DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N–0434]

Final Guidance on Industry-Supported Scientific and Educational Activities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a final guidance entitled ''Final Guidance on Industry-Supported Scientific and Educational Activities'' (hereinafter referred to as the final guidance). The agency sought public comment on a draft version of this final guidance entitled ''Draft Policy Statement on Industry-Supported Scientific and Educational Activities'' (hereinafter referred to as the draft policy statement), which was published in the **Federal Register** on November 27, 1992; and on November 18, 1994, on a related citizen petition. The agency considered the comments received and, where appropriate, revised the draft policy statement to create the final guidance. The final guidance describes how industry may support scientific and educational activities without being subject to regulation under the Federal Food, Drug, and Cosmetic Act (the act). The full text of the guidance is published in this document.

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For general questions about the guidance: Ilisa B. G. Bernstein, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380, or via e-mail at IBernste@oc.fda.gov;

Regarding biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–200), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via e-mail at stifano@cber.fda.gov;

Regarding medical device products: Byron L. Tart, Center for Device Evaluation and Radiologic Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639, or via e-mail at bxt@cdrh.fda.gov;

Regarding human prescription drugs: Norman A. Drezin, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, rm. 17B–17, Rockville, MD 20857, 301–827–2831, or via e-mail at drezinn@cder.fda.gov;

Regarding prescription animal drugs: Edward L. Spenser, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722, or via e-mail at espenser@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 27, 1992 (57 FR 56412), FDA published the draft policy statement. As the agency noted in the introduction to the draft policy statement, these activities may be subject to regulation under the labeling and advertising provisions of the act when they provide information on FDA-regulated products marketed by the supporting companies.

As the introduction also noted, FDA traditionally has not sought to regulate industry-supported scientific and educational activities that are otherwise independent and nonpromotional. Industry-supported scientific and educational activities that are not independent and nonpromotional are not per se illegal, but they are subject to regulation.

FDA published the draft policy statement in response to requests from industry for guidance in this area. Prior to publishing the draft policy statement, the agency engaged in an extensive outreach effort with scientific and health care professionals, industry, consumer groups, and other Government agencies in an attempt to strike a proper balance between the need for industry-supported dissemination of current scientific information and the need to ensure that promotional activities by industry meet the requirements of the law.

Recognizing the importance and delicacy of this balance, the agency invited comments with regard to all issues raised in the draft policy statement.

The agency received 152 comments, which included comments from academic and organized medicine, health care professionals, industry and trade associations, public relations and advertising firms, and commercial continuing education providers. FDA thoroughly considered these comments and revised the draft policy statement where appropriate. In the **Federal Register** of November 18, 1994 (59 FR 59820), the agency sought comment on a citizen petition (Docket No. 92N–0434/CP1) requesting that the agency withdraw the draft policy statement. The agency received about 60 comments in response to this notice.

I. Highlights of the Final Guidance

In response to comments, the agency has made several revisions to the draft policy statement. First, the draft policy statement has been modified to clarify that it is providing guidance on what the agency would look at in determining independence. In doing so, rather than enumerating the elements of a written agreement, the final guidance presents the ideas contained in the elements as factors the agency will consider in evaluating activities and determining independence. Additionally, the text of ''Other Factors in Determining Independence'' indicia that were listed in section II.B. of the draft policy statement (57 FR 56412 at 56414) are now included in the factors the agency will consider in evaluating activities and determining independence. Second, although the final guidance has been modified to place less emphasis on a written agreement between the supporting company and the provider, the agency continues to believe that a written agreement is one way to document what measures were taken by the parties to maintain the independence of the program.

In the final guidance, only 1 of the 10 elements of the written agreement presented in the draft policy statement remains unchanged. The ''Statement of Purpose'' (section II.A.1. of the draft policy statement) has been deleted because the final guidance lists the factors the agency will consider, rather than a suggested written agreement. The text of the ''Control of Content and Selection of Presenters and Moderators'' (section II.A.2. of the draft policy statement) has been modified slightly, but remains substantially unchanged. In the ''Disclosure of Financial Relationships'' (section II.A.3. of the draft policy statement) a factor has been added indicating that when an activity includes discussion of unapproved uses, there should be general disclosure of that fact. Additionally this discussion has been renamed ''Disclosures,'' and all factors that describe a disclosure are listed under this heading. The discussion concerning ''Supporting Company Involvement in Content'' (section II.A.4. of the draft policy statement) has been incorporated into the factor concerning ''Control of Content and Selection of Presenters and Moderators'' of the final guidance. The

discussion of ''Ancillary Promotional Activities'' (section II.A.5. of the draft policy statement) has been narrowed so as to limit promotional activities only in the room in which an activity takes place. The discussions concerning ''Objectivity and Balance'' (section II.A.6.), ''Limitations on Data'' (section II.A.7. of the draft policy statement), and ''Discussion of Unapproved Uses'' (section II.A.8. of the draft policy statement) have been deleted from the final guidance. The ''Opportunities for Debate'' (section II.A.9. of the draft policy statement) has been renamed ''Opportunities for Discussion'' to clarify its intent. The ''Schedule of Activities'' discussion (section II.A.10. of the draft policy statement) has also been deleted from the final guidance.

Much of the draft policy statement's section entitled ''Other Factors in Determining Independence'' appears in the final guidance, with a few modifications. First, the discussions concerning the ''Provider'' (section II.B.1. of the draft policy statement) has been modified slightly, deleting the statement that discussed whether persons who are involved in promotion of a company's products may function in the role as an independent provider. The discussion concerning industry representatives help in logistical assistance (section II.B.2.a. of the draft policy statement) has been deleted from final guidance. The ''Suggestion of Presenters'' discussion (section II.B.2.b. of the draft policy statement) has been incorporated, in part, into the factor concerning ''Control and Content and Selection of Presenters and Moderators'' in the final guidance. The discussion concerning ''Focus on a Single Product'' (section II.B.3.a. of the draft policy statement) has been incorporated into the factor entitled ''Focus of the Program'' in the final guidance. The discussions concerning ''Multiple Performances'' (section II.B.3.b. of the draft policy statement), ''Audience Selection'' (section II.B.4.c.), ''Dissemination'' (section II.B.5.), and ''Complaints'' (section II.B.6.) remain substantially unchanged. The ''Gifts'' (section II.B.4.a.) and ''Emphasis on Noneducational Activities'' (section II.B.4.b.) discussions have been deleted from the final guidance. Finally, the discussion concerning ''Misleading Title'' (section II.B.4.d. of the draft policy statement) has been incorporated into the factor concerning ''Focus of the Program'' in the final guidance.

In general, these revisions are intended to better focus the final guidance on the agency's core concerns—that the provider develop the subject program independent from the influence of the supporting company, and that there is disclosure of relationships between and among the supporting company, provider, presenters, and products discussed that may be relevant to an assessment of the information presented. Thus, while the number of changes may be significant, they do not change the fundamental intent of the final guidance to distinguish industry-supported scientific and educational activities that are free from supporting company influence from those that are not.

II. Summary and Responses to Comments Received

A. General Comments

1. Several comments disputed the agency's assertion that industry-supported scientific and educational activities traditionally have been viewed by the agency as subject to regulation under the act. They maintained that regulation of these activities is an unwarranted expansion of agency authority and that the agency should specifically articulate the basis for its regulatory authority.

FDA has long regulated drugs and devices (including biological products and animal drugs) based on the ''intended uses'' for such products. Under section 201 of the act (21 U.S.C. 321), which defines the terms ''drug'' and ''device,'' the intended use of an article determines whether the article is a drug or device. In general, under the act and the Public Health Service Act, a sponsor who wishes to market any new drug or biological product must demonstrate to FDA that the product is safe and effective for each of its intended uses. (See sections 505(a) and 512(a) of the act (21 U.S.C. 355(a) and 360b(a)) and section 351 of the Public Health Service Act.) A sponsor who wishes to market a new medical device must either demonstrate to FDA that there is a reasonable assurance that the device is safe and effective for each of its intended uses or that it is substantially equivalent to (meaning, in part, that it has the same intended use as) another device for which such a showing is not required. (See sections 510(k), 513(f) and (i), and 515(a) of the act (21 U.S.C. 360(k), 360c(f) and (i), and 360e(a)).) The package insert or product manual (approved professional labeling) which, for approved and/or licensed products, physically accompanies the product, sets forth the uses for which the product has been demonstrated to be safe and effective.

The ''intended use'' of a drug or device refers to the objective intent of the persons legally responsible for the labeling of the product. This intent is determined by such persons' expressions or by the circumstances surrounding the distribution of the article including, for example, labeling claims, advertising matter, or oral or written statements by such persons or their representatives. (See 21 CFR 201.128 and 801.4.) The agency, thus, regulates products based not only on information provided ''with'' the product (approved professional labeling), but also based on information disseminated by or on behalf of manufacturers in other contexts, such as scientific and educational meetings and symposia, books, reprints of articles from scientific journals, in part because all of these activities/materials can create new intended uses for the products, which must be reflected in the approved labeling of the products.

The agency's focus on the manufacturer's characterization of its product in the marketplace is best reflected in the statutory requirement that a drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use. (See section 502(f)(1) of the act (21 U.S.C. 352(f)(1)).) The courts have agreed with the agency that section 502(f)(1) of the act requires information not only on how a product is to be used (e.g., dosage and administration), but also on all the intended uses of the product. (See *Alberty Food Products Co.* v. *United States*, 185 F.2d 321 (9th Cir. 1950) (drug product was misbranded because its labeling failed to state the intended use of the drug (arthritis and rheumatism) as suggested by the company in newspaper advertisements); 21 CFR 201.5)) As previously described, oral statements and materials presented at industry-supported scientific and educational activities may provide evidence of a product's intended use. If these statements or materials promote a use that is inconsistent with the product's approved labeling, the product is misbranded under section 502(f)(1) of the act for failure to bear labeling with adequate directions for all intended uses. If it is a device, it is also adulterated because the listing of unapproved uses in the labeling or advertising of an approved device results in an adulterated medical device under section 501(f) of the act, and misbranded under section 502(o) of the act because premarket notification was not provided as required under section 510(k) of the act.

FDA also finds support for its policy of examining a broad array of information disseminated by companies in the general grant of authority over labeling and advertisements. Section

201(m) of the act defines the term ''labeling'' to include all ''written, printed, or graphic'' materials ''accompanying'' a regulated product. The Supreme Court has agreed with the agency that this definition is not limited to materials that physically accompany a product. If the material supplements, explains, or is otherwise textually related to a product, it is deemed to accompany the product for purposes of section 201(m) of the act. (See *Kordel* v. *United States,* 335 U.S. 345 (1948).)

The agency has adopted a similar interpretation of the term ''advertisement,'' which appears in section 502(n) of the act (prescription drug advertisements) and 502(r) of the act (restricted device advertisements). Although the act does not define the term ''advertisement,'' section 502(n) and (r) of the act indicates that advertisements do not include materials regulated as labeling. In addition, the legislative histories of the 1938 act and the 1962 amendments to the act support a broad construction of what constitutes ''advertising.'' Thus, the agency interprets the term ''advertisement'' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product. Prescription drug and restricted device advertisements that do not comply with section 502(n), (q), or (r) of the act, or regulations issued thereunder, cause a prescription drug or restricted device to be misbranded.

2. Some comments contended that the policy will adversely affect the availability and quality of continuing education for health care professionals. They maintained that the perception of regulatory risk on the part of supporting companies, as well as administrative and financial burdens resulting from compliance with the policy, will cause companies that have supported educational programs to redirect funds to lower risk, more efficient activities.

The agency recognizes the importance of continuing education for health care professionals and recognizes, as well, the traditional role of industry in supporting such activities. With this final guidance, the agency has attempted to address concerns raised by supporting companies, to describe factors the agency will consider in determining whether an industry-supported activity is independent and not generally subject to regulation, and to accommodate industry's need for predictability in these activities. The agency believes that the flexibility accorded companies in the final guidance and in the agency's responses to these comments should provide a reasonable basis for continued support for these activities. Decisions by companies involving allocation of resources for promotion and education are, of course, affected by a variety of factors. The agency cannot ensure that companies will provide a given level of support for professional education within the health care community.

