

May 8, 2008

**Comments of the Coalition for Healthcare Communication
And
The Association for Medical Media
On FDA's "Good Reprint Practices" Draft Guidance**

The Coalition for Healthcare Communication (CHC) in conjunction with The Association of Medical Media (AMM) (formerly The Association of Medical Publishers) applaud the Food and Drug Administration's initiative to set rules for the dissemination of medical journal articles and scientific reference publications, published in the Federal Register on February 20, 2008 (73 Fed.Reg.9342) . The CHC is composed of trade associations and companies engaged in publishing and professional communications related to healthcare. The AMM represents the medical journal publishing community with membership from both the association and independent sides of the healthcare publishing community.

We submit the following comments and recommendations on the "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices."

The CHC is dedicated to assuring the free exchange of scientific information protected by the First Amendment with the confidence that free scientific exchange leads to better patient outcomes. Without this freedom, the diffusion of medical information is diminished, leaving many clinicians without the latest information about developments in patient care behind medical innovation.

At the onset, we wish to note that we believe that this proposed policy paper constitutes one of the most important steps forward by the FDA in the area of "off-label" policy since the famous Washington Legal Foundation cases of the 1990s. Although the WLF litigation made clear that the First Amendment applies to these issues, we believe that FDA in the wake of these decisions had unfortunately left too vague its public policy responsibilities in this area, and failed to clearly articulate policies that comported with the First Amendment and met the needs of U.S. clinicians and their patients. This led, unfortunately in our view, to a situation where other law enforcers, particularly the HHS-IG and plaintiff attorneys, stepped in to interpret the FDA Act and the False Claims Act in ways that have harmed the practice of medicine and patients. We are delighted, therefore, that the FDA is symbolically at least retaking its traditional role in this area with this proceeding.

We fear, however, that some politicians may use this proceeding for purposes that could impede the further development of good policy. For example, as we

have stated elsewhere, we fear that Congressman Henry Waxman's untimely release of the draft of this policy and his related communications appear designed to unnecessarily politicize the matter and derail one of the most important reforms in drug policy in recent memory.

Most important, Congressman Waxman attacked the integrity of articles that appear in peer-reviewed journals and the peer review process itself. Peer-review is a blinded process that works effectively to assure that articles that appear in medical journals meet a high standard for scientific merit, medical accuracy and fair balance. To suggest, as Congressman Waxman does, that health care practitioners and the public cannot rely on peer-reviewed journal articles as a reliable source of medical information flies in the face of decades-long practice. Like democracy, peer review is not perfect. But peer review is by far the best system available to vet new ideas in medical practice.

Moreover, we believe that a new, clear policy in this area promises to clinicians practicing in some of the most difficult areas of medicine-- oncology, psychiatry and pediatrics – to be better informed and to more quickly and effectively treat patients. As you know, the situation addressed here stems from the fact that clinicians are legally permitted to prescribe drugs in a way that benefits their patients, even for uses not approved by the FDA, but reliable scientific information about these uses often is difficult for practicing doctors to obtain.

As we understand this proposal, a new version of this policy would enable drug companies to circulate peer-reviewed articles from the national and international medical research journals to the nation's practicing physicians without fear of FDA or other legal penalties. Moreover, the proposed FDA policy would clarify confusing government enforcement policies on the matter, and largely reinstate many of the provisions of a Congressionally approved "safe harbor" that expired last year.

Thus, we applaud this effort and urge FDA to move swiftly to conclude this matter.

With these goals in mind, we wish to inform you that while AMM represents most major United States medical publishers, it has a long established a code of ethics that addresses directly the objectives of the FDA proposal, and should inform the FDA as its moves to adopt a final policy.. While the complete code is reproduced in exhibit A, these four provisions are most pertinent:

- 1. No editorial material will be published in a publication in return for any monetary compensation or advertising consideration.*
- 2. A member publication will publish no advertisement that might be mistaken for its own editorial material due to style or format without labeling such as an advertisement, clearly and conspicuously.*

3. *Each publication will maintain its editorial integrity and independence from influence by any outside sources, including advertisers and the government.*
4. *Publications will not knowingly accept advertising that contains untruthful, deceptive, or misleading statements.*

While AMM member publications are supported by advertising and/or subscriptions, adherence to this code helps build trust between the healthcare community and the publishing community by establishing separation between the editorial product and any commercial influence. While not without occasional lapses, we believe this code works and helps insure that the content of journals is appropriate and useful to readers. We are proud of our record, and recommend that FDA fully respect it as it formulates these new policies.

In reviewing the proposed guidelines set forth by the FDA, we respectfully request that the following recommendation be considered:

Section IV. Agency Recommendations for Good Reprint Practices, section A. Types of Reprints/Articles/Reference Publications, in part states ***“A scientific or medical journal article that is distributed should not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.”***

We ask that **a distinction be made between ACCME accredited programs appearing in the journal or distributed with journals as special supplements, which may or may not contain off-label discussion, and those special supplements that are not ACCME accredited.** Accredited articles or supplements should be accorded the same treatment as CME delivered in other venues, which allows distribution of CME materials under ACCME guidelines.

We thank the FDA for reviewing our recommendation and considering these changes to the draft of the guidelines.

Sincerely,

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