Statement of Kate Ryan, Interim Program Director
Food and Drug Administration
Public Hearing on FDASIA Sec. 907:
Collection, Analysis, and Availability of Demographic Subgroup Data
April 1, 2014

The National Women's Health Network is a nonprofit advocacy organization that works to improve the health of all women. We bring the voices of women consumers to policy and regulatory decision-making bodies. We are supported by our members and do not take financial contributions from drug companies, medical device manufacturers, insurance companies, or any other entity with a financial stake in women's health decision-making.

The topic of today's public hearing – the inclusion of women and people of color in clinical trials and the availability and accessibility of the resulting evidence to these groups – touches on a central tenet of the Network's mission. Since its founding, the Network has advocated for women and their healthcare providers to receive complete and accurate information about the medical products available to them, particularly the specific benefits a drug or device might offer and risks it might pose to a woman because she is a woman.

For decades, health research was done on men and the results were assumed to apply to women – as though we were just smaller versions of a male body. Although women's health advocates have succeeded in exposing the inaccuracy of that assumption, far too many clinical trials still fail to include enough women to provide adequate information to support women in making informed health care decisions. Because women are less likely than men to be included in clinical trials, we often don't discover if a drug or device is unsafe or less effective for women until after it is on the market, as was the case with Ambien. But this not just about a single drug that exposed women to harm that could have been avoided: eight in ten drugs recalled from the market pose a greater health risk to women than to men. To address this pervasive problem, we partnered with other women's health advocates and Congressional leaders to encourage the establishment of more rigorous inclusion standards and requirements for research through the provision of FDASIA that we are talking about today.

We submitted extensive comments and recommendations in response to the agency's report on the collection, analysis and availability of demographic data that was mandated by FDASIA. The report provided important data, showing significant gaps and deficiencies in achieving adequate

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inclusion in trials, and we appreciate that the agency provided the public with that information. But we are very concerned that the report downplayed these gaps, instead highlighting atypical examples of overrepresentation. We speak today to strongly urge the agency to develop and implement an action plan that addresses the deficiencies revealed by the data and truly meets the needs of women and communities of color.

Specifically, we urge the FDA to address the lack of evidence on sex-specific effects of drugs and medical devices by ensuring that the action plan it develops includes the following requirements: 1) companies submitting trial data to the agency must not only include women and minorities in clinical trials but ensure there are enough in the trial to analyze a drug or device's safety and effectiveness data based on sex, race and ethnicity; 2) companies must evaluate the safety and effectiveness of drugs and devices based on sex, race and ethnicity and the FDA must reject applications that do not include the required information; 3) companies must include sex, race and ethnicity-specific safety and effectiveness information (or lack of information) on the labels of drugs and devices so that it is publicly available; and 4) the FDA must establish procedures to track and publicly report compliance with these requirements on a regular basis and take enforcement action against companies that do not comply.

The FDA has an important opportunity to improve public health by requiring companies to include adequate numbers of women and minorities in clinical trials, evaluate the evidence based on sex, race and ethnicity and make that information available to patients and consumers. Please take it!