April 29, 2016
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Food and Drug Administration, Division of Dockets Management (HFA-305):
RE: Docket No. FDA-2015-N-4952 for “FDASIA 907 Public Meeting: Progress on Enhancing the Collection, Analysis, and Availability of Demographic Subgroup Data; Request for Comments”

To Whom It May Concern:

The National Association of Social Workers (NASW) provides comments regarding the public meeting: Progress on Enhancing the Collection, Analysis, and Availability of Demographic Subgroup Data.

The NASW supports the FDA’s efforts to increase diversity in clinical trials. The NASW represents 130,000 social workers, many of whom interact each day with underserved individuals facing comorbid health conditions. The NASW believes that it is of utmost importance that the FDA convey clear standards for the inclusion of racial and ethnic minority groups in clinical trials and the analysis of clinical trial data by subgroups. The United States is becoming increasingly diverse and current research practices are insufficient to adequately determine effective treatments for a population facing varied genetic, environmental and socio-economic factors that influence health outcomes. Social workers, community partners, and other trusted professionals can support efforts to recruit and maintain participants in clinical trials.

The NASW Recommends:
- Mandate a standard level of participation for subgroups that have high prevalence of the disease or condition being studied.
- Require structured, dis-aggregated data collection regarding age, sex, race, ethnicity, gender identity, and sexual orientation and require the analysis of clinical data by subgroup.
- Engage community stakeholders and trusted community partners to help facilitate communication, as well as targeted outreach, regarding the research process and expectations to prospective participants--particularly ethnic minority populations and women.
- Communicate and provide specific assurances and safeguards against the exploitation of African Americans, communities of color, and inmates, as experienced in the infamous Tuskegee Syphilis Experiments, the legacy of which may contribute to mistrust of the researchers.
- Expand outreach efforts to providers, such as social workers, in social services and health care to assist with recruitment and support participation.
- Demonstrate the health benefits and related value of volunteer participation through the following approaches:
  - Clearly convey the purpose of study processes (i.e. demographic data collection),
  - Keep participants informed at each phase of the study,
  - Provide convenient hours and easily accessible locations,
  - Offer adequate cash compensation and similar incentives for participating in clinical trials,
  - Inform participants of the results of clinical trials and the ways in which the findings can benefit community members and population at large.
Prioritize informing the public of findings in a manner that is clear and accessible, consistent with the Drug Trial Snapshots initiative.

- Continue to train researchers on FDA standards and best practices for engaging underrepresented subgroups.

The NASW supports the FDA in its effort to diversify participation in clinical trials, strive to develop the most effective interventions for diseases and conditions facing our communities, and work toward eliminating health disparities.

Thank you for your consideration,

Sincerely,

[Signature]

Heidi McIntosh
Deputy Director, Programs