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Via Electronic Submission Only
WomensHealthResearch@who.eop.gov
Carolyn M. Mazure, PhD
Director, White House Initiative on
Women's Health Research
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

RE: AdvaMed Recommendations in Response to the White House Initiative on Women's Health Research

Dear Dr. Mazure:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to submit recommendations in response to the White House Initiative on Women's Health Research.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We strongly support the White House's desire to improve research for women's health to improve access to services, procedures, and technologies that will help promote better and more equitable health outcomes. AdvaMed supports new approaches to funding, conduct of research, and inclusion and amplification of the voice of women to shape and encourage the way they are treated and engaged in healthcare. We understand the need to better research and to develop treatments for the conditions that solely impact women, impact women disproportionately, and that impact them differently than men.

Our recommendations are attached. They cover four key areas including:

- Investment in Women's Health Research to include increased diversity, study funding, and payment;
- Improving the research environment for women's health technologies;
- Empowering Women's engagement in health research through amplifying their voice; and

- Improving health outcomes through advancing research for women with specific health conditions.

We stand ready to respond to any questions or concerns related to these recommendations. Please feel free to contact me with any questions.

Sincerely,

DeChane Dorsey
Executive Director, AdvaMed Accel

Enclosure

AdvaMed
Advanced Medical Technology Association

AdvaMed Recommendations
White House Initiative on Women's Health Research

Introduction/Background on AdvaMed and Women's Health Equity Initiative

The Advanced Medical Technology Association ("AdvaMed") is pleased to provide recommendations to the White House Gender Policy Office for consideration by the White House Initiative on Women's Health Research. AdvaMed is the world's largest trade association representing medical technology and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed member companies range from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory, and economic environment that advances global health care by enabling patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

In 2023, AdvaMed established the Women's Health Equity Initiative (WHEI). The mission of the WHEI is to raise awareness regarding the medical technologies that our members make to treat women's health conditions, to include those conditions that are experienced only by women, those that disproportionately impact women, and those that may impact women differently than men, and to raise awareness and reduce inequities related to the need to diagnose, include in research, and improve health outcomes for women. We are pleased to offer the following recommendations on behalf of AdvaMed and members of the WHEI and recognize that their implementation may require engagement and collaboration with Federal agencies and other stakeholders.

Recommendations

1. Increase investment in Women's Health Research to include increased diversity, consistent study funding, and improved technology/procedure payment.

    - Organizations (e.g., private foundations, investors) and agencies that fund research need to incentivize the equitable inclusion of women in studies through earmarked funds for women's health research.
    - There should be increased efforts to engage more diverse populations in women's research. Diversity encompasses many characteristics, including but not limited to race, ethnicity, socioeconomic status, geography, age, and ability. Engagement with a broader range of care facilities, including those serving underrepresented and large populations of minority and low socioeconomic status (SES) patients (e.g., disproportionate share facilities, Historically Black Colleges and Universities (HBCU) medical schools and their affiliated hospitals, and facilities in rural areas) can contribute to better representation of all women in research.
        - Institutions that service underrepresented populations and communities need the infrastructure to conduct research; additional support may further enable them to serve as a research site.
        - Efforts could include more funding to establish and support the clinical research infrastructure within hospitals and medical schools that treat these patients, including those affiliated with HBCUs, to include the ability to conduct research and/or to serve as secondary sites to augment research being conducted at other locations.

- Improve and/or accelerate the process by which devices navigate Federal agency approval processes.
    - For technologies that have a software component, the current approval process is too long. Considering the speed at which new technology is created and updated, especially with the advent of artificial intelligence and machine learning, the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) should determine how to accelerate their respective approval and reimbursement processes. Otherwise, the new products may be considered 'outdated' by the time they receive market approval.
- Willingness to engage in research is in part predicated upon the ability to gain reimbursement and coverage once a product goes to market. Establishing more predictability in how women's health products will be cleared/approved, covered, and paid will influence product development.
    - If new innovative women's health technologies, once FDA-approved, are not reimbursed at appropriate levels, providers and/or hospitals are not incentivized to use them, and patients will not have access to them.
    - Improving the reimbursement landscape to make it easier to get coverage and payment for women's health technologies will encourage increased innovation in this space.
- Agencies such as the National Institutes of Health, National Science Foundation, and Department of Defense fund the development of technology through Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program grants. These agencies could be required to allocate some portion of existing funds via these grant programs for the development of technologies to address women's health needs —thereby spurring innovation without the need for new money.
    - A mechanism should exist for sharing information regarding the technologies developed through SBIR/STTR programs, and their potential for more widespread use. If these technologies, show early data suggesting utility in addressing the condition for which they were developed, the agency should coordinate with other Federal agencies (e.g., FDA, CMS, etc.) to undertake efforts to expand technology access to more women through expedited review or other means.
    - In the current grant process, one Federal agency gathers information and research to determine grant allocation. Agencies funding development of women's health products via SBIR/STTR grants should regularly communicate to better understand the range of technologies being funded and developed and to facilitate access to and broader dissemination of those found to be effective.
- Access to federal funding is especially critical for start-up companies in the women's health space. Small start-ups rely on federal funds for research and development. Funds should be allocated for small start-ups as they work toward market approval of their innovations.
- Make remote and telehealth payment permanent and create payment for Primary Care Providers and others.
    - Women often face barriers in seeking treatment, and participating in clinical trials, including missing work, childcare, and transportation

