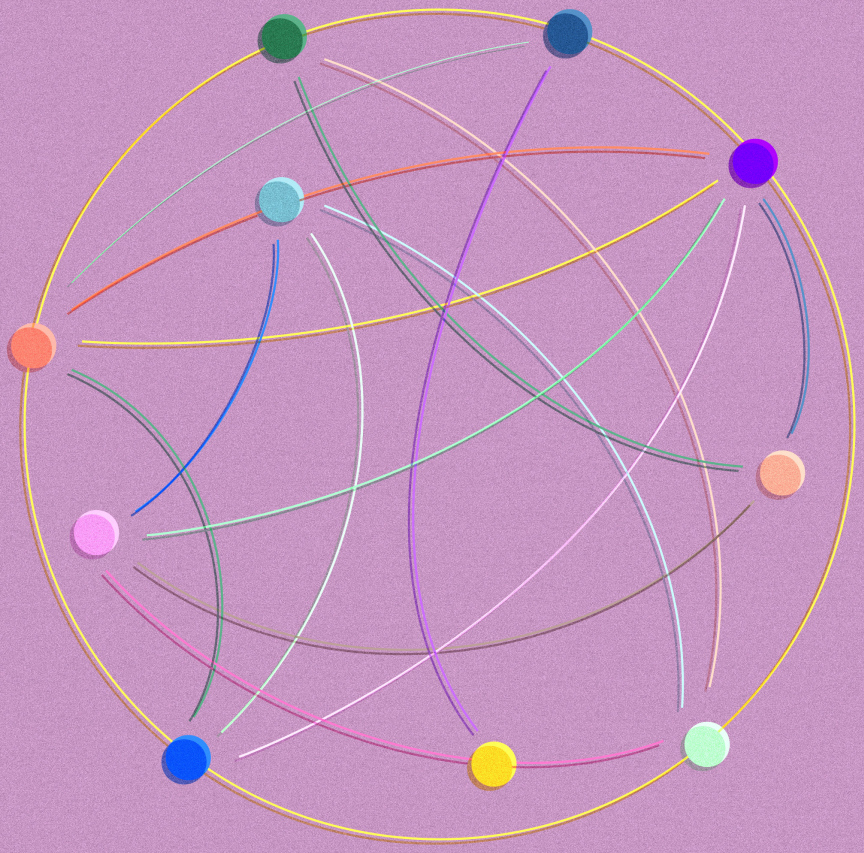


A CALL TO ACTION

A Global Roadmap to Transform Women's Health Innovation

A systems thinking approach to increasing investment.

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OCTOBER 11, 2026

Executive Summary

Women represent nearly half the global population yet remain among the most underserved in modern medicine. Despite growing awareness, sustained momentum, and genuine willingness to act among some of the world's most powerful institutions, investment in women's health innovation continues to stall. The reason is not only a shortage of capital or goodwill. It is a broken system.

This paper argues that the barriers to women's health investment are interconnected and mutually reinforcing: thin evidence weakens the case for coverage, uncertain coverage weakens the case for investment, and scarce investment ensures the evidence never gets built. Because these loops reinforce one another, solving any single bottleneck in isolation leaves the others intact. [1] Breaking the cycle, therefore, requires a systems-thinking approach that maps how these barriers interact and targets the points where a coordinated intervention can shift the behavior of the whole system.

The good news is that this cycle can be broken. Precedents exist in rare disease, oncology, pediatrics, and metabolic medicine where targeted, coordinated interventions at the right leverage points transformed previously unattractive fields into thriving areas of investment and innovation. Women's health is ready for the same transformation.

This paper presents a framework for that transformation, organized around four structural bottlenecks:

- Insufficient coordination
- Antiquated regulatory framework
- Limited understanding of female biology
- Limited access

We propose 10 priority actions directed at the global institutions, governments, regulators, payers, and investors best positioned to address these bottlenecks and harness an opportunity estimated at up to $1 trillion in annual global economic value by 2040. [2] These actions are designed to work together rather than as standalone fixes where each targets a leverage point in the cycle, and their impact compounds when pursued in concert.

