

The Status of Women's Health: the Need for Investment and Innovation in Therapeutics

PSI Webinar on Women's Health

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Definition of Women's Health

Encompasses the health of women across the lifespan

Includes:

| Conditions that Affect Women | Examples |
|------------------------------|---------------------------------|
| Only | Preeclampsia, endometriosis |
| Differently | Cardiovascular disease |
| Disproportionately | Autoimmune disease, Alzheimer's |

McKinsey & Company; Unlocking Opportunities in Women's Healthcare. Feb 2022

Women's Health Needs Continue to be Minimized and Undervalued

“In the US alone, women are the dominant workers, decision-makers, users, and spenders of the \$4 trillion+ US healthcare industry, but their specific needs have often been minimized and undervalued.”¹

Women in the United States make approximately 80% of the health care decisions for their families, yet often go without health care coverage themselves.²

¹L. Greub and E. Epker; Investing in Women's Health is Impact Investing. Fast Company 2023

²S. Matoff-Stepp et al, Women as Health Care Decision-Makers; J Health Care Poor Underserved, 2014

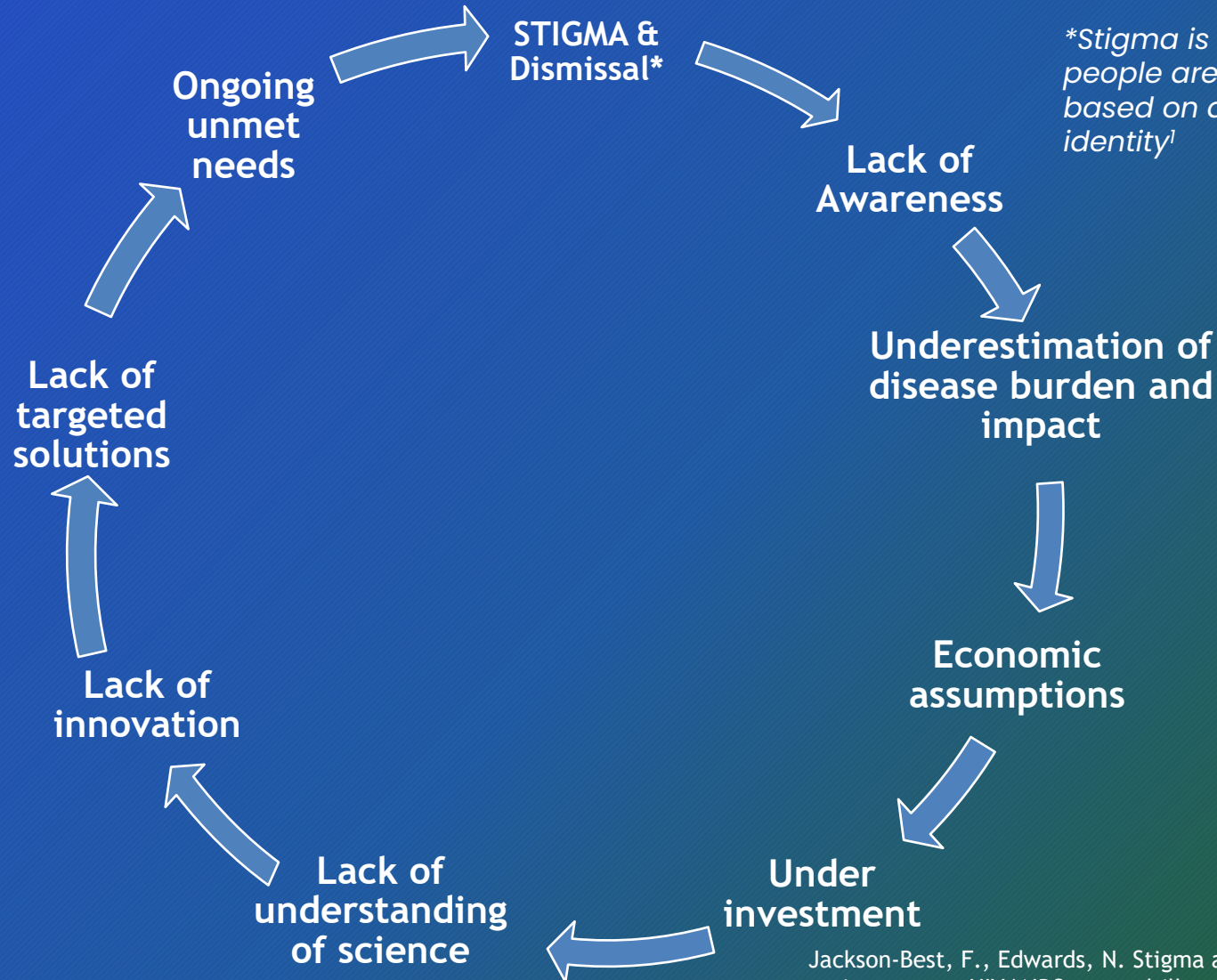
Shocking Statistics in Women's Health

Enormous Opportunity

- One in ten women of reproductive age is estimated to have endometriosis and 1 in 5-25 women have PCOS: no available cures for either condition
- ~800 women die globally every day from preventable causes related to pregnancy and childbirth
- More than 2.2 million women of childbearing age in the US live in maternity care deserts (1,119 counties) that have no hospital offering obstetric care, no birth center and no obstetric provider
 - Maternal mortality rate in the US doubled between 2002 and 2018-black women were disproportionately affected; black women are 3x more likely to die due to pregnancy-related conditions than white women
 - Preeclampsia kills 76,000 women worldwide per year-still treated with magnesium-no effective medical treatment
