



January 5, 2023

Dockets Management Staff
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2008-D-0053

To Whom It May Concern:

I am writing on behalf of the [Continuing Medical Education \(CME\) Coalition](#) to provide comments on the recently issued draft guidance from the U.S. Food and Drug Administration (FDA) regarding communications from firms to health care providers about scientific information on unapproved uses of approved medical products. We appreciate this opportunity to share our perspective.

Founded in 2011, the CME Coalition represents a collection of CME stakeholders from throughout the United States, in addition to other supporters of CME. Our member organizations manage and support the development of health care related continuing education programs that impact more than 500,000 physicians, nurses, and pharmacists 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 American 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.

Today, a portion of this education is underwritten via independent grants from life sciences companies that recognize the societal value in broadening awareness of disease states, standards of care, and new therapies. Accredited Continuing Medical Education (CME/CE)

providers, including many who are members of the CME Coalition, ensure that their educational programs meet rigorous standards, are free from bias, and provide accurate and impartial information. This provides healthcare professionals, as individuals and teams, with a protected space to learn, teach, and engage in scientific discourse in an effort to enhance their knowledge, skills and competencies. In a rapidly evolving field such as medicine, unbiased education through accredited CME/CE represents a cornerstone for maintaining the highest standards of patient care and health care professionalism. But accredited CME is not the only means through which health care professionals or “learners” gain important knowledge regarding the practice of medicine. Indeed, other avenues, including “company-led” education (CLE), have an important role to play as well.

That said, we believe that in every circumstance in which a learner is presented with information, it should be done so in a manner that is fully transparent so that the learner understands the context and source of the content. We believe it is especially important that learners be provided with enough context that they are equipped to understand and recognize the difference between accredited education that is commercially supported, yet fully independent, fair-and-balanced, and free from any and all company influence, vs. education that is company-led and influenced by their commercial supporter(s).

Given the growing availability of CLE, we wish to emphasize the importance of supporting learners in distinguishing between independent CME that is eligible for accreditation credits and CLE. While we believe that there is an important role to play for CLE, we agree with your draft guidance statement that “truthful, non-misleading, factual, and unbiased” communications to health care professionals are critical.

To further these ends, **the CME Coalition supports the recommendation in the SIUU Guidance for Firm Generated Presentation disclosures recommended in Q2 of the guidance that companies “should clearly disclose what portions of the communication are firm generated” and your example “This presentation was developed by FIRM X.”**

In addition, we recommend the inclusion of a requirement for any other company-led education activity to prominently disclose the extent of the company’s involvement, ensuring transparency and enhanced awareness for all learners. While we believe each company should be allowed to craft its own disclosure language, our members have suggested the following language options as potential examples for this type of proposed disclosure:

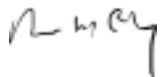
- *Option 1: This activity, which does not offer CE/CPD credit, was developed with financial support and direction from XX Pharma company, which was involved in ... [example:*

faculty selection, content planning, content development, medical accuracy review, and/or distribution.]

- *Option 2: This activity, which does not offer CE/CPD credit, was developed with financial support by XX Pharma company, which had no involvement in faculty selection, content planning, development, or distribution, but received a benefit(s) as a result of sponsoring this activity.*
- *Option 3: This activity was directly developed by XX Pharma Company and while focused on disease-state, it is not independent and does not offer CE/CPD credit.*
 - *Or: This educational content was (and/or these educational resources were) created by XXX Pharma Company.*

Current FDA guidance on Industry-Supported Scientific and Educational Activities ([92N-0434](#)) shares the FDA's recognition of the critical role played by accreditation organizations. It also demonstrates the FDA's commitment to working alongside such organizations in their efforts to ensure industry-sponsored education that is independent and nonpromotional. In alignment with this commitment, we believe this proposed disclosure approach would help to ensure that FDA guidance reflects and safeguards the value of accreditation while allowing for non-independent CLE to serve learners with full transparency.

We thank you for your consideration of our comments on this important issue.



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