10 PRIORITY ACTIONS

1. Establish a formal coordination mechanism with built-in public accountability.
2. Define validated clinical endpoints for priority conditions.
3. Apply the existing incentive toolkit.
4. Mandate sex-disaggregated reporting.
5. Prioritize the conditions most ready for investment.
6. Fund longitudinal cohort studies at scale.
7. Establish a pre-competitive biology fund.
8. Reform payer coverage for women's health.
9. Pilot blended finance models for early-stage investment.
10. Invest in the organized patient and clinical voice.

The authors are committed to convene a core group of leaders to begin executing on these 10 Priority Actions.

1. The Question: Why This Paper, Why Now?

Across the world's leading organizations such as the World Economic Forum, Milken Institute Global Conference, Gates Foundation Global Grand Challenges, and others, women's health has emerged as a priority agenda item. Capital is mobilizing and governments are paying attention. The conversation has shifted from *whether* to invest to *how* to invest.

While we have optimism and momentum, structural barriers remain. Without coordination, even genuine commitment disperses into the same fragmented ecosystem that has failed to produce transformative progress for decades.

This paper was born from a recognition shared by its authors across careers in drug development, early-stage investment, regulated sectors, and global health that this momentum could be wasted unless it is channeled into a coherent, coordinated strategy. Our goal is not to add another voice calling for more investment but instead provide a systems-level diagnosis and a practical roadmap, identifying the highest-leverage actions, sequencing them by dependency, and naming the institutions best placed to deliver each one.

To understand how this momentum can translate into progress, it helps to understand how the system blocking it was built and has evolved. Women's health innovation is a market failure which is a situation where private incentives are insufficient to produce socially optimal outcomes, and where coordinated public and institutional action is required. This paper treats it as such.

2. How History Got Us Here

The current state is not an accident. It is the accumulated result of centuries of gender bias permeating the structures of science and medicine, decades of regulatory overcorrection, and a widespread culture of institutional paternalism that systematically removed women's agency over their own healthcare.

Three moments were particularly consequential:

Thalidomide and the Exclusion from Trials (1960s–1993)
The FDA's rejection of thalidomide, a sedative used to treat morning sickness, was later associated with causing significant fetal abnormalities. This led to the strengthening of the FDA by requiring demonstration of efficacy and full disclosure of side effects prior to approval but also established a legacy of caution that was applied too broadly. As such, from 1977 to 1993, women of childbearing age were formally excluded from most early-phase clinical trials.[3] Male physiology became the scientific default for an entire

generation of drug development. Women were left without sex-specific safety and dosing data for the drugs they take at the same or higher rates than men.

The Dalkon Shield (1970s)
A defectively designed Intra Uterine Device reached approximately 2.2 million American women before its serious harms (e.g, pelvic inflammatory disease, septic abortions, and death) were acknowledged.[4] The reaction resulted in suppressed contraceptive device innovation for a generation, and established a precautionary posture toward women's health devices that persisted for decades.

The Women's Health Initiative and the Estrogen Panic (2002–2003)
A large but methodologically flawed study conducted in women whose average age was 63, far older than those typically initiating hormone therapy for menopause was interpreted as definitive evidence of harm across all hormone therapy. An estimated 46% drop in hormone therapy use followed within six months[5], and the FDA added a black box warning that withdrew effective treatment from an entire generation of women, and chilled investment in women's hormonal health for over two decades. In November 2025, the FDA finally removed that black box warning[6], a decision the clinical community had been requesting since at least 2014.[7]

The pattern is consistent: precaution applied without adequate scientific basis, restrictions placed on entire categories of treatment due to the behavior of a subset, and women's agency over their own healthcare decisions systematically overridden by institutions operating on assumption and fear rather than evidence. This uncovers two competing cost–benefit frameworks: one centered on women's health, agency, and quality of life across the lifespan, and another shaped by a "better safe than sorry" approach that overemphasizes precaution at the expense of women's broader wellbeing, often filtered through a reproductive lens, but the underlying cause runs deeper. Until recently, the researchers designing trials, the regulators reviewing submissions, the payers setting coverage policies, and the physicians translating guidance into practice were overwhelmingly men. Women's conditions were defined as "niche." Their symptoms were dismissed as psychological. The default human in medical science was male. Gender bias did not produce this system through malice, it produced it through invisibility.

