

February 24, 2025

President Donald Trump
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear President Trump:

We write to share insights on ensuring the health and wellness of women – including our mothers and daughters - that can reduce avoidable medical expenditures, strengthen our economy with more productive businesses and communities, and save lives. We look forward to working with you as a business leader who knows the importance of government actions to remove barriers to growth and appreciates how government can play a key role in accelerating valuable scientific knowledge; explosive economic returns and job creation; and life-saving medical innovations coming to market and reaching patients.

Many of us have worked for decades to advance the health of women through research, innovation and access and welcome the chance to collaborate with you to close gaps and advance the health of women. Women's health includes those conditions and diseases that solely (maternal health, endometriosis, fibroid tumors, breast cancer, etc.), disproportionately (autoimmune diseases, Alzheimer's, migraines, mental health, etc.) and/or differently (chronic pain, heart disease, lung cancer, etc.) impact the health of women. Despite this touching all of us directly or indirectly, a gap exists due to unnecessary barriers that we must remove to enable innovation to improve and save lives. Moreover, addressing the 25% more time that women spend in poor health relative to men would boost the global economy by at least \$1 trillion annually and generate the equivalent impact of 137 million women in full-time positions by 2040.¹ When medical research is accurate, well-funded and supported by efficacious regulatory approval and coverage policies, the impact on people's lives and the economy can be life-altering.

Accuracy in Research

The gap that exists in the health of women is due to a lack of research over the last several decades. Ensuring research studies include female animals and humans and collecting data on women and men and how various conditions and innovations impact the health of patients is vital not just to more accurate scientific understanding and better health outcomes, but to incentivizing increased investment in businesses innovating in the women's health space. Adverse drug events are twice as common in women as men and without data and understanding as to why this happens for each therapy and how to rectify it with both FDA support and a business strategy for market adoption, many investors shy away from directing dollars toward women's health or investing in examining sex-based differences. By simply increasing female inclusion in studies representative of disease state in the greater population as well as sex-based data collection and analysis in all NIH- and DoD-sponsored studies through the agency's policy on sex as a biological variable and FDA clinical trials and having journal publications include sex-based data in order to be listed in the NIH Library of publications, your administration could close this gap,

¹ <https://www.mckinsey.com/mhi/our-insights/closing-the-womens-health-gap-a-1-trillion-dollar-opportunity-to-improve-lives-and-economies>

include more accurate labeling and spur more R&D efforts to tailor medical innovations to meet male and female patient needs.²

For example, a study on autoimmune disease ideally would have roughly 75-80% women participants since 75-80% of all patients with autoimmune disease are women and it would 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.³ Meanwhile a study on cardiovascular disease would have roughly 50% women and 50% men since it is the number one killer of both sexes, but has different symptoms and reactions to therapeutics and devices in women and men.⁴ Overall, at least 50% females in the pre-clinical and clinical trials would garner significant gains in furthering more precise research and healthcare for women and men.

Research Funding

Currently, the investment in women's health is quite low as less than 2% private venture funding (when including oncology this rises to 5%) and 8-11% NIH funding is dedicated to this market despite the \$1 trillion opportunity.^{5,6} If the various NIH institutes increased their percentage of grant funding toward women's health research to ensure that the total allocation approaches a more equitable rate and the Office of the Director had additional grant funding to fund more worthy grants in women's health, we could enable researchers and clinicians alike to do more with better evidence to back their decision-making in how innovate and treat patients. Another key area of government research funding is the Advanced Research Projects Agency – Health (ARPA-H) that Congress has authorized and appropriated with bipartisan support since 2022. Much like its parent, DARPA, which was created by President Eisenhower, the ARPA-H has consistently supported high-risk high-reward investment in health that traditional venture has been reluctant to back but can transform patient care. It has funded \$113 million in this space, spanning from maternal and fetal health to menopause to pain. This funding is essential to spurring matching private sector investment as it de-risks the opportunities for VCs, entrepreneurial risk-taking ventures that maintain our global competitiveness, and job creation and business growth—all in addition to advancing women's health.

FDA Approval Process

Too often there are unnecessary delays in the FDA approval process in women's health due to the time dedicated to education on sex differences, the biology of women and how innovations work within the female body. Creating an FDA Center of Excellence in Women's Health or related pilot program with appropriate staff trained and experienced in women's health would allow for greater efficiency and

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7275616/> and <https://pmc.ncbi.nlm.nih.gov/articles/PMC7275616/#:~:text=Women%20experience%20adverse%20drug%20reactions,so%20women%20may%20be%20overmedicated>

³ <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>

⁴ <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>

⁵ <https://www.mckinsey.com/industries/healthcare/our-insights/unlocking-opportunities-in-womens-healthcare>

⁶ https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_WHC_ExecutiveSummary508.pdf and

<https://nap.nationalacademies.org/catalog/28586/a-new-vision-for-womens-health-research-transformative-change-at>

understanding to properly evaluate innovations, convene companies and patients, and guide their approvals, thus accelerating innovations. Many companies and their investors would welcome this additional guidance and incentivization, and get much needed therapies to patients faster.

