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ONE HUNDRED EIGHTEENTH CONGRESS
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February 20, 2024

The Honorable Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write today to express concern that the Food and Drug Administration (FDA) has failed to meet a key deadline to advance our shared goal of enhancing clinical trial diversity, and to urge the agency to take immediate action.

Ensuring that medical products are safe and effective for all populations intended to benefit from them hinges on their clinical testing in diverse populations. Inclusive clinical trial enrollment practices can also increase patients' confidence in effective new treatments.[1] Yet, despite FDA's current recommendations on how to operationalize diversity plans, historically marginalized populations, such as certain racial and ethnic groups and women, are still underrepresented in many clinical trials.[2] In fact, at least one report shows that inclusion of Black patients in clinical trials *declined* over the last decade.[3]

For these reasons, Congress enacted landmark requirements in the Food and Drug Omnibus Reform Act of 2022 (FDORA) for drug and medical device sponsors to submit diversity action plans to FDA ahead of pivotal clinical trials.[4] To provide sponsors with clarity on the format and content of diversity action plans, FDORA required FDA to publish draft guidance no later than December 29, 2023.[5] Yet so far, this guidance has not been made available, which is delaying further implementation of the law. Without FDA first publishing the

[1] Aaron L. Schwartz, *Why Diverse Clinical Trial Participation Matters,* The New England Journal of Medicine (April 6, 2023).

[2] *Id.*

[3] IQVIA, *Global Trends in R&D 2023,* (Feb. 2023).

[4] Pub. L. No. 117-328 (2022).

[5] *Id.*

draft guidance, sponsors will have difficulty preparing to carry out these diversity action plans. This draft is also the first step that must occur before the agency can enforce FDORA's diversity action plan requirement, which only goes into effect 180 days after guidance is finalized. Thus, the failure to meet this critical deadline delays the implementation of important efforts to improve diversity in clinical trials.

We recognize and applaud your stated commitment to promoting diversity of clinical trial participants, as well as the work FDA has done to facilitate recruitment and inclusion of underrepresented populations. This has included publishing nonbinding recommendations on clinical trial diversity planning and holding a public workshop this past November to solicit input on increasing the enrollment of historically underrepresented populations. However, as you know, much more work needs to be done. We urge you to prioritize FDORA's statutory requirements so patients can see the benefit of representative clinical trials as soon as possible.

Thank you for your commitment to working with us in this area. We look forward to receiving an update on the publication of this guidance.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Anna G. Eshoo
Ranking Member
Subcommittee on Health

Kathy Castor
Ranking Member
Subcommittee on Oversight
and Investigations