The consequences of that invisibility are still being measured. Women's reported symptoms have been historically underweighted, dismissed as psychological, or attributed to anxiety and emotional excess rather than physiological causes. The exclusion of women from clinical research was not an isolated policy error, it was a systemic expression of that bias, embedded in the evidentiary base, the regulatory frameworks, the reimbursement systems, and the investment culture. Endometriosis, a condition affecting approximately 10% of women globally[8], takes an average of 7 to 9 years to diagnose.[9] Polyendocrine metabolic syndrome (PMOS), affecting up to 13% of women[10], received just $9-10 million in annual NIH funding as recently as 2022.[11] This bias cannot be corrected by awareness alone. It requires deliberate, sustained institutional effort at every level of the system, which is precisely what the diagnosis and actions that follow are designed to deliver.

3. Proof It Can Be Fixed: Three Case Studies

This history is not an indictment. It is an explanation of how the system was built, and therefore how it can be changed. The following three case studies demonstrate that targeted, coordinated interventions have successfully transformed previously unattractive therapeutic areas into thriving fields of investment and innovation. Critically, each case maps to a different bottleneck in the broken cycle, biology, regulation, and payer access, foreshadowing the diagnosis and actions proposed in Sections 4 and 5.

CASE STUDY 1:
INVESTMENT UNLOCKED BIOLOGY : KIDNEY DISEASE AND THE CANCER MOONSHOT

For decades, kidney disease and many cancers shared the same characteristics now seen in women's health: insufficient mechanistic understanding, no validated drug targets, and investor reluctance born of scientific uncertainty. The turning point in both cases was deliberate, coordinated investment in foundational biology, building the scientific infrastructure from which products could eventually emerge. In nephrology, the FDA and scientific community built the evidence base for a surrogate endpoint [12] while a pioneering biotech demonstrated its clinical relevance through their own trial data. [13] That alignment around proteinuria as the accepted endpoint for IgA nephropathy collapsed trial timelines from decades to months, enabling the first approved therapies [14] and catalyzing over 30 drug candidates within four years. [15] In oncology, sustained public and philanthropic investment epitomized by the Cancer Moonshot launched in 2016 [16] helped establish the scientific foundation that underpinned over 150 FDA approvals in the five years that followed. [17] In both cases, once the foundation existed, private capital followed rapidly. Today, oncology and nephrology are among the most active areas of pharmaceutical R&D.

The lesson for women's health: The same logic applies to women's health: foundational investment in biology and surrogate endpoint validation for conditions like endometriosis and PMOS is the precondition for private investment, not a substitute for it.

CASE STUDY 2:
REGULATORY CHANGE UNLOCKED INVESTMENT : ONCOLOGY, RARE DISEASE, PEDIATRICS, AND COVID

As cancer incidence rose and existing treatments fell short, the FDA introduced incentives that proved as consequential as the science itself: special designations enabling closer agency collaboration, accelerated approval pathways that created urgency, and priority review that shortened time to market. [18] The results, as described above, transformed the oncology field. Prior to the Orphan Drug Act of 1983, rare diseases were known as "orphan diseases" precisely because no pharmaceutical company would invest in treatments for small patient populations; only 38 such drugs had ever been approved in the United States. [19] The economics did not work. The Act changed the calculus by introducing a suite of regulatory incentives: seven years of market exclusivity, tax credits for clinical trial costs, user-fee waivers, and research grants. [20] Within two decades, more than 500 orphan drugs were approved, Over the four decades that followed, the FDA granted 6,340 orphan designations covering 1,079 rare diseases, of which 882 resulted in at least one approval, and an entire industry was

created. [21] Orphan drugs are projected to reach one-fifth of worldwide prescription drug sales by 2030 — a share that has doubled over the past decade.[22] Pediatric medicine saw a similar transformation through a pairing of mandate and incentive: the Pediatric Research Equity Act required manufacturers to study new drugs in children, while the Best Pharmaceuticals for Children Act granted voluntary pediatric studies with six months of additional market exclusivity.[23] Together they produced the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act, which required and incentivized the development of pediatric-specific formulations and doses based on sex- and age-appropriate safety and effectiveness data that had never existed.

