/j.jaac.

<sup>59</sup> de Vries, A. L. C., McGuire, J. K., Steensma, T. D., Wagenaar, E. C. F., Doreleijers, T. A. H., & Cohen-Kettenis, P. T. (2014). Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*, 134(4), 696–704. <https://publications.aap.org/pediatrics/article-abstract/134/4/696/32932/Young-Adult-Psychological-Outcome-After-Puberty?redirectedFrom=fulltext> Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, Skageberg EM, Khadr S, Viner RM. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PLoS One.* 2021 Feb 2;16(2):e0243894. doi: 10.1371/journal.pone.0243894. PMID: 33529227; PMCID: PMC7853497.

<sup>60</sup> Hruz PW. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q.* 2020 Feb;87(1):34-42. doi: 10.1177/0024363919873762. Epub 2019 Sep 20. PMID: 32431446; PMCID: PMC7016442.

<sup>61</sup> Carmichael, P., Butler, G., Masic, U., Cole, T. J., De Stavola, B. L., Davidson, S., Skageberg, E. M., Khadr, S., & Viner, R. M. (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PLoS one*, 16(2), e0243894.

<https://doi.org/10.1371/journal.pone.0243894>. de Vries ALC, Steensma TD, Doreleijers TAH, and Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med* 2011;8:2276–2283.

<sup>62</sup> S. Levine (2017), *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, *J. OF SEX & MARITAL THERAPY* at 7 (“Ethical Concerns”) <http://dx.doi.org/10.1080/0092623X.2017.1309482>. Baram, S., Myers, S. A., Yee, S., & Librach, C. L. (2019). Fertility preservation for transgender adolescents and young adults: a systematic review. *Human Reproduction Update*, 25(6), 694–716. <https://doi.org/10.1093/humupd/dmz026>.

- Puberty blocking may impair the child’s later sexual functioning as an adult as well, a fact now admitted by several leading gender clinicians.<sup>63</sup>
- The long-term effects of puberty blockers remain unknown.<sup>64</sup>

There are also many adverse effects of cross-sex hormones.

- Cross-sex hormones disrupt the function of gonads “and the signals that regulate human reproduction. The infertility that results can be irreversible, particularly where this intervention is undertaken prior to full gonadal maturation.”<sup>65</sup> In addition, “androgen levels achieved in female patients given testosterone exceed those observed in women with polycystic ovarian syndrome and frequently reach levels seen in androgen-secreting tumors with associated cardiovascular risk ...Males receiving estrogen have a fivefold increase in the incidence of thromboembolic stroke.... Adverse metabolic effects that increase the risk of cardiovascular disease have also been reported.”
- Cross-sex hormones carry numerous health risks and cause many irreversible changes in adolescents’ bodies, including genital or vaginal atrophy, hair loss (or gain), voice changes, and impaired fertility. They also increase cardiovascular risks and cause liver and metabolic changes.<sup>66</sup>
- The flood of opposite sex hormones has variable emotional and psychological effects as well.
- The use of cross-sex hormones in adolescent females worsens gender dysphoria, particularly as it relates to the adolescents’ breasts (“chest dysphoria”), leading them to seek double mastectomies for relief.<sup>67</sup>
- The gender affirming model recommends performing mastectomies on the healthy breasts of adolescent girls in order to address emotional discontent. This is an unethical practice described by psychotherapist Alison Clayton as nothing less than “dangerous medicine.”<sup>68</sup>
- The World Professional Association for Transgender Health (WPATH) recently released its proposed “Standards of Care Version 8,” which lower the recommended ages for adolescents to receive cross-sex hormones to age 14, double mastectomy (“chest masculinization”) to age 15,

<sup>63</sup> Abigail Shrier, “Top Trans Doctors Blow the Whistle on ‘Sloppy Care,’” *Common Sense*, October 4, 2021. <https://bariweiss.substack.com/p/top-trans-doctors-blow-the-whistle>. *Bell v. Tavistock and Portman Trust*, High Court of Justice, Royal Courts of Justice, January 12, 2020; <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>.

<sup>64</sup> There are no long-term, rigorous studies on the safety and outcomes of using puberty blockers to disrupt natural puberty in healthy but dysphoric children for an extended time.

<sup>65</sup> Hruz, citing Hembree, W. C., P. T. Cohen-Kettenis, L. Gooren, S. E. Hannema, W. J. Meyer, M. H. Murad, S. M. Rosenthal, J. D. Safer, V. Tangpricha, and G. G. T’Sjoen. 2017. “Endocrine Treatment of Gender-Dysphoric/gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.” *Journal of Clinical Endocrinology and Metabolism* 102:3869–903. doi: 10.1210/jc.2017- 01658.

<sup>66</sup> Blog, “Gender-affirming hormone in children and adolescents,” *BMJ EBM Spotlight*. February 25, 2019. <https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/>.

<sup>67</sup> Olson-Kennedy J, Warus J, Okonta V, et al. Chest reconstruction and chest dysphoria in transmasculine minors and young adults: Compari- sons of nonsurgical and postsurgical cohorts. *JAMA Pediatr* 2018;172: 431e6.

