



Modification of Certain Terminology in Title 21

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The Initiative for Gender Equity in the Public Sector (IGEPS) respectfully submits this comment in response to the Food and Drug Administration's (FDA) proposed rule to modify terminology within Title 21 of the Code of Federal Regulations (CFR) to comply with Executive Order 14168.

IGEPS is an organization dedicated to conducting rigorous, evidence-based research to make public service and public policy more equitable for all individuals. We actively partner with public sector organizations, providing administrators with data-driven tools and resources to make informed, scientifically sound decisions.

Our network comprises research scholars and policy practitioners from diverse academic disciplines, including public administration, economics, public policy, law, and sociology. It is from this multidisciplinary, empirical foundation that we express our profound concern and strong opposition to the proposed elimination, removal, or collapsing of the term "gender" into the biological definition of "sex."

In the social sciences, data is not a political tool; rather, it is the fundamental infrastructure required to diagnose societal problems and measure the efficacy of public interventions. For decades, scholars across our represented fields have established that sex (biological, physiological, and chromosomal attributes) and gender (socially constructed roles, behaviors, self-identities, and structural expectations) are distinct, separate analytical variables. This understanding corresponds with the mainstream and international medical professions, including the [American Medical Association](#), the [American Psychological Association](#), and the [World Health Organization](#).

While these sex and gender variables frequently overlap, they are not synonyms. Social science benefits enormously from maintaining detailed, multiple, and highly descriptive variables because human behavior and public health outcomes are multi-dimensional. The Williams Institute, UCLA School of Law, underscores the importance of collecting sexual orientation and gender identity data in its [report](#), "Removal of Sexual Orientation and Gender Identity from Federal Data Collections" (February 2026). Forcing federal datasets to use "sex" as an all-encompassing proxy for "gender" causes a fatal methodology problem known as variable conflation. With variable conflation, we lose the nuance critical to understanding social phenomena.

At the FDA level, this rule poses immediate risks to the integrity of medical data. Legally stripping out "gender" from clinical trial frameworks, adverse event reporting, and drug safety profiles creates data gaps that are difficult to undo. The rule would isolate U.S. federal regulations from global scientific reporting standards, fundamentally degrading the quality and comparability of American public health research, as the [World Health Organization](#) acknowledges.

Public service must be equipped to serve the public as it actually exists, rather than forcing a complex human reality into a simplified regulatory box. Because the proposed rule degrades data fidelity, undermines evidence-based public administration, and actively harms the scientific validity of federal research, IGEPS strongly urges the FDA to withdraw this proposed rule. The Agency must retain the critical, empirically verified distinction between sex and gender.