ETHICS AND PUBLIC POLICY CENTER

April 7, 2025

Via Federal eRulemaking Portal

Kimberlee Trzeciak
Deputy Commissioner for Policy, Legislation, and International Affairs
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: FDA Notice "Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies," Docket No. FDA-2023-D-5591

Dear Deputy Commissioner Trzeciak:

I am a scholar at the Ethics and Public Policy Center (EPPC), director of EPPC's Administrative State Accountability Project (ASAP), and a former attorney at the Equal Employment Opportunity Commission. I write in response to the Food and Drug Administration's (FDA) January 7, 2025, notice "Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies."[1]

The notice announces draft guidance that "provides guidance on the study and evaluation of sex- and/or gender-specific data in clinical investigations or research involving one or more subjects to determine the safety or effectiveness of a device."[2] The purpose of the new guidance "is to encourage science-driven consideration of sex and/or gender, as appropriate for both the scientific question being addressed and the intended use of the device, when designing medical device clinical studies and reporting data from such studies in accordance with legal requirements."[3]

I take no position on whether guidance on this topic is needed. But I write to support the importance of evaluating *sex*-specific data in medical device clinical studies and to draw the FDA's attention to ways that the draft guidance, specifically its inclusion of gender-specific data, is inaccurate and conflicts with President Trump's executive orders and Department of Health and Human Services (HHS) guidance. Because of the major deficiencies of the draft guidance, the FDA should not finalize the proposed guidance without substantial revision.

A. Sex-Specific Data Matters

The notice states that sex is a "key consideration[] in the development and performance of medical devices" but explains that "[h]istorically, females … have been under-represented in or excluded from many clinical studies," which means females and their health care providers do not have information "regarding the benefits and risks of many medical devices."[4]

[1] 90 Fed. Reg. 1161 (Jan. 7, 2025), https://www.federalregister.gov/d/2024-31526.
[2] *Id.* at 1161.
[3] *Id.*
[4] *Id.* at 1162.

I agree that it is important to evaluate sex-specific data in medical device clinical studies because biological and physiological differences between males and females could impact efficacy and safety. I also support the consideration, when relevant, of factors that are unique to women—like menstrual cycles, menopause, pregnancy, and lactation—in designing, developing, and evaluating medical products. With this consideration, due weight should be given to any risks or harm to the life and health of a mother and her unborn child.

As the HHS Office on Women's Health acknowledges, "[r]ecognizing the immutable and biological nature of sex is essential to ensure the protection of women's health [and] safety[.]"[5] Women are not just smaller men. Information about a medical device's impact on females is necessary for a woman to fully appreciate the benefits and risks and make informed decisions about her health.

B. The Draft Guidance's Discussion of Sex and Gender Is Inaccurate

The draft guidance's discussion of sex and gender is inaccurate and should be corrected in any final guidance.

Of relevance, the definitions section states:

> Use of the term male and female versus man and woman depends upon whether biological or psychosocial factors are under study. For purposes of this document, the terms male and female are used in the context of sex. The terms man, woman, nonbinary and/or transgender are used in the context of gender. In this document, when both sex and gender are relevant to the study, the terms male/man, female/woman, and/or other participants may be used and such usage indicates male and/or man, female and/or woman, and/or other participants. While sex and gender are distinct, they are interrelated and are not necessarily mutually exclusive. Sex and gender and their interactions may drive epigenetic influences and resultant physiologic reactions, influence etiology and presentation of disease, and affect treatment outcomes.
>
> For the purposes of this guidance:
>
> **Sex** is a biological construct based on anatomical, physiological, hormonal, and genetic (chromosomal) traits. Sex is generally assigned based on anatomy at birth and is usually categorized as female or male, but variations occur. Variations of sex refers to differences in sex development (DSD) or intersex traits.
>
> **Gender** is a multidimensional construct that encompasses how an individual self-identifies. Gender may be described across a continuum, may be nonbinary, and may change over the course of a lifetime. Gender may or may not correspond to a person's sex assigned at birth.[6]

The background section states that "historically, as gender was often conflated with sex or otherwise not properly reported in clinical studies, there is a lack of data regarding the underrepresentation of nonbinary, transgender, fluid gender identities and other gender identities."[7] Such data is allegedly "necessary to help improve the generalizability of research results to all intended patient populations,

