Accelerating research for women's health

A policy blueprint to advance innovation to close the women's health gap

The women's health gap

Women comprise half the global population, yet they remain underrepresented and inadequately considered in medical and public health research, resulting in serious gaps in health outcomes and well-being. Although women live longer than men, they spend a substantially greater portion of their lives sick or with disability.

These disparities stem from multiple, reinforcing factors. Research advancing the understanding of and solutions to diseases and conditions that uniquely or disproportionately affect women remains chronically underfunded: globally, only 5 percent of health research funding is directed towards women's health, and just 1 percent addresses conditions beyond cancer.

> Women spend **25 percent more of their lives in poor health**, yet **less than 5 percent of R&D funding** is directed towards women-specific conditions.

Significant gaps persist in understanding sex-based differences in disease biology, presentation, and treatment response. Women have also historically been underrepresented in biomedical and clinical research, and too few studies consistently analyze and report outcomes by sex. One analysis of 650 medical studies found that only half differentiated findings by sex; among those that did, outcomes were less favorable for women nearly two-thirds of the time. Compounding these challenges, many technologies and interventions are not designed with women's needs in mind.

The consequences are profound. Globally, the women's health gap is estimated to account for 76 million years of life lost annually due to poor health or early death. Inequalities are even more severe in low-income countries, where women face disproportionately higher risk of dying from diseases such as HIV, tuberculosis, and malaria, and are 35 times more likely to die in pregnancy or childbirth than women in high-income countries.

The opportunity

Women are central to healthy families, resilient communities, and productive economies, and more than half of the years women spend in poor health are in their prime working years. Closing the women's health gap therefore represents a powerful opportunity to save and improve lives while driving economic growth and societal well-being.

> Closing the women's health gap could **boost the global economy by $1 trillion** and the **US economy by $295 billion** by 2040.

Achieving this goal will require more inclusive research practices, more systematic analysis of sex- and gender-based differences, and accelerated innovation to address leading women's health challenges. With targeted policy actions and sustained investment, the United States can lead a new era of progress in women's health.

A government-wide approach to women's health R&D

US government support for women's health research and development (R&D) spans multiple agencies and programs:

National Institutes of Health (NIH) conducts and funds research to improve women's health across diseases and life stages, while advancing policies to strengthen the inclusion of women in research and integration of sex as a biological variable throughout the research process. Alongside primary investigator-driven investments through institutes/centers, NIH has periodically used targeted innovation challenges to address specific women's health research gaps.

Department of State, through Global Health Programs, supports the delivery and scale-up of maternal, reproductive, and women-centered HIV interventions for women globally. With the integration of the US Agency for International Development (USAID) into the State Department, there is an opportunity to rebuild and expand R&D efforts for maternal and women's health tools previously led by USAID.

Advanced Research Projects Agency for Health (ARPA-H) has supported transformative early- and late-stage biomedical R&D through its Sprint for Women's Health, including novel diagnostics, therapeutics, devices, and digital tools, as well as sex-specific research models.

Department of War advances multi-disease platforms and technologies to prevent and treat sexually transmitted infections (STIs) affecting service members, which have broader relevance for women's health.

Biomedical Advanced Research and Development Authority (BARDA) supports the development of new antibiotics and other tools to address antimicrobial resistance, including technologies relevant to STIs and other reproductive tract infections affecting women.

Centers for Disease Control and Prevention (CDC) conducts surveillance and epidemiological research to inform the use of existing tools and interventions; supports global immunization programs relevant to women's health; and provides technical assistance to strengthen public health systems globally.

Food and Drug Administration (FDA), alongside approving products for use in the United States, advances women's health by integrating sex-specific considerations into regulatory decision-making and promoting the ethical inclusion of women, including pregnant and lactating women, in clinical research.

