

September 11, 2002

VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Docket No. 02N-0209
Request for Comments on First Amendment Issues

Dear Sir or Madam:

On behalf of our client, Arnall Golden Gregory LLP submits these comments, in quadruplicate, in response to the Food and Drug Administration's request for input to ensure that the agency's regulations, guidances, policies, and practices continue to comply with the First Amendment of the United States Constitution. 67 Fed. Reg. 34942 (May 16, 2002). Our client applauds FDA's actions to receive industry comment on this very important matter and appreciates the opportunity to participate in this discussion.

We recognize that FDA must walk a tightrope where, in its own words, "FDA must balance the need and right of Americans to speak and hear information vital to their every day lives against the need to ensure that people are not misled." However, before we respond to some of the specific questions asked by the agency, our client wants to make one point at the outset. FDA should presume that companies want to provide safe and effective therapies to healthcare professionals and consumers in an honest manner. While there are, unfortunately, some companies that might place economics before patient safety, most businesses, including our client, consider it their ethical and corporate responsibility to make patient care the highest priority and to promote their products in an appropriate manner.

We will now respond to some of FDA's questions raised in the May 16 Federal Register notice. Because our client is a pharmaceutical company, our comments focus on those issues that are of most relevance to the promotion of drug products.

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Question

Would permitting speech by a manufacturer, a distributor, and/or a marketer about off-label uses undermine the Federal Food, Drug, and Cosmetic Act's ("FDC Act's") requirement that new uses must be approved by FDA? If so, how? If not, why not? What is the extent of FDA's ability to regulate speech concerning off-label uses?

Comments

No one disputes that FDA has an important role in ensuring that individuals receive safe and effective medications. The agency's mandate is to protect the public health. However, the degree to which FDA regulates the dissemination of information about unapproved uses of approved products, i.e., "off-label" uses, is the issue.

FDA is bound by the statutory provisions concerning off-label promotion described in the FDC Act. The Food and Drug Administration Modernization Act ("FDAMA") provides that, in order to disseminate certain off-label use information, the company must, with limited exception, ultimately obtain FDA approval for a supplemental application. Thus, the agency's question about whether permitting off-label promotion undermines FDAMA's requirement that new uses be approved is a fair one.

Our client believes that FDA's position, which is that FDAMA does not provide the agency with independent authority to regulate manufacturers' speech, is the proper response. See Washington Legal Foundation v. Henney, 202 F.3d 331 (D.C. Cir. 2000). FDA has said that, if a company follows the lengthy and detailed FDAMA requirements on off-label dissemination, FDAMA creates a "safe harbor," i.e., manufacturers who disseminate information according to FDAMA will not be prosecuted. Thus, a company that chooses to submit a supplemental application (because, for example, there are financial benefits) can distribute off-label information with little fear of FDA reprisal, so long as the other FDAMA provisions are met. However, FDA may take enforcement action for dissemination that does not follow the FDAMA requirements under traditional misbranding or unapproved new drug charges, but not based on a FDAMA violation.

Thus, to answer FDA's question, the FDC Act is not undermined by allowing distribution of off-label use information because FDA may act when it believes appropriate, based on the current statutory non-FDAMA framework (e.g., misbranding or unapproved new drug), while also giving the manufacturer the opportunity to provide truthful, although off-label, information to the healthcare community to benefit patients.

In other words, a company may choose to take the most conservative approach and follow FDAMA if it wants to promote off-label uses. However, if a company decides to take more risk, FDA's enforcement role is secured by current law.

The courts have helped FDA identify some boundaries by which the agency may operate in protecting the public health while allowing the dissemination of truthful information to healthcare professionals. Specifically, following the United States District Court's decision in Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999), vacated in part by Washington Legal Foundation v. Henney, 202 F.3d 331 (D.C. Cir. 2000), we offer these recommendations.

(1) FDA should not prohibit, restrict, sanction, or limit a manufacturer from disseminating or redistributing to healthcare professionals any article published in a bona fide peer-reviewed journal, even if the article focuses on the approved product's off-label uses.

(2) FDA should not prohibit, restrict, sanction, or limit a manufacturer from disseminating or redistributing to healthcare professionals any reference textbook, in whole or in part, including any medical textbook or compendium, published by a bona-fide independent publisher and generally available for commercial sale, even if the disseminated material focuses on an approved product's off-label uses.

