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We're Not All White Men

A letter from David A. Brenner, MD, President and CEO of Sanford Burnham Prebys

The history of biomedical research has largely been the history of white men, who have disproportionately been both the drivers of science and the subject of their own studies. White males were presumed to be the human norm; everyone else was an extrapolation.

Of course, such thinking ignored or was ignorant of the fact that many diseases and treatments are either unique or more common to women and minorities. Also, many diseases have different manifestations or responses to therapy in women and minorities than in white men. This lack of diversity in thought and practice was born of many motivations, from bad science to outright racism to misguided notions of chivalry.

In 1977, for example, the U.S. Food and Drug Administration (FDA) issued guidelines to exclude women of child-bearing years from participating in early phase clinical research, except for life-threatening conditions. The guidance was intended to prevent potential harm to the fetus or to a woman's child-bearing future, but it was broadly applied and essentially excluded most women of childbearing age from medical research.

It would be several years before public and private efforts would start to rectify the patriarchal practice, perhaps most dramatically with the creation of the Women's Health Initiative (WHI) in 1991, which began with three clinical studies funded by the National Institutes of Health at the direction of its first female director Bernadine Healy, MD. These trials would investigate cardiovascular disease, cancer and osteoporosis in more than 160,000 postmenopausal women ages 50-79.

The WHI trials were profoundly influential, leading to discoveries like breast cancer rates could be decreased by reduced use of hormone replacement therapy and that hormone replacement therapy did not prevent heart disease. The trials helped save roughly $35 billion in direct medical costs over 15 years, and the scope of the WHI was expanded to include research involving younger women, whose health status and issues are different.

In 1993, the FDA finally reversed its 1977 guidance and Congress passed a law requiring women be included in NIH-sponsored clinical trials. In 2001, the Institute of Medicine issued a report confirming that males and females differ in both physiological and chemical ways.

“Every cell has a sex,” the report’s authors stated. Scientists need to take these differences into account.

As many, many studies have since shown, gender does play a role in numerous diseases and disease-related factors, such the incidence and severity of heart disease, obesity, rheumatoid arthritis, multiple sclerosis and other illnesses. Women's menstrual cycles can cause them to respond differently to drug treatments.

It’s obvious why only men experience prostate cancer and only women get ovarian cancer. It’s not obvious why women are more likely than men to recover language ability after a stroke or why women are at greater risk than men for autoimmune diseases like lupus. The explanation for why women tend to live longer than men, regardless of where they live, how much many they make and many other factors, is woefully incomplete.

So it made absolutely no sense late last month when the Trump Administration indicated that it would be gutting the Women’s Health Initiative, canceling funding to continue monitoring the lives of the original WHI cohort, now in their 80s and 90s, and ongoing research and trials for diseases like cancer and dementia that have enrolled 42,000 women.

The resulting outrage compelled the Trump Administration to promise WHI funding would be fully restored, though WHI investigators have reported that, as of April 25, they had not received official confirmation of restoration from the NIH.

Hopefully, the WHI can return to its work, fully funded. Other groups long ignored or underrepresented in biomedical research will not be so fortunate. Trump’s assault on science — and particular demographic groups — continues unabated. The NIH has terminated more than 800 grants. Nearly one-third of the terminations have been for research that mentioned HIV/AIDS, which disproportionately affects sexual and gender minorities (LGBT+) and one-quarter for studies related to the health of transgender people.

On his first day in office, President Trump issued an executive order declaring there were only two genders: male and female. Trump, who has a bachelor’s degree in economics, said he was restoring “biological truth.”

The NIH and other funding agencies have been ordered to comb through thousands of active research projects for key words like antiracist, historically, inequities, male dominated and underserved. These projects are at risk. At the Centers for Disease Control, website content containing terms like gender, transgender, pregnant person, pregnant people, LGBT, transsexual, nonbinary, assigned male at birth, biologically male, biologically female, he/she/they/them has been edited or removed.

No one yet knows the full implications and consequences of these actions, least of all the people enacting them. But they will be bad. There is no upside to slashing science and slowing, stopping, or reversing decades of progress.

The current crisis in research hurts everyone. The National Science Foundation, which funds basic science research across the spectrum, has been ordered to "stop awarding all funding actions until further notice" and to reject incoming research proposals deemed not "in alignment" with agency priorities. The NIH has scaled back its awards of new health science grants by at least $2.8 billion since the beginning of the year — a roughly 28 percent contraction with more funding cuts looming.

The pain and peril are everywhere, but they hurt first and hardest among those members of society who were just beginning to be embraced (imperfectly) by the rest of us. The history of biomedical research is checkered with racism, bias and myopia; its immediate future appears to be repeating the past.

Sincerely,

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