<sup>68</sup> Clayton, A. The Gender Affirmative Treatment Model for Youth with Gender Dysphoria: A Medical Advance or Dangerous Medicine?. *Arch Sex Behav* (2021). <https://doi.org/10.1007/s10508-021-02232-0>.

male breast augmentation and facial surgery to age 16, and removal of testes, vagina, or uterus to age 17, with flexibility to provide these gender affirming interventions at even younger ages.<sup>69</sup>

***Experience of “detransitioners” provide the compelling evidence of the harms of transitioning.***

In *Irreversible Damage: The Transgender Craze Seducing Our Daughters* (Regnery 2020), Abigail Shrier documents the phenomenon occurring across the country where whole groups of female friends from middle school, high school, and college come out as “transgender.” Shrier argues the vast majority of these girls have been infected by a “social contagion.” Many have been and will be pushed to start the transition process—including medically unnecessary double mastectomies and puberty blocker that can cause permanent infertility—only to realize too late that they are not transgender.

Providing insurance coverage of transition procedures for minors will only exacerbate the number of minors—especially girls—who transition only to later regret it but too late to reverse the damage done.

A 2021 study by Dr. Lisa Littman sheds light on the experiences of “de-transitioners” (detransitioners are individuals who “experienced gender dysphoria, chose to undergo medical and/or surgical transition and then detransitioned by discontinuing medications, having surgery to reverse the effects of transition, or both”). At the time they transitioned, 71% believed that transitioning was their only option to feel better, and two-thirds believed it would eliminate or reduce their gender dysphoria.<sup>70</sup>

The experiences of detransitioners also raise serious questions about the nature of gender affirming care, which quickly affirms a young person’s declaration of a transgender identity (with no questions asked) and often accepts the person’s self-diagnosis of gender dysphoria, without exploring their reasons for transitioning, alternative ways of coping with gender dysphoria, or the possibility that trauma or mental health issues lie at the root of their distress.

For example, 56.7% of detransitioners in Littman’s study believe they received inadequate mental health assessments before transitioning and “65.3% reported that their clinicians did not evaluate whether their desire to transition was secondary to trauma or a mental health condition.” One-third reported feeling pressure to transition, sometimes even from physicians or counselors. 46% reported that, in hindsight, the pre-transition counseling they received oversold the benefits of transition and 26% felt the risks were glossed over. 50% found that transitioning did not, in fact, help their gender dysphoria.<sup>71</sup>

Perhaps most troubling, the majority of detransitioners (58.0%) believe now that their “*gender dysphoria was caused by trauma or a mental health condition,*” and over half felt that “the process of transitioning delayed or prevented them from dealing with or being treated for trauma or a mental health condition.” For these young people, the promises of gender affirming care proved empty, leading them to detransition: “I slowly began addressing the mental health conditions and traumatic experiences that

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<sup>69</sup> WPATH Standards of Care, Version 8, Draft for Public Comment, December 2021, “Adolescent” Chapter, p. 3. <https://www.wpath.org/soc8>.

<sup>70</sup> Littman L. (2021). Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Archives of sexual behavior*, 50(8), 3353–3369. <https://doi.org/10.1007/s10508-021-02163-w>.

<sup>71</sup> Littman L. (2021). Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Archives of sexual behavior*, 50(8), 3353–3369. <https://doi.org/10.1007/s10508-021-02163-w>.

caused such a severe disconnect between myself and my body...”; “I was starting to become critical of transition because I felt that many people were doing it out of self-hatred and started to realize that applied to me as well”; “I was deeply uncomfortable with my secondary sex characteristics, which I now understand was a result of childhood trauma and associating my secondary sex characteristics with those events.”<sup>72</sup>

In *When Harry Became Sally*, undersigned author, Ryan T. Anderson, recounts several stories of those who have “detransitioned.” He summarizes some of the common themes from the stories: “Many people report feeling pressured into transitioning, as if it were their only real option. They regret that medical professionals never explored the underlying psychological issues. They detransitioned because they didn’t find the peace and wholeness they desired by changing their bodies, but did find it when they were able to address past trauma in their lives and come to a better understanding of gender. Many of these people regret the damage done to their bodies and their lost fertility. They feel they were too young to be making such life-altering decisions. They blame a society that was hostile to people like them—particularly to people with same-sex attractions and other gender-nonconforming people—as they believe this hostility contributed to their thinking that transition was the only option.”<sup>73</sup>

Below is one such story:

[I]n 2017, the UK *Guardian* ran an op-ed by someone who had started transitioning as a teenager and came to regret it as an adult. This time it was a girl who spent her childhood as a tomboy, and then as a teen started to live as a boy and began hormonal and surgical treatment:

It wasn’t until I was 15 that I found out about transitioning. Everything fell into place: this was who I was. I realised I could have the body I wanted. When I went to my GP, aged 17, I was told I was too old to refer to children’s services and too young to be seen as an adult; I didn’t get my first appointment until three months after my 18th birthday.

After months of waiting and appointments, none of which included counselling, I finally started on testosterone gel, later switching to injections. It was a huge thing when, at university, my voice broke, and my figure started changing: my hips narrowed, my shoulders broadened. It felt right. Passing as a man, I felt safer in public places, I was taken more seriously when I spoke, and I felt more confident.

