Guidance for Industry

Industry-Supported Scientific and Educational Activities

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I. Background: Promotion, Education, and Independence

Two important sources of information on therapeutic products (human and animal drugs, biological products, and medical devices regulated by the Food and Drug Administration (FDA)) for health care professionals are: (1) Activities (programs and materials) performed by, or on behalf of, the companies that market the products; and (2) activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company. Although both provide valuable and sometimes vital information to health care professionals, the programs and materials performed and disseminated by companies are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act (the act), whereas the truly independent and nonpromotional industry-supported activities have not been subject to FDA regulation.[2]

This jurisdictional line is important because the constraints on advertising and labeling,[3] when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views. In particular, discussions of unapproved uses, which can be an important component of scientific and educational activities, are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion. Thus, the agency, has traditionally sought to avoid regulating activities that are produced

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[1] This guidance has been prepared by FDA's Intra-Agency Working Group on Advertising and Promotion. This guidance represents the Agency's current thinking on industry-supported scientific and educational activities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the industry. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] In this context, the terms ''independent'' and ''nonpromotional'' are not mutually exclusive. The agency views independence as an indication of whether an activity is nonpromotional.

[3] These provisions require the company to ensure that the content does not promote unapproved uses, and that discussions of the company's products are not false or misleading and do not lack fair balance.

independently from the influence of companies marketing the products. The agency recognizes that industry-supported activities can be both nonpromotional and educational.

Demarcating the line between activities that are performed by or on behalf of the company, and thus, subject to regulation, and activities that are essentially independent of their influence has become more difficult due to the increasing role industry has played in supporting postgraduate and continuing education for health care professionals.

The agency traditionally has recognized the important public policy reasons not to regulate all industry-supported activities as advertising or labeling. To permit industry support for the full exchange of views in scientific and educational discussions, including discussions of unapproved uses, FDA has distinguished between those activities supported by companies that are nonpromotional and otherwise independent from the substantive influence of the supporting company and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting company and nonpromotional have not been treated as advertising or labeling, and have not been subjected to the agency's regulatory scrutiny.

In determining whether an activity is independent of the substantive influence of a company, the agency examines whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle. FDA is concerned that companies may influence the content of educational programs both directly and indirectly. Directly, by being involved in the selection of speakers or in the treatment of topics. Indirectly, through the nature of the relationship between the company and the provider (e.g., if the provider has reason to believe that future financial support from the company depends upon producing programs that promote the company's products.)

FDA is responsible for seeing that scientific and educational activities that are not intended to be promotional are designed to be truly independent from substantive influence by the marketers of regulated products. The agency recognizes, however, that the primary responsibility for overseeing the process of postgraduate and continuing professional education and scientific exchange lies with the scientific and health

care communities and accrediting organizations. Accordingly, FDA will work closely with scientific and professional health care communities and accrediting organizations to help ensure that provider activities are independent.

The agency is providing this guidance to describe the agency's enforcement policy with regard to scientific and educational activities supported by industry. The guidance seeks to clarify the distinction drawn by the agency between scientific and educational activities that FDA considers nonpromotional and those that the agency considers promotional, and to provide guidance on how industry may support such activities without subjection to regulation under the labeling and advertising provisions of the act.

This guidance applies only to those company-supported activities that relate to the supporting company's products or to competing products. A company-supported educational activity or part thereof that does not relate to the company's products or a competing product, or suggest a use for the company's products, would not be considered a promotional activity under this guidance.

II. Guidance: Industry-Supported Scientific and Educational Activities

FDA has not regulated and does not intend to regulate, under the labeling and advertising provisions of the act, industry-supported scientific and educational activities that are independent of the influence of the supporting company. Companies and providers who wish to ensure that their activities will not be subject to regulation should design and carry out their activities free from the supporting company's influence and bias, based on the factors considered in evaluating activities and determining independence, as described below. These factors are provided to furnish guidance on the design and conduct of such activities, so that they will be educational and nonpromotional in nature. These factors will be considered as part of an overall evaluation of an activity; no individual factor is likely by itself to stimulate an action based on lack of independence.