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[5] *See* HHS, *Sex-Based Definitions*, https://womenshealth.gov/article/sex-based-definitions (last updated Feb. 19, 2025).
[6] FDA, HHS, Evaluation of Sex-Specific and Gender-Specific Data in Medical Device Clinical Studies: Draft Guidance for Industry and FDA Staff, Jan. 2025, at 2-3 [hereinafter "Draft Guidance"], *available at* https://www.regulations.gov/document/FDA-2023-D-5591-0002.
[7] *Id.* at 4 (internal citations omitted).

including women, nonbinary people, transgender people, people with fluid gender identities, and people with other gender identities that historically have been underrepresented."[8]

While continuing to discuss the alleged importance of sex- *and* gender-specific data throughout the draft guidance, the FDA acknowledges that "there are no universally agreed-upon validated tools for collecting gender-related data within the scientific community," suggesting that participants could be asked "for both their sex assigned at birth and their current gender identity."[9]

The FDA's discussion of sex and gender quoted above and throughout the guidance is inaccurate in multiple ways.

First, the draft guidance falsely states that sex is a construct. Sex is a biological reality, not a construct.

Second, sex is not "assigned at birth." It is determined at conception and cannot change.[10] While sex is often first observed at birth, it can also be determined prior to birth through genetic testing or an ultrasound.

Third, there are only two sexes: male and female.[11] There is no third sex. Those who have a disorder of sexual development (DSD) (often referred to as "intersex") are still either male or female.[12] To the extent that a DSD would impact the efficacy and safety of a medical device, the person's DSD should be considered, but that consideration should be based on the relevant impact of the specific DSD, not the false notion that individuals with a DSD are a "third sex."

Fourth, "gender" as defined in the draft guidance has no place in the clinical evaluation of medical devices. A subjective, self-identified, and changing label that has no connection to any objective criteria does not provide meaningful information about its impact on individuals who identify similarly. The FDA should not encourage the inclusion or incorporation of gender-specific data.

Fifth, the guidance asserts that "[s]ex and gender and their interactions may drive epigenetic influences and resultant physiologic reactions, influence etiology and presentation of disease, and affect treatment outcomes."[13] But declaring oneself to be a certain gender does not change a person's disease and treatment profile.

Sixth, the guidance explicitly implies that women are not necessarily female and that men are not necessarily male.[14] This is false. Women are adult human females and men are adult human males. To imply that a male can be a woman by self-identifying that way, and vice versa, is insulting and wrong.

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[8] *Id.* at 5.
[9] *Id.* at 16.
[10] *See* HHS, *Sex-Based Definitions*, https://womenshealth.gov/article/sex-based-definitions (last updated Feb. 19, 2025) ("The sex of a human, female or male, is determined genetically at conception (fertilization), and is observable before birth…. A person's sex is unchangeable and determined by objective biology.").
[11] *See id.* ("There are only two sexes, female and male, because there are only two types of gametes. An individual human is either female or male based on whether the person is of the sex characterized by a reproductive system with the biological function of producing eggs (ova) or sperm.").
[12] *See id.* ("Rare disorders of sexual development do not constitute a third sex because these disorders do not lead to the production of a third gamete.").
[13] Draft Guidance at 3; *see also id.* at 4 ("Gender also plays an important role in human health and disease.").
[14] *See id.* at 2-3 ("Use of the term male and female versus man and woman depends upon whether biological or psychosocial factors are under study. For purposes of this document, the terms male and female are used in the context of sex. The terms man, woman, nonbinary and/or transgender are used in the context of gender.").

In sum, the FDA should not finalize the draft guidance without substantial revisions, including dropping the inclusion of gender-specific data, the references to "sex assigned at birth" (saying "sex" would be sufficient), and the implication that males can be women and females can be men.

