



**ADVANCING AMERICAN FREEDOM**  
*FOUNDATION*

February 25, 2026

Martin A. Makary M.D., M.P.H.  
The Commissioner of Food and Drugs  
c/o Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: Citizen Petition Pursuant to 21 C.F.R. § 10.30 Requesting the FDA (A) Open a Docket, (B) Hold a Part 15 Public Hearing Regarding the Off-Label Use of Estrogen in Natal Males for Gender Affirmation, and (C) Consider Regulatory Action Including a Boxed Warning Under 21 C.F.R. § 201.80(e)

Dear Director Makary:

On behalf of Advancing American Freedom's 150,374 supporters, we are writing to file a comment in response to the Citizen Petition Pursuant to 21 C.F.R. § 10.30 Requesting the FDA (A) Open a Docket, (B) Hold a Part 15 Public Hearing Regarding the Off-Label Use of Estrogen in Natal Males for Gender Affirmation, and (C) Consider Regulatory Action Including a Boxed Warning Under 21 C.F.R. § 201.80(e). We are deeply skeptical of advocates of "gender affirming care" (GAC) who have proven themselves loyal to ideology rather than evidence-based medical research and the scientific method.

Only by examining the medical evidence and testimonies of those subjected to "gender-affirming care" to public scrutiny can prospective patients truly *choose* hormonal intervention.<sup>1</sup> As Thomas Jefferson said, "Reason and experiment have been indulged, and error has fled before them. It is error alone which needs the support of government. Truth can stand by itself."<sup>2</sup>

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<sup>1</sup> See Advancing American Freedom's response to the FTC's "Request for Public Comment Regarding "Gender-Affirming Care" for Minors," [FTC-2025-0264-0001], <https://www.regulations.gov/comment/FTC-2025-0264-7204>.

<sup>2</sup> Thomas Jefferson, *Notes on the State of Virginia*, Query VI (1781-1782), <https://cooperative-individualism.org/jefferson-thomas-notes-on-the-state-of-virginia-1781-1782.htm>.

In November 2025, the Department of Health and Human Services published a peer-reviewed report entitled “Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices” which demonstrates that “gender-affirming” hormonal interventions lack the benefits its advocates have long claimed.<sup>3</sup> Recognizing similar evidence that hormonal treatment is medically questionable, multiple countries in the United Kingdom, including Sweden, Finland, and Denmark, have already restricted hormone treatments for minors with gender distress.<sup>4</sup>

Instead, the interventions often impose harms on minors who cannot grant informed consent. Multiple European countries in the United Kingdom, including Sweden, Finland, and Denmark, have already restricted hormone treatments.

We agree with petitioners and urge the FDA to create a docket to serve as a repository of evidence. Prospective patients cannot properly consent if the harms of hormonal intervention, such as the permanent loss of fertility, remain hidden.

The need to collaborate and form associations focused on a public concern is a pillar of the American tradition. Observing America in the early Republic, Alexis de Tocqueville noted that America differed from aristocratic societies in that “all citizens are independent and weak; they can hardly do anything by themselves, and no one among them can compel his fellows to lend him their help. So they all fall into impotence if they do not learn to help each other freely.”<sup>5</sup>

Yet, clinicians shaping “gender medicine,” especially those aligned with the World Professional Association for Transgender Health (WPATH), knowingly and consistently provide medical intervention without informed consent. The 2024 leaked WPATH internal communications show as much.

In a panel to educate gender doctors titled “Identity Evolution Workshop” on May 6, 2022, Dr. Daniel Metzinger, a Canadian endocrinologist, reminded the audience that they are “often explaining these sorts of things to people who haven’t even had biology in high school yet.”<sup>6</sup> Further, the panelists noted young patients often attempt to pick and choose the effects of hormone therapy; that children express desires for a deeper voice without developing facial hair or want to feel more feminine without developing breasts demonstrates they do not understand

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<sup>3</sup> Department of Health and Human Services, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices*, November 19, 2025. <https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf>

<sup>4</sup> Azeen Ghorayshi, “Youth Gender Medications Limited in England, Part of Big Shift in Europe,” *New York Times*, April 9, 2024, <https://www.nytimes.com/2024/04/09/health/europe-transgender-youth-hormone-treatments.html>

<sup>5</sup> Alexis de Tocqueville, *Democracy in America*, 898 (Eduardo Nolla ed., James T. Schleifer trans., Indianapolis: Liberty Fund, Inc. 2010) (1840).

<sup>6</sup> Mia Hughes, “The WPATH Files: Pseudoscientific Surgical and Hormonal Experiments on Children, Adolescents, and Vulnerable Adults,” *Environmental Progress* (March 4, 2024), 184, <https://static1.squarespace.com/static/56a45d683b0be33df885def6/t/6602fa875978a01601858171/1711471262073/WPATH+Report+and+Files111.pdf>.

the biological processes they alter.<sup>7</sup> Medical professionals encourage them toward GAC all the same.

The HHS report confirms that gender clinics are still not neutral arbiters of medical care. In 2024, Tamara Pietzke, “a licensed clinical social worker and therapist” in Washington described patients with “comorbid health conditions and complicated life histories” who, nonetheless, were approved for hormone interventions.<sup>8</sup>

One of her patients, a thirteen-year-old girl, had “diagnoses of depression, anxiety, post-traumatic stress disorder, and intermittent explosive disorder” and had “experienced childhood abuse, neglect, and sexual violence.”<sup>9</sup> Despite the facts that the girl never asked for testosterone and “failed to demonstrate an understanding of the hormone” when mentioned, the gender clinic “approved the teenager for testosterone on her first visit.”<sup>10</sup>

When Pietzke refused to “sign a letter of support clearing the patient of any mental health contraindications,” the case was “referred to the hospital’s risk management team” and Pietzke was ultimately told that she should consider “transferring the client ‘to someone who is comfortable with providing gender affirming care.’”<sup>11</sup>

Since gender-affirming clinicians refuse to provide information necessary for informed consent, the public ought to have another way of obtaining reliable information on the benefits or harms of gender-affirming medical intervention.

Thus, we urge the FDA to open a public docket to collect medical evidence on hormonal interventions, specifically for the off-label use of estrogen in natal males, and to hold a hearing to begin restoring informed consent.

Sincerely,

**J. Marc Wheat**  
General Counsel

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<sup>7</sup> *Id.* at 10.

<sup>8</sup> Department of Health and Human Services, *Treatment for Pediatric Gender Dysphoria*, 206.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 207.

<sup>11</sup> *Id.*