B. The First Amendment

3. Several comments contended that the Draft Policy Statement on Industry-Supported Scientific and Educational Activities (Draft Policy Statement) infringes upon the First Amendment to the Constitution. Some comments claimed that the Draft Policy Statement infringed protections afforded to commercial speech.

The agency has considered the First Amendment in developing its policies on industry-supported scientific and educational activities, and believes that the Draft Policy Statement and the Final Guidance are consistent with the First Amendment's protection of freedom of expression. In producing these policy statements (guidance), FDA has sought to accommodate the need for industry-supported scientific and educational activities and the statutory mandate to regulate promotional activities (labeling and advertising) for drugs and devices in accordance with the act and the Public Health Service Act.

1. The Regulation of Drugs and Devices

FDA's guidance on industry-supported scientific and educational activities describes the agency's regulation of drugs and medical devices; it is not intended to regulate speech. It provides insight into the factors FDA will consider when evaluating an industry-supported activity to determine whether it should be subject to regulation as labeling or advertising, and, if so, to ensure that the activity does not misbrand or adulterate the subject drug or device. There are three bases for this conclusion.

First, the guidance applies only to those company-supported activities that relate to the supporting company's product(s) or to competing product(s). A company-supported activity that does not relate to the company's product, a competing product, or suggest a use for the company's product would not be subject to regulation as a promotional activity.

Second, the guidance distinguishes between company-supported activities that are independent of the promotional influence of the supporting company and those that are not. As explained in the guidance, the agency does not seek to regulate industry-supported activities that are independent and nonpromotional.

Third, the regulation of drugs and devices has an unavoidable effect on speech. As explained more fully in response to Comment A.1, the act mandates that FDA regulate products as drugs or devices (including biological products and animal drugs) based on the ''intended uses'' for such products.

Under section 201 of the act which defines, among other things, the terms ''drug'' and ''device,'' the intended use of an article determines whether the article is a drug or device. In general, under the act and the Public Health Service Act, a sponsor who wishes to market any new drug or biological product must demonstrate to FDA that the product is safe and effective for each of its intended uses (sections 505(a) and 512(a) of the act and section 351 of the Public Health Service Act). A sponsor who wishes to market a new medical device must either demonstrate to FDA that there is a reasonable assurance that the device is safe and effective for each of its intended uses or that it is substantially equivalent to (meaning, in part, that it has the same intended use as) another device for which such a showing is not required (sections 510(k), 513(f) and (i), and 515(a) of the act). In addition, all drugs and devices must bear labeling with adequate directions for each intended use. If labeling for a drug or device fails to contain adequate directions for each intended use, the drug or device is deemed to be misbranded (section 502(f)(1) of the act) and subject to seizure or other enforcement actions. For approved or licensed products, the requirement that products bear labeling with adequate directions for use is met by inclusion of the products' FDA-approved professional labeling (package insert or product manual) that sets forth the uses for which the product has been approved/cleared as safe and effective.

The intended use of a drug or device refers to the objective intent of the persons legally responsible for the labeling of the product.

> The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or *oral or written statements by such persons or their representatives.*

(21 CFR 201.128 and 801.4) (emphasis added); see e.g., *Coyne Beahm, Inc., et al.* v. *United States Food and Drug Administration, et al.,* 958 F. Supp. 1060 (M.D.N.C. 1997).

Accordingly, oral statements and materials presented at industry-

supported scientific and educational activities may provide evidence of a product's intended use. If these statements or materials promote a use that has not been approved by the agency (and therefore does not appear in the product's approved labeling), the product is misbranded under section 502(f)(1) of the Act for failure to bear labeling with adequate directions for all intended uses (21 CFR 201.5; *Alberty Food Products Co.* v. *United States*, 185 F.2d 321 (9th Cir. 1950)). The product may also be misbranded if its labeling[1] or advertising is false or misleading (section 502(a), (n), and (q) of the act). If it is a device, it is also adulterated because the listing of unapproved uses in the labeling or advertising of an approved device results in an adulterated medical device under section 501(f) of the act, and misbranded under section 502(o) of the act because premarket notification was not provided as required under section 510(k) of the act.[2] Thus, FDA's regulation of intended uses for drugs and devices is essential to the regulation of such products. The safety and effectiveness of drugs and devices cannot be evaluated in isolation from consideration of their intended uses.

The Supreme Court ''has recognized the strong governmental interest in certain forms of economic regulation, even though such regulation may have an incidental effect on rights of speech * * *'' (*NAACP* v. *Claiborne Hardware Co.*, 102 S.Ct. 3409, 3425 (1982)). (See also *Ohralik* v. *Ohio State Bar Association*, 98 S.Ct. 1912, 1919 (1978) (the government ''does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity'').) Similarly, several lower courts have recognized that in certain areas of extensive Federal regulation (securities, antitrust, transportation, trade, and labor), the Government may regulate communications of the regulated parties without offending the First Amendment. In particular, *SEC* v. *Wall Street Publishing Institute, Inc.*, 851 F.2d 365 (D.C. Cir. 1988), *cert. denied*, 109 S.Ct. 1342 (1989), is most analogous to FDA's regulation of industry-supported scientific and educational activities.

The defendant in *Wall Street Publishing* published a stock market magazine that included feature articles profiling individual companies and portraying the subject firms as appealing investment prospects. Some of the articles were written by the featured company itself, others were written by public relations firms paid by the featured companies, and still others were written by the editors of the magazine, who were paid by the featured companies. Because these arrangements were not disclosed in the magazine, the Securities Exchange Commission (SEC) sought to enjoin the publisher for violations of section 17(b) of the Securities Act of 1993, 15 U.S.C. 77q(b), which makes it unlawful to describe a security for consideration without disclosing the existence of the consideration. The publisher challenged the injunction on, among others, First Amendment grounds.

The court rejected the SEC's characterization of the feature articles as commercial speech and upheld the government's efforts to regulate the magazine based on ''the federal government's broad powers to regulate the security industry'' (*Id.* at 372 (footnote omitted)). According to the court, ''[w]here the federal government extensively regulates a field of economic activity, communication of the regulated parties often bears directly on the particular economic objectives sought by the government, and regulation of such communications has been upheld'' (*Id.* (citations omitted)). This holding stems from the fact that ''[i]f speech employed directly or indirectly to sell securities were totally protected, any regulation of the securities market would be infeasible* * *.'' (*Id.* at 373; see also *Id.* at 374 n.9 (''Requiring disclosure of a material fact in order to prevent investor misunderstanding is the very essence of federal securities regulation.''))

The court noted that:

> [R]egulation of the exchange of information regarding securities is subject only to limited First Amendment scrutiny. Speech relating to the purchase and sale of securities, in our view, forms a distinct category of communications in which the government's power to regulate is at least as broad as with respect to the general rubric of commercial speech * * * In areas of extensive federal regulation * * * we do not believe the Constitution requires the judiciary to weigh the relative merits of particular regulatory objectives that impinge upon communications occurring within the umbrella of an overall regulatory scheme.

Id. at 373. See also *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 46 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 829 (1977) (''[R]ules restricting speech do not necessarily abridge freedom of speech.''); *SEC* v. *Suter*, 732 F.2d 1294 (7th Cir. 1984).

As with securities regulation, the Federal Government exerts extensive authority over the sale and promotion of drugs and devices. Moreover, as previously explained, the Government's ability to regulate speech about these products, like its need to regulate speech concerning the sale of securities, is essential to the regulation of drugs and devices. Yet the regulation of drugs and devices, unlike the regulation of securities, clearly encompasses more than economic activity; it protects consumer health and safety in an area where harm to the public can be direct and immediate.

Accordingly, First Amendment defenses have been raised and rejected in a number of FDA enforcement actions. ''Freedom of speech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act'' (*United States* v. *Articles of Food* * * * *Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975)). The First Amendment does not prohibit the seizure and condemnation of a book that is used to misbrand a product (*United States* v. *8 Cartons, Containing ''Plantation 'The Original' etc. Molasses''*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Articles of Drug*, 32 F.R.D. 32, 35 (S.D. Ill. 1963); but cf. *United States* v. *24 Bottles* * * *''*Sterling Vinegar and Honey''*, 338 F.2d 157 (2d Cir. 1964) (book not used in immediate connection with sale of product is not labeling and does not misbrand product)).

In conclusion, the act requires that FDA regulate drugs and devices based on their ''intended use.'' The term ''intended use'' is broadly defined to capture the manner in which a company characterizes its product in the marketplace. The agency thus must examine the various means by which manufacturers and their representatives provide information about their products to health care professionals and consumers, including statements and materials presented at industry-supported scientific and educational activities, to determine whether the products are being improperly promoted, and therefore misbranded or adulterated. Accordingly, FDA's ability to regulate the communications at such activities is essential to the regulation of drugs and devices. In view of the fact that the regulation of drugs and devices is an area of extensive federal regulation, the agency may regulate the communications at industry-supported

[1] Section 201(m) of the act defines the term ''labeling'' to include all ''written, printed, or graphic'' materials ''accompanying'' a regulated product. (See *Kordel* v. *United States*, 335 U.S. 345, 349–350 (1948).)

[2] It is a violation of the act to, among other things, introduce or deliver for introduction into interstate commerce a misbranded or adulterated drug or device, or to cause the misbranding or adulteration of a drug or device while it is held for sale after shipment in interstate commerce. (See e.g., sections 301(a) and (k) of the act.)

scientific and educational activities without violating the First Amendment.

2. Commercial Speech

Assuming, contrary to the analysis just presented, that industry-supported scientific and educational activities constitute protected speech, they are commercial speech and FDA's regulation of such activities does not violate the First Amendment. Although the Supreme Court has furnished little explicit guidance as to how to determine whether speech is commercial, it has provided some suggestion as to what factors are relevant when making a commercial speech determination. (See *Bolger* v. *Youngs Drug Products*), 103 S.Ct. 2875 (1983) (concluding that informational pamphlets are commercial speech based on a combination of three characteristics (conceded to be advertisements, reference to a specific product, and economic motivation), but not suggesting that each of these characteristics is a necessary element of commercial speech); *S.U.N.Y.* v. *Fox*, 109 S.Ct. 3028 (1989) (speech which proposes a commercial transaction); *Cincinnati* v. *Discovery Network*, 113 S.Ct. 1505 (1993) (speech which proposes a commercial transaction).) Furthermore, the Court has made clear that speech which does more than propose a commercial transaction (linking a product to a current public debate or containing discussions of important public issues) is not necessarily transformed into noncommercial speech (*Central Hudson Gas & Electric Corp.* v. *Public Serv. Comm'n*, 100 S.Ct. 2343 (1980); *Bolger*, 103 S.Ct. at 2880–2881).

Applying the characteristics suggested in *Bolger* (advertisement, reference to a specific product, economic motivation) or the test used in *Fox* and *Discovery Network* (speech which proposes a commercial transaction), industry-supported scientific and educational activities are commercial speech. The guidance at issue only applies to activities that make reference to a specific product, and as explained below, the activities are economically motivated and propose a commercial transaction. Drug and device companies sponsor such programs not only to encourage scientific exchange, education, and corporate goodwill, but more importantly, to convince the audience to prescribe, purchase, or otherwise use the products mentioned. A company-sponsored program that discusses use of a company product carries with it, at the least, an implicit solicitation, and in many cases an explicit one (cf. *Central Hudson*, 100 S.Ct. at 2352 (suggesting that most businesses are unlikely to underwrite promotions that are of no interest to consumers); *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157 (7th Cir. 1977) (advertisement by egg industry trade association claiming no relationship between eggs, cholesterol, and heart disease constitutes commercial speech)).

Indeed, a review of the medical literature on industry-supported scientific and educational activities demonstrates that such activities are economically motivated and propose a commercial transaction. It is significant to note that the number and cost of drug company-supported symposia have increased significantly over the years. In 1974, 16 drug companies sponsored 7,519 symposia, at a cost of 6.5 million dollars. Roughly comparable figures showed that in 1988 the same companies sponsored 34,688 symposia at a cost exceeding 85.9 million dollars.[3] It is reasonable to conclude that drug companies would not spend such large sums of money if they did not view these programs as an effective means to promote their products. Numerous reports in the medical literature support this conclusion.