Then I had chest surgery. It was botched and I was left with terrible scarring; I was traumatised. For the first time, I asked myself, “What am I doing?” I delayed the next steps of hysterectomy and lower surgery, after looking into phalloplasty and realising that I was going to need an operation every 10 years to replace the erectile device.

For many people, surgery goes well as a cosmetic matter, but a botched surgery led this anonymous author to question what she was doing in the first place. And as she notes in her narrative, the medical professionals never provided any counseling to help her understand why she had felt so strongly

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<sup>72</sup> Littman L. (2021). Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Archives of sexual behavior*, 50(8), 3353–3369. <https://doi.org/10.1007/s10508-021-02163-w>.

<sup>73</sup> RYAN T. ANDERSON, WHEN HARRY BECAME SALLY: RESPONDING TO THE TRANSGENDER MOMENT 52 (2018).

that she wanted to be a man. “I had assumed the problem was in my body. Now I saw that it wasn’t being female that was stopping me from being myself; it was society’s perpetual oppression of women. Once I realised this, I gradually came to the conclusion that I had to detransition.” Here’s how that process went:

I have come off testosterone and, as my body has resumed production of its own hormones, I have become someone female who looks like a man. I will always have a broken voice and will never regrow breasts, but my hips and thighs are getting bigger. Being male was more comfortable for me, but remaining on hormones means I would have continued to focus on my body as the problem—when I don’t believe it belongs there. What feels easiest isn’t always what’s right.

I made the best possible decision in poisoned circumstances, and if I hadn’t had treatment when I did, I might not be alive. But I do feel very sad when I think of my fertility: I want to be a parent one day, but it’s likely that being on testosterone has made that more difficult. I’m now in my late 20s and won’t know until I try to have children.

I feel happy for those people transition has helped, but I think there should be more emphasis on counselling, and that [transitioning] should be seen as the last resort. Had that been the case for me, I might not have transitioned. I was so focused on trying to change my gender, I never stopped to think about what gender meant.

The themes expressed in these newspaper accounts are echoed over and over in YouTube videos and blog posts by people who have transitioned only to discover that changing the body did not help the psyche. It may have seemed like the easiest solution to their distress, but “what feels easiest isn’t always right,” as the *Guardian* op-ed pointed out. Many of these people end up detransitioning and learning to embrace their bodily sex. No two people are the same—whether they’ve transitioned or not, whether they’ve detransitioned or not.<sup>74</sup>

This story is not unlike that Keira Bell also from the UK who transition as a teen, but came to regret it. She recounts her experience below:

I began seeing a psychologist through the National Health Service, or NHS. When I was 15—because I kept insisting that I wanted to be a boy—I was referred to the Gender Identity Development Service, at the Tavistock and Portman clinic in London. There, I was diagnosed with gender dysphoria, which is psychological distress because of a mismatch between your biological sex and your perceived gender identity.

By the time I got to the Tavistock, I was adamant that I needed to transition. It was the kind of brash assertion that’s typical of teenagers. What was really going on was that I was a girl insecure in my body who had experienced parental abandonment, felt alienated from my peers, suffered from anxiety and depression, and struggled with my sexual orientation.

After a series of superficial conversations with social workers, I was put on puberty blockers at age 16. A year later, I was receiving testosterone shots. When 20, I had a double

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<sup>74</sup> RYAN T. ANDERSON, WHEN HARRY BECAME SALLY: RESPONDING TO THE TRANSGENDER MOMENT 50–51 (2018) (internal citations omitted).

mastectomy. By then, I appeared to have a more masculine build, as well as a man's voice, a man's beard, and a man's name: Quincy, after Quincy Jones.

But the further my transition went, the more I realized that I wasn't a man, and never would be. We are told these days that when someone presents with gender dysphoria, this reflects a person's "real" or "true" self, that the desire to change genders is set. But this was not the case for me. As I matured, I recognized that gender dysphoria was a symptom of my overall misery, not its cause.

Five years after beginning my medical transition to becoming male, I began the process of detransitioning. A lot of trans men talk about how you can't cry with a high dose of testosterone in your body, and this affected me too: I couldn't release my emotions. One of the first signs that I was becoming Keira again was that—thankfully, at last—I was able to cry. And I had a lot to cry about.

**The consequences of what happened to me have been profound:** possible infertility, loss of my breasts and inability to breastfeed, atrophied genitals, a permanently changed voice, facial hair. When I was seen at the Tavistock clinic, I had so many issues that it was comforting to think I really had only one that needed solving: I was a male in a female body. But it was the job of the professionals to consider all my co-morbidities, not just to affirm my naïve hope that everything could be solved with hormones and surgery.<sup>75</sup>

Bell sued the gender clinic, Tavistock and Portman, arguing that minors under 18 are not competent to give consent to the administration of puberty blocking drugs, the information given to minors by the clinic is misleading and insufficient to ensure that minors are able to give informed consent, and that such actions result in a violation of the minors' rights under Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms.<sup>76</sup> The High Court held:

A child under 16 may only consent to the use of medication intended to suppress puberty where he or she is competent to understand the nature of the treatment. That includes an understanding of the immediate and long-term consequences of the treatment, the limited evidence available as to its efficacy or purpose, the fact that the vast majority of patients proceed to the use of cross-sex hormones, and its potential life changing consequences for a child. There will be enormous difficulties in a child under 16 understanding and weighing up this information and deciding whether to consent to the use of puberty blocking medication. It is highly unlikely that a child aged 13 or under would be competent to give consent to the administration of puberty blockers. It is doubtful that a child aged 14 or 15 could understand and weigh the long-term risks and consequences of the administration of puberty blockers.

