

January 23, 2015

The Honorable Margaret Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA--2014-N-1818, Comments on FDA Drug Trials Snapshots

Dear Dr. Hamburg:

Our organizations appreciate this opportunity to comment on the Food and Drug Administration's (FDA) Drug Trials Snapshots, an initiative to implement one of the steps in the "FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data," as required under Section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

Our organizations believe that data about how new therapies work in women, minorities, and older Americans must be available to the public in a more consumer-friendly manner, and the Drug Trials Snapshots are an important step in making this a reality. The information that FDA is now proposing to make available through the Snapshots has often previously been available only by searching through the voluminous review packages on the FDA's website. We applaud FDA for acknowledging the need for greater transparency and accessibility of this data.

Many of our groups have commented on the low rates of inclusion of women, people of color, and older adults in clinical trials and have been strong advocates for the FDA Action Plan to address this. Adequate representation of patient subgroups in clinical trials is critical to ensuring that products are safe and effective for all. We note that many of the six example Snapshots revealed that there were insufficient numbers of women, people of color, or older adults to allow for any meaningful subgroup analysis. We hope shining a spotlight on these deficiencies through the Snapshots will spur greater efforts by product sponsors, the FDA, and all stakeholders to correct these shortfalls.

While the Snapshots website is a positive step, we propose the following recommendations for making the Snapshots website as user-friendly as possible:

- **Make access to and use of this tool as easy as possible for consumers.** In general, we found the information included on the Snapshots website to be very helpful to patients, and the more technical information found by clicking on the "More Information" button at the bottom of each Snapshot will be helpful for healthcare professionals and researchers. However, FDA can help ensure that consumers can readily find this important information by featuring a link to the Snapshots webpage on the FDA homepage and other FDA web pages frequented by consumers. FDA could also develop widgets and badges that organizations such as ours could add to our websites to help promote the availability of this information. In addition, in order to make it easier for consumers to report adverse event information about a drug or biologic, we suggest including at the bottom of each drug's Snapshot a direct link to the FDA's MedWatch website.

Disparities in sex, age or race subgroups for either the safety or the efficacy of a drug need to be consistently and clearly noted in the Snapshot and preferably in the product label. Similarly, when there are insufficient data to conduct appropriate analyses for subgroup differences in safety or efficacy, this should be stated in the Snapshot, as well as on the label. We also urge FDA to put the participation information into context, relative to disease prevalence, so that patients and clinicians can accurately assess whether a particular subgroup was appropriately represented.

- **Include clinical trial data related to the intersection of age, race, and sex.** We strongly encourage the FDA to provide efficacy, effectiveness, and safety information related to the intersection of sex, age, race, ethnicity, and the intersection of these subgroups for each drug and biologic listed on the Drug Trials Snapshots. The influence of age, gender, race, ethnicity, and especially the intersection of these characteristics on a body's response to medical products can be profound. Consumers assessing the benefits and risks of a particular therapy across multiple subgroup variables could use more complete data demonstrating the varied safety and effectiveness of medical products due to critical demographic subgroup distinctions.
- **Expand the Snapshots effort to make information available for more drugs and biologics, as well as for devices.** While FDA is proposing to make Snapshots available for drugs and biologics as they are approved going forward, we urge you to also make Snapshots available for products that are already on the market, to the maximum extent feasible. We also recommend that you include information from early phase studies for these products. Finally, it is important for FDA to also make similar Snapshots available for medical devices, not just drugs and biologics.
- **Make the content available in multiple languages to ensure non-English speakers can access the information.** Translating the website content into Spanish should be the first priority. Research shows the number of Spanish speaking peoples continues to rise each year and in 2013, almost 13 percent of the US population reported speaking Spanish at home. Though translating the content into Spanish should be considered the top priority, we also urge you to make the content available in as many additional languages as possible.

In closing, we appreciate the FDA's work in developing the Snapshots, and we hope you will adopt our recommendations as you finalize the Drug Trials Snapshots website and move forward with additional Snapshots. Thank you for your consideration of our comments.

Sincerely,
ActivistsAgainstAlzheimer's
African American Network Against Alzheimer's
AIDS Alliance for Women, Infants, Children, Youth & Families
Alliance for a Just Society
American Association of Birth Centers
American Association of Colleges of Pharmacy
American Association on Health and Disability
American College of Cardiology
American Heart Association/American Stroke Association
American Sexual Health Association
Asian Women for Health
Association of Asian Pacific Community Health Organizations

Association of Women's Health, Obstetric & Neonatal Nurses
Breast Cancer Action
ClergyAgainstAlzheimer's
Coalition for Asian American Children & Families
Commission on the Public's Health System
Concilio Latino de Salud, Inc.
Epilepsy Foundation
Feminist Scholars Policy Forum
Immigrant Service Providers Group/Health
LatinosAgainstAlzheimer's
Light House Vision
Lung Cancer Alliance
Maryland Women's Coalition for Health Care Reform
NAACP
National Asian American Pacific Islander Mental Health Association
National Hispanic Medical Association
National Rural Health Association
National Tongan American Society
National Viral Hepatitis Roundtable
National Women's Health Network
Reproductive Justice Collective
ResearchersAgainstAlzheimer's
SCAI - The Society for Cardiovascular Angiography and Interventions
Society for Women's Health Research
Summit Health Institute for Research and Education, Inc.
USAgainstAlzheimer's
WomenAgainstAlzheimer's
WomenHeart: The National Coalition for Women with Heart Disease
Women's Heart Alliance
Women's Research & Education Institute (WREI)