NATIONAL CENTER FOR HEALTH RESEARCH
The voice for prevention, treatment, and policy

1001 Connecticut Ave. NW, Suite 1100
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May 8, 2014

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

Dear Senator Warren,

The National Center for Health Research thanks you and your Senate colleagues for writing to Food and Drug Administration (FDA) Commissioner Margaret Hamburg urging her to improve the Action Plan required by Section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA). We agree with your recommendations that the Action Plan should require "clear and actionable strategies to improve the representation of women and minorities in clinical research, ensure that meaningful subgroup analyses are conducted" and that the data becomes publicly available and accessible.

As you noted in your letter, women are disproportionately affected by heart disease, Alzheimer's, and depression, yet treatments for these diseases were tested mainly on men. In our recent testimony at the FDASIA Section 907 hearing, we stated that it is imperative to have subgroup analyses because "naturally occurring genetic variations may influence the way certain drugs are metabolized and work in women compared to men, older patients compared to younger, and certain racial and ethnic groups." The lack of appropriate diversity in clinical trials submitted to the FDA is continuing this year. In the last three months, we testified at four FDA Advisory Committee meetings about the lack of subgroup analyses: for a drug to treat heart failure, two drugs to treat MRSA, and a device to treat sleep apnea. We pointed out, for example, that no African Americans were in the sleep apnea trial and African American patients comprised less than 5 percent of the cardiac drug trial and less than 6 percent for one of the MRSA drugs. For one of the MRSA drugs, elderly patients made up less than 14 percent of the clinical trial and no subgroup analyses were conducted on these patients or on women. MRSA is especially likely among the elderly, and African Americans are disproportionately harmed by sleep apnea, heart disease, and MRSA, so it is especially harmful to not analyze them in sufficient numbers to determine if these medical products are safe and effective for them. Unfortunately, the FDA recently approved the sleep apnea device even though it was tested on Whites only and women comprised only 17 percent of patients in the trial.

Your letter also notes that these clinical trials that lack diversity are paid for and conducted by industry staff or consultants, not by the FDA. We agree that industry needs to do a better job. At the Section 907 hearing, we stated that it sits "on the shoulders of device and drug companies" to collect representative demographic subgroup data but "the FDA's crucial role is to hold companies accountable." In addition to the sleep apnea device mentioned above, we have repeatedly seen the FDA approve new drugs and devices despite an almost complete lack of diversity, such as clinical trials analyzing treatments for uterine fibroids that lacked African American women, even though African Americans have much more serious health problems from uterine fibroids. FDA recently approved a new indication for an HPV test for women under 30, although the studies included very few women under 30.

We pointed out in our testimony at the FDASIA Section 907 hearing that the FDA should also gather data on companies that are achieving greater and lesser diversity in their clinical trials submitted to the FDA, and the agency should share best practices with companies that need to improve.

As your letter noted, the National Institutes of Health has included women and minorities in clinical trials for two decades. Unfortunately, the FDA was not included in that law because the clinical trials submitted to the FDA are paid for by industry, not taxpayers. We strongly disagree with that justification, since those companies are asking for approval for drugs and devices that will be paid for by federal programs such as Medicare, Medicaid, and the VA, as well as by American taxpayers directly or indirectly through health insurance, premiums, co-payments, and by those who are uninsured. It is the responsibility of the FDA to make sure those drugs and devices are safe and effective for all Americans, not just white men under 55. It is long past time that the FDA required that industry-sponsored clinical trials included and analyzed patients that represent the diversity of our country. Companies will do a better job of conducting research when the FDA stops approving medical products that have not been studied in diverse populations or where no subgroup analyses were conducted to test safety and effectiveness for women, the largest racial/ethnic groups, and the relevant age groups.

In summary, we are very grateful to you for expressing your concerns to Commissioner Hamburg. We look forward to working with you on this important issue, which will affect the health of millions of Americans.

Sincerely,

Diana Zuckerman, PhD
President