In an article entitled ''Physicians and the Pharmaceutical Industry: An Alliance with Unhealthy Aspects,'' *36 Perspectives in Biology and Medicine* 376–394, 385 (Spring 1993), author Robert C. Noble describes industry-sponsored symposia as, ''*an effective method for marketing new drugs*,'' and explains that, ''*[t]he symposium, like the promotional dinner, is frequently given a neutral title that disguises any promotional purpose* * * *'' (emphasis added). (See also Lisa Bero, Alison Galbraith, and Drummond Rennie, ''The Publication of Sponsored Symposiums in Medical Journals,'' *New England Journal of Medicine*, 327:1135–1140, 1992 (demonstrating that published symposia were promotional and not peer-reviewed, and those that were sponsored by a single company focused on single products, had misleading titles, and featured unapproved drugs).)

It has also been suggested that drug companies will not provide financial support for scientific and educational activities unless those activities in some way promote the supporting company's products. An editorial by Stephen E. Goldfinger, in the *New England Journal of Medicine*, addressed the growing support and influence of the drug industry in the education of physicians. According to Dr. Goldfinger:

> The most acceptable kind of educational backing is the least available: donations to providers of continuing medical education that are unrestricted with respect to program topics, speakers, or the backgrounds of the invited registrants. When I have suggested this model to pharmaceutical directors who proclaim a genuine interest in supporting continuing medical education, the usual response is a quizzical smile followed by a gentle reminder of the value of confining our discussion to the realm of the possible. At a minimum, that realm usually requires the topic to be an area ''of interest'' to the sponsor, meaning an area related to a product line in need of promotion.

Stephen E. Goldfinger, ''A Matter of Influence'' (Editorial), *New England Journal of Medicine*, pp. 1408–1409, 1409 (May 28, 1987).

Similarly, 2 years later, Eugene M. Bricker, wrote in the same journal that:

> Most of the medical-service industry's marketing exercises are intended to be both educational and promotional, and some are indeed broadly educational and of excellent quality. This does not alter the fact that promotion is their basic objective; companies would not subsidize marketing methods unless they were rewarding.

Eugene M. Bricker, ''Industrial Marketing and Medical Ethics'' (Editorial), *New England Journal of Medicine*, pp. 1690–1692, 1691 (June 22, 1989). (See also Kenneth Miller, William A. Gouveia, Michael Barza, et al., ''Undesirable Marketing Practices in the Pharmaceutical Industry'' (Letter to the Editor), *New England Journal of Medicine*, p. 54 (July 4, 1985) (Physician and pharmacist members of a hospital pharmacy committee expressing concern that drug company grants to support educational functions, such as talks by visiting speakers, are sometimes clearly linked to a request for the admission of a drug to the hospital's formulary or increased use of the product).)

Moreover, the results of a study by Marjorie A. Bowman and David L. Pearle, ''Changes in Drug Prescribing Patterns Related to Commercial Company Funding of Continuing Medical Education,'' *Journal of Continuing Education in the Health Professions*, 8:13–20, 1988, confirm that industry-supported scientific and educational activities propose a commercial transaction. Doctors Bowman and Pearle analyzed the drug prescribing patterns of physicians attending three different continuing medical education (CME) courses, each of which was subsidized heavily by a single, but different drug company. The course topics were directly related to a set of similar drugs from the same class. Immediately prior to and 6 months after

[3] Senate Labor and Human Resources Committee, Congressional Research Service, Survey of selected pharmaceutical firms, Washington, DC, Government Printing Office, 1991.

each course, the physician attendees were asked to identify the frequency of prescriptions written for the set of drugs. Despite the presumed independence of CME course content, in all three courses the rate of prescribing for the drug of the sponsoring company increased the greatest in absolute terms, while prescribing rates for the other drugs discussed in the program either decreased or did not increase as much. Thus, company funding of such programs does appear to influence physicians' drug prescribing behavior in favor of the sponsoring company's product. (See also Jerry Avorn, Milton Chen, and Robert Hartley, ''Scientific and Commercial Sources of Influence on the Prescribing Behavior of Physicians,'' *American Journal of Medicine*, 73:4–8, 1982 (demonstrating that commercial sources have greater influence over prescribing behavior than scientific sources of information); Robert S. Stern, ''Drug Promotion for an Unlabeled Indication—The Case of Topical Tretinoin,'' *New England Journal of Medicine*,'' 331:1348–1349, 1994 (demonstrating that reports of company-sponsored studies and promotional efforts, including symposia, were associated with a large increase in prescribing for an unapproved indication).)

Thus, if industry-supported scientific and educational activities constitute protected speech, that speech is ''commercial speech'' for purposes of constitutional analysis.

3. The Central Hudson Analysis

Over the past few decades, the Supreme Court has afforded commercial speech limited constitutional protection (*Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 96 S.Ct. 1817 (1976); *Central Hudson*, 100 S.Ct. at 2343; 44 *Liquormart, Inc.* v. *Rhode Island*, 116 S.Ct. 1496 (1996)). In *Central Hudson*, the Supreme Court established a four-prong test to determine whether limitations on commercial speech are constitutional. The test inquires: (1) Whether the speech concerns lawful activity and is not misleading; (2) whether the asserted government interest is substantial; (3) whether the limitation directly advances the governmental interest asserted; and (4) whether the limitation is not more extensive than is necessary to serve that interest (*Central Hudson*, 100 S.Ct. at 2351). Subsequently, in *S.U.N.Y.* v. *Fox*, 109 S.Ct. 3028 (1989), the Court clarified that the fourth prong of the *Central Hudson* test is not a ''least restrictive means'' requirement; rather it requires that the restriction be ''narrowly tailored'' to serve the asserted government interest. Narrow tailoring means ''a fit that is not necessarily perfect, but reasonable'' between means and ends (*Id*. at 3035).

FDA's guidance on industry-supported scientific and educational activities satisfies all four prongs of the *Central Hudson* test.

a. The first prong. Commercial speech that is false or misleading, or that concerns illegal activity, is not protected by the First Amendment and may be banned (*Zauderer* v. *Office of Disciplinary Counsel*, 105 S.Ct. 2265, 2275 (1985); *Ibanez* v. *Board of Accountancy*, 114 S.Ct. 2084, 2088 (1994)). Commercial speech is misleading when it is either inherently likely to deceive or when experience has shown that the speech has in fact been deceptive (In *Re R.M.J.*, 102 S.Ct. 929, 937 (1982)). Regulation of commercial speech that is not misleading, or that is only potentially misleading, must satisfy the remaining prongs of the *Central Hudson* test.

As previously discussed, industry-supported scientific and educational activities that promote an unapproved product, or promote an approved product for an unapproved use, create an unlawful product—a misbranded or adulterated drug or device. Accordingly, industry-supported activities that promote unlawful products ''concern illegal activity'' and may be prohibited.

Although FDA believes that most industry-supported scientific and educational activities are not inherently misleading, they are clearly potentially misleading. The potential to mislead the listener (a health care professional) at such an activity is heightened because the listener must not only determine whether the information presented is scientifically sound, but also whether, or to what extent, the supporting company has influenced the presentation.

Evidence of bias in the content of industry-supported CME programs was demonstrated in a study conducted by Marjorie A. Bowman. Dr. Bowman analyzed the content of two CME programs on calcium channel blocker drugs (approved for treating high blood pressure) that were funded by different drug companies. In each case, the program speakers mentioned positive effects more often in connection with the sponsoring company's drug and negative effects more often with competitors' drugs.[4] A second study that analyzed the publication of industry-sponsored symposia in medical journals concluded that the symposia were promotional in nature and not peer-reviewed, and those that were sponsored by single pharmaceutical companies focused on single drug products, had misleading titles, and featured unapproved drugs.[5] Additionally, there are numerous reports in the medical literature describing deceptive practices in the design and delivery of industry-supported symposia. See e.g., Robert C. Noble, ''Physicians and the Pharmaceutical Industry: An Alliance with Unhealthy Aspects,'' *36 Perspectives in Biology and Medicine* 376–394 (Spring 1993); ''Pushing Drugs to Doctors,'' *Consumer Reports*, 57:87, Feb. 1992 (reporting on drug industry marketing practices that mislead doctors).

The potential to present misleading information at industry-supported activities is a particular concern when unapproved uses are addressed. Usually, unapproved uses have not been vigorously evaluated, or if they have been studied, the results are inconclusive. Thus, unapproved uses tend to lack the same degree of certainty and confidence as FDA approved uses. In fact, the data that can identify risks associated with the unapproved use often do not exist, and therefore complete information about the risks of the new use cannot be provided. This lack of data, of course, does not make all discussions about unapproved uses misleading. However, it is important that the audience understand the limitations on data supporting unapproved uses. The disclosure of such limitations, as recommended in the Final Guidance, will help ensure that the audience understands the uncertainty associated with unapproved uses and not be misled into thinking that such uses are safe and effective.

b. The second prong. FDA's guidance on industry-supported scientific and educational activities serves the substantial Government interest of protecting the health and safety of its citizens by helping to ensure the dissemination of truthful and nonmisleading information about drugs and medical devices. The Supreme Court has repeatedly held that the Government's ''interest in the health, safety, and welfare of its citizens constitutes a substantial interest'' (*Posadas de Puerto Rico Associates* v. *Tourism Co.*, 106 S.Ct. 2968, 2977

[4] Marjorie A. Bowman, ''The Impact of Drug Company Funding on the Content of Continuing Medical Education,''*Mobius*, 6:66–69, January 1986.

[5] Lisa Bero, Alison Galbraith, and Drummond Rennie, ''The Publication of Sponsored Symposiums in Medical Journals,''*New England Journal of Medicine*, 327:1135–1140, 1992.

(1986); *Rubin* v. *Coors*, 115 S.Ct. 1585, 1591 (1995)).

In order to protect and promote the public health, Congress granted FDA broad statutory authority to ensure that promotional activities (labeling and advertising) for drugs and devices are truthful and not misleading. Section 502(a) of the act provides that a drug or device is deemed to be misbranded if its labeling is false or misleading in any particular, and under section 502(q) of the act a restricted medical device is misbranded if its advertising is false or misleading in any particular. A prescription drug is misbranded under section 502(n) of the act unless the manufacturer, packer, or distributor includes in all advertisements with respect to that drug, ''a true statement of * * * information in brief summary relating to side effects, contraindications, and effectiveness * * *.''[6] Similarly, a restricted device is misbranded under section 502(r) of the act unless the manufacturer, packer, or distributor includes in all advertisements with respect to that device, ''a true statement of * * * the intended uses of the device and relevant warnings, precautions, side effects, and contraindications * * *.'' Moreover, section 201(n) of the act specifically explains that if an article is alleged to be misbranded because the labeling or advertising is misleading, there shall be taken into account not only representations or suggestions made in the labeling or advertising, but also the extent to which the labeling or advertising fails to reveal material facts. The dissemination of false or misleading information about drugs and devices can induce physicians to choose therapies that deprive patients of reliable treatment and cause severe morbidity, life-threatening adverse effects, or death.

FDA's guidance also serves to protect the public health by preserving the integrity of the premarket approval process, a second substantial government interest. As explained earlier, by enacting the act, Congress established a premarket approval and clearance process whereby manufacturers must establish that their drugs and devices are safe and effective for each of their intended uses before they can be marketed and promoted for those uses. Manufacturers of drugs and devices are not permitted to promote unapproved products or unapproved uses of approved products, either directly or indirectly, such as through industry-supported scientific and educational activities. This regulatory requirement is an important incentive for manufacturers to conduct studies to determine whether their products are safe and effective. If premarket approval were not required for each intended use and manufacturers were free to promote products for any use, manufacturers would have little reason to do scientific research and to present their data to FDA. Additionally, it is important to note that the approval of a drug or device for one use does not provide assurance that the product is safe or effective for a different use or use in a different patient population. Consequently, the promotion of unapproved uses raises significant safety concerns, which are more fully discussed below.

c. The third prong. FDA's guidance on industry-supported scientific and educational activities directly advances the government's substantial interests. ''[A] governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree'' (*Edenfield* v. *Fane*, 113 S.Ct. 1792, 1800 (1993)).