costs. This is especially true for women identified as having low SES and/or those living in rural areas.
    - As was proven during the COVID-19 pandemic, remote visits and telehealth provided patients with a more convenient method of interacting with their providers and avoiding missed appointments.
    - All payers, including Medicare and Medicaid, should continue to reimburse providers for providing care remotely, when appropriate.
    - Digital, remote, and telehealth technologies can also accommodate collection of data from persons enrolled in clinical research. However, the care providers (e.g., physicians, physician assistants, nurses, nurse practitioners, other allied health professionals) should be reimbursed for this data collection.
- Medicaid should be urged to support access to medical device clinical trials to mitigate hurdles/barriers to participation in clinical trials by their insured populations. Medicaid has already done this for drugs; the same policy, for parity, should apply to devices.

2) Improve the research environment for women's health technologies.

- To improve clinical trial participation numbers, it is important to understand the reasons women agree to join clinical trials (or not), and the reasons they remain in clinical trials (or not). A government or other study of this topic could help researchers and others better understand these dynamics.
- The government could identify women's health areas where there are existing gaps in the pre-clinical research. This will assist in identifying areas where new/additional research is needed.
    - Technology developers should be incentivized to develop products that address women's health concerns. Allocating funding to companies developing technologies in this space could spur innovation. We recommend cooperation between government agencies and private companies to bolster the innovation and development of technologies and products specifically for women's health concerns (including but not limited to oncology, cardiovascular disease, maternal health, conditions that only affect women, conditions that disproportionately affect women, etc.). This could increase product development in this space. Government and private partnerships will accelerate products launching to market.
    - The Department of Health and Human Services and/or other Federal entities can work with and train community-based organizations (e.g., Community Health Centers, Federally Qualified Health Centers, faith-based organizations, social service programs, patient advocate groups, disease specific research organizations, and non-profit entities) to serve as a resource in helping to increase diverse patient participation in clinical research.
- Historically, women have been excluded from some research because of safety concerns. This is particularly true at certain stages of life, such as during pregnancy or post-partum, when lactating, and during menopause. The exclusion of these women from clinical trials ignores the need to determine whether products are as safe and effective for a range of women patients relative to men, or for women at varied stages of life. Clinical investigators should include a diverse range of women in research,

across their lifespans, to understand the impact of new products, absent a compelling reason to exclude them. Women from varied racial and ethnic backgrounds should be included in IDE and NSR studies to be more representative of the general population. This is especially critical for conditions that are more prevalent in younger women, as younger generations tend to be more diverse than older generations. To facilitate inclusion of diverse women in clinical research:

- Encourage technology developers and the FDA to provide a clear and compelling rationale for clinical trial inclusion/exclusion criteria for women.
- FDA should develop guidance to assist device sponsors in understanding the criteria FDA will use when reviewing Investigational Device Exemptions (IDEs) vis a vis inclusion/exclusion criterion for women at all life stages. FDA should also develop guidance for Institutional Review Boards (IRBs) for their review of IDEs and of non-significant risk (NSR) studies vis a vis inclusion/exclusion criterion for women at different life stages, including pregnancy and postpartum.
- Once guidance has been finalized, FDA should train reviewers on the recommended inclusion/exclusion criteria vis a vis woman at all life stages. FDA should also socialize guidance for IRBs on this topic.

- Improve the ability of organizations/companies/persons conducting research to accommodate the inclusion of women by clarifying statutory and regulatory requirements governing the ability to obtain reimbursement and/or cover participation related expenses.
  - Clarifying Stark and Anti-Kickback Statute (AKS) requirements
    - Women bear a disproportionate share of household and familial responsibilities and the ability to appropriately compensate them for participation in clinical research could assist in improved recruitment and retention rates.
    - Lack of clarity regarding appropriate levels of compensation and/or accommodations that can be offered to trial participants compromises the ability to recruit and retain a diverse pool of subjects. Given the costs associated with participation (e.g., time missed from work, transportation, parking, childcare, etc.) it is important to permit payment of a reasonable amount that could help offset some of these costs.
  - The Secretary's Advisory Committee on Human Research Protections (SACHRP) has responsibility for recommending changes to the human subject guidance and provides expert advice and recommendations to the Secretary of HHS on issues pertaining to the protection of human subjects in research. Health and Human Services should work with the SACHRP to modernize human subject protection guidance and regulations to reflect current views on payments to human subjects.
    - A panelist at the recent FDA Public Workshop to Enhance Clinical Study Diversity (November 29 and 30, 2023) argued that current remuneration strategies are failing to adequately motivate different race and ethnic groups and that concerns about paying people to participate in trials are outdated concerns unsupported by evidence.