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<sup>75</sup> Keira Bell, *Keira Bell: My Story*, PERSUASION (Apr. 7, 2021), <https://www.persuasion.community/p/keira-bell-my-story> (emphasis in original).

<sup>76</sup> *Bell v. Tavistock & Portman NHS Foundation Trust* (Jan. 12, 2020), <https://www.bailii.org/ew/cases/EWHC/Admin/2020/3274.html>.



The court found that minors lacked capacity to consent to transgender treatments that cause sterility and impair sexual function.<sup>77</sup>

The costs faced by those who transition because it would be covered by insurance only to later regret their decision must be taken into consideration in the regulatory impact analysis.

***The long-term outcomes of transitioning are not promising.***

Forty-one percent of all adults who identify as transgender attempt suicide at some point in their lives, and those who have had genital surgery are nineteen times more likely than the general population to die by suicide.<sup>78</sup> Other recent studies of adults found similar results after transition surgeries: suicide risks and mental health issues remain high.<sup>79</sup> As clinical and ethical concerns over the outcomes of transition have escalated, Extensive psychotherapy, open to exploring alternative diagnoses and non-invasive ways of managing gender dysphoria, is emerging as the first-line response to adolescent identity distress.<sup>80</sup>

A 2021 Dutch study examining mortality trends over five decades among transgender-identified adults using transgender hormones found no decline in mortality risk, in spite of liberalizing cultural trends and the advent of transgender treatment. Mortality rates among females identifying as transgender men exceeded rates for non-transgender females and showed high rates of “non-natural” causes of death. Similarly, mortality rates for males identifying as transgender women exceeded the general population

<sup>77</sup> For a time, the U.K. determined that children under 16 were categorically incapable of consenting to permanent life-altering medical transition to treat gender dysphoria in the case of *Bell v. Tavistock* (2020), but the decision was overturned. See <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>, and <https://www.judiciary.uk/wp-content/uploads/2021/09/Bell-v-Tavistock-judgment-170921.pdf>, respectively. The decision was later reversed on procedural grounds, and is currently on further appeal.

<sup>78</sup> Dhejne, C, Lichtenstein, P, Boman, M, Johansson, ALV, Långström, N, Landén, M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. *Scott J, editor. PLoS ONE* 2011; 6(2): e16885.

<sup>79</sup> D’Angelo, R., Syrulnik, E., Ayad, S., Marchiano, L., Kenny, D. T., & Clarke, P. (2020). One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Archives of Sexual Behavior*, <https://doi.org/10.1007/s10508-020-01844-2>. Wiepjes, C. M., den Heijer, M., Bremmer, M. A., Nota, N. M., de Blok, C., Coumou, B., & Steensma, T. D. (2020). Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972-2017). *Acta psychiatrica Scandinavica*, 141(6), 486–491. <https://doi.org/10.1111/acps.13164>.

<sup>80</sup> For example, see the following recent publications: Malone, W., D’Angelo, R., Beck, S., Mason, J., & Evans, M. (2021). Puberty blockers for gender dysphoria: the science is far from settled. *The Lancet Child & Adolescent Health*, 5(9), e33–e34, [https://doi.org/10.1016/S2352-4642\(21\)00235-2](https://doi.org/10.1016/S2352-4642(21)00235-2); Griffin, L., Clyde, K., Byng, R., & Bewley, S. (2020). Sex, gender and gender identity: a re-evaluation of the evidence. *BJPsych Bulletin*, 1–9, <https://doi.org/10.1192/bjb.2020.73>; Entwistle K. Debate: Reality check - Detransitioners' testimonies require us to rethink gender dysphoria. *Child Adolesc Ment Health*. 2021 Feb;26(1):15-16. doi: 10.1111/camh.12380. Epub 2020 May 14. PMID: 32406585. <https://pubmed.ncbi.nlm.nih.gov/32406585/>.

