

December 27, 2023

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

Dear Dr. Biden:

As entrepreneurs and executive officers in women's health innovation, we are writing to thank you for launching the White House Initiative on Women's Health Research with President Biden and the White House Gender Policy Office. Your leadership has created tremendous momentum throughout the country for collaboration and bold commitments to finally prioritizing the health of women. As you collect feedback on gaps in women's health research and develop recommended ways to address them, we wanted to share the entrepreneurial perspective and ideas that could move the needle in this area in meaningful ways.

Access to Capital

First, as entrepreneurs there are many challenges we face, but the single biggest one facing all of us is access to capital. Early stage healthcare innovators are usually funded through venture capital (VC) investments or research and development (R&D) partnerships with Big Pharma. However, women's health companies are not able to access these traditional sources of capital. Less than 3% of VC funds went to female-led startups in 2020, and female entrepreneurs are 63% less likely to get VC funding than are male entrepreneurs.¹ With 76% of women's health companies having a female founder—a rate that is three times higher than the overall innovation ecosystem—women's health innovation suffers.²

Additionally, outside of VC capital, less than 2% of Big Pharma R&D dollars are invested into women's health innovations and less than 10% of VCs with check-writing power at their firms are female.³ The NIH spent just under 11% of total research funding on women's health in FY2020, further limiting financial investment in this area.⁴ When women's health focused start-ups do get funded, the valuations are consistently 20% less than other healthcare investments. The larger investment funds that make \$10-50 million investments are not investing in women's health startups, leaving many companies to flounder in the Valley of Death and never translate the science and innovation to reach patients. However, women make up 51% of the population, make nearly 90% of medical decisions for their families, and are 85% of the caregivers.

Therefore, we recommend further support of public-private partnerships to nurture the women's health innovation ecosystem for companies from academia, research institutions, and those that are privately created. The flow of information, access to capital, and availability of networking needs to be inclusive for these groups together, not in silos as has been in the past. Women's health innovation is not a niche space, but it has been treated as such for decades. With your leadership, we can change this. We support

¹ <https://www.axios.com/2020/07/21/women-venture-capital-gender-equality>

² While data for 2023 indicates increasing investment in women's health since 2018, the deal count has decreased and it is primarily in tech and less in life sciences with little investment in innovations addressing root causes of women's health gaps and vague definitions of women's health applied. <https://www.svb.com/trends-insights/reports/womens-health-report/>

³ <https://www.kauffmanfellows.org/journal/women-vcs-invest-in-up-to-2x-more-female-founders>

⁴ https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_WHC_ExecutiveSummary508.pdf

solutions, including tax incentives and government-run fund matching for funds that invest meaningfully in the health of women and believe that this would create powerful momentum that would spark innovation and growth.

Data-Gathering, Analysis and Sharing

Some important first steps are for the government to increase spending on women's health research, apply a more direct approach to data-gathering and centralization, and hold companies accountable when not reporting sex-based data. Specifically, the government should direct research through grants from all departments spanning from the Department of Health and Human Services and the National Institutes of Health (NIH) to the Department of Defense (DoD) to the Veterans Affairs Department (VA) to the National Science Foundation (NSF) – and most especially, the new ARPA-H program – to increase data-gathering and analysis focused on advancing scientific understanding of the health of women. This means providing health research grants to study exclusively women as well as other studies on both women and men that require sex-based differences data be collected, analyzed and reported in order to receive the full grant award. The clinical trials must have representative participation equal to disease impact, which means a study on autoimmune disease should include roughly 80% women as clinical trial participants and a study on heart disease should include roughly 50% women – with women of color being sufficiently represented in all these studies.

Moreover, with appropriate representation in clinical trials where the data is gathered and analyzed by sex, then shared broadly will have an even greater impact. We recommend your creating a Women's Health Research Task Force to coordinate a data-sharing system and organize ongoing communications with an annual convening across agencies and with private sector engagement to pave the way for remarkable advancements in not just increased scientific understanding and accuracy for all medical innovations, but in collaboration among innovators and true progress in the health of women with better informed standards of care. Many federally funded early stage women's health companies as well as academic and private institutions are collecting tremendous amounts of previously unknown real world data that can provide novel insights. These are distinct data from those typically collected in a clinical trial-type setting and are extremely valuable because they reflect how health conditions or products are impacting women in the real world. Government can play an important role in encouraging the collection, amalgamation, disbursement, and investigation of de-identified real world data from these entities through streamlined regulation, financial investment and convenings. With data, we can drive and accelerate innovation, entrepreneurs can bring valuable medical solutions to market, and patients can have better health outcomes that also lower overall medical expenditures. In addition, this concerted effort backed with funding would signal and incentivize the VC community to invest in women's health innovation that further helps the entire ecosystem. If the government increases funding and programs in women's health research with a focus on data, this will attract more venture interest and investment.