FDA's guidance directly advances the Government's interest of protecting the health and safety of its citizens by helping to ensure the dissemination of truthful and nonmisleading information about drugs and devices. The guidance includes a number of suggestions on the design and conduct of industry-supported scientific and educational activities so that they will be free from the promotional influence of the supporting company and not misleading. Such suggestions include, for example, meaningful disclosure of the company's funding of the program and any significant relationship between the provider (an entity, other than a regulated company, that produces the activity or program), presenter, and supporting company; giving the provider full control over the content of the program and selection of speakers; avoiding involvement of the sales or marketing departments of the supporting company in audience selection decisions; and not having promotional activities in the meeting room. Industry-supported activities that are designed and carried out in this manner are less likely to result in the dissemination of false, misleading, or biased information that can adversely affect public health.

On a number of occasions, FDA has become aware of and taken action against industry-supported scientific and educational activities that were false or misleading, and that could have caused harm to patients. For example, a few years ago, agency staff viewed two videotaped presentations on treating gallstone disease that were broadcast nationwide on a cable television network intended for physicians. The videos were produced and paid for by a major drug company and prominently featured a drug marketed by the company for the chemical dissolution of certain gallstones. The programs encouraged doctors to prescribe this drug *instead* of surgery to treat gallstone disease. These representations and suggestions were false or misleading because: (1) The drug is approved only for dissolving certain types and sizes of gallstones in patients for whom surgery is not medically appropriate, or for patients who refuse surgery, and (2) surgery is more effective and is the preferred treatment for almost all patients with gallstone disease.

These industry-sponsored presentations could have caused many physicians to make inappropriate and potentially harmful treatment decisions. After FDA notified the sponsoring company that the programs were false or misleading, the company agreed to take appropriate corrective action.

In a more recent example, a major drug company sponsored a misleading symposium on cyclosporine drug products (approved to prevent organ rejection in kidney, liver, and heart transplant patients), held in conjunction with the annual meeting of the American Society of Transplant Physicians. The sponsoring company's ''pioneer'' (nongeneric) cyclosporine drug product was about to lose patent protection and face competition from lower-priced generic cyclosporine products at the time of the symposium.

An investigation by FDA revealed that the sponsoring company and its agent specifically requested that one invited speaker revise his abstract to remove any references to the impending availability of generic cyclosporine products, to delete or revise sections of text that did not support switching stable patients to the sponsoring company's product, and to make other revisions to his presentation. Despite the speaker's insistence on including his abstract as originally written, the sponsoring company again asked the speaker to revise his abstract and presentation. When the speaker again refused to revise his abstract, it was not

[6] The prescription drug advertising regulations, issued under section 502(n) of the act, provide that an advertisement does not satisfy the requirement that it present a ''true statement'' of information in brief summary if it is false or misleading with respect to side effects, contraindications, or effectiveness (see 21 CFR 202.1(e)(5)(i)). In addition, the regulations list 33 ways in which prescription drug advertisements may be false or misleading (see 21 CFR 202.1(e)(6) and (e)(7)).

included in the program materials disseminated during the symposium.

The sponsoring company's actions to control the content of the symposium resulted in a misleading presentation in that: (1) The sponsoring company implied that the speakers were speaking without editorial input or influence from the sponsoring company, and (2) the sponsoring company foreclosed a full discussion of all cyclosporine drug products. The sponsoring company's efforts undermined the unbiased exchange of scientific information, may have caused physicians to unnecessarily switch stable patients to the company's product, and likely resulted in greater than necessary expenditures by patients. This might not have been the case had the sponsoring company, consistent with the agency's longstanding policy as articulated in the Draft Policy Statement, not influenced the content of the program.

FDA's guidance also directly advances the Government's interest of protecting the public health by preserving the integrity of the premarket approval process. The act requires sponsors to establish that their drugs and devices are safe and effective for their intended uses before they can be marketed and promoted. Consistent with this statutory scheme, FDA has consistently prohibited the promotion of unapproved products and unapproved uses of approved products. As explained earlier, this preserves the incentive for sponsors to conduct the adequate and well-controlled clinical investigations that are necessary to demonstrate whether products are safe and effective for each of their intended uses, and prevents patients from being exposed to unnecessary harms. There are, unfortunately, several examples of harms associated with the promotion of unapproved uses.

For example, several manufacturers of calcium channel blockers (drugs approved to treat a type of chest pain known as angina) attempted to promote these products for use in patients who had recently suffered heart attacks, called acute myocardial infarctions (post-AMI patients). The use of calcium channel blockers in post-AMI patients is not an approved use, and the agency successfully thwarted these promotional efforts. Many studies of post-AMI calcium channel blocker use have failed to show benefits, and some studies suggest that they may cause harm, particularly in patients with poor heart function. Given the many patients who suffer an AMI each year, the loss of life could have been in the thousands if the manufacturers had promoted this use.

In another example, certain approved anti-arrhythmic drugs were illegally promoted for unapproved uses in post-AMI patients. Included in these promotional activities were industry-sponsored lectures, presentations, and other publicity events. Use of anti-arrhythmic drugs for this unapproved use was substantial and growing until a clinical study (the CAST study) was conducted to evaluate definitively the safety and effectiveness of this use. The study produced a highly unexpected result in that the treatment with anti-arrhythmic drugs produced a 2.5-fold increase in mortality. It is estimated that tens of thousands of deaths were associated with this unapproved use.[7]

More detailed information on the preceding examples and additional examples involving drugs, biologics, and devices are contained in an FDA **Federal Register** notice requesting comments on a citizen petition submitted by the Washington Legal Foundation (see 59 FR 59820, November 18, 1994).

FDA's guidance on industry-supported scientific and educational activities protects the integrity of the premarket approval process because it dissuades manufacturers from using such activities as a means to promote unapproved products and unapproved uses; thereby encouraging scientific research and eliminating unnecessary harms to patients. At the same time, however, the agency acknowledges that drug and device manufacturers have an important role in legitimate scientific and educational discussions, including discussions of unapproved products and unapproved uses. Accordingly, the guidance recognizes that discussions of unapproved uses at industry-sponsored activities may be appropriate, and suggests that the provider include a general disclosure to the audience as to whether any unapproved uses will be discussed. This disclosure accommodates the need for industry-supported discussion on unapproved uses, yet helps ensure that the information presented is not misleading so as to be misconstrued as discussion of an approved use.

d. The fourth prong. The agency believes that the guidance is ''narrowly tailored'' and a reasonable approach to protect the health and safety of consumers by discouraging the dissemination of misleading or biased information, and by maintaining the integrity of the premarket approval process. The ''Factors Considered in Evaluating Activities and Determining Independence,'' in section II.A. of the Final Guidance, are ''reasonable means'' of distinguishing industry-supported activities that are intended to be promotional from those that are intended to be nonpromotional and free from the supporting company's influence and bias.

The Supreme Court has expressed a willingness to defer the fourth-prong determination to the regulating body. (See *Fox*, 109 S.Ct. at 3035; *United States* v. *Edge Broadcasting Co.*, 113 S.Ct. 2696, 2707 (1993).) Since *Fox*, the Court has applied the ''reasonable fit'' standard to uphold the regulation of commercial speech. (See *Edge*, 113 S.Ct. at 2705; *Florida Bar* v. *Went For It, Inc.*, 115 S.Ct. 2371, 2380 (1995).) Moreover, the courts have granted greater leeway and upheld reasonable regulation of commercial speech with regard to potentially harmful activities. (See *Edge*, 113 S.Ct. 2696 (upholding Federal prohibition of lottery advertising on radio in nonlottery State); *Anheuser-Busch, Inc.* v. *Schmoke*, 63 F.3d 1305 (4th Cir. 1995), *cert. denied*, 65 U.S.L.W. 3723 (April 28, 1997) (No. 96–1428) (upholding restrictions on outdoor advertising of alcoholic beverages); *Penn Advertising of Baltimore, Inc.* v. *Mayor and City Council of Baltimore*, 63 F.3d 1318 (4th Cir. 1995), *cert. denied*, 65 U.S.L.W. 3723 (April 28, 1997) (No. 96–1428) (upholding restrictions on outdoor advertising of cigarettes).) Certainly, with regard to the regulation of potentially dangerous drugs and medical devices, FDA is entitled to the same, if not greater, deference.

FDA's guidance on industry-supported scientific and educational activities is narrowly tailored. The guidance applies only to those industry-supported activities that relate to the supporting-company's product(s) or to competing product(s). It is directed to the regulated sponsors of such activities (drug and device manufacturers) rather than the participating professionals. It does not apply at all to independent scientists and organizations (e.g., universities, medical societies, professional groups), which may freely participate in or sponsor scientific or educational activities. Additionally, the agency has made clear that it does not seek to regulate all industry-supported scientific and educational activities under the labeling and advertising provisions of the Act. As explained in the guidance, FDA has not regulated and does not intend to regulate industry-supported activities that are

[7] *More Information for Better Patient Care: Hearing on S. 1477 Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 51, 78–79 (1996) (statement of Thomas J. Moore, Senior Fellow, Center for Health Policy Research, George Washington University).

independent of the promotional influence of the supporting company.

The Final Guidance suggests that the provider ensure:

> [M]eaningful 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.

These disclosures are fully consistent with the First Amendment. (See *Virginia Board of Pharmacy*, 96 S.Ct. at 1830 n. 24 (''They may also make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.''); In *Re R.M.J.*, 102 S.Ct. at 926 (''a warning or disclaimer might be appropriately required * * * in order to dissipate the possibility of consumer confusion or deception.''); Zauderer, 105 S.Ct at 2282 and n.14 (holding that disclosure requirements do not violate the First Amendment as long as they are reasonably related to the state's interest in preventing deception, and indicating that disclosure requirements are one of the acceptable less restrictive alternatives to actual suppression of speech).)

The agency's suggested disclosures are reasonably related to ensuring that the audience is in a position to fully evaluate the information presented, in order to avoid being misled, confused, or deceived. The guidance suggests that the disclosures be ''meaningful'' and ''to the audience.'' It does not specify how or when during the activity the disclosures should be delivered, or what should be said. Furthermore, as explained previously, the guidance suggests that the provider disclose whether any unapproved uses of products will be discussed. It recognizes that discussions of unapproved uses may be appropriate.

Finally, in response to comments, the agency made revisions to the Draft Policy Statement (reflected in the Final Guidance) that are additional evidence of ''narrow-tailoring.'' The most significant change was to place less emphasis on the elements of a written agreement between the supporting company and the provider, and instead provide guidance on what the agency will consider in evaluating activities and determining independence (Factors Considered in Evaluating Activities and Determining Independence). The Final Guidance makes clear that the list of factors is not exhaustive and that other factors may be appropriate for consideration in a particular case. The supporting company and the provider are free to adopt alternative approaches to help ensure that activities are independent and nonpromotional.

4. Conclusion

FDA strongly believes that the Draft Policy Statement and the Final Guidance on Industry-Supported Scientific and Educational Activities do not abridge the First Amendment because the agency's ability to regulate such activities is essential to the regulation of drugs and devices, and the regulation of drugs and devices is an area of extensive Federal regulation. If however, such activities are considered protected speech, they are commercial speech. The guidance satisfies all prongs of the *Central-Hudson* test, and thus, does not violate the First Amendment.

C. Scope

4. Several comments from the medical device industry argued that medical devices should be exempt from the policy. Some comments recommended, in the alternative, that there be a separate policy specific to medical devices. They argued that the policy initiative resulted from an effort to address abuses in the pharmaceutical industry, and that such abuses are not characteristic of the educational programs supported by medical device companies. Moreover, they maintained that educational programs for devices are more in the nature of hands-on training programs and thus present unique issues that would make compliance with a number of provisions of the draft policy statement (e.g., multiple presentations, audience selection) impractical or impossible.

