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LIFE SCIENCES AND HEALTHCARE

Focus on Women's Health

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The Establishment of the White House Gender Policy Council and Its Implications for FDA Initiatives and Priorities

On March 8, 2021, President Biden signed an Executive Order, establishing a Gender Policy Council ("the Council") tasked with the broad policy goal of "advancing gender equity and equality" for the purpose of reducing poverty, promoting economic growth, increasing access to education, improving health outcomes, advancing political stability and fostering democracy.[1] The Executive Order reflects a clear intention for federal agencies to prioritize and fully integrate gender equity and equality concerns within their policies and programs. Nearly all Department heads, including the Secretary of Health and Human Services (HHS), are required to serve on the Council, designate a senior official within their department to coordinate with the Council, and be responsible for overseeing the department's efforts to advance the Council's goals.[2]

Two health goals are likely to be at the forefront of this initiative for HHS, and for the Food and Drug Administration ("FDA"), which falls under HHS: (1) "increas[ing] access to comprehensive health care, address[ing] health disparities, and promot[ing] sexual and reproductive health rights," and (2) "address[ing] responses to the effects of the coronavirus disease 2019 (COVID-19) on women and girls."[3] These goals align with some of FDA's existing women's health initiatives, including improving the diversity of clinical studies, developing a better understanding of sex differences in the diagnosis and treatment of certain diseases, and increasing the availability of safety information for treating medical conditions during pregnancy.[4] Given that the COVID-19 pandemic has only emphasized these inequities, we expect that the Gender Policy Council may serve as a platform for FDA to further these initiatives.

Improving Diversity of Study Populations in Clinical Trials

Historically, women have been underrepresented in clinical studies.[5] Citing the risk of birth defects, a 1997 FDA guideline went so far as to

recommend that women of reproductive age be excluded from early phase clinical trials altogether, which also had a chilling effect for including women in later phase trials.[6] Although this recommendation has since been reversed, women continue to be impacted by the historic policy and clinical trials are still working towards proportional representation. As a result, questions remain regarding whether medical products may impact women and men differently, including, for example, whether dosing should be adjusted according to sex.[7] The diversity of impact of the COVID-19 pandemic between men and women and across different racial and ethnic groups has only emphasized the need to ensure that clinical trials include participants that reflect the heterogeneity of the population at large.

To increase women's participation in clinical trials, FDA's Office of Women's Health ("OWH") developed the Diverse Women in Clinical Trials Initiative. Launched in January 2016, the program is aimed at (1) raising awareness about clinical trial participation by diverse women of different ages, races, ethnic backgrounds, and health conditions; and (2) encouraging the industry to share best practices about clinical trial design, recruitment, and subpopulation analyses.[8]

Assessing Biological Differences Between the Sexes and Their Impact on the Diagnosis and Treatment of Disease

With an eye towards improving health outcomes for women, FDA's OWH awards grants and conduct its own research and policy forums geared toward understanding the biological differences between the sexes and their impact on the diagnosis and treatment of disease.[9] For example, FDA is currently engaged in projects specifically focused on the role of sex and gender with respect to three major health issues in the United States: (1) opioid abuse and recovery, (2) nicotine use and dependence, and (2) cardiovascular disease.[10] Given the seriousness of the current pandemic and the alignment with the Gender Policy's Counsel's objectives, we anticipate that FDA's OWH will likely begin initiatives aimed at assessing sex differences in the disease progression and efficacy of treatments for COVID-19.

Safety Information for Treating and Preventing Medical Conditions During Pregnancy

Women and their health care providers have long faced a dearth of safety information for the use of medical products during pregnancy.[11] Unfortunately, this sometimes results in women foregoing altogether the treatment of serious medical conditions during pregnancy, including conditions that can be exacerbated by pregnancy, like anxiety and depression.[12] To address this gap, FDA uses "pregnancy exposure registries"—which collect information on pregnant women who take prescription medicines or vaccines during pregnancy and their newborns—to update drug labeling and guidelines.[13] Additionally, as FDA constantly seeks ways to modernize its approach and evaluate new technological innovations, the OWH has funded research to develop a virtual pregnant woman, an artificially intelligent model, to predict how drugs or vaccines might act in pregnant women.[14]

Indeed, the COVID-19 pandemic has shined a spotlight on this longstanding problem. Because pregnant women are at a higher risk of severe illness and death from the virus, they were excluded from clinical studies for all currently available vaccines. Therefore, there is very little safety information to assist patients and their providers in determining whether the benefits of vaccination outweigh the potential risks. With increasing numbers of pregnant women being vaccinated due to their eligibility as frontline health or essential workers, or due to underlying health conditions (and in many states, pregnancy is considered a qualifying health condition), we expect to see real world data on the vaccines collected through pregnancy exposure registries. We also expect to see an increase in advocacy for the inclusion of pregnant women in clinical trials—in alignment with the objectives of the Gender Policy Council, it would be appropriate for FDA's scientific experts to weigh in on how to do so.

Take-Aways

In light of the Biden Administration's particular focus on sex and gender equities, we should expect FDA to continue its focus on women's health products. Consistent with FDA's focus, the FDA-regulated industry should continue to look for ways to increase awareness about clinical trial participation by a diverse cross-section of the population, including women.

[1] White House, Executive Order on Establishment of the White House Gender Policy Council (March 8, 2021) at § 1, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/03/08/executive-order-on-establishment-of-the-white-house-gender-policy-council/.
[2] *See id*. at §. 2(c); 2(g)-(h).
[3] *See id*. at § 2(b)(vi),(ix).
[4] *See* FDA, Women's Health Research (last visited March 11, 2021), https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research.
[5] *See* FDA, Gender Studies in Product Development: Historical Overview (last visited March 11, 2021), https://www.fda.gov/science-research/womens-health-research/gender-studies-product-development-historical-overview.
[6] *See id*.
[7] *See* FDA, Understanding Sex Differences at FDA (last visited March 11, 2021), https://www.fda.gov/science-research/womens-health-research/understanding-sex-differences-fda.
[8] *See* FDA, Women in Clinical Trials (last visited March 14, 2021), https://www.fda.gov/consumers/womens-health-topics/diverse-women-clinical-trials-campaign-partners; FDA, Diverse Women in Clinical Trials Campaign Partners (last visited March 14, 2021), https://www.fda.gov/consumers/womens-health-topics/diverse-women-clinical-trials-campaign-partners.
[9] *See* FDA, Women's Health Research (last visited March 11, 2021), https://www.fda.gov/science-research/womens-health-research/understanding-sex-differences-fda.
[10] *See id*.
[11] *See* L. Riley *et al*., *Improving Safe and Effective Use of Drugs in Pregnancy and Lactation: Workshop Summary*, AM J. PERINATOL (July 2017) at 826, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6193221/.
[12] See C. E. Creeley and L. K. Denton, *Use of Prescribed Psychotropics during Pregnancy: A Systematic Review of Pregnancy, Neonatal, and Childhood Outcomes*, BRAIN SCI (September 2019) at 235, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6770670/.
[13] *See* FDA, Pregnancy Registries (last visited March 11, 2021), https://www.fda.gov/science-research/womens-health-research/pregnancy-registries.
[14] *See* FDA, An Insight into Women's Health (last visited March 14, 2021), https://www.fda.gov/news-events/fda-insight/fda-insight-insight-womens-health.