Women's Health Innovation Coalition Testimony for the
Subcommittee on Labor, Health and Human Services, Education and Related Agencies -
Committee on Appropriations
Re: National Institutes of Health FY 2023 Outside Witness Testimony

Thank you for the opportunity to comment on the National Institutes of Health (NIH) budget priorities for FY2023. We provide this testimony in support of increased funding for research grants focused on addressing health diseases and conditions that solely, disproportionately and/or differently impact women within the FY2023 Labor, Health and Human Services, and Education Appropriations bill.

The Women's Health Innovation Coalition (WHIC) is a group of innovators, investors, clinicians, analysts, and executives with the shared goal of advancing innovation in women's health. We source innovative solutions to address unmet needs in diseases, conditions, and indications that impact the health of women and minorities. Through collaborative advocacy and policy efforts, we are working to drive initiatives that demonstrate women's health is not a niche market and to promote greater gender–relevant data transparency and increased investment in R&D to bring innovations to market that address gaps in care that harm women and minorities and result costly medical expenditures.

We have identified eight areas of health that solely, disproportionately, or differently impact women, requiring further government research investment and better education and awareness among patients and clinicians in order to advance scientific understanding and medical innovations:

Cardiovascular Health
Cardiovascular disease affects one in sixteen women over the age of 20, is responsible for nearly one in five deaths annually for women, and women 55 and under are twice as likely to die from a heart attack than men.[1] Furthermore, women are seven times more likely to be misdiagnosed and discharged in the middle of a heart attack than men, as men and women present with different symptoms during cardiovascular distress and too many physicians continue to be trained to only see signs in white men.[2] Women with cardiovascular disease are also more likely to report poorer patient experience, lower health-related quality of life, and poorer perception of their health when compared with men.[3] This translates to unnecessary costs across the United States healthcare system, as unrecognized and inadequate treatment of cardiovascular diseases will surpass $1 trillion by 2035.[4]

[1] Mayo Clinic, October 4, 2019: https://www.mayoclinic.org/diseases–conditions/heart–disease/in–depth/heart–disease/art–20046167
[2] Coya Partners, 2020: https://www.coyapartners.com/blog
[3] Victor Okunrintemi, Javier Valero-Elizondo, Benjamin Patrick, et. al, "Gender Differences in Patient-Reported Outcomes Among Adults with Atherosclerotic Cardiovascular Disease", December 10, 2018, https://www.ahajournals.org/doi/10.1161/JAHA.118.010498
[4] RTI International, "Cardiovascular Disease Costs will exceed $1 Trillion by 2035", February 14, 2017: https://www.rti.org/news/cardiovascular–disease–costs–will–exceed–1–trillion–2035

Autoimmune and Immunological Diseases

With 80 percent of all patients diagnosed with autoimmune diseases being women and 100 types of them predominantly affecting women, this area of health must be addressed.[5] Part of this disparity can be attributed to many autoimmune disorders' tendency to affect women during periods of extreme stress, such as pregnancy, or during period of hormonal change.[6] There are few treatments available for many autoimmune diseases, which can be uncomfortable, painful and impact a woman's ability to work and care for her family. Autoimmune diseases are also extremely costly, as the National Institutes of Allergy and Infectious Diseases has estimated that the cost of treating autoimmune disease in the U.S. is greater than $100 billion annually.

Oncology

Women bear the burden of inequitable oncological treatment options as well as disparities in specific cancers. For example, one in five people who are diagnosed with lung cancer have never smoked, yet non –smoking women are three times more likely to have the disease.[7] Gender disparities are also pervasive in terms of treatment options, as a recent study showed that the odds of receiving radiation were 60 percent for women and 70 percent for men, and the odds for receiving intensive chemotherapy were 35 percent for women versus 46 percent for men.[8] In terms of mortality, the ratio of cancer deaths versus non –cancer deaths was 1.92 times higher for women than for men.[9] Cancers also disproportionately impact minorities and populations with social, environmental, and economic disadvantages that hinder access to healthcare. African American and Caucasian women have similar rates of breast cancer, yet African American women are more likely to die from the disease. Hispanic and African American women also have higher rates of cervical cancer than women of other ethnic groups, with African American women having the highest rates of death from cervical cancer.[10] In addition, ovarian cancer is the only gender –specific cancer with greater than 50 percent mortality rate, and accounts for more deaths than any other cancer of the female reproductive system with Black women having a much higher 5 –year mortality rate (62 percent) vs. Caucasian women (54 percent).[11]