The agency declines to exempt medical devices from the final guidance. The statutory concepts of labeling, advertising, and intended use do not differ for drugs and medical devices. ''Hands-on'' training sessions sponsored by device manufacturers are inherently product-specific and generally do not fall within the description of independent and nonpromotional educational programs that are contemplated by the final guidance. Training provided or supported by device manufacturers related to labeled uses would present no difficulty for the sponsor. Industry-supported training for off-label uses, however, will ordinarily be viewed by the agency as violative of the act.

5. Several comments from the animal drug industry and the veterinary community contended that animal drugs should be exempt from the policy. They argued that the animal drug industry is not prone to the same abuses as the human drug industry, that the process by which continuing education programs are provided to veterinarians is not comparable to the process by which continuing education is provided to other health care professionals, and that the administrative burdens and resulting expense imposed by the policy would restrict the availability of educational programs for veterinarians.

The agency acknowledges that the processes by which continuing education is provided for veterinary health care professionals differs in many ways from continuing education for other health care professionals. Nevertheless, the basic principles embodied in the final guidance, the importance of independence, disclosure, and educational design and intent apply to veterinary continuing medical education just as they apply to other industry-sponsored professional education.

6. Several comments addressed the scope of activities that are affected by the policy. Some comments contended that the scope of the policy has been appropriately narrowed to scientific and educational activities directed to health care professionals. They supported the exclusion of activities directed at business, policy, or other nonhealth care professional groups. Other comments argued that the scope should be narrowed further to encompass only those industry-supported educational activities directed to health care professionals who are involved in prescribing or administering regulated products. Several comments expressed concern that the scope of activities to which the policy applies, beyond live presentations, is unclear. They expressed concern about the extent to which the policy applies to presentations in electronic and other media. They contended that the policy should set forth the limitations of its application and, moreover, should expressly exempt written materials from the scope of its application.

Although this final guidance is intended to address industry-supported scientific and educational activities directed to health care professionals, the agency anticipates that presentations to other audiences may lend themselves to the principles described in this final guidance. It is understood that a large majority of health care professionals participate in the diagnostic and therapeutic management of patients and are, therefore, in a position to either prescribe, influence prescribing, or monitor the effectiveness of regulated medical products. Information

presented at continuing education programs may have a significant impact on these health care professionals.

There is no basis for applying a substantially different policy to industry-supported educational or scientific activities that are broadcast, electronically recorded, or disseminated via other emerging media.

7. One comment requested that the agency clarify that the policy applies generally to continuing medical education and also to industry-supported educational activities directed to health care professionals. The comment was concerned that the reference to continuing medical education, in the first sentence of the first paragraph of the background section of the draft policy statement, suggests that the scope of the policy may be limited to continuing medical education.

The agency agrees with the comment and has revised the language to refer to ''continuing education for health care professionals.''

8. One comment was concerned that the language in the background section of the draft policy statement implies that only independent activities, as described in the draft policy statement, can be considered educational activities. The comment stated that accredited educational activities that are not free from company influence, yet *not* inconsistent with approved labeling for any company product discussed, will no longer be regarded as legitimate educational activities.

The final guidance is not intended to distinguish between education and promotion and does not suggest that company influenced activities are illegitimate or noneducational. To clarify this intent, FDA has added a sentence to the background section, which states that the agency recognizes that industry-supported activities can be both nonpromotional and educational. The final guidance is intended to distinguish between industry-supported activities that the agency does not intend to regulate because they are otherwise independent of company influence and those that are subject to regulation because of the substantive influence of the supporting company. Company-influenced activities that provide information to health care professionals on regulated products may be educational in nature. They are, nevertheless, subject to regulation and, thus, must be consistent with approved labeling.

9. Some comments were concerned that the policy narrows or eliminates the ability of companies to engage in scientific exchange as provided for in § 312.7(a) (21 CFR 312.7(a)) (human drugs) and § 511.1(b)(8)(iv) (21 CFR 511.1(b)(8)(iv)) (animal drugs). The comments contended that the draft policy statement seems to subject company-controlled scientific exchange to regulation because it is not an independent activity. They contended that appropriate company-controlled scientific exchange should be expressly exempted from regulation in the policy.

This final guidance seeks to clarify the distinction between the concepts of promotion/commercialization and industry-supported scientific exchange set forth in §§ 312.7(a) (human drugs) and 511.1(b)(8)(iv) (animal drugs). Programs supported by companies that are not otherwise independent scientific or educational activities are subject to regulation as product promotion/commercialization.

10. Several comments contended that the policy is fundamentally flawed in that it institutionalizes industry support for continuing education activities for health care professionals. One comment argued that part of the definition of continuing medical education should be that it is nonsubsidized. Other comments recommended that the agency encourage multiple-source funding for educational activities to minimize the potential for bias as the policy may not be adequate to prevent the subtle bias inherent in a single sponsor situation.

The ''institutionalization'' of industry support for continuing education predates the agency's draft policy statement. The agency has sought to avoid, through its policy, undue interference with the availability of continuing education. Although FDA shares the concerns of some health care professionals that substantial reliance on industry funding may result in bias in continuing education, such should be addressed by the profession rather than by the agency. Although enlisting multiple sponsors would likely reduce the potential for bias toward any one product, the agency believes that this approach may not be practical, in all instances, for all FDA-regulated products.

D. Background: Promotion, Education, and Independence

11. Some comments objected to language in the background section of the draft policy statement indicating that, in assessing whether an industry-supported activity is independent, the agency will examine whether and to what extent the company ''is in a position to influence'' the presentation. They contended that the correct inquiry is whether a company has actually influenced a presentation, not whether a company was in a position to influence the presentation.

The agency cannot, in all cases, presume a provider to be independent merely because there is no documented attempt by the supporting company to influence the program. Business relationships or other relationships may influence a provider. A provider whose continued existence depends on the funding and goodwill of a supporting company may, for practical purposes, be in the same position as a company employee, who depends on his or her salary. Whether or not a company is in a position to influence the presentation is important in determining whether the activity is independent.

12. One comment objected to the first sentence of the fifth paragraph to the background section of the draft policy statement; this sentence indicated that, in assessing whether an activity is independent, the agency will examine whether and to what extent the company is in a position to ''otherwise use the presentation as an advertising vehicle.'' The comment contended that this language is ambiguous as to what might cause the agency to conclude that a supporting company has otherwise used a presentation as an advertising vehicle.

The agency agrees that clarification may be helpful. Accordingly, FDA has revised the text to state that the agency will examine whether and to what extent the company is in a position to ''otherwise transform an ostensibly independent program into a promotional vehicle.''

13. One comment suggested that the example provided in the parenthetical statement in the fifth paragraph to the background section of the draft policy statement (57 FR 56412 at 56413) be changed from ''if the provider believes that future financial support from the company depends upon producing programs that promote the company's product'' to ''if the provider *has reason to believe * * *.*''

The agency agrees with the suggested change and has revised that section of the final guidance accordingly.

E. Policy: Scientific and Educational Activities Supported by Industry

The draft policy statement, in discussing FDA policy generally, stated that the agency ''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'' (57 FR 56412 at 56413). The agency further stated that

''companies and providers who wish to ensure that their activities will not be subject to regulation should design and carry out their activities based on a written agreement * * * that the provider will be solely responsible for designing and conducting the activity * * *.''

14. Some comments contended that to make the provider solely responsible for design and conduct of an educational activity excessively restricts supporting company involvement. They suggested revising the text to make the provider ''ultimately'' responsible for design and conduct of an educational activity.

In order to maintain the concept of independence described in this final guidance, it is important to retain the concept of provider ''sole responsibility'' for the design and conduct of the activity. This guidance is not designed to restrict companies from continuing to provide programs for health care professionals, but to distinguish between activities that are otherwise independent from the promotional influence of the supporting company and those that are not. A provider who merely adopts a company-designed presentation has not functioned as a truly independent educational provider.

1. Written Agreement—Generally

Although the draft policy statement did not require a written agreement, it did state that a written agreement can ''play an important role in helping to ensure that an industry-sponsored activity comes within the safe harbor traditionally recognized by the agency for independent scientific and educational activities'' (57 FR 56412 at 56413). The draft policy statement also described 10 elements the agency would anticipate in such written agreement.

As discussed in comment 15 of section II.E.1. of this document, the final guidance was modified to place less emphasis on a written agreement, but states that a written agreement is one way to document what measures were taken by the parties to maintain the independence of an activity.

15. Several comments suggested that a written agreement between the provider and supporting company was required and overly burdensome, both substantively and administratively. These comments identified a number of possible consequences including, foremost, that the written agreement would function as a disincentive for industry to support continuing education, resulting in fewer and lower quality educational activities. Several comments objected to the written agreement in general as overly restrictive and intrusive, containing too many elements, unwieldy, and/or impractical. The comments suggested, among other things, that there should be no requirement at all, that the agreement should provide only that the provider exercises final control and that the agreement should provide only that the program be objective, balanced, and scientifically rigorous, and that there be disclosure with all other details left to the parties. Other comments recommended that the agency develop a ''generic'' written agreement, or alternatively, provide guidance to national accrediting organizations as to the content of acceptable standardized written agreements. Still other comments were supportive of the concept of a written agreement, did not anticipate that written agreements would be unduly burdensome, and moreover, maintained that the written agreement would improve the process of developing meaningful educational activities. Some comments suggested that, for their purposes, the fact that clear guidance, which distinguishes regulated from nonregulated activities exists, may be more important than what the guidance actually contains. The comments complained that the lack of guidance, and resulting uncertainty as to the regulatory consequences of industry support for scientific and educational activities, have made industry reluctant to provide support for these activities.

As noted earlier, the agency has clarified its intention that a written agreement between the supporting company and the provider is recommended, and *not* required. The final guidance recognizes that a written agreement is one way of documenting the measures taken by the provider and the supporting company to ensure independence of an activity. The agency does not anticipate that a written agreement would be an undue burden for any of the parties involved in continuing education for health care professionals. Moreover, the agency anticipates that such agreements will enhance, rather than detract from, the quality of industry-supported educational activities.

16. One comment contended that failure to abide by the terms of a written agreement should subject the parties to additional penalties beyond those currently provided for in the act.

The agency believes that its existing statutory authority is sufficient to address industry-supported activities that are subject to regulation and may be violative.

2. Statement of Purpose

The draft policy statement's ''Statement of Purpose'' section (section II.A.1.) advised that the company and the provider should agree that the program ''is for scientific or educational purposes and not for the purpose of promoting any product and that any discussion of the company's products will be objective, balanced and scientifically rigorous'' (57 FR 56412 at 56413).

FDA has deleted the ''Statement of Purpose'' section because the elements of a written agreement are no longer described in the final guidance.

3. Control of Content/Selection of Presenters

The draft policy statement stated that the provider would be responsible for exercising full control over the planning of the program's content, including the selection of presenters and moderators. The draft policy statement indicated that companies should ''play no role in the selection of presenters or moderators other than responding to provider requests'' for such persons, but that companies could make unsolicited suggestions of speakers to ''nationally recognized accrediting organizations that compile lists of speakers * * *'' (57 FR 56412 at 56413). The draft policy statement specified further details regarding requests for speakers, such as having companies agree to provide, where reasonably possible, the names of more than one suggested presenter and to ''disclose all known significant financial and other relationships between the company and suggested presenter.'' The draft policy statement stated that providers should agree to seek suggestions for presenters from sources other than the company, to make independent judgments on appropriate presenters, and to select presenters ''representing an appropriate diversity of legitimate medical opinion on the topic under discussion when the format permits * * *'' (57 FR 56412 at 56413). Additionally, the draft policy statement stated that providers should agree to disclose whether a presenter was suggested by the company. The final guidance includes a factor concerning ''Control of Content and Selection of Presenters and Moderators'' (section II.A.), which contains most of the concepts described in the draft policy statement.

