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FREELANCE FOCUS

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Q1: How do continuing medical education/continuing education (CME/CE) medical writers balance the need for accurate scientific representation with the pressure to create content that aligns with pharmaceutical industry interests?

You'd think there was no need to even ask this question. But you'd be wrong. I once worked on a CME/CE project in which a supporter complained that faculty didn't give sufficient attention to the supporter's therapy in a live pre-conference education session. Subsequently, the education provider asked me to include additional material about the supporters' product in the downloadable slide deck "to keep the supporter happy." This behavior flouts a fair and balanced approach to content, threatens content integrity, and damages the regulatory firewall.

Accredited CME/CE content must be independent of any third-party influence or commercial interest. Standards and mechanisms have evolved in the United States to regulate the planning and delivery of CME/CE content and establish a firewall between commercial interests and education content. These standards and mechanisms are different in other parts of the world. In the United States, the Accreditation Council for Continuing Medical Education's (ACCME) 2020 Standards for Integrity and Independence in Accredited Continuing Medical Education specify the types of organization that can provide education, the types of content that they can create, and the criteria for creation. At a minimum, accredited CME/CE content must be evidence-based and adopt a fair and balanced approach to describing and evaluating relevant therapeutic interventions within a recognized standard of care for a given condition or disease. To this end, ACCME requires that education sponsors (often, but not exclusively, pharmaceutical manufacturers) have no role in determining content, editing, or providing materials to support the content.

Medical writers are instrumental in developing content for the purpose of educating health professionals on how to provide care for and treat patients. As such, we are *de facto* bricks in the regulatory firewall. It's our job to ensure that content meets the requirements of accreditation, so we need to be meticulous in the sources we review and use to create that content. We also need to be aware of the mechanisms in place to protect content integrity and prevent commercial influence. These mechanisms include financial and conflict of interest disclosures as well as independent and thorough content review processes. For the most part, these mechanisms are sufficient to maintain the firewall.

However, writers need to be aware that when pharmaceutical manufacturers issue requests for proposals to design and deliver education programs or activities, they have internal objectives that they expect such education to meet. The business and sales managers within education provider organizations know this. Their role in securing funding via the grant development process involves a delicate dance to ensure that content remains firmly within the 2020 ACCME Standards framework, yet also implicitly appeals to supporter interests. At times, they might zealously communicate these interests to writers. This is a form of tacit pressure. Similarly, when needs assessments are narrowly focused on a specific therapy compared with objectively identifying clinical and professional practice gaps, content is already skewed toward sponsor interests. Writing extensively about clinical trial data for one particular therapy is a common way that content gets skewed.

As writers, we are bricks in the firewall between industry and education, charged with maintaining content independence and integrity. We can do this by raising our awareness of areas in which tacit pressure can creep into the content development process and by pushing back on any potential to breach the firewall.

—Alex Howson

It is not unusual for a pharma/biotech client to try to "spin the data" in a Continuing Medical Education (CME) or other educational article so that a favorable light shines on their own drugs or therapeutic agents. The Accreditation Council for Continuing Medical Education (ACCME) has published guidelines/rules for CME material to qualify for accreditation and, presumably, most CME providers do try to adhere to these guidelines. You can access these guidelines easily

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via Google search. Nonetheless, some companies and/or their agencies will try to slither in a little bias toward a company product—this is not very difficult if the writer/author is clever.

Whether you are involved in *accredited* CME, Continuing Education (CE) for pharmacists, nurses, or *nonaccredited* educational material sponsored by a pharma/biotech company, the ethics remain the same, even if specific "rules" have not been published. Members of AMWA, as professional medical writers, are ethically obligated to pay attention to guidelines about content, sources, references, authorship, contributions, and acknowledgements.

How to balance the needs vis à vis pressure from clients? First, we must speak freely and openly with clients to let them know when the ethical lines are starting to be crossed. Second, if we are going to be asked to spin toward the positive—or even hide data, perish the thought—it is essential that we address this in fair balance with other similar and likely competitive therapies by including appropriate information about the other products as well.

If you do not have the moral integrity, or the professional confidence, to speak openly with your client about such things, probably you should not be a medical writer in pharma/biotech. These messages can be delivered quite diplomatically, no need for friction or hard feelings. We simply explain the rules, regulations, and guidelines around ethics in medical communication. Please note: if your client refuses to adhere to ethical standards and insists on the spin, I suggest you tacitly drop that client. (But, just in case of a future lawsuit,always make sure your recommendations are in writing, either in an email or within a manuscript—without in any way accusing the client, of course.) I have had to do this numerous times; it is not easy, but I do it. So should you.

—Cathryn D. Evans

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Q2: When working on manuscripts involving multiple authors, how can medical writers help manage authorship disputes and ensure fair credit allocation following ethical guidelines?

It is not within the purview of a freelance medical writer to determine authorship or mediate their disputes—at least it should not be. If clients are passing this responsibility on to you, they are essentially asking you to be more than a medical writer; they want you to be the Project Manager, a function that pays more than medical writing, so be sure to raise your rate if a client asks this of you.

Yes, I have had to take this role at different times. Generally, I am crystal clear in my communication with coauthors (and clients) about guidelines and regulations; likewise, I am usually well aware of the politics within companies and academia, so I address the issue directly. The politics are out of our hands—this is up to the client and/or the chief author, investigator, or scientist. We cannot take responsibility for the politics.

