Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 2085

RE: Docket No. FDA-2021-D-0789

September 24, 2024

Dear Commissioner Robert Califf,

On behalf of the Continuing Medical Education (CME) Coalition, I am pleased to comment on the recently issued draft guidance from the Food and Drug Administration (FDA) regarding diversity action plans (DAPs) to improve enrollment of participants from underrepresented populations in clinical studies.

Founded in 2011, the CME Coalition represents a collection of CME stakeholders throughout the United States in addition to other supporters of CME. Our member organizations manage and support the development of healthcare continuing education programs that impact more than 500,000 physicians, nurses, pharmacists, and advanced practice providers annually.

Graduation from medical, nursing, or pharmacy school and completion of residency training are the first steps in a career-long educational process for health care professionals. To take advantage of the growing array of diagnostic and treatment options, health care professionals must continually update their technical knowledge and practice skills to stay abreast of the rapid pace of scientific discovery and innovation. CME is a trusted mainstay for such learning, holding a vital role in the delivery of innovative health care to patients. Recognized as an essential part of continued professional development for health care professionals, most state licensing authorities require the completion of a certain number of hours of accredited CME within prescribed timeframes to maintain medical licenses.

Because of the direct engagement CME providers have with health care providers, the CME Coalition commends the FDA's recently updated guidance on DAPs and the agency's continuous commitment to increasing diversity in clinical trials. We believe that greater inclusion of underrepresented populations is crucial to improving the generalizability and relevance of clinical trial outcomes, ultimately leading to better healthcare for all individuals. By ensuring that clinical trials reflect the

diversity of the population, the FDA is taking a significant step toward reducing health disparities and enhancing the safety and efficacy of medical products for all patients.

To effectively implement DAPs and promote health equity, we urge the FDA to recognize CME as a key component of its strategy to implement DAPs. CME providers already engage directly with health care providers and clinician learners, and as such, these organizations are uniquely positioned to assist with implementing DAPs and promoting health equity. This collaboration can leverage the strengths of both entities to educate health care professionals, engage communities, and ensure diverse participation in clinical trials — ultimately improving outcomes across the health care space. To promote this collaboration, we have outlined several strategies for the FDA to take into consideration:

I. Developing Comprehensive Educational Programs

CME providers are uniquely positioned to create educational programs for health care professionals that foster cultural humility and enhance their understanding of the significant impact that diversity, equity, and inclusion education can have on real-world clinical interactions. In collaboration with the FDA, these programs should seek to train health care professionals in effective communication and recruitment strategies tailored for diverse populations that account for race and ethnicity, socioeconomic status, LGBTQIA+ identities, and other historically marginalized groups. Additionally, CME providers can develop content that includes culturally tailored materials that are not only translated into multiple languages, but transcreated to ensure that health care professionals are equipped to engage with all communities and cultures.

These programs should also include modules on partnering with the community. CME providers can collaborate with the FDA to create training that empowers health care professionals to build trust within communities, leverage local resources, and actively involve community members in the clinical trial process. These efforts are vital for ensuring diverse representation and participation.

II. Involving Diverse Health Care Providers

Additionally, the FDA should partner with CME providers, who are uniquely positioned to both identify and engage health care providers representing diverse backgrounds, perspectives, experiences, and patient populations, across a variety of disease states, to develop training that highlights the importance of recruiting diverse investigators and staff to increase diversity among clinical trial sponsors. These programs can offer best practices for identifying and supporting health care providers from various backgrounds, fostering inclusive research environments.

Health care providers serving underrepresented populations play a significant role in improving trial diversity. As such, special attention should be given to these professionals to equip them with the knowledge and skills needed to conduct inclusive clinical trials. CME can play a pivotal role in preparing these professionals to meet the FDA's diversity goals, and the content of these educational programs can emphasize the pivotal role of healthcare providers who serve underserved communities — highlighting their contributions and reducing barriers to trial participation.

III. Providing Educational Tools and Resources

To further promote trial diversity, the FDA and CME providers, can collaborate on developing culturally appropriate materials — such as multilingual brochures, videos, and interactive learning tools — that address the unique concerns and misconceptions surrounding clinical trial participation especially in underserved communities. These materials could also feature immersive, scenario-based modules that reflect real-world experiences of diverse patient populations. This will allow healthcare professionals to engage with patients with cultural humility with the goal of overcoming common barriers to clinical trial participation. By empowering healthcare professionals with these tools, we can foster greater trust, inclusivity, and engagement in clinical trials across all populations.

IV. Establishing Continuous Feedback Mechanisms

Continuous improvement is critical to the long-term success of DAPs. The FDA, in collaboration with CME/CE providers, should establish robust feedback mechanisms that enable regular updates and revisions to educational content. These updates should be informed by real-time input from both healthcare professionals and trial participants, ensuring that the material remains relevant, effective, and responsive to the evolving needs of diverse populations. Furthermore, workshops, conferences, and forums can be organized to share best practices, discuss challenges, and celebrate successes in promoting diversity in clinical trials. This will foster a community of learning and innovation committed to enhancing diversity in clinical trials.

Conclusion

Collaboration between the FDA and CME providers is vital for the successful implementation of Diversity Action Plans in clinical trials. By jointly developing comprehensive educational programs, engaging diverse healthcare providers, creating culturally appropriate resources, and establishing continuous feedback loops, we can ensure that healthcare professionals are well-prepared to engage diverse populations effectively. This partnership will pave the way for more inclusive clinical trials, improved health outcomes, and reduced health disparities.

Sincerely,

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