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October 1, 2026

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

RE: Department of Health and Human Services, Food and Drug Administration, Proposed Rule, "Modification of Certain Terminology in Title 21": 21 CFR Parts 10, 56, 106, 201, 251, 310, 312, 314, 329, 600, 803, 862, 866, 870, 882, 1114; [Docket No. FDA-2026-N-2886] RIN 0910-AJ26

Dear Secretary Kennedy,

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) Proposed Rule, "Modification of Certain Terminology in Title 21."[1]

The National Catholic Bioethics Center (NCBC) is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences. NCBC provides consultations to institutions and individuals seeking its opinion on the appropriate application of Catholic moral teachings to these ethical issues. NCBC has a membership of over five hundred members, a number of whom are institutions representing thousands of healthcare professionals.

The National Association of Catholic Nurses, USA (NACN-USA) is a non-profit organization of nurses from diverse backgrounds and specialties. NACN-USA shares in the ministry of Catholic Nursing including healthcare that respects the sacred gift of human sexuality. NACN-USA members practice in a very large variety of healthcare settings and seek to address the best interest of their patients, regardless of their sex, diagnosis and the resulting needs, including those suffering from gender incongruence.[2]

The Catholic Medical Association (CMA) is a national, physician-led community that includes as members about 2700 physicians and healthcare professionals nationwide in all fields of practice. CMA

[1] 91 Fed. Reg. 48785 (Aug 3, 2026). https://www.federalregister.gov/documents/2026/08/03/2026-15671/modification-of-certain-terminology-in-title-21-reopening-of-the-comment-period.

[2] "Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex…." See World Health Organization, "Gender Incongruence of Adolescence and Adulthood," *ICD-11* (2019).

represents faithful Catholics in the healthcare field so that its members can grow in faith, maintain ethical integrity, and provide excellent healthcare in accordance with the teachings of the Catholic Church. CMA members practice in a very large variety of healthcare settings and seek to address the best interest of their patients, regardless of biological sex, including those suffering from gender incongruence.[3]

NCBC, NACN-USA, and CMA are interested in supporting language which clarifies that there are only two biological sexes, male and female, because this clarity upholds the dignity and truth of the human person, which is paramount to effective health care.

The Proposed Rule by the FDA, a subagency of the Department of Health and Human Services (HHS), would "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[.]"[4] The NCBC, NACN-USA, and CMA support this Proposed Rule because it recognizes and clarifies the fact that there are only two biological sexes, male and female.

The change from the word "sex" to "gender" under the administration of former President Joe Biden caused confusion and ambiguity, as "gender" was redefined to include many false gender "identities" not in accord with the reality that a person is either biological male or biological female sex at birth. During his term, President Biden issued an executive order, which directed federal agencies to interpret civil rights protections against sex discrimination to include sexual orientation and gender identity.[5] Reverting in government policy to the use of the term "sex," as proposed in this Proposed Rule, provides greater clarity which is necessary for accurate data collection, and the proper diagnosis and treatment of patients, especially minors being victimized by the transgender agenda.[6]

Federal agencies supporting the Proposed Rule are using this opportunity to "alter the 'gender' language inserted by the Biden administration and replace it with the "sex" designation that the administration says is more accurate."[7] The term "gender," as used by the Biden administration, is ambiguous because it is interpreted to mean not the biological sex (male or female) but any gender identity a person may claim that is not in accord with their biological sex. This ambiguity is a rejection of basic biology which must be clarified.