COVID-19 demonstrated that the regulatory system is capable of extraordinary speed when institutional will is present. Two mechanisms were decisive: Advanced Market Commitments, which guaranteed purchase volumes before vaccines existed and gave manufacturers the financial certainty to invest at risk, and Emergency Use Authorization, which created a defined legal pathway for authorizing products before full approval data were available. Together they enabled multiple vaccines and therapeutics to reach patients within months, drawing on frameworks built on the rare disease and oncology playbooks.[24]

The lesson for women's health: the regulatory and financing tools that transformed oncology, rare disease, pediatrics, and COVID-19 response already exist. Women's health does not need new ones. It needs the same institutional will to deploy them.

CASE STUDY 3: PAYER CHANGE UNLOCKED ACCESS : CGMS FOR TYPE 1 DIABETES AND GLP-1S FOR OBESITY

Continuous glucose monitors (CGMs) for Type 1 diabetes faced years of payer resistance despite compelling clinical evidence of benefit. The path to broad coverage required sustained advocacy by patient organizations, scientific societies, and health economists who demonstrated that the upfront cost of device coverage was far outweighed by the downstream reduction in hospitalizations, complications, and long-term disease burden. [25] Once coverage decisions shifted, adoption accelerated, the market expanded, and a virtuous cycle of investment and innovation was enabled. [26]

GLP-1 receptor agonists show what the same fight looks like before it is won. Obesity's classification as a "lifestyle issue" rather than as a chronic disease sustained years of payer resistance. Commercial coverage is now expanding, but fewer than half of large employers cover the drugs for obesity [27], and Medicare still cannot cover them at all [28], reaching beneficiaries only through temporary programs that route around the statutory bar rather than removing it. [29]

The lesson for women's health: The same argument, made rigorously, by the right coalition of advocates, health economists, and policymakers, is waiting to be made for endometriosis, PMOS, and perimenopausal conditions. When it is, markets will form as rapidly as they did for CGMs and GLP-1s. Payer coverage decisions are not simply downstream consequences of regulatory approval, they are active policy choices with enormous consequences for market formation.

COMMON THREAD: *In each case, a coordinated intervention at a specific leverage point broke a cycle of underinvestment and created conditions for sustained progress. Women's health requires all three simultaneously.*

4. The Diagnosis: A Broken System with Four Bottlenecks

The core problem in women's health investment is a self-reinforcing system of barriers that collectively prevent progress at every stage of the value chain. Understanding this system is essential to breaking it.

THE CYCLE: *Scant/inaccessible capital → weak evidence base → undefined regulatory paths → payer reluctance → commercial failure → scant capital*

Each step in this cycle is both a consequence of what precedes it and a cause of what follows. Investors hesitate because evidence is insufficient. Evidence is insufficient because researchers are underfunded and women have been systematically excluded from all aspects of research. That same scarcity of funding and career opportunity pulls scientific talent away from the field: physician-scientists and translational researchers with the expertise to carry a women's health discovery from bench to bedside can build steadier, better-resourced careers in therapeutic areas with established funding streams and clearer paths to market, so many gravitate elsewhere, leaving too few specialists to move promising biology into viable investigational candidates. Regulatory paths are undefined because the evidence base to establish validated endpoints does not yet exist. Payers decline to cover novel treatments, demand lower prices relative to non-women's health products / indications [30], or impose significant barriers to access (e.g., step edits and prior authorizations) [31] due to regulatory conservatism, including decades-old black box warnings or limitations for treatment duration [32], which signal risk to investors. The talent pool that has the experience to navigate regulatory and payer hurdles is limited and cannot manage the broad range of solutions and this talent also choose to go elsewhere for greater growth opportunities. Products fail commercially because physicians lack the time and infrastructure to manage burdensome prior authorization processes, and patients cannot access care. This burden falls with particular force on women's health: gynecologists are reimbursed at rates too low to support the dedicated access infrastructure that oncologists and rheumatologists rely on, leaving new treatments cycling through denial, appeal, and abandoned prescriptions — and even when approved, prohibitive copays send patients back to older alternatives that will reliably be filled. A survey of 1,000 physicians in the United States conducted in late 2024 found that practices process an average of 39 prior authorization requests per physician each week, consuming roughly 13 physician and staff hours, and that 40% of physicians employ staff dedicated solely to prior authorization: an administrative tax that falls hardest on newly approved products without established coverage pathways. [33] Increased risk of commercial failure confirms investors' hesitation and narrows the career case for the next generation of women's health researchers and specialists even further. And so the cycle continues.

