

RESEARCH FROM MARS CAN FAIL PATIENTS FROM VENUS

BY JIM GREENWOOD, PRESIDENT AND CEO, BIO

Despite rules and directives pushing for clinical trials to include proportional representation of both sexes, some researchers and developers are still behind the curve. FDA, BIO and nonprofit organizations are providing new tools and resources that can help ensure diverse patient populations receive the full benefits of newly commercialized medicines.

Historically, federal dollars flowed to medical research with a disproportionate focus on men's health.

There are several reasons for this. Decades ago, many scientists shortsightedly concluded men were easier to study because they weren't subject to frequent hormonal changes that could complicate a study's design or the interpretation of its results. Also, safety concerns for pregnant women once resulted in overly broad exclusions of women with "child-bearing potential" from many clinical studies.

The last quarter-century has brought a greater focus on the opportunity cost of uneven representation in clinical studies. When it comes to gender, in particular, we now know unequivocally that a person's sex can influence disease presentation, diagnosis, severity and treatment.

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Certain chemotherapy drugs have more side effects in women than men. Women may need lower dosages of certain medications due to differences in body weight compared with men. **Research** suggests that women may be 20 to 70% more likely to develop lung cancer than men who smoke the same number of cigarettes. Meanwhile, colon cancers are frequently misdiagnosed because the disease can present differently in women than men

In 1993, Congress passed the National Institutes of Health (NIH) Revitalization Act, a federal rethinking of the participation levels of women and minorities in clinical research.

And since 1998, FDA has required that clinical trial data for all new drug approvals include breakdown by gender, race, ethnicity and age.

The legislation and FDA's more recent **guidance** in 2016 were much-needed breakthroughs, but not a cure.

Today, the NIH review process treats inclusion of women and minority subjects as an indicator of a proposal's scientific merit, and NIH staff tracks these metrics for consideration in making grant awards.

FDA has launched an Office of Women's Health Research focused on advancing the science of women's health. FDA also operates an Office of Minority Health charged with increasing data available on racial and ethnic minorities, where significant disparities exist in clinical trial representation -- especially among minority women.

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Scott Gottlieb, FDA

Cardiovascular disease is the top killer of American women; risk factors, symptoms and prognoses are often different compared with men. Yet a cardiovascular study published this **April** found women to be under-represented in clinical trials for new heart medicines.

The study examined women's enrollment in FDA clinical studies for 36 cardiovascular disease drugs from 2005 to 2015. On average, 46% of individuals enrolled were women. But prevalence-to-population ratios found women to be under-represented (<0.08) in trials for new drugs to treat coronary artery disease (0.6), acute coronary syndrome/myocardial infarction (0.6) and heart failure (0.5 to 0.06).

These findings led FDA Commissioner Scott Gottlieb to declare in a May **speech** that “we still have more work to do.” He issued a call to action for clinical investigators to discern why women were under-represented in so many cardiovascular trials.

“We need to identify and correct the factors that lead to the screening of fewer women,” Gottlieb said.

Under-representation in clinical trials could lead to the approval of new treatments that are less effective in women than men or less effective among ethnic minorities than in whites.

Last year, BIO ratified a set of **diversity principles** to better foster inclusion throughout the life sciences sector. BIO’s initiative is focused on helping companies achieve more diversified leadership structures.

Biopharmaceutical leadership teams should have firsthand expertise in the biological realities and cultural considerations of the different populations they serve. In fact, BIO’s first diversity principle states our belief that bioscience companies’ products and services should be intended to address the needs of a diverse population.

Drugmakers can take a number of steps to be part of the solution in achieving proportional representation in clinical trials. This includes supporting the FDA’s **Diverse Women in Clinical Trials initiative** and helping to disseminate a **tool kit** created to promote awareness of clinical trial opportunities for women. Companies can also participate in FDA **workshops and webinars** dedicated to the recruitment and retention of women for clinical studies.

Biotech companies also can seek out new partnerships with research institutes that specialize in women’s health. This summer, in my capacity as BIO CEO, I sat down with Nicole Oshurak, director of corporate partnerships at the Magee-Womens Research Institute and Foundation (MWRI).

The growing appetite of drug developers to partner with women’s health researchers is a real trend -- and, I believe, a harbinger of further strides to come.

With \$40 million in NIH grants last year, MWRI is the country’s largest research institute devoted exclusively to women’s health research. Its investigators conduct research studies with major institutions, universities and medical centers around the world. Now, the group is exploring industry partnerships beyond NIH funding with the hope of getting breakthroughs to more patients.

The institute participated in its first BIO International Convention in June, and Oshurak says she was flooded with requests for business meetings by potential industry partners. The growing appetite of drug developers to partner with women’s health researchers is a real trend -- and, I believe, a harbinger of further strides to come.

On Oct. 9-10, MWRI will hold the **Magee-Womens Research Summit** in Pittsburgh. The conference will unveil the winner of the \$1 million Magee Prize award for scientific collaboration to advance women’s health.

One of MWRI’s most enduring contributions to medical research is its maintenance of the world’s largest maternal infant database containing information from more than 200,000 births spanning two decades. That project is part of its 9-90 research, which focuses on how human life in the womb for the first nine months can predict and change the course of a person’s health over the next 90 years.

Another key organization driving change in this area is Society for Women’s Health Research. The group hosts interdisciplinary networks committed to filling in knowledge gaps about how certain conditions impact women differently, such as migraines; Alzheimer’s disease; sleep disorders; breast cancer; and metabolic, urological and musculoskeletal conditions. The organization also has launched the Organization for the Study of Sex Differences, a scientific society dedicated to promoting research on how sex and gender differences impact disease treatment.

Women are 51% of the world’s population, and they carry to term 100 % of our collective future. All of us stand to benefit significantly from medical research better calibrated to reflect this reality.

Jim Greenwood represented Pennsylvania’s 8th district in the U.S. House of Representatives from 1993 to 2005. He has served as BIO President and CEO for the last 13 years.

COMPANIES AND INSTITUTIONS MENTIONED

Biotechnology Innovation Organization (BIO), Washington, D.C.
Magee-Womens Research Institute and Foundation (MWRI), Pittsburgh, Pa.
National Institutes of Health (NIH), Bethesda, Md.
Organization for the Study of Sex Differences (OSSD), Baltimore, Md.
Society for Women’s Health Research (SWHR), Washington, D.C.
U.S. Food and Drug Administration (FDA), Silver Spring, Md.