COPS ONLINE: FDA's Regulation of Internet

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When Internet use accelerated in the late 1990s, some observers thought the new technology would add an impossible burden to the Food and Drug Administration's regulation of promotion and advertising. The new technology would allow almost instantaneous global transmission of information about drugs, biologics, and medical devices. FDA's task of regulating this information gusher was analogized to the little boy using his finger to plug a hole in the dike. It seemed FDA would have to rethink its entire approach to regulating promotion and advertising, especially off-label use promotion. Indeed, in October 1996, FDA had a public meeting to discuss how it should regulate this revolutionary new medium.

Surprisingly, it is now clear that the Internet is one of the FDA's best enforcement tools. The Internet allows FDA to gather evidence of promotional violations more quickly and easily than ever before. Many companies are providing FDA with written and often irrefutable evidence of violations of the Federal Food, Drug and Cosmetic Act (FD&C Act) through aggressive postings on the Internet. Now, FDA's compliance officials can instantaneously investigate a company that has been brought to their attention, or just cruise the Internet looking for violators, without leaving their office. As a result, FDA's output of untitled letters and warning letters for promotional violations is on the rise. The Center for Devices and Radiological Health (CDRH), in particular, is on track this year to issue a record breaking number of warning letters for alleged medical device promotional violations. From an enforcement standpoint, it has unexpectedly

turned out that the Internet's information gusher is a double-edged sword.

An equally surprising outcome of the Internet revolution is how little FDA has had to change its enforcement approach. The majority of FDA's untitled letters and warning letters focus on the same type of violations that are pursued in the offline world. Probably a majority of FDA's Internet-based warning letters to medical device companies allege that statements on the company's Web site either promote a device for a new intended use requiring a separate premarket notification [510(k)] clearance or premarket approval application (PMA) or unlawfully promote an investigational device. These alleged violations reflect CDRH's traditional legal theories and no new statute or regulation has been proposed or promulgated by FDA to reach such violative activity.[1] Likewise, many of the untitled and warning letters sent to drug companies allege the same violations that the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Center for Drug Evaluation and Research (CDER) historically has alleged against offline promotion and advertising, chiefly lack of fair balance and false or misleading claims. Again, CDER has neither requested nor obtained new legal authority to address these problems.[2]

A Few New Twists

The uniqueness of the Internet's technology has created some new issues. The most important appears to be the problem of what global companies can post on their Web site regarding products that have received approval in other countries for uses not yet approved by FDA. It used to be relatively easy to segregate promotional materials for the US market from marketing to the rest of the world (ROW). Because of the global nature of the Internet, however, information on a company's Web site is accessible across national boundaries. What should companies do about information that is lawful in foreign jurisdictions but not in the US?

FDA's position is that a company's Web site must conform to the US clearance or approval status of its products if it is accessible from the US. This means that the Web site should clearly indicate what intended uses and indications for a product have been cleared or approved and which ones are unapproved or investigational in the US. However, the mere use of disclaimers and caveats indicating that a device is not cleared in the US for a specific use generally will not pass enforcement scrutiny. Rather, FDA has indicated that one acceptable approach is to maintain separate links relating to US products versus foreign products within a single site. Often, this can be accomplished with a "gateway" home page with separate links for US and foreign visitors. If there is no link between information on US and foreign products, FDA appears ready to agree that the Web site does not violate the rules against off-label promotion or promotion of investigational products. The key is building some form of firewall between the US section of the Web site and ROW product information describing uses or products not approved in the US.

Another novel aspect of Internet technology is hyperlink capability. May a company's Web site link to other sites, message boards, or chat rooms that provide off-label information about the company's products? FDA's position is that a company is responsible for information posted on a linked site in the same way that it is responsible for other information that it disseminates on its own site or in its own promotional brochures. Generally, if it would be permissible under FDA regulations to disseminate such information offline (e.g., a journal article reprint), then the link is probably permissible online and vice-versa. FDA officials have stated that a direct link to an article on off-label uses likely will be considered violative.

It is less clear what FDA's position is if a company's Web site links to another site or forum with changing content that may come to include off-label information. Most likely, FDA would look at the nature of the site and attempt to discern whether the company had a promotional intent. On the one hand, a link to a pertinent trade association Web site probably would be acceptable, even if the trade association subsequently posted a discussion of an off-label use of a firm's product. On the other hand, it probably would be unacceptable for a company to link intentionally to a chat room or message board known to be devoted to off-label discussion of its products.

To date, these issues have been largely theoretical. No publicly available warning letters appear to have addressed these possibilities and FDA appears focused on the more traditional violations discussed above. Nevertheless, these are becoming very real issues for which both the pharmaceutical and device industries are seeking some clarification.

Finally, the use of Web sites to com-

municate information about a company rather than just the regulated product raises issues about what is acceptable to communicate to different segments of the public audience. For example, FDA has recognized that companies need to communicate information about their activities and present and future products to investors and other members of the financial community. Yet, a press release aimed at investors when posted on a company's Web site is equally available to potential customers. It appears that FDA generally will permit press releases and announcements that include off-label information (e.g., foreign approval of a use not approved in the US) if it appears for only a reasonable time and is not directed at customers or potential customers. A good practice is to place the information on a separately labeled "investor information" portion of the Web site. FDA still may object if the information remains for a prolonged time or a press release egregiously promotes unapproved products or off-label uses.

Conclusion

Because FDA holds companies responsible for their Web site content in the same manner as other promotional material, it is advisable for companies to have a policy that subjects all material to regulatory review prior to posting. If Web-based activities occur in real time (e.g., a hosted forum or chat room), the nature of the planned activity should be scrutinized and guidelines established in advance. The bottom line is that information disseminated on the Internet should be subject to the same compliance review that the more conventional promotional material used over the years by the regulated industries has been subjected to.

In a compliance review, a company also should apply the same kinds of tests as for information disseminated offline. A good reality check is to ask whether dissemination of the same information offline would be acceptable to FDA. Of course, the global nature of the Internet and the possibility of real time content and communication forums create some new wrinkles. If a company follows the suggestions outlined above for those scenarios, it will minimize the risk of compliance problems.

Unfortunately, FDA has changed its mind with regard to issuing generic guidance as to what are acceptable promotional practices in the Internet area. Instead, the only way now to discern FDA policy is to carefully review the warning letter trends and listen to the responsible FDA officials at public meetings as to what types of activities cross the line into violative acts.

When in doubt with regard to a specific promotional activity on the Internet, the best course is to seek the advice of those knowledgeable in the field and determine whether there is a valid legal rationale for the proposed activity. If the conclusion is that the activity is in a gray area or close to the line, prudence would dictate taking the conservative approach to avoid the FDA cops online.

NOTES:

1. 21 CFR §§ 801.4, 812.7.
2. 21 USC § 352(n); 21 CFR § 202.1(e).

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