Rachel Morrison, the director for the Administrative State Accountability Project at the Ethics and Public Policy Center, has submitted formal comments in support of the project: "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,"[8] The protection of sex-based rights has been negatively impacted by the erroneous use of terms, and is inconsistent with federal civil rights law: Title VII of the *Civil Rights Act* prohibits an employer from discrimination based on *sex,* not

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[3] *Id.*
[4] *Op cit.,* 91 Fed. Reg. 48785 (Aug 3, 2026).
[5] *Executive Order 13988*, "Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation". *The White House* (January 21, 2021). Archived from the original on January 18, 2025.
[6] HHS, "Wolves in White Coats: How Doctors and Hospitals Pushed and Profited from the Fraud of 'Gender Medicine'" (August 13, 2026). https://www.hhs.gov/press-room/hhs-report-insurance-coding-sex-rejecting-procedures-minors.html.
[7] Stephen Dinan, "Trump's first year has changed the way government speaks," *The Washington Times* (Wednesday, December 24, 2025). https://www.washingtontimes.com/news/2025/dec/24/trumps-first-year-changed-way-government-speaks/.
[8] *Id.*

"gender identity."[9] Unfortunately, such inaccuracy in the interpretation by the federal government of such terms was added to by the U.S. Supreme Court in *Bostock v. Clayton County,* determining that discrimination based on sexual orientation or gender identity is a form of discrimination "because of sex."[10] In dissenting opinions Justice Samuel Alito, Justice Clarence Thomas, and Justice Brett Kavanaugh argued that the word "sex" in civil rights law meant biological sex and did not encompass sexual orientation or gender identity. Justice Brett Kavanaugh wrote that updating the 1964 statute to explicitly cover sexual orientation and gender identity was a decision that should have been made by Congress through legislation rather than by the judiciary.[11] This Proposed Rule will contribute to the accurate legal understanding of legislative intent of our sacred civil rights laws.

Catholic healthcare particularly has been victim to this ideological driven misapplication of the law. There have been at least two instances in which such healthcare organizations were labeled as discriminatory for refusing to remove healthy organs from persons seeking sex-rejecting procedures to address their gender dysphoria,[12] when, in fact, Catholic healthcare will not remove healthy organs as a general principle.[13]

Furthermore, the NCBC, NACN-USA, and CMA support the clarification of the term "sex" because this clarity protects patients, and in particular women, from discrimination, a protection which is guaranteed under the 14th Amendment's Equal Protection Clause.[14] Beginning with *Reed v. Reed*, the U.S. Supreme Court set the precedent that equal protection applies to discrimination by sex. In 1971, for the first time since the *Fourteenth Amendment* had gone into effect in 1868, the Court had struck down a state law on the ground that it discriminated against women in violation of the Equal Protection Clause, by prohibiting differential treatment based on *sex* (emphasis added).[15] In *United States v Virginia*, the U.S. Supreme Court also applied Equal Protection to federal actions by stating that sex-based discrimination must be justified by "exceedingly persuasive justification."[16] Without such justification, discrimination by sex violates the equal protection clause.[17] The use of the term "sex" by the HHS and FDA will ensure that no unconstitutional discrimination will occur.

Critically important to the NCBC, NACN-USA, and CMA is the fact that the use of the term "sex" instead of "gender" clarifies that, physical differences between men and women are enduring: "The two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both."[18] Proper health care requires that an individual is treated according to his or her biological sex, regardless of any false "gender identity." For example, patients identifying as female, but who are biologically male presenting in an emergency room can put their lives at risk for non-identification as male from prostate or testicular cancer. Likewise for a patient identifying as male, but who biologically

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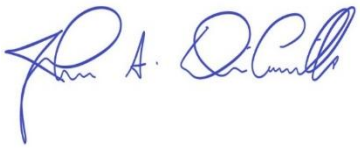
[9] Public Law 88-352 (Pub. L. 88–352), enacted July 2, 1964.
[10] *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020).
[11] In dissenting opinions from the June 15, 2020, U.S. Supreme Court case *Bostock v. Clayton County*.
[12] Paul Gessler, "Transgender man wins lawsuit against St. Joseph after hospital cancels hysterectomy," CBS Baltimore (Updated on: January 13, 2023 / 10:06 PM EST). https://www.cbsnews.com/baltimore/news/transgender-man-wins-lawsuit-against-st-joseph-after-hospital-cancels-hysterectomy/. Also, see *Minton v. Dignity Health.* *https://www.aclunorcal.org/cases/minton-v-dignity-health-sex-discrimination/.*
[13] U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services,* 7th ed. (November 2025) N. 30.
[14] U.S. Const. amend. XIV, § 1
[15] *Reed v. Reed*, 404 U.S. 71.
[16] *United States v. Virginia*, 518 U.S. 515, 534.
[17] *Id.*
[18] *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)).

