

Closing the gender health gap is a \$1 trillion opportunity

For centuries, women's health has been neglected across science, medicine and technology. A new report from the World Economic Forum suggests tackling this could unlock a \$1 trillion economic boost with the potential to change the lives of 3.9 billion women.

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The US Food and Drug Administration (FDA) was established in 1906 and the first chemotherapy drug was used to treat cancer in 1942. In 1977, the FDA issued a policy recommending that women of childbearing age be excluded from participating in clinical research studies. It was not until 1993, when the US Congress passed the National Institutes of Health (NIH) Revitalization Act, that women were recommended to be included in clinical trials in the USA¹⁻³. Furthermore, it only became a requirement in April 2022 that men and women be represented equally in trials and that the data be disaggregated in the analysis. The exclusion of women from the very trials that underpin evidence-based medicine, coupled with a lack of willingness by many innovators to invest in women's health, means this gap has widened over decades⁴.

For most of history, women have been treated with medicines which have not been scientifically assessed through the lens of a female body—a lens that we now know can strongly impact a spectrum of health issues ranging from prevention and treatment of cardiovascular diseases, to pain, psychiatric conditions and sports injuries⁵. So, how could the biological differences between men and women be accounted for by physicians when women were historically considered to be 'tiny men' in the eyes of healthcare providers?⁵

Having held positions as both an obstetrician and a gynecologist for over 35 years, from my experiences as a woman and with the knowledge obtained throughout my time at Ferring Pharmaceuticals—where I'm currently Research and Development VP of Reproductive Medicine and Maternal Health—I understand the power of evidence-based medicine. Without a doubt, I welcome the findings of the January 2024 report that was developed by McKinsey Health Institute in cooperation with a coalition led by the World Economic Forum, and co-produced by Ferring⁶. This significant publication is long overdue and sets out the case for change in stark terms.

The report presents the gender health gap as a \$1 trillion opportunity to improve lives and economies, and to change the health of 3.9 billion women⁶. Closing this gap would lead to fewer premature deaths, and the largest impact could be that women avoid 24 million life-years lost due to ill health⁶. The report's launch in Davos, Switzerland, at the World Economic Forum placed this agenda on the center stage and called for bold policy action for change. In February 2024, the Biden Administration answered by announcing a \$12 billion investment in women's health research with the goal to "fundamentally change how our nation approaches and funds women's health research"⁷. This is welcome progress in the US, but it is just an initial step—without consideration of realistic actions to fix this, progress in closing the women's health gap may be stalled.

Let the numbers paint the picture of the disregard of women's diseases

Only 1% of research and development funding focuses on non-cancer-related women's health. Yet women make up roughly 50% of the world's population^{8,9}. This 1% is still narrowly focused on a limited number of female-specific conditions: gynecological infections, contraception, fertility, maternal health, menopause and other gynecological conditions⁹ (Fig. 1). The numbers tell us that something is not working—more than 800 women die every day from preventable causes related to pregnancy and childbirth⁹. A study conducted in Denmark across 21 years showed that women were diagnosed later than men for more than 700 diseases. For cancer, it took women two and a half more years to be diagnosed. For diabetes, the delay was four and a half years¹⁰. Women are 52% more likely than men to have an adverse drug reaction and are 29% more likely to die from an adverse drug reaction¹¹.

Delayed diagnoses and unfair dismissals of health concerns from healthcare professionals can force women out of the workforce through ill health. Women are spending an average of nine years in poor health across their lives—25% longer than men⁶. Addressing the women's health gap could generate the equivalent impact of 137 million women accessing full-time work positions⁶. Collectively, this means the women's health gap equates to 75 million years of life impacted by poor health⁶.

The women's health gap is a research gap

Despite physicians highlighting the many differences when treating men or women, these have not been reflected in the design of clinical trials. This has created misunderstandings in clinical practice and led to gaps in clinical training. For example, in 2023,

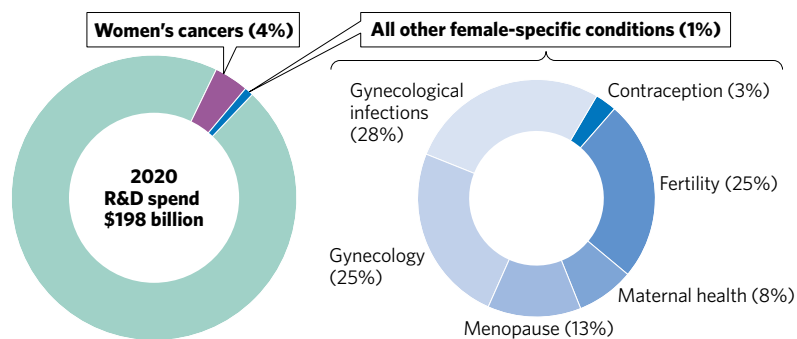


Fig. 1 | Biopharma research and development spend in 2020. Adapted from McKinsey & Company, 2022.

the *Brigham and Women's Hospital Magazine* interviewed women physicians who gave firsthand examples of training gaps. One physician mentioned little recognition of sex differences between male and female hearts during her training, despite evidence proving the effect sex hormones have on cardiovascular disease⁵. Another found that women experience greater pain sensitivity and are more frequently diagnosed with chronic pain conditions yet consistently receive worse pain care than men. A greater number of women experience neurologic and psychiatric conditions compared with men, with different risk factors, symptoms and drug responses⁵. Estrogen—an important part of the female hormonal profile—is suspected to play a larger role in diseases than predicted⁵. For example, in some cancers, women may live longer than men after chemotherapy. This has been linked to biomarkers which suggest these sex differences are because of estrogen-responsive tumor pathways⁵.

