

January 12, 2024

Dr. Jill Biden
First Lady of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear Dr. Biden:

We would like to thank you for launching the White House Initiative on Women’s Health Research. While many of us have been working in the trenches for decades to advance the health of women through research, innovation and access, your announcement has sparked broader interest among industry stakeholders to work together to elevate this issue, create public-private partnerships, and finally make the health of women a national priority. We would like to partner with you to ensure that research reaches all patients, especially those marginalized in this country based on sex, race, sexual orientation, income, education, ability status, and geography, among others.

Overview

As a professor, you know the importance of creating and maintaining an ecosystem that supports and nourishes research and data that is accurate and translates into increased scientific understanding, innovation, and meaningful impact in people’s lives. Research that is not based on the “real world population” across the United States is less accurate and doesn’t advance the health of all human beings, not just that of women. Finally, research that informs and turns into innovation must reach all patients, especially in underserved populations, to advance the health of women. Therefore, we would like to share the following insights and recommendations to address these priorities for the White House Initiative on Women’s Health Research.

Women’s Health Research Funding

With less than 2% private venture funding (when including oncology this rises to 5%) and 11% NIH funding dedicated to women’s health, the first recommendation is for the government to increase research spending on women’s health.^{1, 2} By requiring the NIH institutes to dedicate a minimum percentage of their grant funding toward women’s health research that ensures the total allocation is two to three times higher than 11% and to include at least 50% females in the pre-clinical and clinical trials it funds, we would garner meaningful data to advance further research and the health of women overall. Moreover, an annual report available to the public on this spending by each of the institutes would illuminate and incentivize greater integration of sex-based research and data collection and analysis across the board.

¹ <https://www.mckinsey.com/industries/healthcare/our-insights/unlocking-opportunities-in-womens-healthcare>

² https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_WHC_ExecutiveSummary508.pdf

Recommendations to Improve Research Funding

1. Allocate a minimum percentage goal of annual funding to women's health research priorities; recommended minimum is to double the current ~11% of total funding within the next two fiscal years and reach ~50% within five fiscal years
2. Within the funded research, mandate inclusion of >50% of self-identified females representing the actual US population in NIH-funded clinical trials
3. Provide an annual report made publicly available on spending by each institute on women's health research.

Disease Impact Representation in Research

Research that doesn't include participants who are representative of disease impact also makes the data we use for research, innovation and medical care incomplete and dangerous. With adverse drug events twice as common in women, accurate sex-based data being reported and included on the label is vital to the health and safety of women.³ Specifically, to address this, women and people of color must be participants in studies in proportion to the disease impact among these populations to ensure accurate data is generated, analyzed and used for drug labeling, further research and development (R&D), and healthcare delivery. These data must be published as such to advance scientific understanding as well. For example, a study on autoimmune disease should have roughly 75-80% women participants since 75-80% of all patients with autoimmune disease are women and it should have significant participation by people of color as African American, Native American and Hispanic women are more susceptible to autoimmune diseases than the general population.⁴ Meanwhile a study on cardiovascular disease should have roughly 50% women and 50% men since it is the number one killer of both sexes, but should analyze how therapies impact women and men differently since both the symptoms and expression of heart disease vary by sex.⁵ In addition, with the highest percentage of all deaths caused by heart disease when stratified by race being Black (Non-Hispanic) at 22.6%, roughly 22% of heart disease study participants should be of this race.⁶

A final example is in cancer where among all cancers, Black and American Indian/Alaska Native (AIAN) people have higher mortality rates and for major cancers the mortality rate by education level within each race is substantially larger than the Black-White disparities, underscoring how poverty contributes to disparities in health.⁷ Diversity in studies is key to gathering accurate data and addressing these disparities. For example, women are disproportionately represented among non-smokers with lung cancer as non-smoking men represent 2-6% of total lung cancer cases among men, but non-smoking women represent

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7275616/>.

⁴ <https://medicine.musc.edu/departments/dom/news-and-awards/2022/may-2022/understanding-autoimmune-disease-disparities#:~:text=The%20disproportionate%20rates%20at%20which,Ramos%2C%20Ph>

⁵ <https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20disease%20is%20the%20leading,groups%20in%20the%20United%20States.&text=One%20person%20dies%20every%2033,United%20States%20from%20cardiovascular%20disease.&text=About%20695%2C000%20people%20in%20the,1%20in%20every%205%20deaths>

⁶ <https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20disease%20is%20the%20leading,groups%20in%20the%20United%20States.&text=One%20person%20dies%20every%2033,United%20States%20from%20cardiovascular%20disease.&text=About%20695%2C000%20people%20in%20the,1%20in%20every%205%20deaths>