is female, she can be undiagnosed for cervical cancer and endometrial cancer, or even a life-threatening ectopic pregnancy. For both sexes, the undisclosed use of hormone replacements, such as the off-label use of estrogen with biological males can lead to significant health hazards. The dangers of off-label use of estrogen on biological males include cardiovascular disease, venous thrombo-emboli, and infertility, as well as significantly increased risk of cognitive impairment, metabolic anomalies, some cancers, and autoimmune disorders.[19] Since the dangers to young males are multifocal and potentially life-threatening, Blackbox Warnings of the federal government should be required.[20]

Finally, the harm done to minors with gender incongruence caused by so-called gender affirmation has been catastrophic as documented in HHS's "Wolves in White Coats: How Doctors and Hospitals Pushed and Profited from the Fraud of 'Gender Medicine'."[21] Minors subjected to these sex-rejecting procedures increasingly are recognizing the harm to which they have been subjected and they are seeking justice.[22] The origins of all of this harm have been facilitated by the confusion in terminology, equating "gender" to "sex."

In conclusion, The National Catholic Bioethics Center, the National Association of Catholic Nurses, USA, and the Catholic Medical Association support this Proposed Rule to modify the terminology in Title 21. The Proposed Rule recognizes that there are only two biological sexes, male and female. FDA's proposed use of the term "sex" will provide greater clarity in measuring data, diagnosing and treating patients, protecting the unconstitutional violation of civil rights, and protecting minors from the "gender-affirming" ideology. Furthermore, we are very grateful for this opportunity to provide public comment regarding the Proposed Rule for the "Modification of Certain Terminology in Title 21."[23]

Respectfully submitted,



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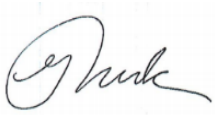

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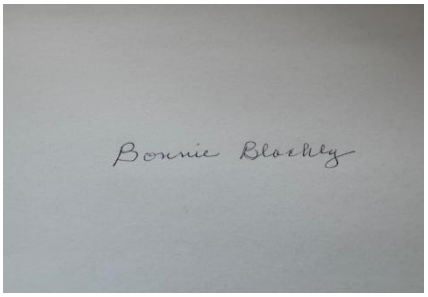
[19] Mayo Clinic, "Feminizing hormone therapy" (ND). Last viewed September 30, 2026. https://www.mayoclinic.org/tests-procedures/feminizing-hormone-therapy/about/pac-20385096.
[20] 21 C.F.R. § 201.80(e).
[21] *Op cit,* HHS (August 13, 2026).
[22] See, Identity Crisis, *IW Features* (2022), https://www.iwfeatures.com/watch/identity-crisis/ (providing a list of detransitioners and their compelling stories of being misinformed about the need to transition.); Chloe Cole, *Written Testimony of Chloe Cole for Kansas House Bill 2071* (Jan. 28, 2025), Kansas Legislature, House HHS Committee, Committee Document No. CTTE_H_HHS_1, https://www.kslegislature.gov/li/b2025_26/committees/ctte_h_hhs_1/documents/testimony/20250128_01.pdf (highlighting her story from transition to detransition); Matt Fradd, *Trans Surgeries: The ACTUAL Story! w/ Chloe Cole,* YouTube (May 31, 2024). https://www.youtube.com/watch?v=_tGseOJI6iI; and *Chloe Cole's Testimony*, Purpose Driven Lawyers (July 27, 2023), https://purposedrivenlawyers.com/chloe-coles-testimony/.
[23] 91 Fed. Reg. 48785 (Aug 3, 2026). https://www.federalregister.gov/documents/2026/08/03/2026-15671/modification-of-certain-terminology-in-title-21-reopening-of-the-comment-period.



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