The research community has known about the impact of estrogen on health, disease and treatment for a while, but in the past this has not been rationally incorporated into milestone trials³. Indeed, one might say that at times it has been irrationally incorporated, such as when a study of the effect of estrogen on the secondary prevention of cardiovascular disease in post-menopausal women in 1970 was conducted solely on men. The rationale for enrolling 8,341 men and no women was that the background noise of women's peri- and post-menopausal hormones would alter results and complicate analysis¹².

This lack of inclusion presents a wide spectrum of issues which require stratified research for women. However, even if we focus on gynecology and reproductive issues—which have long been acknowledged as typical 'women's issues'—we still find that research efforts, funding and investment are lacking. According to experts at Imperial College London, less than 2% of medical research funding is spent on pregnancy, childbirth and female reproductive health¹³.

When it comes to emerging pipelines, the endometriosis treatments available highlight an unmet need in female reproductive research—this disease, which is undertreated and underdiagnosed¹⁴, sits in a market worth an estimated \$180–220 billion, yet few assets are in the pipeline⁶. This suggests that a hidden emotional and economic impact from the lack of investment is further widening the gender health gap. Another comparison worth making for reproductive health shows that investment is unbalanced and unfavorable for women: as of 2015, there were five times more scientific studies into erectile dysfunction than premenstrual syndrome (PMS), despite erectile dysfunction affecting an estimated 19% of men while PMS affects 90% of women¹⁵. Despite centuries of unconscious bias and skewed results, even as recently as 2019 women still trailed men in research trials¹⁵.

Lack of investment delays our understanding of women's diseases

Let's use cancer as a benchmark to examine how much our understanding of women's diseases is lagging behind. When the term 'war on cancer' was launched 50 years ago, all types of the disease were thought to be similar enough to approach with the same treatments—drugs were designed to stop rapidly growing cells and it was believed that all cancers would behave the same in response to this¹⁶. After decades of research funding and pharmaceutical investment, we now know that no two cancers are alike. Women's diseases are being grouped similarly to how cancer was 50 years ago—lumped together into categories such as endometriosis, PMS, pelvic pain, polycystic ovary syndrome (PCOS) and menopause, despite these conditions being their own subcategories¹⁷.

Investment is key to driving growth and understanding for diseases. Women's health has been seen, until recently, as a marginal area of academic or commercial investment. Few venture funders have prioritized women's health or women's products—a lack of women making venture capital investments has also contributed to this gender disparity¹⁸.

Have we seen any progress when it comes to investment and collective action from pharmaceutical companies and governments? Prior to the Biden Administration's pledge, a new alliance was formed to promote women's health at the World Economic Forum in Davos in January 2024¹⁹. The Global Alliance for Women's Health is committed to contributing its expertise, resources and influence to advance initiatives that promote women's health, ensuring that it becomes a shared responsibility across diverse sectors. The World Economic Forum's seminal report produced in conjunction with the McKinsey Health Institute is the first to quantify the economic impact, while making the case for timely action to address it. The alliance aims to unite leaders around the world to commit to close the gap and help address the lack of funding and investment.

The McKinsey Health Institute report concluded, from an economic perspective, that it's not solely a lack of research funding in women's biology that's to blame. A lack of female scientists entering reproductive biology and technology in this field plays a part too. This is worth addressing: female research teams are 35% more likely than male teams to develop medical treatments that primarily benefit women⁶.

The disease landscape of women's health naturally spans the course of a lifetime. By lacking information about the life course of women's diseases, such as endometriosis and menopause, healthcare providers are misunderstanding how conditions affect a woman at different life stages, ultimately impacting the process of designing innovative therapeutics²⁰. Pharmaceutical and other investors have avoided these areas due to the perceived high risk and high cost of developing drugs in this space²¹. The lack of investment into the basic etiology of these pathologies has left this area without the capital needed for innovation.

Delaying female inclusion in clinical trials has ultimately caused a domino effect of subsequent hurdles. The lack of basic research in women's health further topples the domino line, and has made women's health a very unattractive area for pharmaceutical companies to invest in.

Closing the gap for societies and economies globally

The women's health market continues to face challenges as healthcare evolves and the individual, human cost of this disparity remains striking. Take postpartum hemorrhage as an example. No woman should die while giving birth. But, every year, 70,000 women die from postpartum hemorrhage. This accounts for at least a fifth of all maternal deaths, with the vast majority (90%) occurring in lower- and lower-middle-income countries²². To use endometriosis as another example, the average time from when women report a first complaint to being given the correct diagnosis is now up to 10 years, which carries significant social, public health and economic implications, not to mention pain, fatigue, depression, anxiety and infertility^{23,24}. Addressing the unmet need in reproductive, maternal and child health could boost the economy by \$50 billion, but more importantly it has a huge human and societal impact⁶.