Hruz, P. W. (2020). Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *The Linacre Quarterly*, 87(1), 34–42. <https://doi.org/10.1177/0024363919873762>; Levine, S.B. Reflections on the Clinician’s Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav* 50, 3527–3536 (2021). <https://doi.org/10.1007/s10508-021-02142-1>. Levine SB. Correction to: Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Archives of Sexual Behavior*. 2021 Nov;50(8):3537. DOI: 10.1007/s10508-021-02195-2. PMID: 34725753.

morality rates for males; causes of death were attributed to of cardiovascular disease, lung cancer, HIV-related disease, and suicide.<sup>81</sup>

A 2020 large Dutch study followed transgender-identified persons for a median of 10 years follow-up and found that suicide deaths for males identifying as “transwomen” slightly decreased over time but remained unchanged for females identifying as transgender men. Additionally, the study found high suicide rates among transgender-identified persons compared to the Dutch general population, in spite of treatment. Suicides occurred at all stages of transition, with the average time to suicide approximately six years after transition treatments were begun.<sup>82</sup>

***Recent international reconsideration of transition in minors.***

The unethical nature of these interventions has drawn global attention, leading health authorities in Finland, Sweden, and the UK to end or curtail gender-affirming interventions for minors.<sup>83</sup> Some countries that pioneered social and medical transition interventions are now scaling back due to the widespread harms they have inflicted on children. For example, the Karolinska Hospital in Sweden has ended the practice of prescribing puberty blockers and cross-sex hormones to gender-dysphoric patients under the age of 18 after having been a world-leading provider of such treatments.<sup>84</sup> State medical authorities in Finland revised treatment guidelines in June 2020 to disfavor medical interventions for treatment of gender dysphoria in minors and prioritize psychotherapy as the first-line treatment for gender dysphoric minors.<sup>85</sup>

A Swedish teen who underwent medical transition and then de-transitioned after suffering substantial bodily harm describes the “gender affirming” medical protocol this way: “They’re experimenting on young people...we’re guinea pigs.”<sup>86</sup>

As discussed above, a landmark case against the National Health Service in 2020 by “detransitioner” Keira Bell found that minors lacked capacity to consent to gender affirming treatments that cause sterility and impair sexual function, causing the NHS to suspend the use of puberty blockers

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<sup>81</sup> Christel JM de Blok, Chantal M Wiepjes, Daan M van Velzen, Annemieke S Staphorsius, Nienke M Nota, Louis JG Gooren, Baudewijntje PC Kreukels, Martin den Heijer, Mortality trends over five decades in adult transgender people receiving hormone treatment: a report from the Amsterdam cohort of gender dysphoria, *The Lancet Diabetes & Endocrinology*, Volume 9, Issue 10, 2021, Pages 663-670, ISSN 2213-8587, [https://doi.org/10.1016/S2213-8587\(21\)00185-6](https://doi.org/10.1016/S2213-8587(21)00185-6); <https://www.sciencedirect.com/science/article/pii/S2213858721001856>.

<sup>82</sup> Wiepjes CM, den Heijer M, Bremmer MA, Nota NM, de Blok CJM, Coumou BJJ, Steensma TD. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017).

<sup>83</sup> Becky McCall and Lisa Nainggolan, Transgender Teens: Is the Tide Starting to Turn? Medscape. April 26, 2021. <https://www.medscape.com/viewarticle/949842>.

<sup>84</sup> See [https://segm.org/Sweden\\_ends\\_use\\_of\\_Dutch\\_protocol](https://segm.org/Sweden_ends_use_of_Dutch_protocol). Lisa Nainggolan, Hormonal Tx of Youth With Gender Dysphoria Stops in Sweden, Medscape. May 12, 2021. <https://www.medscape.com/viewarticle/950964>.

<sup>85</sup> Summary of a recommendation by COHERE 16.6.2020 Finland. COHERE website: <https://palveluvalikoima.fi/en/frontpage>. *The Council for Choices in Health Care in Finland (COHERE Finland) works in conjunction with the Ministry of Social Affairs and Health, www.palveluvalikoima.fi.*

<sup>86</sup> Mission: Investigate. Trans Children (“Trans Train 4”), November 26, 2021. <https://www.svtplay.se/video/33358590/uppdrag-granskning/mission-investigate-trans-children-avsnitt-1>.

and institute new procedures to ensure better psychological care.<sup>87</sup> As a result of a major UK evidence review, the National Health Service in the UK no longer describes puberty blockers as “fully reversible,” citing negative effects on bone density, social and emotional maturation, and other aspects of development.<sup>88</sup> The NHS has commissioned additional evidence reviews.<sup>89</sup>

Psychotherapists in Australia and New Zealand recently issued a new policy statement emphasizing mental health treatment for gender dysphoric minors, rather than transition, and stressing the importance of assessing the “psychological state and context in which gender dysphoria has arisen,” before any treatment decisions are made.<sup>90</sup> “The bedrock principle of all clinical practice,” writes psychologist David Schwartz, is “[f]irst, do no harm.”<sup>91</sup> Mandated coverage for “gender affirmation” for minors is legally, medically, and ethically indefensible. The U.S. gender industry, however, is noticeably out of step with the growing international consensus that recognizes the use of puberty blockers and cross-sex hormones in minors carries significant risk of harm, with little benefit.

***Prohibition against age discrimination cannot require coverage of transition services for minors.***

The proposed rule states that “[a]ge limits, when applied to services that have been found clinically indicated for all ages, are presumed to be discriminatory under § 156.125. Therefore, limiting coverage of hearing aids that are medically necessary to enrollees based on age presumptively conflicts with the prohibition under § 156.125 against discriminatory health plan design.” 87 Fed. Reg. 665. This reasoning cannot be applied to coverage of transition services. As discussed above, it is far from established that such services are “medically necessary” and they certainly have not been “clinically indicated for all ages.” As such, excluding minors from coverage of any transition services that are covered for adults is not discriminatory—presumptively or otherwise. Cross-sex hormones, puberty blockers, and surgeries can have long-lasting, irreversible consequences, including sterilization, that minors especially are unable to fully appreciate and consent to. Requiring coverage of transition services for minors will increase the likelihood that minors will transition only to later regret the choice.

