Society for Women's Health Research

October 22, 2019

Submitted via email to:
MBX.OSTP.WHBioeconomy@ostp.eop.gov

Kelvin Droegemeier, PhD
Director, Office of Science and Technology Policy

Re: Request for Information (RFI) 84-FR-47561: Request for Information on the Bioeconomy

Dear Dr. Droegemeier,

The Society for Women's Health Research (SWHR) commends the Office of Science and Technology Policy (OSTP) on pursuing improved understanding of notable gaps, vulnerabilities, and areas to promote and to protect in the United States bioeconomy. We support the goals outlined in the September 9, 2019, Request for Information (RFI) 84-FR-47561 and are pleased to provide the following information on areas for future attention in the field of biotechnology, particularly concerning women's health and biological sex disparities. We also commend OSTP for convening its recent Summit on America's Bioeconomy, which gathered national experts for a discussion on how the U.S. can best remain a leader in the field of biotechnology.

SWHR is a nearly 30-year-old national nonprofit dedicated to promoting research on biological sex differences in disease and improving women's health through science, policy, and education. Because of SWHR's advocacy efforts, women are now routinely included in most major medical research studies, and scientists funded by the National Institutes of Health (NIH) are required to consider sex as a biological variable in their research. SWHR is committed to ensuring researchers consider the unique needs of women across all areas of health care, including in relation to innovative treatments falling under the umbrella of biotechnology.

The biotechnology industry has made enormous advances over the past decades. Global pharmaceutical spending is driven in large part by biotechnological innovation, with biotechnology products estimated to represent 27% of the

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international market.[1] It is an exciting area for continued research and investment, given the potential for advances in both preventative health care and treatment of debilitating and rare illnesses. As therapies become increasingly personalized, we encourage OSTP to remember the unique considerations of women across the lifespan.

SWHR offers two recommendations to consider when pursuing further government investment, oversight, and protection of the bioeconomy:

1. Prioritizing Research Designs Exploring Sex as a Biological Variable (SABV) in Biotechnology Research
2. Prioritizing Research Addressing Areas of Unique Importance to Women's Health

Prioritizing Research Designs Exploring Sex as a Biological Variable (SABV) in Biotechnology Research

SWHR strongly supports the use of research designs that 1) prioritize the representative inclusion of women and diverse patient populations, and 2) explore sex differences in regard to patient outcomes and response to treatment. It is well-known that sex differences exist at all levels: cellular, molecular, and systems. Furthermore, it is understood that these differences affect response to treatment for a variety of drugs and biologics.

The federal government mandated adequate inclusion of women in NIH-sponsored clinical trials in the 1990s;[2] however, a 2015 Government Accountability Office report suggests there is no current system in place to monitor adherence to inclusion standards, meaning that much is still unknown regarding sex and gender representation in research.[3]

SWHR has long supported the idea that studying, analyzing, and reporting on sex differences should be standard practice across all research. Exceptions should only occur in scientifically justified cases, such as when a study focuses on a sex-specific condition (e.g., pregnancy) or prior evidence suggests no sex differences exist. Improved transparency and consistency in reporting sex-difference findings will help to shed additional light on disparities. Training on the inclusion of sex differences in research design and analyses should occur early on in a scientist's career in order to help make these efforts mainstream within the field.

As biomedicine becomes more personalized, with the ability to tailor therapeutics to a patient's individual genetic variations, sex must be considered as a crucial part of treatment development. Research funded by government agencies, including NIH and the Food and Drug Administration (FDA), should take into account SABV and not only seek to meet inclusion standards, but also to understand how response to treatment differs across sex and gender.

A 2016 *Health Affairs* article suggested the following methods of reducing health disparities within genetic research: 1) prioritizing minority-focused genetic research, 2) incorporating

[1] Deloitte. *2019 US and Global Life Sciences Outlook.* Accessed at: https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/us-and-global-life-sciences-industry-trends-outlook.html
[2] Liu, K.A. & Dipietro Mager, N.A. (2016). Women's involvement in clinical trials: historical perspective and future implications. *Pharmacy Practice (Granada).* doi: 10.18549/PharmPract.2016.01.708
[3] National Institutes of Health. *Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research.* (2015). Accessed at: https://www.gao.gov/assets/680/673276.pdf

community-based participatory research techniques to allow for needs-based investigation, 3) increasing research on gene-environment interactions, and 4) implementing health disparities training within scientific education. SWHR agrees that focus on these areas would reduce not only sex and gender disparities, but disparities within minority populations as well.

