

FOOD & DRUG LAW

Colliding, again, with the First Amendment

As the FDA charges after speech-based conduct, the public may lose out on valuable info.

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The First Amendment guarantees that Congress shall make no law abridging the freedom of speech. This protection encompasses commercial speech, which the U.S. Supreme Court said in *Central Hudson Gas & Electric Corp. v. Public Service Commission* (1980) “assists consumers and furthers the societal interest in the fullest possible dissemination of information.”

The U.S. Food and Drug Administration (FDA) doesn’t always hear this message. When it is not aiming its enforcement efforts against false or misleading information, the agency has a history of losing First Amendment challenges. Yet the FDA continues its pursuit of speech-based conduct—from Internet promotion to dissemination of information about off-label drug uses to the color of cigarette labeling—frequently when the information conveyed is not misleading.

This should trouble not just FDA-regulated companies but consumers, too. The information that companies regulated by the FDA seek to disseminate can be of tremendous value to the public. Information about unapproved uses for approved drugs, for example, may improve—maybe even save—the lives of many Americans. Yet even when such information has scientific support, the FDA and prosecutors might pursue its dissemination as a criminal violation.

A quick review of the past dozen years shows several instances in which the federal courts turned back speech restrictions involving FDA-regulated products.

In *Pearson v. Shalala* (1998), the U.S. Court of Appeals for the D.C. Circuit determined that the FDA violated the First Amendment rights of dietary-



supplement marketers by refusing to allow them to make certain health claims on product labels.

The same year in *Washington Legal Foundation v. Friedman*, the U.S. District Court for the District of Columbia ruled that certain information about unapproved or off-label uses of approved drugs was a form of commercial speech protected by the First Amendment. The judge enjoined the FDA from prohibiting manufacturers from disseminating reprints of peer-reviewed journal articles and from suggesting content to continuing medical education providers.

On appeal in *Washington Legal Foundation v. Henney*, the D.C. Circuit dismissed the case because the FDA conceded that relevant statutes and agency-issued guidance documents merely provided drug makers with “safe harbors” from some agency oversight but did not independently authorize the FDA to prohibit the speech in question. The appellate court did not, however, “criticize the reasoning or conclusions of the district court.”

In *Thompson v. Western States Medical Center* (2002), the Supreme Court ruled that the FDA Modernization Act’s prohibition on truthful speech about pharmaceutical compounding (the mixing of drugs to treat individual patients) was unconstitutional because it was more extensive than necessary to protect the FDA’s interest in

preserving the integrity of the new drug approval process.

A WARNING SURGE

Recent signs suggest that the FDA is growing more aggressive in its pursuit of speech-based conduct.

The FDA has sharply increased the number of violation letters from the Division of Drug Marketing, Advertising and Communication. The marketing division sent 41 enforcement letters in 2009, compared to 21 letters in 2008.

This surge may have arisen, in part, because of FDA-wide changes in procedures for reviewing violation letters implemented in mid-2009. Warning letters are typically issued for violations that may lead the FDA to pursue enforcement action if not corrected, while untitled letters are generally issued for less serious violations. Although any letter challenging the content of a manufacturer’s advertising and promotion could chill the exercise of constitutional rights, the agency may no longer subject all such letters to review by the Office of Chief Counsel. The more serious warning letters still receive that office’s oversight, but untitled letters may go out without legal review.

Of the 41 letters the marketing division sent in 2009, 14 untitled letters challenged sponsored links on Internet search engines. The division alleged that the sponsored links made representations and/or suggestions about the efficacy of the products but did not communicate any information about the risks.

Before these letters were issued, most companies followed a “one-click” rule: If Internet users could reach FDA-mandated risk information within one click of the sponsored link, it was generally thought

to be acceptable. The one-click rule was viewed as analogous to the prevailing practice of placing risk information in a magazine or journal advertisement on a page separate from the body of the advertisement. The FDA hasn't generally objected to forcing readers of a printed publication to look at another page to read risk information.

