Closing the health care disparities gap for women and minorities

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A new action plan released by the Food and Drug Administration (FDA) to increase the participation of women, minorities, and the elderly in research trials was welcomed today by four leading health organizations as taking an important step toward closing the health care disparities gap. The groups called on the agency to implement the plan swiftly.

The American Heart Association, National Women's Health Network, Society for Women's Health Research, and WomenHeart: The National Coalition for Women with Heart Disease said the "FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data" will not only help boost representation of these population groups in clinical trials, but also will lead to more analyses on how medical drugs and devices affect women and men differently.

The groups particularly applaud the FDA for finalizing its guidance on the evaluation of sex-specific data in medical device studies and for establishing a steering committee and website to oversee and track progress on implementing the action plan. The groups, however, urged the FDA to do even more.

The FDA's Action Plan was required by the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law in July 2012. The act directed the FDA to review medical product applications to determine the extent to which data on how new drugs and devices affect certain subpopulations is being collected, evaluated and released publicly. By taking the actions outlined in the plan, the FDA

will emphasize the need to look for sex, race, ethnicity and age-based differences through medical research, allow subgroup-specific data to be more widely available for use in medical practice, and improve the participation of women and minorities in research trials.

"Guaranteeing greater diversity in research trials will help ensure that patients and their health care professionals have the most up-to-date information needed to make the best decisions about care and treatment," said the four organizations. "By carrying out the actions recommended by the FDA plan, we can advance our nation's efforts to achieve the high quality health care that women and minorities want and deserve."

While the organizations applauded the FDA's work to address the many issues they highlighted in testimony before the agency earlier this year, they called on the FDA to:

- Establish and clearly spell out for application sponsors the consequences of not collecting or analyzing subgroup data;
- Take action to address concerns related to the under-inclusion of women, minorities and the elderly in early phase trials; and
- More aggressively move forward with additional, standardized subgroup information in the labeling of medical products.

"Gender, race and age play a decisive role in how heart disease, stroke and other forms of cardiovascular disease affect us. Yet, these key populations are often left out of the research necessary to better understand the diverse impact of these diseases," said Nancy Brown, CEO of the American Heart Association. "That's why the FDA must not allow this new plan to just gather dust on a shelf. It's critical that these actions be carried out rapidly and aggressively, and we look forward to working with the FDA to implement this plan."

"Women and their health care providers need complete and accurate information about the medical products available to them, particularly the specific benefits a drug or device might offer and the risks it might pose to her because she is a woman," said Cynthia Pearson, executive director of the National Women's Health Network. "The current lack of information exposes women to harm that could be avoided by more inclusive requirements for clinical trials. While the FDA Action Plan is a step in the right direction, the agency must do more than remind and encourage industry to include women and minorities in trials and analyze the data. The FDA must require that companies do this to ensure that that the products women use are safe and effective for them."

"The Society for Women's Health Research is pleased that the FDA heard our call for the need to release demographic data and establish training for all reviewers to look for sex differences. One of SWHR's key priorities for more than 20 years has been making sure this data is appropriately analyzed and reported by the FDA," said Phyllis Greenberger, president and CEO of the Society for Women's Health Research. "Still, the Action Plan falls short in several important areas. The FDA should do more to prioritize finding out how medical products affect women and men differently and report that information to patients and health care providers, especially since there have been significant discoveries of sex differences from biomedical research in the last two decades."

"Women and their health care providers are tired of waiting for access to data demonstrating whether drugs and devices are safe and effective for their use. The FDA has studied this problem for decades, yet the problem has not been fixed," said Lisa M. Tate, CEO of WomenHeart: The National Coalition for Women with Heart Disease. "Implementation and enforcement of these recommendations would go a long way toward assuring that providers can recommend appropriate treatments for 51 percent of the U.S. population, including the 43 million women living

with or at risk for heart disease."

In the coming months, the organizations will submit additional comments and recommendations about the FDA Action Plan and work with the agency and Congress to address continuing areas of concern vital to the health of women, minorities and older Americans.

Provided by American Heart Association