Prioritizing Research Addressing Areas of Unique Importance to Women's Health

In addition to considering SABV, biotechnology research and investment must consider the specific research opportunities that are uniquely important in the field of women's health. Research surrounding some of the most common chronic illnesses, including heart disease and certain types of cancer and dementia, suggests there may be sex-based differences in morbidity and mortality risks.[4,5,6]

Of course, disorders and conditions specifically related to women's biological sex are also areas of importance to the women's health market, including gynecological disorders such as endometriosis, uterine fibroids, and polycystic ovary syndrome; reproductive health changes such as menopause; and genetic disorders such as Turner syndrome and Rett syndrome.[7] Finally, there are a host of diseases that are predominantly prevalent in woman, such as migraine headache[8] and a variety of autoimmune conditions.[9]

These are important areas to consider with regards to biomedical and biotechnology research, given that: 1) women comprise more than half of the U.S. population and provide the majority of caregiving[10] and 2) women make more than 70% of health care spending decisions.[11] Women's spending in the health care market is typically significantly higher than men's spending,[12] and the global women's health market is estimated to exceed $50 billion by 2025.[13]

Women's biomedical research therefore represents an area for investment with high upside. Sex and gender differences in disease are, as mentioned, often overlooked. Research has trended toward a one-size-fits-all approach without specifically examining the role women's

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[4] Silander, K. et al. (2008). Gender differences in genetic risk profile for cardiovascular disease. *PLoS One.* doi: 10.1371/journal.pone.0003615

[5] Tevfik Dorak, M. & Karpuzoglu, E. (2012). Gender differences in cancer susceptibility: An inadequately addressed issue. *Frontiers in Genetics.* doi: 10.3389/fgene.2012.00268

[6] Podcasy, J.L. & Epperson, C.N. (2016). Considering sex and gender in Alzheimer disease and other dementias. *Dialogues of Clinical Neuroscience.* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5286729/pdf/DialoguesClinNeurosci-18-437.pdf. Accessed October 2019.

[7] NICHD (2016). What health issues or conditions are specific to women only? https://www.nichd.nih.gov/health/topics/womenshealth/conditioninfo/whatconditions. Accessed October 2019.

[8] Victor, T.W., Hu, X., Campbell, J.C., Buse, D.C., & Lipton, R.B. (2010). Migraine prevalence by age and sex in the United States: a life-span study. *Cephalalgia.* doi: 10.1177/0333102409355601

[9] Ngo, S.T., Steyn, F.J., & McCombe, P.A. (2014). Gender differences in autoimmune disease. *Frontiers in Neuroendocrinology.* doi: 10.1016/j.yfrne.2014.04.004

[10] Kaiser Family Foundation State Health Facts. Population Distribution by Gender. 2017 Timeframe. https://www.kff.org/other/state-indicator/distribution-by-gender/?currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D. Accessed October 2019.

[11] Matoff-Stepp, S., Applebaum, B., Pooler, J., & Kavanaugh, E. (2014). Women as health care decision makers: implications for health care coverage in the United States. *Journal or Health Care for the Poor and Underserved.* doi: 10.1353/hpu.2014.0154

[12] CMS. US Personal Health Care Spending by Age and Gender, 2010 Highlights. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/2010AgeandGenderHighlights.pdf. Accessed October 2019.

[13] Frost & Sullivan. (2018). Femtech – time for a digital revolution in the women's health market. https://ww2.frost.com/frost-perspectives/femtechtime-digital-revolution-womens-health-market/. Accessed October 2019.

health can play in opening up the market. We encourage OSTP to prioritize research on diseases and therapeutics that will have a significant benefit to women's health, as this will have a significant impact on overall population health as well.

In order for biomedical research and investment to address areas of interest in women's health, we also must consider the inclusion of diverse voices in the scientific research community. Currently, biotechnology is a field dominated by men — only 1 in 4 executives within medtech and biotech are women.[14] Continuing to prioritize government engagement with, funding of, and training for women scientists can only result in improved outcomes within the women's health area of biotechnology. Increasing numbers of women leaders within the biotechnology sphere will help to shine a light on health issues specific to or more commonly experienced by women across the lifespan.

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Thank you for providing this opportunity to comment on RFI 84-FR-47561 and for OSTP's consideration of the information provided. We look forward to serving as a resource on sex and gender differences in women's health, which is leading to critical discoveries of how women and men differ in fundamental ways and how these differences affect disease risk, pathophysiology, symptoms, diagnostic sensitivity and specificity, and response to therapy. If you have questions, please contact Melissa Laitner, Director of Science Policy, at 202.496.5002 or melissa@swhr.org.

Sincerely,

Amy M. Miller, PhD
President and Chief Executive Officer
Society for Women's Health Research

[14] Healthcare Businesswomen's Association (The progress of women executives in pharmaceuticals and biotechnology: a leadership benchmarking study abstract. https://www.hbanet.org/sites/hba/files/docs/Research_Studies/EDGE-White-Paper-Abstract-v2.pdf. Accessed October 2019.