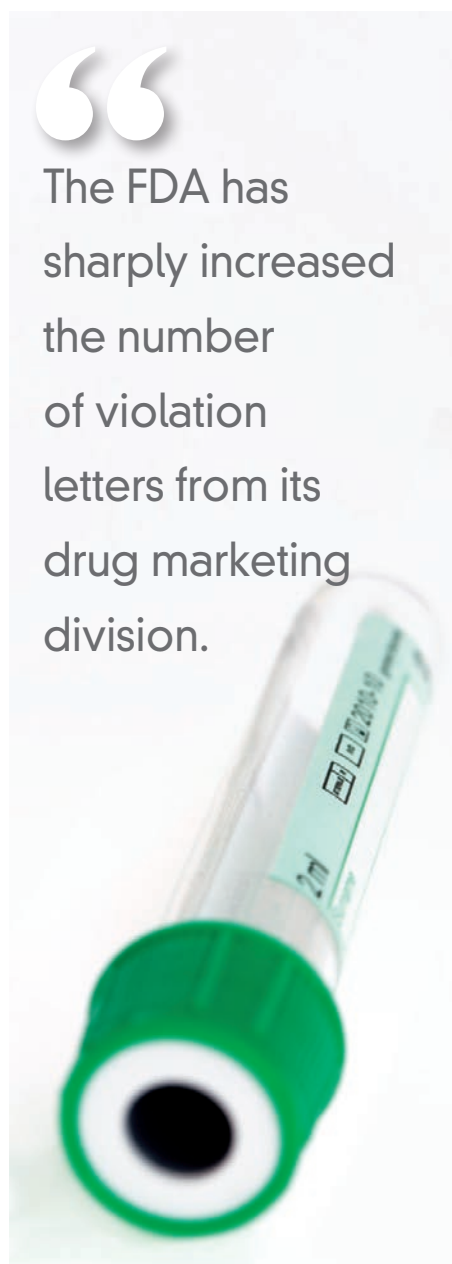
The FDA's announcement of this new policy—that one click is not close enough—through a spate of violation letters highlights the ambiguity that exists generally in the agency's regulation of promotion on the Internet. Although the FDA held a public meeting in September 2009 to discuss the regulation of online statements made by drug manufacturers, the agency has not issued clear guidance. The lack of such guidance overall chills First Amendment rights and makes it more likely that the FDA will infringe speech freedoms on the Internet.

SUING TO SPEAK

In the past year, the agency and federal prosecutors have also pursued several enormous settlements involving off-label drug promotion. Pharmaceutical companies, threatened with the devastating prospect of exclusion from federal programs or debarment, paid penalties of more than \$3.7 billion in 2009—even though this is an area in which the FDA has given little guidance as to how a drug maker can lawfully communicate truthful information. (One notable exception: a guidance regarding the distribution of peer-reviewed literature about off-label uses was issued at the end of the last administration.)

In October, Allergan Inc. filed a lawsuit in the U.S. District Court for the District of Columbia seeking a declaratory judgment that speech restrictions about off-label uses of its product Botox violate the First Amendment. Specifically, Allergan cited its fear of prosecution for providing information about Botox's off-label uses to accompany FDA-required warnings to health care professionals about "a rare but serious safety risk potentially associated with the use of Botox to treat spasticity." At the time of the lawsuit, Botox was not approved for treatment of spasticity.

Allergan argued, quite persuasively, that, because the government forced Allergan to speak about certain off-label uses, "the Government can hardly claim a legitimate interest in suppressing Allergan's truthful, non-misleading speech about those off-label uses." The company's lawsuit calls



into question the central legal theories on which the government has relied in major pharmaceutical prosecutions.

Tobacco manufacturers have also recently contended—with some success—that various advertising and labeling provisions enforced by the FDA violate the First Amendment.

The manufacturers brought suit to enjoin certain provisions of the Family Smoking Prevention and Tobacco Control Act, signed into law in June 2009. On Jan. 5, in

Commonwealth Brands Inc. v. U.S., the U.S. District Court for the Western District of Kentucky enjoined the FDA from enforcing a ban on color and graphics in tobacco labeling and advertisements after concluding that the ban failed for a lack of tailoring. Notwithstanding this court order, the FDA issued a Federal Register notice on Jan. 19, suggesting that it might have the power to ban colors on cigarette packages.

The 2009 statute prohibits the use on tobacco products of "the descriptors 'light,' 'mild,' or 'low' or similar descriptors" that would suggest that some cigarettes are safer than others after June 22, 2010 (absent pre-approval by the FDA). The FDA has suggested that the phrase "similar descriptors" might cover the use of colors on cigarette packages (such as the familiar gold of Marlboro Light packs), even if colors serve to signal differences in the flavor of the products rather than differences in their safety.

The FDA's proposed interpretation is questionable under the statute. When coupled with the other restrictions under the act on a tobacco company's ability to communicate about lawful characteristics of its products, it is likely unconstitutional as well.

The FDA is heading for even more First Amendment battles. Rather than continuing its aggressive push against speech by companies that sell lawful products that consumers value, the agency should be developing guidance about ways in which companies can communicate truthful, scientifically accurate information to the public. Too often, it silences the good speech along with the bad.

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