 - Preterm labor affects over 15 million pregnancies annually; root cause is poorly understood--no approved treatment in the US
 - Menopausal symptoms reduce quality of life-few non-hormonal solutions

Endometriosis: Epidemiology, Diagnosis and Clinical Management; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5737931>; <https://www.who.int/publications/i/item/9789240068759>; <https://www.marchofdimes.org/maternity-care-deserts-report>; <https://www.marchofdimes.org/black-maternal-health-week-2023>; Preeclampsia Foundation; <https://www.who.int/news-room/fact-sheets/detail/preterm-birthL>; Greub and E. Epker; Investing in Women's Health is Impact Investing. Fast Company 2023

The Vicious Cycle of Under-Investment in Women's Health



**Stigma is a social process through which people are distinguished or labelled based on attributes, illness, disability, or identity¹*

Jackson-Best, F., Edwards, N. Stigma and intersectionality: a systematic review of systematic reviews across HIV/AIDS, mental illness, and physical disability. BMC Public Health 18, 919 (2018). McKinsey & Company; Unlocking Opportunities in Women's Healthcare. Feb 2022 <https://femaleforwardtogether.com/why-we-e>
Bever, L. From heart disease to IUDs: How doctors dismiss women's pain. Wash Post, Dec 2022

Only 9 Drugs Ever Approved and Marketed for Obstetrical Indications (First Box)

Drugs Approved Specifically for Obstetrical Indications

- Methylergonovine maleate (Methergine)
- Oxytocin (Syntocinon nasal spray and Pitocin for injection)
- Ritodrine (Yutopar)—**no longer marketed**
- Dinoprostone (Prepidil and Cervidil)
- Magnesium sulfate
- Doxylamine succinate and pyridoxine hydrochloride (Diclegis)
- Hydroxyprogesterone caproate (Makena)—**now withdrawn**

Drugs Prescribed for Approved Indications, Used in Pregnancy

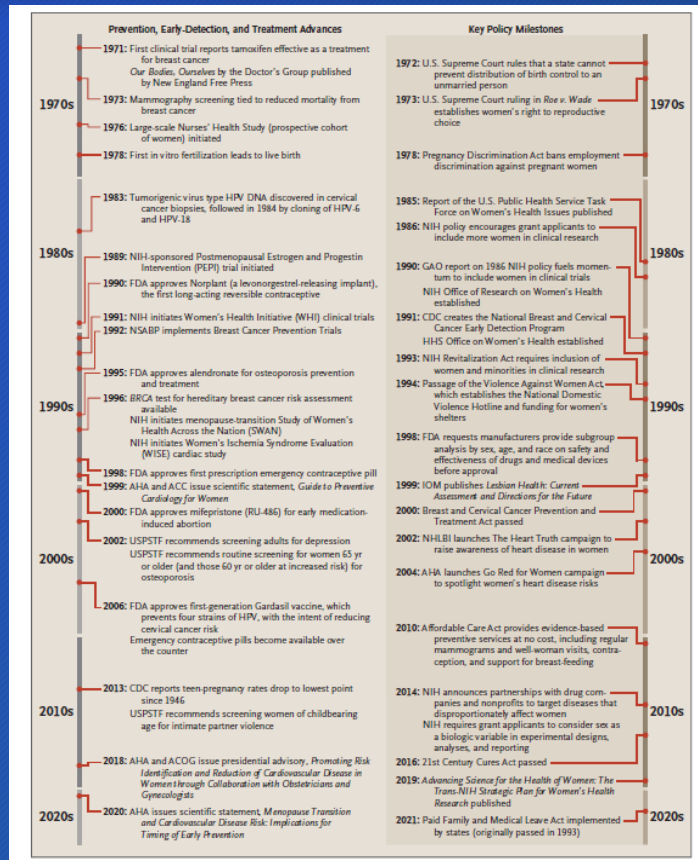
- Antiseizure medications
- Antihypertensive medications
- Beta-adrenergic inhalers for asthma
- Antibiotics
- Glucocorticoids for autoimmune diseases