The implications are stark. Just 4% of all biopharma R&D spending targets female-specific conditions. [34] Of the 37 prescription drugs approved by the FDA in 2022, only two addressed conditions specific to women. [35] Women spend on average 25% more of their lives in poor health than men, in part because treatments for their conditions have never been developed. [36] This is compounded by a long-standing undervaluation of conditions that affect women exclusively, differentially, or disproportionately. Addressing this disparity could unlock more than $1 trillion in annual global GDP by 2040. [37]

The case studies above are instructive about where and how to intervene. In nephrology, the breakthrough was foundational biology, specifically the willingness to invest in building the scientific infrastructure, including a validated surrogate endpoint, before private capital was ready to follow. In oncology and rare disease, it was regulatory will, the deliberate application of existing incentive tools to a field that had previously been deemed too difficult or too small to attract them. In diabetes and obesity, it was payer policy, demonstrating the full economic case for coverage in terms that changed the financial logic for an entire market. Each intervention targeted a different point in the broken cycle. Each produced a different unlock. Women's health requires all three, which is why the four bottlenecks below are not a menu of options but a single interconnected agenda. Progress on any single one without the others will recreate the conditions that have defeated previous efforts.

1/ Insufficient Coordination

The women's health ecosystem is not short of committed actors but alignment among them is lacking. For instance, advocacy campaigns overlap, fundraising efforts are duplicated and policy agendas compete. The global convening institutions that could orchestrate a coordinated response have instead produced a fragmented landscape of well-intentioned but poorly sequenced efforts. The missing ingredient is not another initiative. It is a formal mechanism that assigns responsibilities, sequences actions, and holds institutions publicly accountable for delivery. Coordination is listed first because it is the prerequisite for everything that follows.

2/ Antiquated Regulatory Framework

The absence of validated clinical endpoints for conditions like endometriosis, PMOS, and perimenopausal disorders is the single most important structural barrier in women's health. Without regulator-accepted endpoints, trials cannot be efficiently designed, investors cannot model returns, and even well-funded science cannot produce approvable drugs. The tools to define these endpoints exist and have been applied successfully in oncology and nephrology. They have not yet been systematically directed at women's health. Similarly, the regulatory incentives that unlocked oncology and rare disease have yet to be systematically applied to women's health. This is a prioritization problem not a scientific problem.

3/ Limited Understanding of Female Biology

Many women's health conditions lack the foundational biological understanding that makes a disease tractable to drug development — a problem that manifests differently across conditions depending on whether data is entirely absent, sex-disaggregated

analysis has never been applied, or existing datasets were built on male norms that systematically excluded female-specific patterns. Few single private actors can justify funding the pre-competitive infrastructure that would benefit the entire ecosystem. [38] This is a pure market failure, and it requires philanthropic, public, and mission-driven capital to resolve — not as charity, but as the deliberate construction of the scientific foundation from which private investment can follow.

4/ Limited access

Even where science exists and regulatory approval has been granted, women's health innovations frequently fail to reach patients because coverage policies have not kept pace. In some cases, payers have continued to follow the logic of regulatory guidance that has since been withdrawn. The absence of reimbursement codes for novel interventions, and the failure to model the full economic cost of diagnostic delay, mean that the financial case for coverage expansion has simply not been made. Until it is, coverage reform will lag both the science and the clinical need. In Europe, the access barrier takes a different form. The EU HTA Regulation, applicable since January 2025, introduced Joint Clinical Assessments: a single EU-level review of clinical evidence that replaces duplicated national evidence assessments while leaving pricing and reimbursement decisions with member states. [39] Its scope is being phased in, beginning with oncology medicines and advanced therapies, extending to orphan products in 2028 and all new medicines in 2030. [40] How women's health stakeholders engage with its implementation will shape the European access landscape for a decade.