17. Several comments objected to the provision in the draft policy statement concerning presenters suggested by the supporting company. The comments objected in particular to the statement that the provider agrees to disclose

when it has selected a presenter suggested by the supporting company. These comments contended that such disclosure is unnecessary because it unfairly raises the specter of bias as to that presenter and, moreover, the ''Disclosure of Financial Relationships'' element of the draft policy statement (section II.A.3.) provides for adequate disclosure of any significant relationship between the presenter and the supporting company. Other comments contended that the supporting company should under no circumstances be permitted to suggest presenters.

As stated in the draft policy statement, there is a perceived need on the part of some providers for assistance from supporting companies in identifying appropriate speakers. The agency is unwilling, at this time, to infer undue influence by the supporting company if it responds to a request from such a provider. Health care professionals are entitled to know the nature of any involvement by supporting companies in educational efforts. However, the agency agrees with the comment that disclosure of any significant relationship between the provider, supporting company, and presenters or moderators would be sufficient. The possibility of unwarranted bias against presenters suggested by industry should be dealt with in the open environment of scientific exchange. Accordingly, the final guidance does not address specific disclosure of the supporting company's suggestions for speakers or moderators.

18. Some comments objected to the statement that a supporting company, when responding to a provider request for suggestions of presenters, agree to disclose all known significant financial and other relationships between the suggested presenter and the supporting company. They argued that this provision is burdensome and redundant in light of the disclosure obligation in the ''Disclosure of Financial Relationships'' section of the draft policy statement (section II.A.3.).

The agency believes that a presenter's significant relationships with a supporting company are, like a presenter's qualifications, essential to a provider's informed decision as to the appropriateness of a suggested presenter. Although the final guidance does not specifically state that the agency will consider whether the supporting company disclosed such relationships, it is suggested that this type of disclosure be made.

The agency does not agree that this disclosure is redundant with the ''Disclosures'' section of the final guidance (section II.A.) because the two provisions serve different purposes. The disclosure made by the supporting company when suggesting a speaker is to assist the provider in evaluating the appropriateness of the suggestion. The ''Disclosures'' section of the final guidance is to inform the audience, at the time of the program, of the presenter's relationship with the supporting company in order to provide the audience a perspective from which to evaluate the information conveyed by the presenter. The agency does not view the supporting company's disclosure when suggesting a presenter as more comprehensive than the disclosure to the audience in the ''Disclosures'' section.

4. Disclosure of Financial Relationships

The draft policy statement suggested that, as part of the written agreement, the provider agrees to ''ensure meaningful disclosure'' of the company's funding of the activity and ''any significant relationship between the provider and the company and between individual presenters or moderators and the company * * *'' (57 FR 56412 at 56413). In the final guidance, this provision is incorporated in the general ''Disclosures'' section.

19. Several comments sought clarification as to what is meant by ''meaningful'' disclosure and ''significant'' relationships. Several comments also contended that this provision is an administrative burden, and that it places a disproportionate burden on the provider, as opposed to the supporting company and presenters.

Significant relationships are relationships that may give rise to actual or perceived conflicts of interest. The concept of disclosure of relationships that may give rise to conflicts of interest has specific and well-understood application to medical and scientific discourse (e.g., in publication and in the peer-review process). The agency envisions that this provision can be satisfied by disclosing the existence of and characterizing significant relationships, and need not include further detail such as the amount of compensation or funding received. Thus, this disclosure should impose only a minimal burden on providers, presenters, and supporting companies. Where there is a question as to whether a relationship is significant, providers, presenters, and supporting companies should disclose the existence of the relationship.

Meaningful disclosure is disclosure that is reasonably calculated to reach the relevant audience in a manner that will alert them to potential biases. The provider should determine how to ensure that disclosure is meaningful.

20. One comment contended that significant relationships between the supporting company and providers and presenters should preclude any characterization of the activity as an independent educational activity inasmuch as disclosure is not adequate to cure the taint of influence.

It is neither practical nor justified to make a potential conflict of interest an absolute bar to participation in an independent educational activity. Disclosure of such potential conflicts is a workable means to address the potential for bias in medical and scientific contexts, and there is no reason to believe that it will be any less workable in addressing the potential for bias in the context of industry-supported scientific and educational activities.

21. Another comment argued that disclosure is the only element of the written agreement that should be retained, that company involvement should be permitted, and that it should be left to the judgment of the audience as to how to evaluate the content of the program.

While disclosure may be deemed by some in the health care profession a proper solution to concerns about bias, the agency's concerns are not wholly satisfied by disclosure. Under the act, the regulated industry cannot promote its products for unapproved uses, or otherwise promote drugs, biologics, or medical devices in ways not consistent with approved labeling, even in the context of unbiased presentations in which the company's role is fully disclosed. Discussions of unapproved uses, or other matters not consistent with approved labeling, should occur in a context of independent scientific or educational activity produced by organizations and individuals who are not involved in marketing the products. Thus, disclosure alone is not adequate to ensure independence in industry-supported scientific and educational activities as it does not insulate such activities from the substantive influence of supporting companies.

5. Supporting Company Involvement in Content

The draft policy statement suggested, as part of the written agreement, that a company agree not to engage in scripting, targeting of points for emphasis, or other activities that are designed to influence a program's content. The draft policy statement indicated, however, that companies could provide ''limited technical assistance * * * in preparing slides or

audiovisual materials * * *'' (57 FR 56412 at 56413). In the final guidance, this discussion is included in the ''Control of Content and Selection of Presenters and Moderators'' factor. Although discussion regarding ''limited technical assistance'' is not included in the final guidance, as discussed in the response to comment 22 of section II.E.5. of this document, technical assistance is a concern.

22. Several comments recommended that the agency more clearly define the limits of permissible technical assistance. Some comments argued that the policy should preclude all technical assistance, as to permit such assistance opens the door to influence. Other comments raised concerns that the policy is overly restrictive as to technical assistance in which supporting companies may engage. Several comments argued that supporting companies should be allowed to script, target points for emphasis, and provide unlimited technical assistance so long as such influence does not unfairly bias the program.

The agency continues to believe that the supporting company should not engage in activities that could influence the presentation's content. Activities such as scripting and targeting points for emphasis can have a direct effect on the presentation's direction, balance, and overall message. A company-designed and financed presentation, even if approved by an independent provider, remains, in the agency's view, an activity that is not independent.

In addition, because the agency shares the concern that technical assistance may open the door to influence, the agency suggests that the supporting company should provide limited technical support only in response to an unsolicited request for assistance from either the provider or a presenter.

6. Ancillary Promotional Activities

The draft policy statement indicated that the written agreement should include an agreement by supporting companies to not have any promotional activities or promotional exhibits ''in the same room or in an obligate path to the educational activity, unless the exhibit is within an area that is designated for general exhibits and includes exhibits from different companies marketing alternative or competing therapies.'' Additionally, providers would agree that no advertisements for the supporting company's products would appear in any materials disseminated in the program room (57 FR 56412 at 56413). The final guidance states that one factor the agency will consider is whether there are promotional activities in the meeting room.

23. Many comments were concerned about the scope of this element on ancillary promotional activities by supporting companies, specifically the language on promotional activities occurring in an obligate path to the educational activity. These comments asserted that this aspect of the policy was, in general, unduly restrictive; contrary to the normal practice of placing exhibits in advantageous locations; it would have a disproportionate effect on smaller, sole-sponsored, local meetings to the extent that it may make supporting companies reluctant to fund local continuing education activities; and it placed FDA, inappropriately, in the position of influencing meeting facility layout, including routes of ingress and egress into meeting facilities. As a consequence, the comments argued that certain facilities would become more or less attractive venues for educational activities on the basis of physical layout alone. One comment contended that the discussion regarding ancillary promotional activities is overly permissive and blurs the distinction between independence and promotion, which the comment viewed as contrary to the stated purpose of the policy. Another comment argued that the close juxtaposition of an independent educational activity and a promotional activity may sharpen rather than blur the desired distinction.

The agency is persuaded that the language in the draft policy statement regarding promotional activities in an obligate path to the educational activity should be deleted from the final guidance. This provision is problematic in that its application may turn on the physical layout of a building, and thus may favor certain facilities and providers. Moreover, the agency is not convinced that this is necessary to preserve the distinction between an independent educational activity and a promotional activity. The agency gives some credence to one comment's observation that the close juxtaposition of an independent educational activity and a promotional activity may be as likely to sharpen as to blur the desired distinction between independent and promotional activities. Because its contribution to preserving the distinction between an independent activity and a promotional activity is uncertain, there is not adequate justification for this provision in light of its differential impact on affected parties. Consequently, the final guidance has been revised to suggest that ancillary promotional activities should not take place in the actual meeting room.

24. Several comments interpreted the draft policy statement as precluding a sole exhibitor from having a promotional exhibit at either a sole or multi-sponsored educational activity. The comments objected that this would cause the issue to turn on whether other exhibitors chose to exhibit.

These comments misinterpret the draft policy statement. The provision on ancillary promotion would not preclude sole exhibitors from exhibiting at either sole-sponsored or multi-sponsored programs. The final guidance, as revised, merely suggests that promotional activities (sole exhibitors or otherwise) not take place in the meeting room. Companies are otherwise free to exhibit at sole or multi-sponsored programs without threatening the independent status of the activity.

7. Objectivity and Balance and Limitations on Data

The draft policy statement contained two sections, entitled ''Objectivity and Balance'' and ''Limitations on Data'' as part of the suggested written agreement. Under ''Objectivity and Balance'' a provider would agree to take steps to ensure that data are objectively selected and presented, that both favorable and unfavorable information about a product are fairly represented, and that there is a ''balanced discussion of the prevailing body of scientific information'' about a product and reasonable, alternative treatment options. In ''Limitations on Data'' the provider would agree to have ''meaningful disclosure'' of any limitations or uncertainty on data. Neither of these elements are included as factors in the final guidance.

25. Several comments maintained that these two sections would place excessive regulatory burdens on providers because providers would be obliged to screen presentations in advance and would appear to be responsible for the behavior of presenters who are, to an extent, beyond the provider's control. Other comments argued that these sections are inconsistent with the concept of independence because they effectively regulate content in an ostensibly independent program in a manner similar to the fair balance requirement in FDA's advertising regulations. Some comments argued that these elements are necessarily subjective in practice and that, among other things, time limitations, venue, and educational objectives may influence the extent to which a program is considered balanced or discusses data limitations. Other

comments maintained that these elements state only that which should reasonably be expected in legitimate, independent scientific discourse and thus are not appropriately the subject of a regulatory policy. They maintained that having these elements as part of the written agreement is paternalistic because it does not credit the audience with the intelligence and means to require objectivity and balance and to put presented data in its appropriate context. Still other comments supported these elements.

The agency is persuaded that these elements are not necessary to help ensure that sponsored programs are nonpromotional and independent of the supporting company's influence, and that there is adequate disclosure of relationships and information that is relevant to the audience's assessment of information presented. The agency is also persuaded that objectivity, balance, and disclosure of data limitations are commonly understood to be elements of typical, independent scientific discourse. The agency is convinced that these issues should be left to providers, presenters, and accreditors of educational activities and, therefore, these elements are not included as factors the agency will consider in determining independence.

8. Discussion of Unapproved Uses

The draft policy statement suggested that if unapproved uses are discussed, the written agreement include an agreement by the provider that presenters disclose that the product is not approved in the United States for the use under discussion. The final guidance states that the agency will consider whether there is meaningful disclosure, at the time of the program, to the audience of whether any unapproved uses of products will be discussed.

26. Several comments contended that this element is inconsistent with the concept of an independent program, burdensome, and would limit scientific exchange. Several comments added that the ultimate content of presentations is beyond the control of providers and that it would be cumbersome to flag discussion of unapproved products or uses throughout a program or presentation. Comments from the oncology community argued that this aspect of the written agreement would be especially burdensome for oncology educational programs because it would likely apply to the bulk of product uses discussed. One comment suggested using a general disclaimer in the program materials that not all products or product uses to be discussed are approved uses in the United States, rather than requiring presenters to specifically identify those unapproved uses.

The agency is persuaded that this disclosure, as presented in the draft policy statement, has the potential to be burdensome and unwieldy in practice, particularly in specialty areas where a high percentage of product use is for unapproved uses. Therefore, the final guidance does not include as a separate factor that providers have presenters disclose that a particular product or use is unapproved.