A history of policy progress

Over the past four decades, the United States has made significant progress in advancing women-centered research and institutionalizing the study of sex-based differences. Seminal milestones include:

- **1985:** Report of US Public Health Service Task Force on Women's Health Issues identifies systemic gaps in women's inclusion in clinical research, catalyzing subsequent reforms.
- **1990 (codified 1993):** Creation of the NIH Office of Research on Women's Health (ORWH), to coordinate research across NIH and monitor inclusion of women in research; women's health focal offices are later established at the Department of Health and Human Services (HHS), as well as FDA and CDC.
- **1993:** NIH Revitalization Act mandates inclusion of women and minorities in all NIH-funded clinical research and requires sex-based analyses in Phase 3 trials. The same year, FDA rescinds its 1977 guidance excluding women of childbearing potential from early clinical trials and issues new guidance encouraging their inclusion in Phase 1 and 2 trials, requiring inclusion in Phase 3, and mandating analysis of data by sex, race, and ethnicity.
- **2002:** NIH establishes network of research centers focused on advancing translational research on the role of sex differences in women's health.
- **2012:** Food and Drug Administration Safety and Innovation Act directs FDA to report on and

strengthen collection and analysis of clinical trial data by sex, race, and ethnicity.

- **2014-2015:** FDA implements the Pregnancy and Lactation Labeling Rule, creating new narrative risk summaries and explicitly highlighting data gaps.
- **2016:** NIH implements its Sex as a Biological Variable Policy requiring grantees to factor sex into research design, analysis, and reporting. Legislation establishes the Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC), which releases recommendations in 2018 to advance safe inclusion of these groups in clinical research.
- **2019:** NIH launches its first comprehensive, NIH-wide strategic plan to advance women's health research.
- **2024:** ARPA-H launches its Sprint for Women's Health.

Despite this progress, substantial gaps remain between policy intent and practice. While women are now enrolled in clinical trials at rates comparable to men, underrepresentation persists in certain subgroups, and pregnant and lactating women continue to be routinely excluded. Sex-based analyses remain inconsistent, and many diseases and conditions uniquely or disproportionally affecting women remain under-researched and underfunded. Closing these gaps will require sustained investment and targeted policy actions.

The vision

GHTC envisions a world where **every woman, everywhere**, has access to safe, effective, and affordable health technologies designed with her needs in mind. We see a future where women are meaningfully engaged at every stage of the R&D process, from priority-setting to design, testing, and delivery, ensuring innovations reflect the realities of their lives.

By closing persistent funding gaps and advancing inclusive, gender-responsive innovation, GHTC aims to accelerate the development and equitable distribution of solutions that improve health outcomes, strengthen health systems, and unlock the full social and economic potential of women globally.

Recommendations for action

Increase investments in women's health R&D

Congress should increase funding for priority agencies and programs that advance women's health research and innovation.

For fiscal year 2027, Congress should appropriate:

- **NIH:** $51.303 billion, including:
  - **ORWH:** $115.740 million
  - **National Institute of Child Health and Human Development (NICHD):** $1.933 billion
  - **National Institute of Allergy and Infectious Diseases:** $7.500 billion
- **State Department Global Health Programs:** $9.499 billion, including:
  - **Prevention, Treatment, and Response Initiative (PTRI):** ≥$50.000 million

Agencies should ensure these resources support both foundational research and product development targeting women's health needs.

Codify women's health R&D at the State Department

For decades, USAID played a critical role in advancing the development of affordable, fit-for-purpose technologies for use in low-resource settings. This work included maternal health innovations, women-centered HIV prevention products, multipurpose prevention technologies, and other tools addressing unmet needs. By supporting late-stage product development in areas often underserved by other agencies, USAID filled a unique and essential gap within the US global health innovation ecosystem. Following USAID's integration into the State Department, questions remain about

how and where this specialized product development function will continue.

To preserve this critical capability, Congress should:

- Continue and expand investment in the PTRI through annual appropriations, building on the no-less-than $50 million investment established in fiscal year 2026 to support the R&D of new global health technologies.
- Direct that maternal health technologies be included as a priority investment area within PTRI through appropriations report language, recognizing the significant unmet need for innovation in maternal health and the historical role of US investments in advancing lifesaving solutions for women and newborns.
- Authorize PTRI in statute to provide long-term stability, clear congressional direction, and accountability for sustaining advanced product development efforts that address persistent global health challenges.