Approved Drugs Prescribed in Pregnancy for Unapproved Uses in Pregnancy

- Antenatal steroids to enhance fetal lung maturity
- Indomethacin to stop preterm labor

Wesley BD, Sewell CA, Chang CY, Hatfield KP, Nguyen CP. Prescription medications for use in pregnancy: Perspective from The US Food and Drug Administration. *Am J Obstet Gynecol.* 2021. [doi: 10.1016/j.ajog.2021.02.032](https://doi.org/10.1016/j.ajog.2021.02.032)

Attention to Women's Health is Growing



Nichols FH; History of the Women's Health Movement in the 20th Century

2020:

- COVID 19-uncovers serious inequities for women, particularly women of color
- Organon spinout from Merck

2021:

- WHAM Report

2022:

- McKinsey Report
- Roe v. Wade overturned

2023:

- Gates/NIH Women's Health Innovation Opportunity Map
- White House Initiative announced

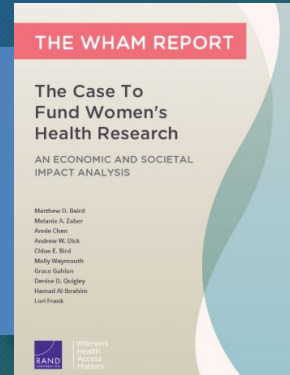
2024:

- Biden Executive Order on Women's Health

Stuenkel CA and Manson JE; Women's Health-Traversing Medicine and Public Policy. NEJM 2021
<https://www.inc.com/springboard/3-ways-to-disrupt-traditional-practices-in-womens-health.html>
 McKinsey & Company; Unlocking Opportunities in Women's Healthcare. Feb 2022

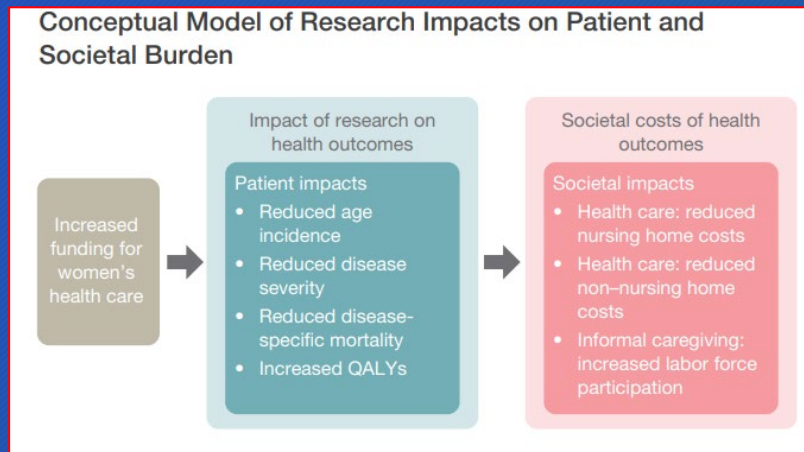
The WHAM Report

i.e., the Proof that Women's Health is NOT a Niche Market



The Case to Fund Women's Health Research

- Collaboration with Rand Foundation and diverse panel of experts
- Calculated impacts across 30 years of doubling the current NIH funding

