



May 17, 2022

The Honorable Frank Pallone
Chairman, House Committee on Energy and
Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member, House Committee on
Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Rogers:

On behalf of the Digital Health for Equitable Health (DHEH) Alliance, I am writing to support the clinical trial diversity provisions contained within the recently published draft version of legislation reauthorizing the user fee programs for various product types.

The DHEH Alliance (www.dhehalliance.org) was established to uniquely bring together multi-sector stakeholders, leaders, and advocates to promote a more digitally inclusive and accessible society that transforms health delivery for underserved populations. Our members include life sciences companies, community-based groups, Historically Black Colleges and Universities, and other organizations. The DHEH Alliance supports policies and initiatives that provide increased access to digital health technologies in underserved populations in an effort to mitigate or remove existing barriers to high-quality healthcare.

Our goal is to reduce health care disparities in underserved populations by increasing and improving access to care using digital health technologies. The COVID-19 pandemic has shown us that COVID-19 mortality and other social health determinants and outcomes have inequitably impacted specific communities. We believe that the increased expansion and use of digital technology in healthcare provides many opportunities to reach these underserved communities to reduce health disparities.

Toward that end, we support the legislation's provisions that promote diversity in clinical trials and advocate for diversity in clinical trials that evaluate digital health technologies. Clinical trial diversity is imperative for health equity. Enhancing the meaningful representation of diverse participants in clinical trials would help provide information and generate data about populations that have been historically underrepresented and understudied. Additionally, diversity in clinical trials of digital technologies will help prevent further expansion of the already existing digital health divide and will ensure the usefulness and utilization of these new technologies for all people. These provisions promise to improve access of products during trials and after such products are cleared or approved for marketing. Specifically, we were pleased to see language that:

- Requires drug and device sponsors to submit a “diversity action plan” that includes the sponsor’s goals for enrollment in the clinical trial or trials involved and an explanation for how the sponsor intends to meet such goals;



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- Requires development and issuance of a relevant FDA guidance and subsequent evaluation of whether more statutory or regulatory action is needed; and
- Requires FDA to work with manufacturers, patients, and other stakeholders to convene at least one public meeting to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical trials.

By increasing the diversity of clinical trial populations, these provisions will go a long way toward promoting the use of innovative digital technologies that provide a promising channel to overcome health inequities. With the surge in the development of digital healthcare technologies, ensuring meaningful access for all populations is essential.

Given the disparities in healthcare across our society, further exacerbated by the COVID-19 pandemic, Congress must enact provisions such as these. Please let me know if there's anything the DHEH or its members can do to support these efforts. If you have any questions about DHEH, please contact Michael Werner at michael.werner@hklaw.com or me. Thank you for your leadership and consideration of our views on such critical issues.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Werner".

On behalf of the Digital Health for Equitable Health Alliance