The agency, however, believes that the fact that a program may include discussion of products or product uses that are not approved is a matter that warrants disclosure. This fact, along with acknowledgment of the supporting company's funding of a program, is important to an audience's assessment of the information presented. The agency believes that a less burdensome disclosure than that proposed in the draft policy statement would suffice. The agency agrees with the comment that a single, general disclosure as to whether a program, or individual presentations in a program, will include discussion of products or product uses that are not approved would be adequate to address the agency's concern. Therefore, FDA has deleted the ''Discussion of Unapproved Uses'' element from the final guidance, and the factor discussing ''Disclosures'' has been revised to suggest that the provider ensure meaningful disclosure, at the time of the program, to the audience of whether any unapproved uses of products will be discussed. Ideally, such disclosure should occur in conjunction with disclosure of the supporting company's financial support for the program. This disclosure could take the form of a statement in the program materials or be delivered verbally at the start of the program.

27. Several comments contended that presenters should be permitted to report on foreign regulatory status, and pending U.S. applications and supplements for products discussed.

Nothing in this final guidance should be construed as barring presenters from discussing the foreign regulatory status of a product, or indicating that a product being discussed is the subject of a pending new drug application or supplement in the United States.

9. Opportunities for Debate

The draft policy statement included an element that the provider agree, in the case of live presentations, to provide ''meaningful opportunities for scientific debate or questioning'' during the program (57 FR 56412 at 56414). The final guidance includes a similar factor entitled ''Opportunities for Discussion.''

28. Several comments contended that it is not always practical to provide meaningful opportunities for debate because such opportunities may be contingent on the size of the program, time constraints, willingness of an audience to participate, and other factors unrelated to a program's independence. These comments maintained that an opportunity for debate should be a goal of an independent program, but not included in all activities. Other comments asked the agency to clarify what is meant by ''meaningful opportunities'' for debate.

The agency agrees that opportunities for debate should be a goal of an independent program, but it is not practical or appropriate in all activities. Factors unrelated to a program's independence could intercede to preclude an opportunity for meaningful debate. The agency's inquiry concerning this factor likely would be whether a program format reasonably afforded an opportunity for discussion, and such opportunity was nonetheless not provided. This finding may suggest an intent to insulate from peer scrutiny the data and ideas presented. As with the other factors in this final guidance, a finding that a meaningful opportunity for discussion was denied may suggest that a program was not independent despite representations to the contrary.

Certain comments seeking clarification of what is meant by a ''meaningful opportunity for scientific debate or questioning'' seem to have inferred a more stringent concept than was intended. The goal contemplated is no more than a reasonable opportunity for the type of question and answer session typical of continuing education activities. The agency has changed the word ''debate'' to ''discussion'' to reflect this less structured intent.

10. Schedule of Activities

The draft policy statement suggested that the company and provider agree to, and record in the written agreement, the dates, times, and locations of all presentations (57 FR 56412 at 56414).

29. Several comments contended that it is overly burdensome to have a supporting company and provider identify all presentations to be held. They maintained that this is problematic in that not all future programs may be anticipated at the time a provider and supporting company enter into an arrangement. Several comments maintained that the fact of multiple presentations of the same program should not be viewed as

suggesting possible promotional intent so as to warrant higher scrutiny. Some comments argued that it is desirable to repeat certain programs for public health reasons, that demand for additional programs suggests that a program is valuable, and that repeat presentations are desirable as they are the most efficient way to disseminate valuable information. Some comments contended that there should be a distinction between multiple programs that were agreed to in advance of any presentation and those that were agreed to after the fact, and only the later should be subject to higher scrutiny.

The agency is convinced that it may be difficult for a supporting company and provider to document the dates, times, and locations of all presentations in advance and, therefore, has removed this element from the final guidance. The agency, however, remains convinced that, in some circumstances, the fact of multiple presentations may be an indicator of supporting company influence. The agency agrees that multiple presentations of the same program are more troublesome when a supporting company agrees to fund additional programs after having viewed the initial program. This opportunity to view a program in advance of a decision to fund additional programs provides an obvious degree of control over content of multiple presentations. Thus, these programs would be viewed with greater scrutiny.

F. Other Factors in Determining Independence

The draft policy statement stated that if, notwithstanding the presence of a written agreement, a question is raised regarding product promotion, FDA would consider several ''possible indicia of company influence.'' These factors included, among others, an examination of the relationship between the provider and supporting company, the provider's involvement in the company's sales or marketing, logistical assistance provided by the company, the program's focus (whether the program concentrated on a single product), and gifts to encourage attendance (57 FR 56412 at 56414). The draft policy statement also indicated that ''no individual factor is likely by itself to stimulate an action based on lack of independence.'' Many of the factors that were discussed in the ''Other Factors in Determining Independence'' section of the draft policy statement (section II.B.) have been retained in the final guidance.

30. Several comments advised deleting this entire section from the policy. Another comment contended that the articulated factors undercut the protection afforded by the policy by permitting post hoc review of a provider's decisions for indications of possible influence.

The agency believes that it is important to consider the actual conduct of the parties in determining whether a supporting company has acted to transform an educational activity into a promotional presentation for its products. By including this discussion in the ''Factors Considered in Evaluating Activities and Determining Independence'' (section A. of the final guidance), the agency believes that there will be less concern regarding post hoc review.

1. Relationship Between Provider and Supporting Company

The draft policy statement noted that legal, business, or other relationships between the company and the provider might place the company in a position whereby it could influence the content of the activity. This discussion is contained in the final guidance as a factor the agency will consider.

31. Some comments contended that there should be clarification of the types of relationships that predispose a supporting company to influence content. Some comments argued that ''influence'' is too expansive or vague a term, and that, a more appropriate inquiry would be supporting company ''control.''

As discussed in response to comment 14 of section II.E. of this document, a company-designed presentation does not become independent merely because it is approved by a provider who has final editorial control. The agency believes that ''influence'' is the most appropriate term to describe the basic concept of independence. The final guidance does, however, identify several types of relationships that may predispose a supporting company to influence content (e.g., legal relationships, business relationships, a provider that is owned by, or is not viable without the support of the supporting company).

32. One comment contended that legal, business, or other relationships should not be at issue where ''a provider has documented independence through accreditation from a major accrediting organization.''

There is no basis for assuming that accreditation of the provider by a major accrediting organization will, in and of itself, ensure that the provider will not be subject to influence as a result of a relationship with the supporting company.

2. Provider Involvement in Sales or Marketing

The draft policy statement listed, as another factor in determining independence, the provider's involvement in advising or assisting in the sales or marketing of a company's product. The discussion in the draft policy statement stating that ''individuals who are involved in promotion of a company's products may not function in the role of independent provider, but could be selected by an independent provider to function as a speaker or moderator'' (57 FR 56412 at 56414) has been deleted. The remaining discussion is listed in the final guidance as a factor the agency will consider.

33. Some comments identified situations where this provision may be interpreted so as to preclude institutional providers and/or companies from interacting due to minor or unrelated involvement with the supporting company.

The primary concern of the agency, as reflected in the draft policy statement, is with relationships that may affect the provider's independence. A relationship between a provider member or employee and a supporting company will not, in and of itself, imply influence by the company. If, however, company employees or individuals acting on behalf of the company are actively involved in provider decisions on the content of provider activities sponsored by the company, there may be a reason to question the provider's independence.

34. Some comments contended that this provision does not adequately distinguish between advertising agencies involved in sales and advertising, and communications companies involved in education, which also may be viewed as a marketing function, nor does it allow for the existence of advertising and communications (or education) divisions within the same company.

FDA acknowledges that certain providers are often involved in both promotional activities and independent educational activities. The involvement of a provider in both types of activities does, however, raise questions about whether an educational activity is, in fact, being utilized as part of a promotional campaign.

While the final guidance does not preclude the use of the same provider in a promotional effort and an independent educational activity, such an arrangement poses obvious difficulties. Companies choosing to engage a provider in both activities should be especially concerned about the

assignment of provider personnel to the different activities. The agency will not ordinarily regard provider personnel who serve as company agents for company promotional activities to be independent for other company-sponsored scientific or educational activities.

3. Provider's Demonstrated Failure to Meet Standards

The draft policy statement identified, as a factor in determining independence, the provider's record of failure to meet standards of independence, balance, objectivity, or scientific rigor when putting on ostensibly independent educational programs (57 FR 56412 at 56414). This discussion is listed in the final guidance as a factor the agency will consider.

35. Some comments sought clarification as to what is meant by, or what criteria support a conclusion of, ''demonstrated failure to meet standards'' on the part of a provider. Some comments contended that this is an unworkable requirement as supporting companies are not in a position to know of a provider's past failures to meet standards in its educational programs.

It is not unreasonable to expect due diligence on the part of companies when contracting with providers. In exercising due diligence, supporting companies should conduct a reasonable evaluation of all information readily available about a provider.

4. Logistical Assistance

Another factor in determining independence contained in the draft policy statement was the extent of logistical assistance provided by the supporting company. The draft policy statement specifically mentioned that ''significant contact'' between industry representatives and presenters might indicate an attempt to influence a presentation (57 FR 56412 at 56414). As discussed in comment 36 of section II.F.4. of this document, this discussion has been deleted from the final guidance.

36. Several comments argued that the logistical assistance element was too ambiguous a standard as it is not clear what is meant by ''significant contact.'' Some comments argued that, notwithstanding any ambiguity, significant contact between a presenter and a supporting company representative should not be an indicator of influence as the agency's inquiry should focus on actual attempts to influence or control the content of a presentation. They maintained that supporting company representatives have ongoing relationships with presenters that would make compliance with a generalized ''significant contact'' standard problematic.

While the agency believes that the ''significant contact'' standard is amenable to clarification, it need not be, as the agency is persuaded that its inquiry concerning contacts between a presenter and a supporting company in conjunction with a sponsored program should focus on attempts to influence, rather than on volume or nature of contacts. A supporting company, among other factors for determining independence, should not script, target points for emphasis, or engage in other activities that are designed to influence the content of a program. The agency believes that factor alone is adequate to address the agency's concern as to contact between a supporting company representative and a presenter in conjunction with a sponsored program. Therefore, discussion of the logistical assistance provision has been deleted from the final guidance.

5. Suggestion of Presenters

The draft policy statement acknowledged that some providers perceive a need to ask the supporting company to suggest presenters. The draft policy statement stated that if a company suggests presenters 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,'' FDA might infer promotional intent on the company's part (57 FR 56412 at 56414). This discussion has been incorporated, in part, into the factor concerning ''Control of Content and Selection of Presenters and Moderators'' in the final guidance.

37. Some comments contended that a supporting company may not be in a position to know if a presenter it suggests has been the subject of complaints with regard to presentations viewed as biased in favor of the company's products. They maintained that this provision should expressly indicate that supporting companies are only accountable for knowingly suggesting presenters that have been the subject of such complaints.

The agency believes that the company should be familiar with the presenter's background and should be willing to make a reasonable inquiry before recommending the name of a presenter to the provider. In the final guidance, this discussion has been incorporated in the factor concerning ''Control of Content and Selection of Presenters and Moderators.''

38. Some comments contended that there should be no inference of promotional intent arising from a supporting company's suggestion of a presenter who has been involved in promoting a company's products. They argued that actual influence of, rather than intent to influence, an activity is the relevant inquiry, that the scope of activities that may be viewed as involvement in product promotion is unclear, and that any relationship between the presenter and the supporting company can be adequately addressed through disclosure.

The agency is concerned about the ability of a supporting company to hire an individual to engage in promotional activities for the company and to actively support the appearance of the same individual as a presenter in an independent educational activity sponsored by the company. The agency does not agree that a retrospective finding of actual influence, which may be extremely difficult to document, is the relevant inquiry. The issue is whether the company is in a position to influence program content by suggesting a presenter who is a paid product promoter. The suggestion by supporting companies of presenters selected from their company maintained list and/or their marketing consultants may be viewed as an attempt to influence the content of the program. The agency will not ordinarily infer such intent when a provider independently selects a presenter who has been involved in product promotion for a supporting company. Disclosure cannot overcome the lack of independence that will ordinarily result from companies suggesting promoters as presenters in such programs.