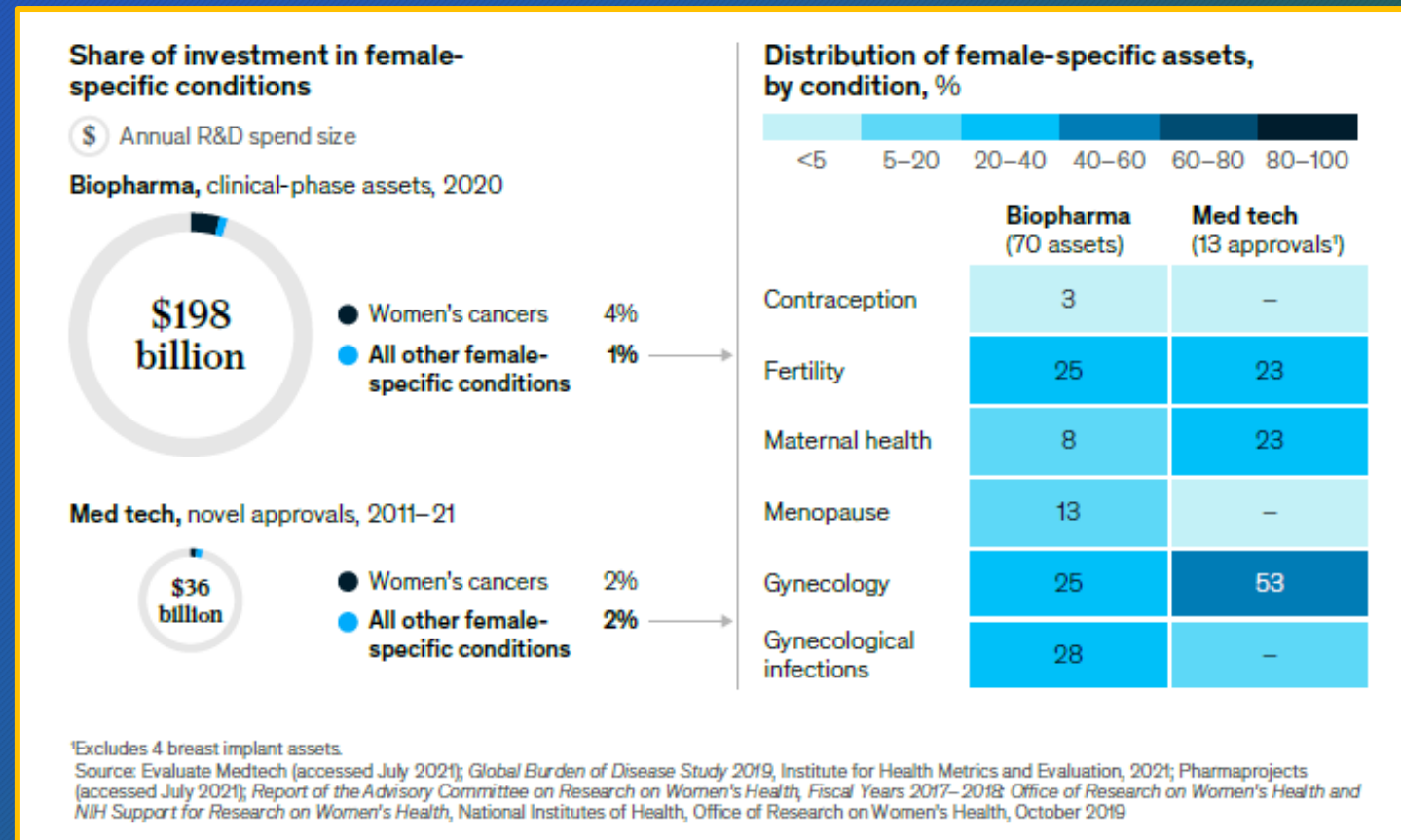


Main Finding:

Investing \$350 million in women's health would generate \$14 billion to our economy

The McKinsey Report Unlocking Opportunities in Women's Healthcare

- In 2020, 1% of all biopharma R+D spend went toward female-specific conditions, excluding oncology
- Stark contrast between largest women's health investment fund (\$72 million) vs billions in the largest venture capital funds



Innovation Equity Forum (IEF)



Women's Health Innovation Opportunity Map 2023

50 High-Return Opportunities
to Advance Global Women's Health R&D

White House Women's Health Initiative

THE WHITE HOUSE



NOVEMBER 13, 2023

FACT SHEET: President Joe Biden to Announce First-Ever White House Initiative on Women's Health Research, An Effort Led by First Lady Jill Biden and the White House Gender Policy Council

*The new initiative will fundamentally change how we
approach and fund women's health research.*

Biden Executive Order

MARCH 18, 2024

FACT SHEET: President Biden Issues Executive Order and Announces New Actions to Advance Women's Health Research and Innovation

- Integrate women's health across the federal research portfolio
- Prioritize investments in women's health research
- Galvanize new research on women's midlife health
- Assess unmet needs to support women's health research
- Foster innovation and discovery in women's health
- Expand and leverage data collection and analysis related to women's health
- Strengthen coordination, infrastructure, and training to support women's health research
- Improve women's health across the lifespan

Recommendations Toward Further Maximizing the Women's Health Ecosystem

- Build the business case for investment in Women's Health therapeutics
 - Increase numbers of women in top decision-making positions across the healthcare ecosystem
 - Establish NIH Institute for Women's Health
 - Establish FDA Center of Excellence for Women's Health
 - Provide education and support to academic researchers on translation of potential therapies from bench to bedside
 - Continue to advocate for the health of women
- ❖ *Stamp Out Stigma!*