<sup>87</sup> Becky McCall, NHS Makes Child Gender Identity Service Changes After High Court Ruling, Medscape, December 04, 2020. <https://www.medscape.com/viewarticle/941781>.

<sup>88</sup> National Institute for Health and Care Excellence (NICE), <https://arms.nice.org.uk/resources/hub/1070905/attachment>, NHS England, 11 March 2021. [https://doi.org/10.1515/jpem-2021-0180](https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3d transgender%26s%3dDate; Puberty blockers have significant effects on bone density, during a time of important bone growth. Biggs, Michael. “Revisiting the effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria”, <i>Journal of Pediatric Endocrinology and Metabolism</i>, vol. 34, no. 7, 2021, pp. 937-939, <a href=).

<sup>89</sup> *Id.*

<sup>90</sup> Betsy McCall, Psychiatrists Shift Stance on Gender Dysphoria, Recommend Therapy, Medscape, Oct. 7, 2021. <https://www.medscape.com/viewarticle/960390>.

<sup>91</sup> David Schwartz (2021): Clinical and Ethical Considerations in the Treatment of Gender Dysphoric Children and Adolescents: When Doing Less Is Helping More, *Journal of Infant, Child, and Adolescent Psychotherapy*, DOI: 10.1080/15289168.2021.1997344. Harm includes “physical or mental damage” including “a diminishing of known functionality

**III. The proposed rule is an end-run of Section 1557 and court orders, and is not required by *Bostock*.**

Throughout the proposed rule, CMS reiterates that it is not relying on authority from section 1557 of the ACA for its proposal to add sexual orientation and gender identity as protected bases in six nondiscrimination provisions. Yet in the preamble, CMS discusses section 1557 in depth. 87 Fed. Reg at 585, 589, 592 595–597.

**Section 1557.** Section 1557 guarantees that no individual can be denied benefits in a federally run or federally funded health program because of their membership in well-established categories of civil rights law, including race, color, national origin, sex, age, or disability.<sup>92</sup> It does so by incorporating the nondiscrimination provisions from four existing federal civil rights laws, including the prohibition against discrimination “on the basis of sex” in Title IX of the Education Amendments of 1972.<sup>93</sup> As Ryan T. Anderson and Roger Severino noted in 2016: “Section 1557 of the ACA does not create special privileges for new classes of people or require insurers and physicians to cover or provide specific procedures or treatments.”<sup>94</sup>

In 2020, HHS issued section 1557 regulations clarifying that Congress did not delegate HHS authority to expand the scope of protected bases under section 1557.<sup>95</sup> Under the 2020 regulations, “sex discrimination” was defined “according to the plain meaning of the word ‘sex’ as male or female and as determined by biology.”<sup>96</sup> The 2020 regulations rescinded regulations from 2016 that redefined “sex” to include “termination of pregnancy” and “gender identity.” 85 Fed. Reg. 37160.

Instead of attempting to promulgate new regulations through the public notice and comment process that would rescind the 2020 regulations and adopt regulations similar to the 2016 regulations, HHS unilaterally issued a “notification of interpretation and enforcement” on May 10, 2021, stating: “Consistent with the Supreme Court’s decision in [*Bostock v. Clayton County*] and Title IX, beginning today, OCR will interpret and enforce Section 1557’s prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity.”<sup>97</sup>

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<sup>92</sup> 42 U.S.C. § 18116.

<sup>93</sup> *Id.* § 18116(a) (citing Title IX, 20 U.S.C. § 1681 et seq.). Title IX also contains a religious exemption (and an abortion exemption), which states that Title IX does not apply to a covered entity controlled by a religious organization if its application would be inconsistent with the religious tenets of the organization. 20 U.S.C. § 1681(a)(3).

<sup>94</sup> ROGER SEVERINO & RYAN T. ANDERSON, PROPOSED OBAMACARE GENDER IDENTITY MANDATE THREATENS FREEDOM OF CONSCIENCE AND THE INDEPENDENCE OF PHYSICIANS, HERITAGE FOUNDATION BACKGROUNDER NO. 3089 2 (Jan. 8 2016), <https://www.heritage.org/health-care-reform/report/proposed-obamacare-gender-identity-mandate-threatens-freedom-conscience>.

<sup>95</sup> Nondiscrimination in Health and Health Education programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160 (June 19, 2020).

<sup>96</sup> *Id.* Both the 2016 Rule and the 2020 Rule declined to recognize sexual orientation as a protected category under Section 1557.

<sup>97</sup> U.S. Dep’t Health & Hun. Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 3 (May 10, 2021), <https://www.hhs.gov/sites/default/files/ocr-bostock-notification.pdf>.