The Global Alliance for Women's Health hosted by the World Economic Forum is key to making a global impact, providing a multisector platform to shape the future of women's health. The alliance aims to put women's health on the global agenda, unlock more investments for women's health, and advance women's health research and innovation. Collaboration across companies and nations is crucial. Corporate allegiance to closing the gap may cause minimal impact without international collaboration. Nations are responsible for individual attitudes towards investment in female healthcare. Without a global movement dedicated towards improving research and outcomes for women's health, changes will become more difficult to realize. But one must start somewhere. So, what changes do we want to see from companies?

Organizations must take accountability and elevate research into women's health. With the baseline provided by the World Economic Forum report, and with plans to track progress on a yearly basis through the Global Alliance for Women's Health, innovations-based biopharmaceutical companies have a unique opportunity

to step-up on their inclusion and diversity agendas, as part of their measurable environmental, social and governance (ESG) commitments. Companies should lead by example in driving global social progress, challenging perceptions and embracing responsibilities to create an equal, inclusive platform.

Performance and impact indicators can include bringing more women into research, development and leadership positions; strengthening the representation of women in clinical trials in tune with disease prevalence; ensuring the collection, analysis and reporting of gender-disaggregated data; establishing new types of research and development partnerships that can lead to new innovation and medical solutions to address major unmet needs in women's health, such as endometriosis; and employee policies and benefits that promote women's health and cultivate environments where women feel empowered to speak openly about their health needs.

Companies need to firmly commit to investment in women's diseases, but to do so there needs to be a profitable business case. Currently this is a difficult task due to two main reasons: the regulatory hurdles and the payors failure to see women's diseases as an unmet need. Let's start with the regulatory hurdles. Currently, for drugs given to women planning to conceive, both the FDA and the European Medicines Agency (EMA) require follow up of the children's health which is of course an important safety assessment, but it also adds significant costs to already expensive trials. In Europe this is usually only 6 months, however for the FDA it is a 2-year follow up. And this is only one of several regulatory hurdles that can deter pharmaceutical companies from investing in women's health. The other critical issue in the business case is educating payors on the value of new therapeutics for diseases affecting women. The impact of diseases such as endometriosis and PCOS can be devalued when inexpensive and readily available medications—such as oral contraceptives and non-steroidal anti-inflammatory drugs (NSAIDs)—are deemed sufficient. However, more efficient drugs that treat the cause of the illnesses rather than the symptoms are needed. Education regarding the unmet needs is required to shift perceptions and generate understanding that the price point necessary for generating a solid business case for companies is preventing them from investing in this space.

To overcome both regulatory and payor hurdles, and prioritize innovation in women's diseases, companies must collaborate extensively by engaging all the critical stakeholders to educate, value, protect and promote women's health (Fig. 2). Roundtables with global leaders in academia, industry, regulatory affairs, payors, investors and patients are needed to change behaviors, transform the healthcare paradigm for women and close the health disparities that exist.

This is not the first time we have demanded changes to meet women's health needs. But this time, there is a report that underpins these calls with details of the distinct economic and human costs of inaction. Women have a right to the same healthcare as men. This goes beyond just availability. Women deserve medicines which have been subjected to an equivalent quality of rigorous research and clinical trials. They deserve to receive the most effective medicines. This equitable access must extend worldwide, without exception. Not only can this add years to a woman's life expectancy, but it also means their children may contribute to more productive and better-educated societies, which in turn leads to a healthier future for us all²⁵.

But beyond being a human rights issue and the morally the right thing to do, investing in women's diseases is increasingly being seen as commercially lucrative. Women control over \$31.8 trillion in worldwide spending²⁶ and account for 80% of consumer purchasing decisions in the healthcare industry²⁷. Based on prevalence and high unmet need, the market potential for endometriosis treatments is estimated at \$180–220 billion global based on today's share of endometriosis patients seeking treatment⁶. Private equity and venture capital investors are throwing their hats in the ring and collectively invested \$2.2 billion in funding over the past four

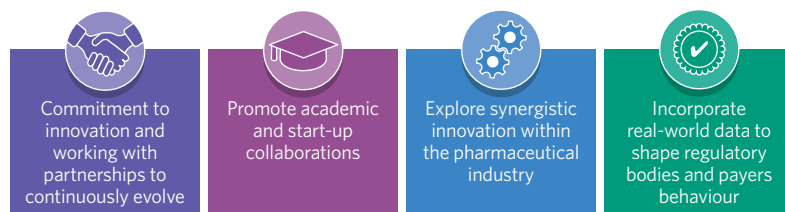


Fig. 2 | Strategies to prioritize research and development in women's health.

years²⁸. The timing is right given the huge unmet need and resulting opportunity—pharmaceutical companies that continue to pass on investing in women's diseases may find themselves left by the side of the road by players that take advantage of this high-potential market.

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