(3) FDA should not prohibit, restrict, sanction, or limit a manufacturer from suggesting content or speakers to an independent program provider relating to a Continuing Medical Education ("CME") program or other symposium, even if an approved product's off-label uses are discussed.

(4) FDA should take enforcement action against a manufacturer if the disseminated materials are false or misleading or if the information clearly presents a public health risk.

(5) FDA may require a manufacturer that sponsors or provides financial support for the dissemination of materials that discuss an approved product's off-label uses (e.g., in journal articles, in reference textbooks, or at CME seminars) to disclose its interest in the product and that the off-label uses discussed are not FDA-approved uses.

(6) FDA may take enforcement action against dissemination of information about a product that has not been approved by FDA for any use.

(7) FDA can impose restrictions on the dissemination of off-label information directly to consumers.

(8) FDA can take enforcement action against a manufacturer that suggests or represents particular off-label uses for a specific product are FDA-approved.

(9) The agency can require the company disseminating the off-label information to provide the healthcare professional with a copy of the appropriate package insert or instructions for use, as well as a disclaimer that the information discusses off-label uses and should be carefully reviewed in its entirety to evaluate the applicability of the information to a particular patient.

(10) FDA can require the manufacturer to provide warnings, if known, about the product's off-label uses to ensure the safe and effective administration of the product.

(11) Rather than pursuing enforcement action first, FDA should consult with the company to evaluate the risks and benefits to the public health relating to a particular off-label promotion. It is possible, and likely, that the two sides can reach a compromise or agreement that protects, and also educates, the public.

Question

Do FDA's speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?

Comments

We have offered in our previous response possible alternative approaches that the agency could take to protect the public health while not imposing overly restrictive constraints.

Certainly, those FDA regulations that attempt to prevent the dissemination of false, misleading, and dangerous information are commendable and proper. However, FDA's imposition of overly-burdensome requirements, which are well-documented and do not need to be repeated here, to implement FDAMA goes too far. By raising the bar as high as it has done, the agency has discouraged companies from disseminating

truthful information for fear of enforcement. As a result, healthcare professionals do not receive material that could benefit patients. Instead, the recommendations set forth in these comments strike an appropriate balance where the interests of FDA, industry, and the public are best served.

FDA should also remember that, according to FDAMA and the court decisions, off-label information should go only to healthcare professionals and not directly to patients. This policy is appropriate and reasonable. As a result, FDA's concerns should be ameliorated when it recognizes that the educated and well-trained healthcare professional will carefully review the disseminated materials and exercise independent medical judgment to evaluate the benefit of the information to a particular patient. The so-called Learned Intermediaries should be allowed to practice medicine, using all of the available information at their disposal to help the patient; FDA should let the professionals do their jobs. Of course, FDA can always take enforcement action if the off-label information is false, misleading, or dangerous.

In addition, FDA must recognize that the marketplace, to some extent, ensures the dissemination of truthful information. Plaintiffs' lawyers, other federal (e.g., the Federal Trade Commission) and state agencies, consumers, healthcare professionals, and competitors will challenge untruthful and dangerous claims, whether through a product liability or Lanham Act lawsuit, complaints, or actions brought to the National Advertising Division of the Council of Better Business Bureaus. While FDA plays an integral role in protecting the public health, there are other sources that will help to achieve this goal.

Question

Are there any regulations, guidance, policies, and practices FDA should change, in light of governing First Amendment authority?

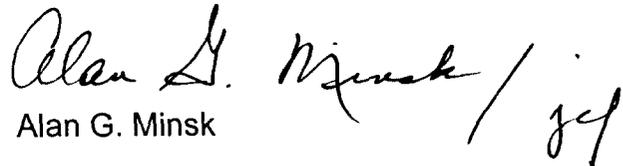
Comments

The involvement of FDA's Office of Chief Counsel in reviewing proposed Notices of Violation or Warning Letters to ensure consistency and that they are not overly restrictive is a positive step. Further, we would suggest, if it is not done already, that, in general, FDA communicate first with the company before issuing a regulatory letter in an effort to resolve the dispute. Of course, if the company has a history of violative conduct or the promotion presents a significant health risk, FDA should act aggressively and quickly. In fact, it may be appropriate for FDA to take more non-traditional

enforcement action, such as the imposition of substantial fines or product seizure, to punish a repeat offender or for egregious and dangerous conduct.

On behalf of our client, we appreciate the opportunity to provide these comments. If you have any questions, please feel free to contact us.

Sincerely,


Alan G. Minsk

AGM:jcf