A. Factors Considered in Evaluating Activities and Determining Independence

FDA will consider the following factors in evaluating programs and activities and determining independence:

(1) Control of Content and Selection of Presenters and Moderators

The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of speakers and moderators. In so doing, the agency will look at whether the supporting company has engaged in scripting, targeting points for emphasis, or other actions designed to influence the program's content. In addition, the agency will consider if the company has suggested speakers who are or were actively involved in promoting the company's products or who have been the subject of complaints or objections with regard to presentations that were viewed as misleading or biased in favor of the company's products.

(2) Disclosures

The agency will consider whether there was meaningful disclosure, at the time of the program, to the audience of: (1) The company's funding of the program; (2) any significant relationship between the provider, presenters or moderators, and the supporting company (e.g., employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of products will be discussed;

(3) The Focus of the Program

The agency will consider whether the intent of the company and the provider is to produce an independent and nonpromotional activity that is focussed on educational content and free from commercial influence or bias. The agency will also consider whether the title of the activity fairly and accurately represents the scope of the presentation.

The agency also will look at the focus of the activity to determine if the central theme is based on a single product marketed by the company or a competing product, except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies. This is not to suggest that each treatment option must be discussed with precisely equal emphasis. However, emphasis on a newer or, in the view of the presenter, more beneficial treatment modality should be provided in the context of a discussion of all reasonable and relevant options.

(4) Relationship Between Provider and Supporting Company

The agency will consider whether there are legal, business, or other relationships between the company and the provider that could place the company in a position whereby it may exert influence over the content of the activity (e.g., a provider that is owned by, or is not viable without the support of, the company supporting the activity).

(5) Provider Involvement in Sales or Marketing

The agency will consider whether individuals employed by the provider and involved in designing or conducting scientific or educational activities are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product.

(6) Provider's Demonstrated Failure to Meet Standards

The agency will consider whether the provider has a history of conducting programs that fail to meet standards of independence, balance, objectivity, or scientific rigor when putting on ostensibly independent educational programs.

(7) Multiple Presentations

The agency will consider whether multiple presentations of the same program are held.[5]

(8) Audience Selection

The agency will consider whether invitations or mailing lists for supported activities are generated by the sales or marketing departments of the supporting company, or are intended to reflect sales or marketing goals (e.g., to reward high prescribers of the company's products, or to influence ''opinion leaders'').

(9) Opportunities for Discussion

In the case of a live presentation, the agency will consider whether there was an opportunity for meaningful discussion or questioning provided during the program.

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[5] FDA recognizes that some repeat programs can serve public health interests. The Department of Health and Human Services sometimes actively encourages multiple presentations on selected urgent topics.

(10) Dissemination

The agency will consider whether information about the supporting company's product presented in the scientific or educational activity is further disseminated after the initial program, by or at the behest of the company, other than in response to an unsolicited request or through an independent provider as discussed herein.

(11) Ancillary Promotional Activities

The agency will consider whether there are promotional activities, such as presentations by sales representatives or promotional exhibits, taking place in the meeting room.

(12) Complaints

The agency will consider whether any complaints have been raised by the provider, presenters, or attendees regarding attempts by the supporting company to influence content.

B. Additional Considerations

The foregoing list of factors is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case.

One means of documenting the measures taken to ensure independence of an activity is to have a written agreement between the provider and the supporting company. This document should reflect that the provider will be solely responsible for designing and conducting the activity, and that the activity will be educational, nonpromotional, and free from commercial bias. While not required, a written agreement, coupled with the factors described above, can provide valuable evidence as to whether an activity is independent and nonpromotional.

III. FDA'S Cooperation With Major Accrediting Organizations

FDA recognizes the important role accrediting organizations can play in ensuring that industry-sponsored educational activities are independent and nonpromotional. The agency also recognizes the importance of avoiding undue Government interference in postgraduate and continuing education for health

care professionals, as the agency seeks to ensure that company promotional activities meet applicable legal requirements. Thus, the agency will continue to work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers.

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