Regulatory and Reimbursement Challenges

Second, entrepreneurs face challenges in not just raising capital, but in moving through the regulatory process. The FDA approval process can be lengthy and uncertain in general, but in women's health, we often find the expertise is lacking and conditions, such as endometriosis, are not even understood as chronic, debilitating conditions. The FDA often classifies drugs as potentially hormonally active with no scientific basis, then requires unnecessary additional burdens of proof for innovations and/or unnecessary labeling restrictions that both delay and limit patient access to important potential therapies. It also can use end points that aren't very meaningful or near impossible to meet from the patient's perspective, especially female patients, which makes recruitment a challenge and keeping patients in the study throughout the trial a significant challenge. These barriers also disincentivize investments. In addition, only four FDA Breakthrough Devices in obstetrics have ever been granted, and just a couple

in gynecology.⁵ Breakthrough considerations must include those conditions that significantly impact not just mortality but quality of life for women that directly impacts their ability to work, care for their families, and thrive and contribute to the national economy.

Overall, significant gaps in understanding not just the conditions that solely impact women, but in how diseases and conditions impact men and women differently continue to exist within FDA. Therefore, creating a new FDA Center of Excellence (COE) on Women's Health with staff training in women's health evaluating submissions; convening industry, patients and clinicians; and ensuring transparency, understanding and progress are key pillars of the COE would show investors and entrepreneurs that the FDA is serious about advancing these innovations. These challenges at FDA are a major reason why women's health entrepreneurs cannot raise large rounds of capital, as VCs and Big Pharma companies are often concerned that it is too high risk to try bringing innovative new programs forward. As a result, important innovations do not reach female patients that could effectively advance the health of women.

Third, the reimbursement system is yet another major hurdle for entrepreneurs in women's health. Many innovations are approved by the FDA but then languish in both the public and private reimbursement systems due to lack of reimbursement or gender discrepancies in reimbursement rates resulting in lower pay for women's health providers that disincentivizes advancement in care. Studies indicate some progress in more equitable reimbursement for female-specific procedures, however, there is a lower relative value of work, driven by specialty-specific compensation rates, for procedures performed for women-only than equivalent men-only procedures.⁶ Moreover, the Centers for Medicare and Medicaid (CMS) often does not appreciate, define, recognize, code or reimburse for the distinctive needs of women across all stages of life, resulting in potentially life-threatening gaps or delays in coverage, which in turn impacts private insurance decisions.

For example, a multi-biomarker combined with genomic testing platform for adnexal masses (occurring in 1 in 5 women) for ovarian cancer (which has a 50% mortality rate, the highest among all gender-specific cancers) with more specificity than the general CA-125 test thus enabling earlier, more accurate diagnosis and appropriate specialty care was approved by FDA in 2009, yet there is no national coverage by Medicare or private insurers. Another example is focused ultrasound therapy for uterine fibroids (occurring in 75% of women) that is non-invasive and allows women to resume their normal lives the same day unlike surgery, which was approved by FDA in 2004, but still nearly a decade later, is not reimbursed by Medicare and sporadically by private insurers. Within Medicaid, pregnant patients are often not provided coverage for essential services by both Medicaid and private payers, despite rising maternal and neonatal mortality rates. In certain state Medicaid programs pregnancy is not considered a high-risk condition that reflects a gender bias against unique health concerns borne only by women. Clearly, if CMS were to establish a Women's Health Division with requisite training and talent in women's health, some of the gaps in coverage could be addressed and ensure women's health research that generates valuable innovations reaches patients.

In addition, CMS's new Transitional Coverage for Emerging Technologies (TCET) program and existing National Coverage Determination (NCD) program serve as obtrusive barriers to care for patients, especially women who continue to not be adequately represented in clinical trials according to disease impact. As participation in clinical trials is a major decision driver for CMS, this keeps

⁵ <https://www.statnews.com/2023/02/10/pregnancy-complications-heart-disease-risks-later-life/>. Two gynecology Breakthrough Designation products include Axena Health for fecal incontinence that often follows childbirth and Maddorra for vagina atrophy.

