

July 6, 2026

Via Federal eRulemaking Portal

Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, DC 20201

RE: FDA Proposed Rule, “Modification of Certain Terminology in Title 21”; Docket No. FDA-2026-N-2886, RIN 0910-AJ26

Dear Secretary Kennedy:

We are scholars at the Ethics and Public Policy Center, and we write to offer brief comment on the Food and Drug Administration’s (FDA) Proposed Rule, “Modification of Certain Terminology in Title 21.”¹

The Department of Health and Human Services’ (HHS) subagency, the FDA, invites public comment on a Proposed Rule to extend approval of changes made to forms related to “modify certain terminology in Title 21 of the Code of Federal Regulations (CFR) to comply with Executive Order (E.O.) 14168, ‘Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,’ issued on January 20, 2025. Specifically, this proposed rule, if finalized, will remove the term ‘gender’ wherever it appears and either replace it with the term ‘sex,’ or delete reference to gender, as applicable[.]”² **We support this proposal.**

We applaud the FDA for opposing gender ideology and recognizing biological truth in its regulations. There are two sexes—male and female. While “gender” historically was used synonymously with sex, the term is now often used to mean something other than binary, biological sex. Biology is not bigotry. As Supreme Court Justice Ruth Bader Ginsburg recognized, “Physical differences between men and women ... are enduring,” “inherent,” and “remain cause for celebration”: “[T]he two sexes are not fungible.”³

EO 14168 recognized that there are “two sexes, male and female,” “these sexes are not changeable,” and the sexes are “grounded in fundamental and incontrovertible reality.”⁴ The order further directed agencies, like HHS, to “enforce all sex-protective laws to promote this reality” and to use the

¹ 91 Fed. Reg. 24380 (May 5, 2026), <https://www.federalregister.gov/d/2026-08826>.

² *Id.*

³ *United States v. Virginia*, 518 U.S. 515, 533 (1996) (second alteration in original) (quoting *Ballard v. United States*, 329 U.S. 187, 193 (1946)).

⁴ 90 Fed. Reg. 8615 (Jan. 20, 2025), <https://www.federalregister.gov/d/2025-02090> (defining “sex” for the purpose of Executive Branch interpretation and application of federal law as referring “to an individual’s immutable biological classification as either male or female”).

term “sex” and not “gender” in relevant polies, documents, and regulations.⁵ As Rachel Morrison has told the *Washington Times*, “Using the term ‘sex’ instead of ‘gender’ provides clarity, improves the quality and utility of information collected, protects sex-based rights, and reflects biological reality, not subjective self-perception.”⁶

Thank you for the opportunity to provide public comment.

Sincerely,

Rachel N. Morrison, J.D.
Fellow and Director
Administrative State Accountability Project
Ethics & Public Policy Center

Samuel Lucas
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⁵ *Id.*

⁶ Stephen Dinan, *Trump’s First Year Has Changed the Way Government Speaks*, Wash. Times (Dec. 24, 2025), <https://www.washingtontimes.com/news/2025/dec/24/trumps-first-year-changed-way-government-speaks/>.