The State Department should also leverage its budding Innovation Fund to support the development of maternal and reproductive health technologies and women-centered HIV prevention products.

Preserve critical NIH infrastructure for women's health

As Congress and the administration consider potential NIH reauthorization or restructuring, it is essential to preserve ORWH and NICHD as standalone entities.

ORWH provides NIH-wide leadership, coordination, and accountability for women's inclusion in research, while NICHD anchors scientific expertise in pregnancy, maternal health, and women's life stage conditions. Eliminating or subsuming these offices would risk reversing decades of progress by diluting the focus on women's health, weakening cross-NIH coordination, and further marginalizing critical research that has been historically underfunded and understudied. Population-specific research infrastructure is not duplicative—it is corrective, ensuring that NIH investments reflect biological realities and clinical needs for women. Congress and the administration should explicitly protect ORWH and NICHD as independent components of NIH, reaffirming their missions and authorities.

Strengthen the NIH strategy on women's health research

NIH's current five-year *NIH-Wide Strategic Plan for Research on the Health of Women* concludes in 2028. NIH should launch an inclusive, transparent consultative process to inform the next strategy.

This updated plan should:

- Expand emphasis on late-stage research and product development, including creating or strengthening dedicated funding mechanisms for women's health product development targeting areas that are under-addressed by commercial investment.
- Align with global gaps and health needs in low-resource settings.
- Strengthen and standardize NIH-wide tracking, reporting, and accountability for women's health investments.

Advance safe inclusion of pregnant and lactating women in research

Pregnant and lactating women remain routinely excluded from clinical research, resulting in major evidence gaps and limited approved products. As a result, clinicians and patients often make decisions without adequate data on safety, dosing and effectiveness, despite the fact that most women confront the need to take medications during pregnancy or breastfeeding. This can lead to delayed care, suboptimal treatment, and preventable harm to both women and infants.

Excluding these groups does not eliminate the risks they face, but rather shifts them into the real world without the benefit of controlled data. Carefully designed research can minimize risk while generated critical evidence to guide care.

To advance the safe, ethical inclusion of pregnant and lactating women in research, Congress should pass the Advancing Safe Medications for Moms and Babies Act, which would implement key recommendations of the PRGLAC. The bill would modernize human subjects regulations to remove pregnancy-based barriers to research participation, establish a national clinical trials clearinghouse to improve visibility and enrollment of pregnant and lactating women, and strengthen coordination across NIH, FDA, and HHS.

Federal research funding agencies, including NIH, BARDA, ARPA-H, and the State Department, should also make explicit R&D investments to address evidence and product gaps for pregnant and lactating women, in alignment with their respective missions and mandates.

Sustain and institutionalize women's health accelerator programs

NIH and ARPA-H have demonstrated the value of time-bound, milestone-driven accelerator programs in advancing innovations for critical unmet women's health needs. Through NIH's Rapid Acceleration of Diagnostics Technology (RADx® Tech) for Maternal Health Challenge, Technology Accelerator Challenge for Maternal Health, and Rapid Acceleration of Diagnostics Technology Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays (ACT ENDO) Challenge, as well as ARPA-H's Sprint for Women's Health, these agencies have advanced promising women's health tools to market and seeded a pipeline of potential future breakthroughs.

both agencies should institutionalize women's health accelerator programs as a recurring component of their health portfolio. These accelerator-style programs address an important funding gap, given women's health products have historically been underfunded by commercial markets. They also provide unique value by pairing targeted, milestone-based funding with forms of non-financial support, including technical assistance, regulatory guidance, and commercialization expertise—helping innovators move promising ideas toward proof of concept, commercialization, and eventual impact.

Future programs should continue to prioritize neglected and underserved areas of women's health and provide support across development stages.