⁷ <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21812>

approximately 20% of cases among women.⁸ For women with breast cancer, there are about 85% higher mortality rates among Black women aged 30–49 years and 136% higher rates among Black women aged 20–29 years.⁹ For women with ovarian cancer, where half of all women die within five years of diagnosis—the highest mortality rate of any sex-specific cancer—African-American women experience the poorest 5-year relative survival (36%) while survival for white women is approximately 46%.¹⁰ This gap is attributed to earlier age and later stage at diagnosis and disparities across the entire care continuum of ovarian cancer, including diagnosis, treatment, and precision testing.¹¹ Other studies have found race- and sex-based implicit bias as an additional contributing factor in health care delivery and outcomes, which must be addressed in government funded research and when obtaining approval from the Food and Drug Administration (FDA).^{12, 13}

In addition to ensuring diversity and proportionate representation in research that NIH and other federal agencies are funding by mandating half of animal studies include females and by mandating representation by disease impact by sex and ethnicity in clinical trial participation, the government should provide additional funding and guidance to research grant recipients for the explicit purpose of designing clinical trials to align with this inclusive approach that ensures more precise, accurate findings. The same combination of mandates and support should be provided by the FDA in the approval process to enable grant recipients and drug and device sponsors to succeed in generating accurate data that informs medical decision-making for the benefit of all patients. By creating an FDA Center of Excellence in Women’s Health with appropriate staff and training to evaluate innovations, convene companies and patients, and guide them through the approval process, this would accelerate bringing innovations to patients. Many companies are well-meaning but need this additional guidance and incentivization to ensure they run effective, diverse clinical trials.

Recommendations to Improve Disease Impact Ratio Representation in Research

1. Mandate that women and people of color must be participants in NIH-funded clinical studies in proportion to the disease impact among these populations to ensure accurate data is generated, analyzed and used for drug labeling, future R&D, and healthcare delivery
2. Mandate 50% of animals in pre-clinical studies be female unless the disease being studied only exists in males.

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3827695/> Of note, the overall rate of lung cancer diagnoses is almost equal among women and men, yet only 15% of NIH lung cancer research is allocated to projects focused specifically on women, according to the WHAM Report. https://thewhamreport.org/wp-content/uploads/2022/10/TheWHAMReport_Lung_technical.pdf

⁹ <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21812>

¹⁰ <https://www.sciencedirect.com/science/article/abs/pii/S0065230X20300026?via%3Dihub>

¹¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10278570/#:~:text=Black%20patients%20had%2017%E2%80%93survival%20compared%20with%20White%20patients.&text=Potential%20explanations%20include%20earlier%20age,social%2C%20not%20biological%2C%20construct>

¹² Results of this review suggest that implicit bias against Black, Hispanic/Latino/Latina, and dark-skinned individuals is present among many health care providers of different specialties, levels of training, and levels of experience.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638275/>

¹³ <https://academic.oup.com/pnasnexus/article/1/4/pgac157/6671566>

3. Provide additional funding and guidance to research grant recipients for the explicit purpose of designing clinical trials to align with this inclusive approach that ensures more precise, accurate findings.
4. Require journal publications to include sex-based data, including data by race, in order to be listed in the NIH Library of publications.
5. Create an FDA Center of Excellence in Women’s Health with appropriate staff and training to evaluate innovations, convene companies and patients, and guide through the approval process to accelerate bringing innovations to patients.

Access to Care and Innovation

Yet another concern as you work to reshape the ecosystem for women’s health research is how we bring innovations into care delivery equitably across the United States. According to a recent study, “Despite increased coverage, millions of Americans continued to experience barriers to access to care, which were disproportionately more prevalent among those identifying as Black or Hispanic.”¹⁴ Reaching underserved populations in an accessible, affordable way is key to overcoming current barriers that are more pronounced for people of color, women, low-income and geographically located far from care and/or have few transportation options to access care. These same barriers make participation in clinical trials that can be lifesaving very challenging. Therefore, we ask you to consider the real world lived experience of women, people of color and underserved populations and their access to innovation when building out your research agenda. Research and innovation that does not consider the equitable delivery of care fails to achieve quality and outcomes improvement. We must look closely at the role of cost and affordability in determining access.

Developing effective technologies and therapies for patients is vital, but when this innovation happens, it can exacerbate disparities. For example, bringing rapid testing of biomarkers into the home and to medically underserved populations is essential to improving public health as a nation as well as for individual health. During COVID, innovation in diagnostics exploded with new at-home options that improved access, time-to-treatment, and outcomes. However, the disease impact was still far more severe among Black and Brown populations. This means we still need to ensure the ecosystem fosters innovation but delivers it as equitably as possible. Another example of innovation reaching patients where they live is blood and urine testing at home for everything from Urinary Tract Infections (UTIs) to Sexually Transmitted Infections (STIs) to Diabetes. Advances in research and innovation can help equalize access and overall health even further, especially for women who often have uniquely challenging barriers to traditional healthcare access: childcare responsibilities, shift work, and the juggling of children and jobs and/or limited access to transportation.