Access to Care and Innovation

Yet another concern is how innovations can reach patients effectively across rural, urban and all communities. Reaching populations in an accessible, affordable way is key to overcoming current barriers, such as being geographically located far from care with few transportation options. Therefore, we ask you to consider the real world lived experience of patients, their access to innovation and the role of cost and affordability in shaping access.

For example, women 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. In addition, 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.⁷ The percentage drops to 18% when 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. Removing out-of-pocket healthcare costs such as taxes on feminine products, diapers and related items would make a significant difference on the ability for women to access care, thrive and contribute to our economy.

CMS Reimbursement

As you know, many innovations approved by the FDA are not covered by CMS, TRICARE uniformed services health care program, and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). In addition, the reimbursement rates can be skewed as male urological surgeries have the dollar value on average that is 27.67% higher than their female-specific equivalent procedures (some of which are necessary following childbirth).⁸ The government could play a stronger role in closing these gaps by working with innovators as they move through FDA approval and onto CMS, TRICARE, CHAMPVA and private insurers’ reimbursement systems by having companies provide a plan for reaching all patients to be able to access new innovations. Making these plans public and providing annual reports on sex-based data among these patient populations would incentivize intentionality and effectiveness and help insurers to implement this access. These are valuable steps the government can take to increase access to women’s health innovations, improve new business growth opportunities, and de-risk the investments made by VCs.

Maternal Health, Mental 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. Today, an estimated 2.2 million U.S. women live in “OB-GYN deserts” and 4.7 million more live in areas with limited access – with many of these areas being in rural parts of the country where it can take several hours to reach a medical facility.⁹ In addition, inadequate clinician

⁷ <https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/womens-health-equity-disparities.html>

⁸ https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=4774&context=faculty_scholarship

⁹ <https://www.marchofdimes.org/maternity-care-deserts-report>

training and a shortage of medical professionals is impacting the health of women throughout the country and in all age groups spanning from puberty to pregnancy to menopause.¹⁰ The impact is particularly severe among communities of color. Within maternal health, Black 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.^{11, 12} Research and innovation in pre-eclampsia, preterm labor and postpartum hemorrhage remain direly needed for all women to improve outcomes. 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. There is a unique role that the government can play in attracting these clinicians to address care gaps.

Inter-Agency Coordination

Overall, government could lead the way in creating economic incentives and dashboards that measure and convene researchers, clinicians, entrepreneurs and patients to exchange information and partner in advancing R&D and medical innovations to address women's health to close these health gaps. Adding meaningful funding to this coordination and data-sharing effort, removing silos and increasing communications and collaborations that include private sector and cross-government cooperation that ensures all agencies work together will enable accelerated pathways to bring innovations to patients will ensure that thorough, holistic and productive advancements are achieved with real impact on the economy.

In conclusion, there are many challenges and opportunities when it comes to advancing women's health and bringing innovation to market that you and your administration are well-positioned to accelerate will generate enormous economic return. The most pressing areas where access to innovation will have the greatest impact are from ensuring accuracy in research with representative pre-clinical and clinical participation, increasing research funding in broad women's health areas, closing the gap between FDA approval and coverage by both private and government payers, prioritizing maternal health and gynecological access for all women in all age groups, and organizing inter-agency coordination to advance knowledge and collaborations in women's health to reach all patients throughout the country.

Thank you for your consideration. We are eager to work with you to address these issues. If you have questions, please contact Liz Powell at lpowell@G2Gconsulting.com.

Sincerely,

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CC: Speaker Johnson, Majority Leader Thune, Minority Leader Jeffries, Minority Leader Schumer and entire U.S. Congress

¹⁰ <https://www.marchofdimes.org/maternity-care-deserts-report-2022#:~:text=The%20new%20findings%3A&text=In%20maternity%20care%20deserts%20alone,women%20with%20no%20maternity%20care>

¹¹ [https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm#:~:text=In%202021%2C%20the%20maternal%20mortality,\(Figure%201%20and%20Table\)](https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm#:~:text=In%202021%2C%20the%20maternal%20mortality,(Figure%201%20and%20Table))

¹² <https://minorityhealth.hhs.gov/infant-mortality-and-african-americans#:~:text=Non%2DHispanic%20black%2FAfrican%20American,%2DHispanic%20whites%2C%20in%202020>

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