Public Citizen

PUBLIC CITIZEN FOUNDATION
Ralph Nader, Founder

January 26, 1993

Dockets Management Branch
Food and Drug Administration
12420 Parklawn Drive, Rm. 1-23
Rockville, MD 20857

Re: Docket No. 92N-0434, Comments by PCHRG on Draft Policy Statement on Industry Supported Scientific and Educational Activities

Dear Sir or Madam:

We have one general disclaimer about the regulations and then a few specific comments. The disclaimer is that while the regulations may be an improvement over the status quo, they are by no means ideal. They institutionalize drug company sponsorship of continuing medical education, and no doubt these companies will largely sponsor conferences favorable to their products. The FDA states that it is wrong "if the provider believes that future financial support from the company depends upon producing programs that promote the company's products." But realistically, the guidelines can do little to alleviate that danger. They represent an extraordinary cave-in to drug industry/organized medicine pressures.

But rather than dwell on the fundamental flaws of the plan, the comments describe how the policy could realistically be changed in the short term to maximize its effectiveness. But first, one over-arching flaw: The use of major accrediting organizations to monitor the law would seem suspect. It will be difficult, if not impossible, for organizations that receive money from pharmaceutical companies to be responsible for applying the law to them.

Part II, A, "Written Agreement"

Are there any new penalties for violating this written agreement? If so, they should be spelled out. If not, then what makes the written agreement differ from other FDA regulations? I think that breaking this written agreement should bring extra penalties on a company, and that the FDA should make this clear to the pharmaceutical industry.

Part II, A.4. "Supporting Company Involvement in Content"

We find it troubling that the FDA will permit the companies to produce slides and audiovisual materials for speakers in the conferences. Why is this necessary? Anyone who has ever given a presentation knows how to make slides and other AV materials. Why sanction any contact between the companies and the presenters? Isn't that providing a perfect opportunity for undue influence?

Part II, A.5. "Ancillary Programming Activities"

In a previous version of these guidelines, the FDA made it clear that the conferences could not be opportunities to sell products to physicians. Now the company just has to agree not to have sales reps in the room of the educational activity or "in an obligate path to the educational activity." In other words, the company can set up shop right next door and take advantage of unapproved use discussions at the conference to lobby doctors to prescribe. It would seem that this would create a very hazy line between independence and promotion and thus is contrary to the spirit of the guidelines.

Part II, B.4.a. "Gifts"

We are assuming that "travel or lodging subsidies" are deemed inappropriate by the FDA. The statement is confusing, however, and may lead some to believe that such inducements are permissible. The guidelines should make clear that fancy entertainment expenses (e.g. moonlight cruises) count as gifts.

Part II, B.4.b "Emphasis on noneducational activities: "The announcement and promotion of the meeting focuses less on its educational content than on leisure or recreational activities."

This standard seems to set up a 50-50 balance: as long as the announcement is 50 percent educational, it's okay. This is actually weaker than the AMA guidelines as we understand them. A better standard is that the "announcement and promotion of the meeting" focuses *predominantly or almost exclusively* on educational aspects.

Sincerely,

Sidney M. Wolfe, MD
Director, Health Research Group
Public Citizen

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