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8602770/>

innovations from reaching women. Similar challenges exist within TRICARE and the Veterans Health Administration (VHA) in making reimbursement decisions. If investors and entrepreneurs knew that CMS, TRICARE and VHA were committed to covering medical innovations to meet the needs of women, this would open the doors to more innovators coming forward to create businesses around their work and more deal flow between VCs and women's health R&D companies. This commitment could be demonstrated with a special Center of Excellence on women's health within FDA, a designated women's health Breakthrough pathway, and a Women's Health Division within CMS to better understand clinical utility of innovations for women.

Patient Privacy and Autonomy

Fourth, varying state-by-state restrictions on the delivery of women's healthcare has had a catastrophic impact upon physician-patient privacy and autonomy. The inability to have frank health conversations surrounding family planning and reproductive health is incredibly detrimental to not just women, but to their families at large. While many women choose not to conceive or are unable to conceive, for the millions who do every year their pregnancy health has enormous ramifications on their lifelong health as well as that of their offspring – the next generation of humanity. There is inadequate data regarding the health impacts to women and their families since the *Dobbs* decision, leaving clinicians and entrepreneurs uncertain of how to aid these patients effectively. In addition, pregnant persons are often excluded from intervention-based research studies, perpetuating a dearth of adequate treatment innovation for these patients and further contributing to inequities for women.

The consequence of this is that we lack first line, disease modifying medications for conditions that uniquely impact women, like endometriosis and PCOS, among others. The medications we do have are “band aids” for symptom management but do not cure these conditions. Women are less likely to respond to drugs in general and when they do take medications, they experience adverse drug reactions twice as often as men.⁷ Moreover, women outlive men but disproportionately burden the healthcare system in their later years through higher reliance on nursing homes, in large part because of complications during their younger years from pregnancy and/or menopause that impacts all women. These include urinary incontinence that impacts 25% of women, osteoporosis where 80% of patients are women, and Alzheimer's where 75% of the patients over 65 are women, among many other chronic conditions that disproportionately impact women. It benefits all of us to enable open communications between doctors and patients where privacy is protected and accurate data can be gathered to inform the health of women during all stages of life. These real world experiences and data inform not just care, but research. Therefore, to the extent the government can shape the system to truly protect and advance the health of women, it will contribute to better outcomes, research, even scientific knowledge that can impact the health of men, as well as better healthcare utilization and lower expenditures overall.

Recommendations

In sum, we recommend:

- Federal Women's Health Innovation Investing entity to fund women's health startups, with an emphasis on programs seeking funding for studies that will support FDA filings or clinical trials.
- Incentives program (e.g. Qualified Small Business Stock (QSBS) tax credits) explicitly for women's health investment. This can include a matching element to leverage and entice private investment to help fund both early and growth stage startup companies in women's health.
- Increased funding for NIH and other federal departments for health research grants to study exclusively women as well as studies on both women and men that require sex-based differences data be collected, analyzed and reported in order to receive the full grant award.

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7275616/>

- Women’s Health Research Task Force to coordinate a data-sharing system and oversee real world sex-based data collection, amalgamation, and categorization from all federally funded institutions into a centralized resource that becomes available for entrepreneurs and researchers. The Task Force should convene regularly and establish incentives for data to flow easily and be inclusive of private sector engagement and data.
- FDA Center of Excellence in Women’s Health to dedicate more resources to recruiting experts, evaluating opportunities, and accelerating the review of women’s health innovations, including diseases that solely, disproportionately or differently impact women.
- Designation of an FDA Breakthrough Pathway focused on the health of women.
- CMS Women’s Health Division with requisite training and talent in women’s health to ensure innovations approved by FDA are effectively and appropriately evaluated and reach patients.
- Support of social science research into the impacts of state regulations upon women's health and physician-patient autonomy since the *Dobbs* decision.
- Requirement of the inclusion of pregnant persons in clinical intervention research for drugs likely to be prescribed to pregnant or pre-menopausal women, with adequate medico-legal protection.

Thank you for your consideration of our views as leaders in launching and growing businesses focused on research and innovation to advance the health of women. The White House Initiative on Women’s Health Research holds great promise as we strive to address the gaps that continue to persist and fundamentally improve the lives of millions of women. We look forward to partnering with you in this critical endeavor. If you have any questions or would like to discuss our ideas, please contact Liz Powell at lpowell@G2Gconsulting.com or (202) 445-4242.

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