—Cathryn D. Evans

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Q3: How can medical communicators navigate cultural and linguistic differences in a global health care context, ensuring their work is accurate and culturally sensitive?

Medical communicators must always consider their audiences when developing content, but there's more to it than simply writing in one style for regulators, in another style for health care professionals, and in another style for lay audiences. There are differences in the way people learn and in the way people understand that go beyond reading and education levels. For example, although it may have been thought at one time that visuals are the best way to communicate to people with low reading skills, infographics have become a popular way to communicate the results of clinical trials to health care professionals.

The ability to access and utilize information is influenced by so many factors: race, ethnicity, age, culture, religion, sex, gender identity, sexual orientation, socioeconomic status, geography, physical ability, and neurobiology among them. With so many possibilities, is it surprising we're all different? That may be the biggest thing we have in common!

Although medical communicators should have always thought about at least some of this, diversity, equity, and inclusion (DEI) finally being at the forefront makes it a lot easier. Now our companies and clients are thinking about it, too. I think they're also more receptive to our doing something about it. It was wonderful when the American Medical Association *(AMA) Manual of Style, 11th Edition*, gave us permission to use "they" as a singular pronoun. The circles we used to have to write around a sentence in order to de-gender it!

One of the best ways I can think of for medical communicators to navigate cultural and linguistic differences in the global health care universe is to think about DEI constantly and allow it to drive questions up front about how a particular communication piece will be delivered, to whom it is intended, and what considerations can and should be made to optimize its value to this audience. This should be an actual topic of conversation at the beginning of any project—an agenda item! Establishing these guardrails from the beginning will help us develop content that is best suited to achieve its communication objective. I also think it is important for us

to consider the characteristics we give to patients when writing hypothetical case studies and patient journeys.

—Brian Bass

Much medical writing already occurs in a global context, requiring cultural awareness to ensure content resonates across different health care settings. Writers must consider linguistic, cultural, and identity differences to create inclusive materials that engage diverse audiences. We need to bring this same awareness to cultural and linguistic differences in a US health care context. If you're a writer in CME/CE, you are already likely doing so via the concept of cultural competence.

Almost 20 years ago, the Commonwealth Fund defined cultural competence as "the ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients." To this end, accreditation bodies such as ACCME, the American Nurses Credentialing Center, and the Accreditation Council for Pharmacy Education expect CME/CE providers to integrate cultural competence into education for the intended learner audience, be they physicians, pharmacists, or nurse practitioners. The California Medical Association, which accredits CME organizations in California, has also developed standards to ensure the inclusion of cultural and linguistic competency statements in accredited CME, as well as content that addresses, implicitly or explicitly, topics like communication skills, health care disparities, biases/stereotyping, cross-cultural pharmacological issues, and sociocultural factors that affect health beliefs and behaviors. ACCME is also working to ensure that DEI is incorporated into all aspects of accredited education.

A primary way to integrate cultural competence standards to CME/CE is by broadening representation within education content, such as in patient cases. We can diversify the social, cultural, and linguistic characteristics of patient cases by using diverse names, describing different marital statuses and relationships, and including images that represent people with disabilities, as well as Black, Indigenous, and additional people of color, and people in lesbian, gay, bisexual, transgender, queer, intersex, asexual, and many other identities (LGBTQIA+) communities. We can also educate ourselves on cultural norms related to communication, decision-making, family dynamics, spirituality, and other factors affecting health and health care.

Many tools and resources are available to help us navigate cultural and linguistic differences in both the United States and the global health care context, and to integrate cultural competence standards into CME/CE.

The Association of American Medical Colleges Diversity and Inclusion Toolkit is a terrific place to start, with resources on how to think about power and privilege, cross-cultural communication, and the diversity of identities in health care contexts. The Disabled and Here collection, Photoability, Tonl, the Gender Spectrum collection, and many other archives provide access to inclusive images. Resources such as the Inclusive Language Playbook: Writing for LGBTQ+ Communities,the 11th edition of the *AMA Manual of Style*, and the Council of Science Editors' perspective on inclusive sex/gender language can help writers avoid discriminatory or stigmatizing language.

—Alex Howson

Reference

1. DeTora LM, Lane T, Sykes A, DiBiasi F, Toroser D, Citrome L. Good Publication Practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. *Ann Intern Med*. 2023;176(3):eL220490. doi:10.7326/M22-1460

Online Resources for Freelance Writers

ACCME Standards for Integrity and Independence in Accredited Continuing Medical Education: https://accme.org/publications/standards-for-integrity-and-independence-accredited-continuing-education-pdf

ACCME Accreditation Criteria: https://www.accme.org/accreditation-rules/accreditation-criteria

International Committee of Medical Journal Editors: Defining the Roles of Authors and Contributors: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Association of American Medical Colleges: Diversity and Inclusion Toolkit: https://www.aamc.org/professional-development/affinity-groups/cfas/diversity-inclusion-toolkit/resources

Inclusive Language Playbook: Writing for LGBTQ+ Communities: https://communicatehealth.com/wp-content/uploads/ch-lgbtq-playbook.pdf

Council of Science Editors: Inclusive Language Communication: https://www.councilscienceeditors.org/inclusive-language-communication

Inclusive Imagery:
https://www.awesomefoundation.org/en/projects/114332-disabled-and-here
https://tonl.co/
http://photoability.net/
https://genderspectrum.vice.com/