Taken together, these four bottlenecks explain why previous efforts have fallen short, and why the response must address all of them in concert. The lesson these bottlenecks share is worth stating plainly. New capital flowing into the current system will encounter the same roadblocks as existing capital. The Orphan Drug Act did not just fund rare disease research, it changed the rules of the game. Alignment around clinical endpoints and payer coverage in nephrology did not just benefit one company, it created a pipeline and a market. Sustainable investment requires a functional ecosystem, and building that ecosystem is what the actions that follow are designed to achieve. Capital is necessary but not sufficient. The actions below are not a call for more of the former: they are a roadmap for building the latter.

5. The Ask: 10 Priority Actions

This paper is a call to action. The following priorities are sequenced by dependency, mirroring the four bottlenecks identified above. Each names the actor responsible for delivering it. We believe these ten interventions will have the greatest leverage on the broken cycle, in the order they need to happen.

ENHANCED COORDINATION

1/ Establish a formal coordination mechanism with built-in public accountability

Global conveners including the World Economic Forum, Gates Foundation, Milken Institute, and their peers should formally divide responsibilities via a published assignment matrix defining who does what, by when, and accountable to whom and

commit to publishing annual assessments of progress against the four bottlenecks. Overlapping campaigns, duplicative research investments, and competing policy agendas dilute impact and waste resources that the field cannot afford to lose . This action is the prerequisite for all others. Without it, the remaining nine actions will encounter the same fragmentation that has defeated previous efforts. Additionally, as women's health is an underfunded area, we cannot afford to waste resources.

ENABLING REGULATORY FRAMEWORK

2/ Define validated clinical endpoints for priority conditions
FDA and EMA initiate a prioritized, time-bound process modelled on the Kidney Health Initiative to establish accepted endpoints for endometriosis, PMOS, and perimenopausal conditions within 24 months. This single action has more potential to unlock private investment than any other action on this list. It is not technically complex but requires regulatory leadership and the will to prioritize.

3/ Apply the existing regulatory incentive toolkit
FDA issues published guidance actively encouraging breakthrough therapy designation, accelerated approval, and priority review vouchers for women's health conditions, with proactive outreach to sponsors. The tools exist and they have transformed oncology and rare disease. However, they have not yet been systematically directed at women's health and doing so requires no new legislation only action.

4/ Mandate sex-disaggregated reporting
Regulatory agencies should require all clinical trials to analyze and report outcomes by sex. The evidentiary foundation for women's health has been built on data that did not adequately represent women. This mandate begins to correct that at the source, and its effects will compound across every trial conducted, and resulting treatments, from this point forward.

Organizations such as the Milken Institute, FDA Office of Women's Health, Reagan-Udall Foundation and the European Medicines Agency are uniquely positioned to tackle regulatory change and are already working on these topics.

BIOLOGY

5/ Prioritize the conditions most ready for investment
A coordinated prioritization exercise convened by global scientific bodies with input from patient advocates, clinicians, and industry identifies the three to five conditions with the greatest unmet need and highest biological tractability. The building blocks exist and academic institutions worldwide are already generating relevant science. Coordinating those efforts would unlock progress far faster than starting from scratch. By creating a shared prioritization framework that connects what already exists. .

6/ Fund longitudinal cohort studies at scale
Governments, academic medical centers, and philanthropic funders should coordinate to build longitudinal datasets for priority conditions, capturing the decades-long health trajectories that cross-sectional research cannot reveal. These cohorts should be

designed from the outset to also embed periods of intensive wearable monitoring at key biological moments, including adolescence, reproductive years, and perimenopause, generating high-resolution biological signal within the long-term arc. Preliminary work in this model has already surfaced patterns invisible to traditional research. Building this infrastructure at scale will transform every downstream element of the system, from trial design to regulatory review to payer modelling.

7/ Establish a pre-competitive biology fund

A blended capital structure combining public grants, philanthropic co-investment, and industry contribution funds the translation of basic science into validated drug targets and biomarkers, structured explicitly as shared infrastructure rather than proprietary advantage. Few single actors can justify this investment alone which is why it must be done collectively, and why the coordination mechanism in the first action is the prerequisite for this one.

Organizations such as Nuttall Women's Health, Wellcome LEAP, NIH Office of Research on Women's Health, the Gates Foundation, and Horizon Europe are uniquely positioned to fund critical biology research and are actively deploying funding.

