The National Organization for Women strongly supports changes in Food and Drug Administration (FDA) regulations, guidance documents and decisions that affirm the position that the agency will not approve any medical product for all populations if the product has not been tested on major demographic subgroups, with detailed subgroup analyses. Because the United States has become more racially and ethnically diverse and a significant proportion of the population is aging, it is critical that companies be required to conduct clinical trials on subjects that are reflective of this nation’s diversity. Hispanics constituted 17 percent of U.S. population in 2012, with African Americans composing 13 percent and persons over 65 totaling 12 percent, with the current and soon-to-be retiring 77 million member “baby boom” generation totaling 25 percent of U.S. population.

The inadequate representation of women and of racial and ethnic communities as well as of older persons in clinical trials is clear from the 907 report. Variation in response to drugs and devices by sex, race, and age (especially children and adults over 55) has been documented. The FDA standard of safety and efficacy for all drugs and devices cannot be demonstrated for each major demographic group when clinical trials are conducted primarily on white males under the age of 55. The long-standing and current lack of diversity in clinical trials puts at risk the health of major segments of the population.

Because some companies have been reticent to invest in pre-market or post-market clinical trials on diverse populations, it is imperative that the FDA be firm in their directive in this area, and enforce the requirement for diversity and subgroup analyses. Regulations must unequivocally state that all applicants for FDA approval of devices, drugs and biologics provide data on safety and effectiveness by sex, age, race and major ethnic groups. Additionally, the demographic subgroups should be of sufficient size to separately analyze for safety and efficacy in both pre-market and post-market studies. Data on each subgroup should be reported consistently in order to maximize usefulness.

A draft guidance that was developed in 2011 for sex-specific analysis should be finalized; however, since FDA guidance is merely guidelines, not requirements, the question is: when will the FDA adhere to the guidelines in labeling if the agency is not willing to require companies to follow diversity
guidelines in order to obtain approval? Given that nearly 30 years have passed since it was first brought to public attention the paucity of women subjects in clinical trials, more rigorous requirements enforced by the FDA, are long overdue. NOW urges the clear and understandable presentation of the effects on demographic subgroups on all current labels, including information indicating that not enough data were collected on subgroups to analyze and draw conclusions about the potential safety or effectiveness for those groups. Approval should not be assumed for major subgroups that were not analyzed separately. It should be required that detailed label information on sex, race and ethnic subgroup analyses be presented in a standard format, with easy-to-find sections and easy-to-understand language for patients and their doctors.

We thank you for the opportunity to comment on this subject of great importance to women’s health and their use of drugs and devices that should be found to be safe and effective for their sex.