Aging and Bone Health

A women's risk of bone fracture is equal to her combined risk of breast, uterine, and ovarian cancer, which is four times the rate of men. Of the ten million Americans with osteoporosis, approximately 80 percent are women and a proximately one in two women over age 50 will break a bone because of osteoporosis.[12] Studies have shown that there are multiple reasons why women are more likely to get osteoporosis than men. Women tend to have smaller and thinner bones, and women's estrogen, a hormone that protects bones, decreases when women reach menopause.[13] This prevalence of bone diseases is not only dangerous for women but is also extremely costly. The annual cost of osteoporosis –related bone breaks is $19 billion for patients, their families, and the healthcare system, and is expected to continue to rise.

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[5] The Prevalence of Autoimmune Disorders in Women: A Narrative Review, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7292717/

[6] Angum, Fariha et al. "The Prevalence of Autoimmune Disorders in Women: A Narrative Review." Cureus vol. 12,5 e8094. 13 May. 2020, doi:10.7759/cureus.8094

[7] Brigham and Women's Hospital, "Why Women's Health Can't Wait", 2014, https://www.brighamandwomens.org/assets/bwh/womens–health/pdfs/connorsreportfinal.pdf

[8] Ibid

[9] Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2017. CA: A Cancer Journal for Clinicians 2017; 67(1):7–30

[10] National Cancer Institute, "Cancer Disparities," https://www.cancer.gov/about–cancer/understanding/disparities

[11] American Cancer Society, https://www.cancer.org/content/dam/cancer –org/research/cancer –facts –and –statistics/cancer –facts –and –figures –for –african –americans/cancer –facts –and –figures –for –african –americans –2019 –2021.pdf

[12] https://www.nof.org/preventing –fractures/general –facts/what –women –need –to –know/

[13] National Osteoporosis Foundation "What Women Need to Know" https://www.nof.org/preventing–fractures/general–facts/what–women–need–to–know/

Gynecological and Sexual Health

Several gynecological conditions women face throughout their lives and especially as they age are often ignored with insufficient diagnostics and treatments. For example, the annual gynecological exam does not screen for ovarian cancer and 1 in 5 women have masses, yet few diagnostics can catch the cancerous tumors during the critical early stages, especially among women of color who are most often diagnosed too late and die sooner. In addition, more than 4,000 women enter menopause every day in the U.S., but only one in five OB/GYN residency programs provide menopause training to support them and nearly 80 percent of medical residents admit that they feel "barely comfortable" discussing or treating menopause.[14] Also, 84 percent of women experience menopause symptoms, and more than one in ten (12 percent) say their symptoms can be severe or debilitating. Yet menopause is understudied and misunderstood by physicians and researchers alike with few treatments available for the impact on women that is so severe, many stay home or retire early when they are otherwise in the prime of their career. Most do not understand when symptoms are ignored or misdiagnosed during menopause years, they can lead to severe complications, preventable death, and avoidable and costly medical expenditures. These conditions cost the U.S. healthcare system four times the costs of their non –symptomatic peers. Globally, menopause –related productivity losses can amount to more than $150 billion a year and if costs to the healthcare system are included, the total price tag of menopause could be higher than $810 billion.[15]

Reproductive Health

Disparities in maternal and reproductive health are also a major concern in the U.S. Studies document decades –long racial and ethnic disparities in several areas of reproductive health, including contraceptive use, care for sexually transmitted infections and the human papillomavirus (HPV) vaccination among younger women aged 18 to 25 years, as well as reproductive cancers, preterm deliveries, and maternal morbidity and mortality in all age groups.[16] Most women lack sufficient resources, information and access to care related to perinatal mood and anxiety disorders (PMADs), the number one complication resulting from pregnancy and childbirth. Half of perinatal women with a diagnosis of depression do not get the medical treatment that they need, resulting in poor patient outcomes and increased societal costs. The total annual societal costs incurred by PMADs, including maternal productivity loss (such as loss of work productivity and missing work), greater use of public sector services (such as welfare and Medicaid), and higher health care costs due to worsened maternal and child health, was $14.2 billion in 2017. This equates to $4.7 billion in productivity losses, $2.9 billion in maternal health expenditures, $3.3 billion in preterm births, and $1.6 billion in child behavioral and developmental disorder spending.[17] These staggering costs and the devastating effects for mothers who suffer from PMADs must be discussed and addressed.