The proposed rule states that it “aligns with the HHS’ Notice, released on May 10, 2021, that HHS interprets and enforces section 1557’s and Title IX’s prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity, based on the Supreme Court’s decision in *Bostock v. Clayton County*.” 87 Fed. Reg. at 586. CMS also cites to Executive Order 13988 and a March 26, 2021, Department of Justice (DOJ) memorandum. *Id.* The Executive Order states “that it is the Administration’s policy to prevent and combat discrimination on the basis of gender identity and sexual orientation, and that under *Bostock*’s reasoning, laws that prohibit sex discrimination also prohibit discrimination on the basis of gender identity and sexual orientation, so long as the laws do not contain sufficient indications to the contrary.”<sup>98</sup> The DOJ memorandum “determined the court’s reasoning in *Bostock* applies to Title IX and thus that Title IX’s prohibition on discrimination on the basis of sex includes discrimination on the basis of gender identity and sexual orientation.”<sup>99</sup>

The proposed rule ignores the fact that on December 31, 2016, a federal district court in *Franciscan Alliance v. Burwell*<sup>100</sup> entered a nationwide preliminary injunction against enforcement of the Section 1557 regulations in so far as they were purporting to prohibit discrimination based on “gender identity.” The court held that it would violate the Administrative Procedure Act to expand the scope of sex discrimination under Title IX to encompass gender identity.<sup>101</sup> Section 1557, of course, granted HHS explicit authority to HHS to prohibit “sex” discrimination in certain HHS funded programs. Yet an existing nationwide injunction *to this day* prevents HHS from reinterpreting sex discrimination to cover gender identity in the health care context. Like the CMS proposed rule, HHS attempted to require insurance coverage of transition treatments in 2016 but was blocked by the *Franciscan Alliance* court. CMS has even less authority for attempting to reimpose such a condition because it cannot even cite Section 1557 as a basis. Instead, it defers to policy arguments. As shown in this comment, the policy arguments fail to provide non arbitrary justification for the proposal. But even if the CMS contentions were based on sound medical and scientific evidence (which they are not), they would still fail for lack of statutory authority. “We think it is a good idea” simply will not suffice, especially when it is being done transparently as a way to get around an existing nationwide injunction.

***The Bostock decision did apply to the medical context.***

CMS cites the *Bostock* decision, the DOJ Memo on *Bostock*, and HHS’s related Notice of Interpretation but this reliance is misplaced. *Bostock* does not provide statutory support for CMS’s proposal. To the contrary, it applied Title VII of the Civil Rights Act of 1964, which *may* have implications for Title IX of the Education Amendments of 1972, which are incorporated by reference in, Section 1557 of the ACA, *not* any statute that CMS is purporting to rely on for this proposal.

Moreover, *Bostock* presumed sex is a biological binary, never used the phrase gender identity, and specifically disclaimed broad application outside of the employment context of hiring and firing based on “transgender status.”<sup>102</sup> The Court made clear that any question that would “sweep beyond Title

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<sup>98</sup> Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, January 20, 2021, *see* 86 Fed. Reg. 7023.

<sup>99</sup> U.S. Dep’t of Justice, Memorandum on Application of *Bostock v. Clayton County* to Title IX of the Education Amendments of 1972 (Mar. 26, 2021), <https://www.justice.gov/crt/page/file/1383026/download>.

<sup>100</sup> 227 F. Supp. 3d 660, 695 (N.D. Tex. 2016).

<sup>101</sup> *Id.* at 689.

<sup>102</sup> 140 S. Ct. 1731, 1737 (2020).

VII to other federal or state laws that prohibit sex discrimination,” were for “future cases” and that the Court was not prejudging any such questions because “none of th[o]se other laws [we]re before [them].”<sup>103</sup>

For the manifold number of reasons stated in this document, sex and gender identity questions in the medical context are about as far as one can get from the question of adverse employment actions based on transgender status. It would be arbitrary and capricious to import the narrow Title VII framework to health care through this proposed rule.

#### **IV. The proposed rule does not adequately address conscience and religious freedom concerns.**

The Court in *Bostock* also acknowledged doctrines protecting religious liberty, such as the “super statute” the Religious Freedom Restoration Act (RFRA), were not at issue or decided.<sup>104</sup> Like the Supreme Court in *Bostock*, the proposed rule also acknowledges legal protections for conscience and religious freedom. But the preamble merely states: “In enforcing the nondiscrimination provisions in the corresponding CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb–4) and all other applicable legal requirements.” 87 Fed. Reg. at 597.

The proposed rule states that HHS will comply with laws protecting the exercise of conscience and religion, but HHS has taken steps to the contrary. HHS has “folded” the Conscience and Religious Freedom Division and prohibited the dedicated, expert career staff in the division from working on those issues. HHS also recently revoked the authority of the HHS Office for Civil Rights to enforce RFRA violations, instead stating that each department will ensure compliance. As such, it is now on CMS to explain how it will enforce the proposed nondiscrimination provisions in ways that comply with federal conscience and religious freedom protection laws. CMS must elaborate on the application of RFRA and other conscience protection laws with respect to its regulations.