Access is also limited by cost. Employed women aged 19-64 spend \$15.4 billion (20%) more than employed men in out-of-pocket healthcare costs each year, based on deductibles, coinsurance, and out-of-pocket maximums, worsening existing gender wage disparities.¹⁵ The percentage drops to 18% when

¹⁴ <https://pubmed.ncbi.nlm.nih.gov/33173905/>

¹⁵ <https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/womens-health-equity-disparities.html>

maternity-related services are excluded. This differential often called the “pink tax” means as innovations are developed and enter the marketplace, access can remain a significant challenge.

In addition, insurance coverage plays a role in determining access and affordability of care for most patients. For example, essential screening beyond a mammogram, or what is called “supplemental screening” for breast cancer is covered sporadically despite the life-saving technology that falls into this category being in the marketplace and readily available for years. Approximately 40-50% of all women have dense breasts and mammograms cannot detect tumors in half of all women with dense breasts because the tumor and the tissue are both white in the x-ray image.¹⁶ In fact, 70% of women with breast cancer have dense breasts. MRI, ultrasound and Molecular Breast Imaging are technologies readily available, but insurance often doesn’t cover these technologies and many physicians do not refer patients to them because of lack of coverage. Breast cancer is 99% survivable when caught early but for almost half of all women it is a 50:50 chance of receiving a false negative and only some can afford accessing technology beyond a mammogram that costs approximately \$400 each. This technology and many others in women’s health are not quickly and fully reviewed and recommended by the U.S. Preventive Services Task Force (USPSTF). This validation barrier ensures decades of research to advance medical innovation does not reach all patients, unnecessarily causing harm and taking women’s lives.

Overall, access to innovation means access to information, diagnostics, care and treatment that every person deserves to have in order to understand their baseline health and ensure proactive detection of disease. Evidence generation is required to inform medical policy and reimbursement. Therefore, women’s health research must go beyond the laboratory to include strategic planning for reaching patients through implementation research, pilot programs, collaborations with all participants in the ecosystem, and better information gathering, sharing, and reporting. Evidence generation with the goal of acceptance of the evidence and subsequent validation by governing bodies like the FDA and USPSTF ultimately leads to reimbursement. Insurance coverage by both private payers and government payers is a critical dimension of access to innovation as it influences cost and affordability. Women’s health research can be made more accessible by engaging with payers to understand factors influencing coverage and the level of evidence required for reimbursement. As part of the White House’s efforts to advance women’s health research, payers should be consulted to discuss where processes enabling innovation can be supported given how behind we are on women’s health research, e.g. “pilot programs” to measure health and cost improvements following initial validation, a ‘jump the queue’ process for care models and technology specifically dedicated to addressing gaps in women’s health that currently fall outside of medical policy.

Additionally, the government could play a stronger role in this effort by working with innovators as they move through FDA approval and onto Centers for Medicare and Medicaid Services (CMS), TRICARE uniformed services health care program, and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) health benefits program’s reimbursement systems by requiring a plan for reaching all patients, especially marginalized populations, to be able to access new innovations. Making these plans public would incentivize intentionality and effectiveness and working with insurers to implement this access is key. Government should provide an annual report to the public on the status of not only newly approved drugs and devices, but of their impact on and plans for reaching patients based

¹⁶ <https://aacrjournals.org/cebpa/article/30/10/1913/665633/Breast-Density-Awareness-and-Knowledge-in-a#>

on sex- and race-aggregated data and real world evidence of what is needed to enable access. These are valuable steps the government can take to increase access to women’s health innovations.

Recommendations to Improve Access to Care and Innovation

1. Use a multi-dimensional definition of access that includes an understanding of geographic, cost, and psychographic barriers when the government is evaluating access to care.
2. Require planning for equitable access for all populations when bringing innovation to market via government sponsored programs.
3. Conduct a review of reimbursement within government and establish parity in what male and female patients pay for care and in the reimbursement rate provided to clinicians.
4. Expand access to priority innovations in women’s health through a “Breakthrough” process for faster implementation into USPSTF guidelines, which shape the services payers are willing to reimburse.
5. Work with payers to increase coverage of important innovations that advance the health of women as soon as possible by proactively sharing reports once women’s health innovations are FDA approved with them and the USPSTF, requesting information on their review process and timing for coverage.
6. Mandate clear communication from the government and designate women’s health pathway for coverage for CMS, TRICARE and VHA.
7. Require industry to provide meaningful commercialization and adoption guidelines for how innovations will reach diverse patients equitably and make these publicly available.
8. Produce an annual report on the status of newly approved drugs and devices and their impact on care and outcomes as well as plans for reaching patients based on sex- and race-aggregated data.