ACCESS

8/ Reform payer coverage for women's health

Payers should systematically review women's health coverage policies against current clinical evidence, beginning with the conditions most affected by historically overcautious regulatory guidance. In parallel, payer organizations should work with clinical societies to build reimbursement frameworks for novel women's health interventions, and commission health economic analyses that model the full cost of diagnostic delay. Recent mapping of the reimbursement landscape by the Milken Institute, has identified nine structural barriers between women's health innovations and coverage, from insufficient billing codes to payer frameworks that fail to recognize conditions affecting women exclusively or disproportionately.[41] The financial case is established. Coverage reform is a question of institutional priority, not scientific readiness.

9/ Pilot blended finance models for early-stage investment

Governments and development finance institutions should design and launch public-private partnership structures and impact bonds specifically adapted to the current stage of women's health market maturity. The private sector is willing to follow where the risk has been reduced and the public sector has the tools to reduce it. What is missing is not mechanism or precedent, both exist in global health and climate finance, but the decision to apply them here, with the urgency this moment demands. In Europe, the building blocks are particularly well placed: the European Investment Bank and the European Innovation Council already have the mandates to anchor blended finance structures. The missing step is directing them explicitly toward women's health.

Organizations such as Centers for Medicare & Medicaid Services, Business Group on Health, UnitedHealth Group, the European Investment Bank, and the European

Innovation Council are uniquely positioned to address access and reform payer coverage.

ADVOCACY AS ENABLING CONDITION

10 / Invest in the organized patient and clinical voice

Educated patients create demand, trained clinicians generate evidence and informed policymakers maintain commitment. Patient advocacy organizations, clinical societies, and medical schools should work in concert to build the informed, activated ecosystem that makes every other action on this list politically sustainable. This means structured programs to educate women about the treatments they are missing and the policy changes that would expand their access to care; clinical training that explicitly addresses diagnostic bias and equips physicians to recognize and act on women's symptoms earlier; and a coordinated effort to learn from the advocacy models that transformed HIV, rare disease, and oncology. None of this happens on the same timeline as a regulatory guidance document or a payer coverage review. But without it, the reforms achieved through the other nine actions will not be defended, scaled, or sustained. Advocacy is not the loudest ask in this paper, but it is the one that determines whether the others stick.

Organizations such as the American College of Obstetricians and Gynecologists, the Society for Women's Health Research, and the Women First Research Coalition have already begun this work. The National Strategy to Close the Women's Health Gap, launched in July 2026 by the Society for Women's Health Research and endorsed by more than 30 organizations, asks Congress for $20 billion over ten years across research and innovation, policy modernization, data infrastructure, workforce, and public education. [42] With its largest allocations, $7 billion each for research and for the clinical and research workforce, tracking closely to the constraints identified throughout this paper. [43] None of that money has been appropriated yet.

What Success Looks Like

If these actions are taken in concert, the authors believe the following outcomes are achievable within a decade:

- A reduction in average diagnostic delay for endometriosis and PMOS from 7–10 years to under 2 years, enabled by validated biomarkers, trained clinicians, and educated patients.
- Regulator-accepted objective clinical endpoints for the five highest-priority women's health conditions, enabling efficient, approvable clinical trials.
- Payer coverage policies for women's health that reflect current clinical evidence, enabling commercial markets to form and attract sustained private investment.
- A 10-fold increase in pharmaceutical R&D investment in women's health, driven by de-risked regulatory paths, defined endpoints, and reliable commercial returns.
- Longitudinal datasets capturing the health trajectories of hundreds of thousands of women, providing the foundational infrastructure for the next generation of diagnostics, therapeutics, and preventive interventions.
- A virtuous cycle of investment, evidence, regulatory confidence, and commercial success that becomes self-sustaining — no longer requiring intervention to maintain momentum.

We believe that the opportunity is real, the tools exist and the precedents are instructive. The remaining ingredient is coordination and the deliberate, accountable alignment of the world's most capable institutions around a shared diagnosis and a shared plan.

Women cannot wait for that alignment to happen on its own. This paper is an invitation to make it happen now.

About the Authors

This paper was developed by a team of practitioners with careers spanning drug development, investment, regulated sectors, and global health policy. The authors welcome engagement from all stakeholders.

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