Dear Acting Commissioner Sharpless:

For over 25 years, Congress has repeatedly directed NIH and FDA to adopt initiatives to increase clinical trial diversity. Most recently, the 2012 FDA Safety and Innovation Act (FDASIA) included Congressional mandates for a report and action plan “addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity is included in applications to FDA.”

The resulting report under the 2012 FDASIA found continuing underrepresentation in clinical trials. For example, 13% of African Americans have Type 2 diabetes, but are less than 5% of participants in relevant clinical studies. Hispanic data could not even be analyzed; either it was not collected or not reported. Previous analyses have estimated Hispanics at less than 8% of clinical trial participants, despite being 18% of the overall population. In the area of Genome Wide Association Studies (GWAS), a review of 2016 data found that Hispanics were less than 1% of participants, a significant concern given the importance of GWAS to the future of personalized medicine and the development of new treatments and cures.

Given a lack of meaningful improvement, following the 2012 FDASIA requirements, Congress included in the FDA Reauthorization Act of 2017 a mandate for a public meeting and report on clinical trial diversity. The National Alliance for Hispanic Health is pleased to provide the following comments on the proposed FDA guidance (84 FR 26687), Enhancing the Diversity of Clinical Trial Populations, resulting from the FDA Reauthorization Act of 2017 mandate.

- **Inclusive Trial Practices.** Rather than only reference, FDA should require all clinical trial sponsors to develop and implement a community-based participatory research (CBPR) plan. Requiring a CBPR plan would be particularly impactful because it should stimulate sponsors to adopt many of the FDA’s other recommendations. Furthermore, elements of CBPR including co-development of study designs with affected communities, use of trusted community agencies, and adequate funding of community partners should be emphasized.

- **Trial Design.** The FDA should mandate that sponsors present trial designs that produce findings overall as well as by race, ethnicity, and gender. Any trial sponsor not meeting such inclusion standards should be mandated to submit an exclusion request. Such exclusions should by rare, not the norm, and only granted in cases where the product will not be approved for nor marketed to specific population groups (e.g. a product intended for use...
only by women could exclude men in the trial design). To support transparency, a link to the case for exclusion by the sponsor and the FDA rationale for granting the exclusion should be made publicly available on clinicaltrials.gov and in Drug Trials Snapshots. Furthermore, a notice to providers should be made upon any drug approval of the populations for which specific population findings were not produced in the clinical trial.

- **Other Design and Conduct Considerations.** For any products studied and approved on a non-representative population, FDA should require phase 4 studies demonstrating results in heterogenous populations. Furthermore, FDA now requires every review division to document their patient interactions related to a product’s pending NDA or BLA approval. To this FDA should add a requirement for documentation of efforts to enroll diverse populations and how the review division determined that the product would be safe/effective for use in populations not adequately represented in the trial.

Narrow, homogeneous trials are not good science and they do not serve our public and personal health needs. Our nation’s investment in biomedical research has been of enormous benefit in developing clinical knowledge that can contribute to treatments and cure. Clinical trial diversity is a largely missing element and we look forward to adoption of policies by the FDA, as outlined above, that will ensure that the clinical trial enterprise truly benefits all.

If the Alliance can provide any additional information, please feel free to contact me or Adolph P. Falcón, Executive Vice President, at afalcon@healthyamericas.org or 202-797-4341. Thank you for your consideration of these comments.

Sincerely,

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President and CEO
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