See for example, the Harvard Catalyst Guidance: Paying Research Participants: Ethical Guidance for IRBs and Investigators.

3) Empowering Women's engagement in health research through amplifying their voice.

- Funding or supporting Public Health Announcements (PHAs) and media campaigns to educate women on the importance of participation in clinical trials for lifesaving and innovative treatments, including emphasizing that trial participation provides access to the gold standard of care, can help increase the number of women participating in clinical research.
  - Support education on appropriate conduct of clinical research, to include protection of sensitive and confidential health data.
  - Research protocols and training should emphasize that data collected during research is private and protected to address concerns of women who are reluctant to share their personal data.
- Conducting PHAs that address the need to hear, believe, and address women's health concerns.
  - Educate researchers and caregivers on treating all women and all patients in accordance with treatment guidelines and reevaluating guidelines to ensure they are equitable.
- Support the education of clinical and physician specialty societies and of Institutional Review Boards on the importance of recruitment of diverse populations including women in clinical trials.

4) Improve health outcomes through advancing research for women with specific health conditions.

- *Recommendations to improve maternal health and decrease maternal mortality and morbidity:*
  - Support research and development of technologies that address complications of pregnancy and labor and delivery, including but not limited to delivery-related infections, postpartum hemorrhage, preterm labor, pre-eclampsia, cardiovascular events, and postpartum depression.
  - Support research into the economic burden of pregnancy complications and maternal morbidity and mortality, to demonstrate the potential economic impact of technologies that can improve clinical outcomes.
  - Improve diagnosis and treatment of conditions impacting pregnancy, birth, and the postpartum periods through promoting awareness regarding gaps in maternal health outcomes. This research should encompass mental health disorders, including depression and anxiety, which can impact the developing fetus.
  - Enhance efficiencies and scale of infertility care.
  - Women's reproductive health experiences have been long overlooked. Researching/evaluating barriers and inequities impacting contraception and fertility care will improve access and can impact the development and availability of more widely available, efficient, and high-quality, treatments.

- Support additional research to address knowledge gaps in managing pregnant individuals with rare/genetic diseases (e.g., sickle cell disease), including opportunities for these patients to participate in clinical trials.

- *Recommendations to improve Cardiovascular Health:*
  - Fund and/or support PHAs and media campaigns to educate women and their clinicians on the differing signs and symptoms of cardiovascular disease (CD) in women and in understanding that CD is the number one killer of women.
  - Research and development of treatments and technologies for cardiovascular disease, a condition that impacts women and men at equal rates, should be based on data from a more representative population of women. Encourage more, and diverse, women to participate in cardiovascular research through PHAs targeting this demographic—to facilitate improved and increased enrollment of women in cardiovascular trials.

- *Recommendations to improve breast cancer outcomes:*
  - Breast cancer diagnoses can be impacted by breast density. Nearly half of all women who are 40 and older who get mammograms are found to have dense breast tissue. Women who identify as Black, Jewish, or Asian are more likely to have dense breasts.
  - Make funding available to develop technologies that utilize software and other technologies in diagnosing cancer in women with dense breast tissue.
  - Include women with dense breast tissue in breast cancer research.
  - Encourage insurers to cover and pay for extra screening for women with dense breast tissue.

- *Recommendations to improve menopausal health:*
  - Menopause is a health condition that will impact most women for up to 1/3 of their lives and can impact quality of life and earning potential.
  - Encourage research related to the various stages of menopause to understand the impact of this life-stage on women and the resultant impact on women to underpin development of technologies to address menopausal symptoms.
  - Urge payers to cover and pay for technologies to address women living with menopausal symptoms.

- *Recommendations to Improve Women's Mental Health:*
  - Understanding and developing technologies to address the impact of mental health disorders in women is pivotal in mitigating the damage caused to women, their families, communities, and the overall economy.

- Research to understand differences in the effectiveness of treatments for mental health conditions, like PTSD, on women can drive the development of alternative technologies to treat these conditions thereby enabling affected women to reengage in society and the workforce.
- PTSD is common among sexual and combat trauma survivors but a deficit of mental health professionals to provide care via the current standard limits women's access to care. Research into other methods of providing safe and effective treatments to address these populations, while managing the reality of specialist shortages, is needed.