6. Focus on a Single Product

The draft policy statement indicated that one factor in determining independence might be whether the program content was focused on a single product marketed by the supporting company or a competing product except when existing treatment options were so limited as to preclude any meaningful discussion of alternative therapies. The draft policy statement noted that each treatment option did not have to be discussed with equal emphasis, but that emphasis on newer or more beneficial treatments should be provided ''in the context of a discussion of all reasonable and relevant options'' (57 FR 56412 at 56414). This discussion has been incorporated in the factor concerning the ''Focus of the Program'' in the final guidance.

39. Some comments contended that focus on a single product should not be regarded as a factor that may suggest lack of independence, as single product programs are useful, especially during a product's launch phase, and choice of topic should be at the provider's discretion and should confer no negative inference.

FDA agrees that single product programs may be useful, especially during a product's launch phase. However, the agency also recognizes that single-product programs raise unique concerns about the independence of a program, because such programs inherently lack the presentation of competing therapeutic modalities.

40. Several comments contended that to suggest that a program emphasizing a single product do so in the context of a discussion of all reasonable and relevant options is unreasonable or impossible given the time constraints of a typical educational activity.

The final guidance does not suggest that a program emphasizing a single product do so in the context of a discussion of all reasonable and relevant options. However, the agency will consider, as one of several factors, a program's focus on a particular therapy when other reasonable and relevant options are either not discussed or are de-emphasized.

7. Multiple Presentations

The draft policy statement indicated that multiple performances of the same program might result in a higher level of agency scrutiny than single-performance programs (57 FR 56412 at 56414). The final guidance states that the agency will consider whether multiple presentations of the same program are held.

41. Several comments contended that multiple presentations should not be viewed as suggesting promotional intent so as to warrant higher scrutiny. They argued that it is desirable to repeat certain programs for public health reasons, that the demand for multiple programs suggests that a program is a valuable one, and that repeat presentations are desirable as they are the most efficient way to disseminate valuable information. Some comments contended that there should be a distinction between multiple programs that were agreed to before the fact and those that were scheduled after the fact. They contended that only the latter should be subject to a higher level of scrutiny.

Multiple presentations are just one of a number of factors the agency considers in determining the level of scrutiny to be applied. Footnote 4 of the draft policy statement explicitly recognized that repeat presentations can serve public health interests and that Public Health Service components sometimes actively encourage multiple presentations on selected urgent topics. FDA agrees that an agreement to conduct multiple presentations arrived at prior to commencement of the initial presentation raises fewer questions than an agreement arrived at after commencement. The opportunity of a sponsor to view the initial presentation before agreeing to fund additional presentations provides an obvious degree of control over content of multiple presentations.

42. Some comments sought clarification of the scope of activities that may be deemed multiple presentations. The comments described examples such as a single broadcast to multiple sites via electronic media, and a multiple presentation at a single location for the purpose of accommodating several nursing shifts.

A single broadcast to multiple sites would be regarded as a single presentation because the sponsoring company could not apply added control to the additional sites. Thus, the presentation at each site enjoys an equal degree of independence. This is only slightly less true for multiple presentations to accommodate several shifts on the same day, especially when the multiple presentations have been contracted for in advance. Of course, the delay might be 1 or 2 weeks to accommodate those who might have been on a different rotation or 1 or 2 months to accommodate newly hired employees. FDA believes that any increased opportunity for a sponsoring company to deny funding for subsequent presentations or to edit them will raise a question with regard to independence.

8. Gifts

The draft policy statement indicated that one factor in determining independence might be gifts or inducements (other than token gifts) provided to encourage attendance (57 FR 56412 at 56414). The final guidance does not contain this factor.

43. One comment argued that this provision should be deleted because it merely duplicates the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

ACCME-accredited programs do not represent the full range of activities to which this final guidance applies, and moreover, providers of ACCME-accredited programs may not, in all instances, comply with ACCME-guidelines. Nonetheless, this factor has been deleted from the final guidance because, upon reconsideration, the agency is not convinced that the use of gifts or inducements to encourage attendance is a reliable factor in determining independence.

9. Emphasis on Noneducational Activities

The draft policy statement indicated that an emphasis on noneducational activities (such as leisure or recreational activities) would be another factor in determining independence (57 FR 56412 at 56414). The final guidance does not contain this factor.

44. Some comments contended that the agency's concern over whether the announcement and promotion of an educational activity focuses more on the educational content than on leisure or recreational activities ancillary to the activity is vague and that the agency should provide objective criteria for assessing this issue. One comment contended that this provision appears to create a weaker standard than that of the AMA guidelines on gifts to physicians as it seems to indicate that a program announcement or promotion that focuses equally on education and leisure would be appropriate. They urged that the language be changed to require that the program announcement and promotion focus ''predominantly'' or ''almost exclusively'' on the educational aspects of the program.

The agency continues to view the AMA guidelines as an appropriate standard for health care professionals. Although the agency agrees that program promotion, including program announcements, should focus predominantly on the educational content of the program, it does not consider greater focus on leisure or recreational activities as reason to believe that the program may be lacking independence.

10. Audience Selection

Under the draft policy statement, another factor in determining independence was whether the supporting company's sales or marketing departments generated the invitation or mailing lists for supported activities, or whether such lists were intended to reflect sales or marketing goals (such as rewards for high prescribers of the company's products or to influence ''opinion leaders'') (57 FR 56412 at 56414). This discussion is listed in the final guidance as a factor the agency will consider.

45. Several comments objected to limitations on supporting company involvement in selecting or otherwise

generating audiences for educational activities. Some maintained that supporting company-generated mailing lists should be permitted. Some maintained that providers should be permitted to enlist the aid of the supporting company's sales representatives to generate audiences by distributing program invitations, or by other means, and that this involvement should not suggest a lack of independence unless a supporting company is solely responsible for generating an audience.

The agency continues to view company involvement in audience selection and/or solicitation for attendance as undermining program independence. The involvement of company sales representatives in the invitation process creates an opportunity for a sales presentation on the product that is likely to be discussed at the program. This may invite a discussion of unapproved uses in a promotional context, thus making the educational program a part of the company's promotional campaign. In addition, supporting company involvement in the audience selection process invites the development of lists that target health care professionals who are deemed important to attend by the supporting company. It also invites the selection of a large number of ''peer influence'' professionals who are likely to be strong supporters of the company's products. This provides an opportunity for bias and indirect influence on the content of the program, and it allows the program to be used as a promotional vehicle for targeted health care professionals.

46. Some comments contended that the selection of ''opinion leaders'' as a target audience should not raise an issue inasmuch as such physicians are deemed important by genuinely independent providers as well as companies. They argued that opinion leaders are likely the most efficient purveyors of information derived from educational activities that, by their very nature, are accessible to only a limited number of physicians.

The focus on opinion leaders is a standard promotional tactic to speed acceptance of a new product so as to more rapidly increase market share. The agency's understanding of educational needs assessments by providers is that educational programs generally are not directed to specific opinion leaders. It is the agency's understanding that there is no such policy on the part of major accrediting organizations such as ACCME. It is reasonable to question whether a program that targets ''opinion leaders'' may do so for promotional purposes. This inference of possible promotion, however, is only one of many factors to be considered should a question be raised concerning an educational activity purported to be independent.

47. One comment contended that supporting companies should be permitted to furnish providers with complete specialty and subspecialty mailing lists.

The agency would not object to a supporting company furnishing a provider with complete specialty or subspecialty mailing lists.

11. Misleading Title

The draft policy statement indicated that a program's title might demonstrate a lack of independence if the title failed to fairly represent the scope of the presentation (57 FR 56412 at 56414). This discussion has been incorporated in the factor concerning the ''Focus of the Program'' in the final guidance.

48. One comment argued that, where the title is under the direction and control of the provider, it is not the proper subject of a promotional inference as to the supporting company.

Although the title of a program may ostensibly be under the direction and control of the provider, the agency has observed that a misleading title may reflect a lack of independence and a desire on the part of the provider to promote the supporting company's products under the guise of education. For example, a program entitled ''New Approaches to Hypertension'' that focuses on a single product manufactured by the sponsoring company may suggest to the agency that the program is designed to promote the company's product. A misleading title is not, in and of itself, dispositive with regard to the issue of promotional intent. It is only one of a number of factors to be considered by the agency.

12. Dissemination

Under the draft policy statement, if information about the supporting company's product presented in the scientific or educational activity is further disseminated after the initial program or publication, by or at the company's behest, other than in response to an unsolicited request or through an independent provider, this would be another indication of possible company influence (57 FR 56412 at 56414). This discussion has been incorporated into the final guidance as a factor the agency will consider.

49. Some comments maintained that the independence of an educational activity is enduring and that the public health is better served by making written, printed, or graphic program materials readily available to health care professionals.

Written, printed, or graphic materials containing product information and disseminated by, or on behalf of, a product manufacturer are generally viewed as promotional labeling. If, on the other hand, the materials are prepared and disseminated by the provider for educational purposes, or the materials are disseminated by the company in response to an unsolicited request, this would not generally be considered as a possible indication of company influence.

50. One comment contended that footnote 6 of the draft policy statement (which noted that repeat performances are permitted when the decision is made by the provider, possibly with review by a nationally recognized professional organization) should be deleted, as it appears to be more restrictive for repeat presentations than other provisions in the draft policy statement.

The agency believes that footnote 6 of the draft policy statement is consistent with other provisions of the draft policy statement. As suggested in the text of the draft policy statement, multiple performances may cause the agency to exercise greater scrutiny. However, a decision made by the provider that multiple presentations are warranted provides some assurance that there is a genuine professional need for repetition of the program. Nevertheless, FDA no longer believes that this footnote is necessary and has deleted it from the final guidance.

51. One comment suggested that the reference to ''publication'' in section II.B.5 of the draft policy statement be struck as this appears not relevant to the range of activities contemplated by the policy.

FDA agrees with the comment and has removed the reference to ''publication'' from the final guidance.

13. Complaints

Another factor for determining independence under the draft policy statement concerned complaints from the provider, presenters, or attendees regarding attempts by the company to influence content (57 FR 56412 at 56414). This discussion has been incorporated into the final guidance as a factor the agency will consider.

52. Some comments contended that complaints should be independently substantiated before becoming a basis for the agency inferring promotional intent and that the agency should clarify the mechanism for reporting complaints.

In general, the agency will not infer promotional intent by a supporting company without an investigation that substantiates, to the agency's satisfaction, a complaint or allegation.

The agency declines to establish a formal mechanism for reporting complaints. FDA receives information through various means, both formal (as in requests for meetings) and informal (such as letters and telephone calls). The agency will exercise its judgment and discretion in deciding whether to take action on a complaint.

G. FDA Reliance on Major Accrediting Organizations

The draft policy statement acknowledged that accrediting organizations can play an important role in ensuring that industry-sponsored activities are independent and nonpromotional. The draft policy statement indicated that FDA would seek to rely to the extent possible on major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers (57 FR 56412 at 56414). In the final guidance, this section has been renamed ''FDA's Cooperation With Major Accrediting Organizations'' and it states that the agency will continue to work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers.

53. Some comments questioned the extent of FDA's intent to rely on, and to defer to, major accrediting organizations.

Although FDA recognizes the valuable role that accrediting organizations can play in ensuring that industry-supported educational activities are independent and nonpromotional, FDA cannot rely exclusively on such organizations. The ultimate responsibility for monitoring inappropriate promotion in these programs lies with FDA. Accordingly, the final guidance has been revised to clarify that FDA intends to work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers.

III. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above). Requests and comments are to be identified with the docket number found in brackets in the heading of this document. Comments may be submitted at any time and will be used to determine whether to revise the guidance further.

Dated: November 24, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

The text of the final guidance follows:

BILLING CODE 4160–01–F

Guidance for Industry

Industry-Supported Scientific and Educational Activities

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy
November 1997

Guidance for Industry[1]

Industry-Supported Scientific and Educational Acivities

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

[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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