Cognitive and Brain Health

Cognitive and brain function is another health area in which significant disparities exist between men and women. Two –thirds of Alzheimer's patients over 65 are women and two –thirds of caregivers are women.[18] Moreover, despite clear biological differences in cognitive function, women are not proportionately represented throughout the research process, and female –specific cognitive diseases are not proportionately funded. In medical research for anxiety disorders, 90 percent of animal subjects are male, though women

[14] https://www.aarp.org, Note this study also found 84 percent of women say that their menopausal symptoms interfere with their lives, including at work.

[15] Reenita Das, a partner and senior vice president for healthcare and life sciences at consulting firm, Frost & Sullivan, https://apple.news/AkFLvCBgGST6IKWENlXbf_w

[16] Obstetrics & Gynecology: February 2021 – Volume 137 – Issue 2 – p 225–233, doi: 10.1097/AOG.0000000000004224

[17] Mathematica Policy Research, "Societal Costs of Untreated Perinatal Mood and Anxiety Disorders in the United States", April 29, 2019, https://www.mathematica.org/download–media?MediaItemId={E24EE558–B67B–4BF6–80D0–3BC75DB12EB6}

[18] Centers for Disease Control and Prevention, https://www.cdc.gov/aging/caregiving/alzheimer.htm

are twice as likely to be diagnosed with anxiety in their lifetime.[19] Although two –thirds of Alzheimer's patients are women 66 percent of animals used in Alzheimer's research are male or of an "unspecified gender," which are mostly male. There is also a stark disparity in funding allocation, as just 12 percent of the National Institutes of Health (NIH)'s 2019 budget of $2.4 billion for Alzheimer's disease research went toward projects specifically focused on women. Not only does this hinder innovation, understanding, and treatment of Alzheimer's disease, it also results in severe economic consequences. If $300 million had been shifted to the NIH's Alzheimer's budget to focus on women's brain health in that same year, it would have produced over $930 million in economic benefits, including quality of life improvements, and reduced medical costs.[20]

Adverse Drug Events

While recent clinical studies have included more women, for decades, the patients who participated in clinical trials for new drugs skewed heavily male. As a result, many drugs commonly prescribed to this day do not account for gender differences making them ineffective or causing patient harm. Today, most pre –clinical trials continue to exclusively use male mice and male animals even though sex differences are found at the cellular level. Few pre –clinical trials use both sexes to inform the next phase of studies in humans, and even if experiments do include female animals, the subgroup analyses by sex are not reported.[21] During the next phase of research when the clinical trial includes women, often for the first time, and always at a level far below the actual representation of women in prevalence rates for the disease for which the drug is being developed to treat, this underrepresentation is magnified with greater room for error and ADE occurrence.

Recommendations

With the continued failure to address so many women's health issues, we must increase NIH investment in advancing research in these areas. An analysis of NIH funding patterns found that in nearly three–quarters of the cases where a disease afflicts primarily one gender, the funding pattern favors males, in that either the disease affects more women and is underfunded, or the disease affects more men and is overfunded. Furthermore, the disparity between actual funding and that which is commensurate with burden is nearly twice as large for diseases that favor males versus those that favor females.[22] Finally, just 11 percent of NIH research dollars are dedicated to women's health.

Therefore, we ask that Congress increase funding and programmatic investments for the NIH to prioritize all health conditions that solely, disproportionately or differently impact women and minorities. We must improve scientific understanding, investment, research, treatments, diagnostics and awareness for these populations that represent over half the population. We are eager to work with you in this endeavor, find ways to match government funding by incentivizing private investment in this research, and work in a concerted effort to advance the health of women and minorities. Thank you for your consideration.

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19 Gender Differences in Anxiety Disorders: Prevalence, Course of Illness, Comorbidity and Burden of Illness, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135672/

[20] Women's Health Access Matters, "Societal Impact of Research Funding for Women's Health in Alzheimer's Disease and Alzheimer's Disease Related Dementias," April 2021, https://thewhamreport.org/wp–content/uploads/2021/04/TheWHAMReport_ADRD.pdf

[21] It is time to integrate sex as a variable in preclinical and clinical studies, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056479/

[22] Arthur A Mirin, "Gender Disparity in the Funding of Diseases by the U.S. National Institutes of Health" July 30, 2021, https://pubmed.ncbi.nlm.nih.gov/33232627/