- When will the nondiscrimination not apply to religious organizations and person?
- Will CMS require religious organizations that have sincerely held religious beliefs relating to gender and sexuality to provide and pay for insurance plans that cover procedures, such as cross-sex hormones and surgery for minors, that violate those beliefs?
- Will non-religious insurers be permitted to provide religious organizations with insurance plans that do not cover procedures that violate their sincerely held religious beliefs?
- How can a religious organization claim an exemption or contest a plan that provides coverage for services that violate their conscience or religious beliefs? Should such organizations file complaints with OCR or should they contact CMS directly? Or will those organizations have to sue in federal court to vindicate their conscience and religious freedom rights?
- Will this regulation be used as a basis to require all employers to cover transition services?

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<sup>103</sup> *Id.* at 1753.

<sup>104</sup> *Id.* at 1753–54.

V. **The proposed rule raises other concerns.**

***The proposed rule would disallow legitimate prohibitions on coverage for cosmetic surgery.***

In the 2020 Section 1557 Rule, HHS clarified that it was not discriminatory for insurers to decline to cover surgeries that removed non-diseased tissue in people with gender dysphoria. This is because removal of healthy tissue to address psychological discomfort related to one's appearance is the quintessential definition of cosmetic surgery, which is traditionally not covered by insurance, and certainly not as an *essential* health benefit. A significant number of women have persistent emotional and psychological distress because of their breast size, which helps explain why breast augmentation is the leading cosmetic surgery procedure in America.<sup>105</sup> Regardless of the level of psychological relief felt, such surgeries are not generally covered by insurance. But breast reconstruction surgery after breast cancer is covered, even if a patient desires it primarily for psychological reasons. Why so? Because surgery is a *physical* intervention, and in the first case, there is no physical trauma or disease to treat, while in the second there clearly is. The same distinction applies to hair transplant surgeries in men. Male pattern baldness is not a disease that inhibits a bodily function. Hair loss causes intense and persistent psychological distress in some men such as to qualify as body dysmorphic disorder under the DSM V,<sup>106</sup> yet hair transplant surgeries are generally not covered by insurance even under those circumstances.

It is thus incumbent on the agency to identify every other instance where it has required insurance coverage of surgical interventions to treat purely psychological distress related to the presence of healthy, non-diseased tissue. If the answer is that there are none other than those related to gender dysphoria, the agency must explain why that is. Why must insurers cover breast augmentation in a boy who identifies as a girl as opposed to a woman who is clinically obsessed with her smaller than average breast size and has suffered anxiety and avoided social situations for years as a result? The agency must explain why it considers the first an essential health benefit but the latter can only receive cognitive behavioral therapy and psychological treatment. It would be stunningly arbitrary and capricious for the agency to deem one, and only one, clinical body dysmorphia not only worthy of surgical coverage, but essential. And not only one surgery, but a variety of augmentations, tucks, reshapings, and inserts must be provided. Under the proposed regulation, a gender dysphoric man is not only entitled to be reshaped to look somewhat like a woman, he is entitled to be transformed into a facsimile of a lingerie supermodel if he desires. All he would need is a doctor to say his dysphoria symptoms persist to qualify for yet another surgery.<sup>107</sup>

***The proposed rule does not elaborate on the scope of its application.***

Of the six nondiscrimination provisions, the proposed rule would change five involve EHBs which effect small group and individual plans. The sixth regulation, however, 45 CFR § 147.104(e) has broader reach. Guaranteed availability of coverage applies to individual, small group, and fully insured large group plans. The discussion of 45 CFR § 147.104(e) only mentions “group and individual markets” and does not specify which groups specifically its provisions apply to. Similarly, there is no discussion in

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<sup>105</sup> American Society of Plastic Surgeons, *Plastic Surgery Statistics Report*, (2018).

<https://www.plasticsurgery.org/documents/News/Statistics/2018/plastic-surgery-statistics-full-report-2018.pdf>.

<sup>106</sup> Diagnostic and Statistical Manual of Mental Disorders 5 at DSM-5 300.7 (F45.22).

[https://www.theravive.com/therapedia/body-dysmorphic-disorder-dsm--5-300.7-\(f45.22\)](https://www.theravive.com/therapedia/body-dysmorphic-disorder-dsm--5-300.7-(f45.22)).

<sup>107</sup> Relatedly, the regulation must make clear that prior authorizations for those insurers that voluntarily choose to cover gender dysphoria treatments are not discriminatory and are part of reasonable medical management practices.

the RIA about large group plans in particular. As such CMS has not given the public full opportunity to provide public comment or analyzed the regulatory impact on large group plans as required by law. Application to large group plans will lead to more conflicts with religious organizations. Because CMS did not adequately address breath of who this will apply, it should not apply to large group fully insured plans.

***The proposed rule's comment period is too short.***

Under EO 12866, for most rules, an agency should give the public at least 60 days for meaningful comment. Similarly, the APA suggests less than 30-days is highly problematic and suspect. Here, the 145-page, triple-columned proposed was published in the federal register on January 5 and public comments are due January 27, which means the public only had 22 days to provide input on a complex, major and economically significant proposed rule. This is unacceptable. We ask CMS to reopen the comment period to give the public a minimum of 60 days to provide meaningful input as required by law.

**VI. Conclusion.**

We urge CMS to withdraw its proposal with respect to all provisions concerning sexual orientation and gender identity.

Sincerely,

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