Maternal Health and Gynecological Care

A critical aspect of innovation access is maternal health that extends into all aspects of the mental and physical health of women. The *Dobbs* decision, geographic barriers to care for patients, and the clinician shortage make access to this care particularly challenging. The *Dobbs* decision did not just accelerate significant restrictions on abortion access and care, but on overall maternal and gynecological care, leading to inadequate clinician training and a shortage of medical professionals throughout the country. As you know, Black maternal mortality rates are nearly three times higher than among white women and Black infants are almost four times as likely to die from complications related to low birthweight.^{17,18} Research and innovation in pre-eclampsia, preterm labor and postpartum hemorrhage remain direly needed for all women to improve outcomes. However, an estimated 2.2 million U.S. women live in “OB-GYN deserts” and 4.7 million more live in areas with limited access.¹⁹ Data now indicates that states with the most restrictive abortion laws also have worse maternal mortality rates and clinicians do not want to work in

¹⁷ [https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm#:~:text=In%202021%2C%20the%20maternal%20mortality,\(Figure%20%20and%20Table\)](https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm#:~:text=In%202021%2C%20the%20maternal%20mortality,(Figure%20%20and%20Table))

¹⁸ <https://minorityhealth.hhs.gov/infant-mortality-and-african-americans#:~:text=Non%2DHispanic%20black%2FAfrican%20American,%2DHispanic%20whites%2C%20in%202020>

¹⁹ <https://www.marchofdimes.org/maternity-care-deserts-report>

states that are enacting laws restricting the ability to practice medicine in the best interest of female patients.^{20, 21, 22} Many fear infertility restrictions are next.

As the system crumbles with OB-GYN practices shutting down and access to care deteriorating in certain parts of the country, other mental and physical health care needs are often ignored. Therefore, efforts are needed to support equitable care delivery research to develop innovation in maternal health, OB-GYN care, contraceptive care, infertility, mental health and all areas of health, as well as in the delivery of all of the above to patients. We believe that OB-GYN physicians, Women's Health Nurse Practitioners, midwives, and Family Medicine physicians as well as community health workers will play critical, multidisciplinary roles in solving the maternal health crisis and access to care in maternity care deserts. Government support is needed to ensure that we can attract these clinicians to address care gaps.

Moreover, by creating economic incentives and dashboards to measure and convene researchers, clinicians and patients to exchange information and partner in advancing R&D and medical innovations to address these issues, the government can play an important role in closing these gaps. Adding meaningful funding to this effort, removing silos and increasing communications and collaborations that include private sector and NIH, FDA, CMS, AHRQ and HRSA all working together to enable accelerated pathways to bring innovations to patients will ensure thorough, holistic and productive advancements are achieved.

Recommendations to Improve Maternal Health and Gynecological Care

1. Create a grant program to place reproductive health clinicians in “OB-GYN deserts” to ensure access to care, which can include medical school repayment programs and other creative ways to incentivize removing these deserts in care.
2. Include maternal health within the Healthcare Effectiveness Data and Information Set (HEDIS) to measure performance - just as breast cancer screening and immunizations are tracked, so should maternal health care and outcomes.
3. Convene researchers, clinicians and patients from within government (i.e., NIH, FDA, CMS, AHRQ and HRSA) and outside government to exchange information and partner in advancing R&D and medical innovations to address maternal health and contraception gaps through annual symposiums and on-going engagements.
4. Create financial incentives through grant programming or reimbursement systems for organizations that plan to and solve access gaps.

In conclusion, there are many challenges and opportunities when it comes to women’s health research and bringing innovation to market in a way that is equitable and meaningful in advancing the health of women. The most pressing areas where access to innovation will have the most impact in population health are from increasing research funding in women’s health, ensuring diverse and representative pre-clinical and clinical participation, closing the gap between FDA approval and inclusion in USPSTF guidelines and

²⁰ <https://www.axios.com/2022/07/05/maternal-mortality-death-abortion-ban-roe>

²¹ <https://www.axios.com/2023/04/18/abortion-ban-states-drop-student-residents>

²² <https://states.guttmacher.org/policies/> and <https://pubmed.ncbi.nlm.nih.gov/33173905/>

coverage by both private and government payers, prioritizing maternal health and reproductive health access, and organizing convenings to advance knowledge and collaborations in women's health to reach all patients throughout the country.

Thank you for your consideration. This White House Initiative on Women's Health Research can lead in addressing these women's health research gaps. We encourage you to make equitable access to innovation the core of this effort in order to fundamentally advance the health of women. If you have questions, please contact Liz Powell at lpowell@G2Gconsulting.com.

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