C. The Draft Guidance's Discussion of Sex and Gender and Inclusion of Gender-Specific Data Conflicts with President Trump's Executive Orders and HHS Guidance

The draft guidance's discussion of sex and gender and inclusion of gender-specific data is reflective of the Biden-Harris administration's promotion of gender ideology. On day one, President Trump revoked multiple Biden-era executive orders that directed federal agencies to promote gender ideology, including:

- Executive Order 13985 on "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" (Jan. 20, 2021);
- Executive Order 13988 on "Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation" (Jan. 20, 2021); and
- Executive Order 14075 on "Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals" (June 15, 2022).[15]

The same day, President Trump also issued an executive order entitled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government."[16] I specifically direct you to the following aspects of the President's Executive Order:

- Section 2(a) recognizes "sex" as "an individual's immutable biological classification as either male or female" and "not a synonym for and does not include the concept of 'gender identity.'"
- Section 2(b) recognizes "women" and "girls" as "adult and juvenile human females, respectively."
- Section 2(c) recognizes "men" and "boys" as "adult and juvenile human males, respectively."
- Section 2(d) recognizes that a "female" is "a person belonging, at conception, to the sex that produces the large reproductive cell."
- Section 2(e) recognizes that a "male" is "a person belonging, at conception, to the sex that produces the small reproductive cell."
- Section 2(f) recognizes: "'Gender ideology' replaces the biological category of sex with an ever-shifting concept of self-assessed gender identity, permitting the false claim that males can identify as and thus become women and vice versa, and requiring all institutions of society to regard this false claim as true. Gender ideology includes the idea that there is a vast spectrum of genders that are disconnected from one's sex. Gender ideology is internally inconsistent, in that it diminishes sex as an identifiable or useful category but nevertheless maintains that it is possible for a person to be born in the wrong sexed body."
- Section 2(g) recognizes that "'Gender identity' reflects a fully internal and subjective sense of self, disconnected from biological reality and sex and existing on an infinite continuum, that does not provide a meaningful basis for identification and cannot be recognized as a replacement for sex."
- Section 3(a) instructs the Secretary of HHS to "provide to the U.S. Government, external partners, and the public clear guidance expanding on the sex-based definitions set forth in this order."

[15] 90 Fed. Reg. 8237 (Jan. 28, 2025), https://www.federalregister.gov/d/2025-01901.
[16] 90 Fed. Reg. 8615 (Jan. 30, 2025), https://www.federalregister.gov/d/2025-02090.

- Section 3(b) states that federal agencies "shall enforce laws governing sex-based rights, protections, opportunities, and accommodations to protect men and women as biologically distinct sexes" and directs the agencies to "give the terms 'sex', 'male', 'female', 'men', 'women', 'boys' and 'girls' the meanings set forth in [the] order when interpreting or applying statutes, regulations, or guidance and in all other official agency business, documents, and communications."

- Section 3(c) directs that "[w]hen administering or enforcing sex-based distinctions," federal agencies "shall use the term 'sex' and not 'gender' in all applicable Federal policies and documents."

In response to President Trump's executive orders defending women and children, HHS announced on February 19, 2025, that it was launching a webpage "to promote guidance on sex-based definitions and other resources on efforts to protect women and children."[17] As Dorothy Fink, MD, Deputy Assistant Secretary for Women's Health, explained, "HHS recognizes that biological differences between females and males require sex-specific practices in medicine and research to ensure optimal health outcomes."[18]

The webpage provides the following definitions:

- ***Sex*** is a person's immutable biological classification as either male or female.
- ***Female*** is a person of the sex characterized by a reproductive system with the biological function of producing eggs (ova).
- ***Male*** is a person of the sex characterized by a reproductive system with the biological function of producing sperm.
- ***Woman*** is an adult human female.
- ***Girl*** is a minor human female.
- ***Man*** is an adult human male.
- ***Boy*** is a minor human male.[19]

These definitions conflict with the FDA's discussion of sex and gender in its draft guidance. Any final guidance should reflect these definitions and the policies in President Trump's executive orders.

Conclusion

For the reasons stated above, I urge the FDA to carefully examine its draft guidance in light of President Trump's executive orders and HHS guidance. The FDA should not finalize the draft guidance without substantial revision. I hope this public comment helps the FDA better carry out its important responsibilities and ensure that its actions and policies reflect the President's priorities and directives.

Sincerely,

Rachel N. Morrison, J.D.
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[17] Press Release, HHS, HHS' Civil Rights Office Takes Action to Support President Trump's Executive Orders to Protect Minors and Restore Biological Truth (Feb. 20, 2025), https://www.hhs.gov/about/news/2025/02/20/hhs-civil-rights-office-takes-action-support-president-trumps-executive-orders-protect-minors-restore-biological-truth.html.
[18] *Id.*
[19] HHS, *Sex-Based Definitions*, https://womenshealth.gov/article/sex-based-definitions (last updated Feb. 19, 2025).