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Group of experts issues recommendations for NIH on diversity of sex in research

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A diverse group of experts from academia, industry and advocacy is offering recommendations to the National Institutes of Health (NIH) as the federal research institution works to increase the inclusion of female animal models and achieve a balance in the use of male and female cells and animals in preclinical studies. The recommendations, available online now, will be published in the May issue of *FASEB Journal*.

The Georgetown Consensus Conference Work Group, a gathering of basic science, medical and population health researchers, in addition to experts from publishing, industry, advocacy and policy, assembled at Georgetown University Medical Center in September 2014 to develop recommendations that would "aid the NIH as it selects, implements, monitors, and optimizes strategies to correct the over-reliance on male cells and animals in preclinical research," the authors write.

In May 2014, NIH Director Francis S. Collins, MD, PhD and Janine A. Clayton, MD, director of the NIH Office of Research on Women's Health, wrote in the journal Nature that preclinical research "overly relies on male cells and animals." The NIH announced it would address the problem by enacting policy changes. As part of the Fiscal 2015 appropriations legislation, Congress urged the NIH to move forward with these important changes.

The Georgetown Consensus Group says such policy changes are needed because over-reliance on males in research "obscures key sex differences that could guide clinical studies."

"Sex is a fundamental biological variable with profound consequences," the group writes. "Underrepresenting female cells and animals in preclinical research has resulted in a poorer understanding of the biological, physiological and pathophysiological mechanisms in the female compared to the male."

The group's four recommendations to the NIH include:

2) Implementing educational initiatives that would effect a culture evolution to ensure changes in policy are not superficial and "gamed" in practice;

3) Identifying exception criteria for not balancing the sexes in preclinical research; and

4) Targeting resources to develop new tools and supporting research that will efficiently reveal sex differences that are important to health outcomes.

The lead author of the recommendations, Kathryn Sandberg, PhD, says sex differences are evident down to the level of cell biochemistry and genes. "Men and women are not the same, but when they are treated that way, medicine suffers. The Food and Drug Administration has withdrawn several drugs from the market, and therapeutic doses have been changed, because of the after-market discovery of serious toxic side effects in women," she says.

Sandberg, director of Georgetown University Medical Center's Center for the Study of Sex Differences in Health, Aging and Disease, says one such example is the prescription sleep aid zolpidem, which was re-labeled after the drug was discovered to have more adverse side effects in women.

The Georgetown Consensus Group refers to the finding by the U.S. General Accounting Office, that 8 of 10 prescription drugs pulled from the U.S. market by the Food and Drug Administration "posed greater health risks for women than for men."

The group concludes, "The opportunities for drug discovery, new and improved therapeutics and regimens and medical devices arising from research on the impact of biological sex in physiology and pathophysiology are vast. We cannot afford to delay their discovery another day."

Sandberg reports report having no personal financial interests related to the commentary.

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