Panel Analyzes First Amendment Concerns Raised in Pharmaceutical Regulation

Summary of "FDA and the First Amendment"--October 21, 2002

Recent court decisions reflect increasing judicial interest in the constitutional protections afforded to speech regarding the safe and effective use of pharmaceutical drugs. In the late 1990s, two U.S. district courts ruled that the U.S. Food and Drug Administration's (FDA) regulations governing the provision of journal articles to doctors describing the off-label uses of drugs overstepped its bounds.[1] In 2002, the U.S. Supreme Court held that FDA restrictions on pharmacists' advertising of compounding services violated the First Amendment.[2]

In response to this increasing judicial scrutiny of its regulation of commercial speech in the pharmaceutical market, the Food and Drug Administration issued a notice in the Federal Register last May soliciting comments about how it could best fulfill its mission consistent with First Amendment protections. "Recent years have witnessed increased attention by consumers to their own medical care. The public's interest in, and access to, useful and truthful information about medical products have skyrocketed," noted the FDA's release. The FDA asked several questions, such as: are there better arguments for regulating speech regarding drugs than there are for dietary supplements? How prominent do disclaimers need to be? How far can FDA go in regulating speech concerning so-called "off-label uses" (*i.e.,* those for which the FDA has not given approval)? Finally, the FDA asked whether any of its regulations or practices generally were thought to run afoul of the First Amendment. In all, the FDA sought input in nine different areas of free speech and regulation.

The Federalist Society's Administrative Law and Free Speech practice groups presented a joint panel on the Food and Drug Administration and the first amendment at the National Press Club to discuss the issues raised by this solicitation. Panelists included Richard Cooper, former Chief Counsel to the FDA; Arnold Friede of pharmaceutical manufacturer Pfizer; Richard Samp of the Washington Legal Foundation (WLF); William Schultz, a former FDA Associate Commissioner for Policy; Bruce Silverglade of the Center for Science in the Public Interest (CSPI); and William Waller, the Chair of the Federalist Society's Food and Drug subcommittee. Erik Jaffe, Chair of the Society's Free Speech subcommittee, introduced the panel.

Jaffe established the framework by outlining the current state of commercial free speech. Constitutional protection of commercial speech, as currently understood, has four elements, said Jaffe. First, it could neither be false nor misleading, nor relate to unlawful activity. Second, the government needed a "substantial interest" if it was to regulate commercial speech. Third, such regulations had to directly advance that substantial interest. Finally, such regulation could not go further than the substantial interest.

The WLF's Samp begun by expressing gratitude that the FDA was concerned about free speech issues, noting that, prior to 1976, the concept of commercial free speech really did not exist in constitutional law. Most recently, Samp noted, the Supreme Court's decision in *Thompson v. Western States* had finally applied the commercial speech doctrine explicitly to the FDA, and further clarified that FDA restrictions on speech were not justified regardless of the rationale should other means of accomplishing it be available. As a result, the Court rejected the government's argument that the best way to regulate compounding was by restricting advertising rather than direct regulation.

Samp turned to the various interests that the FDA could use to justify restrictions on commercial speech. The first is to prevent misleading speech. The next interest is to establish and enforce the approval process for drugs. Should manufacturers not be required to prove their claims to the FDA, there would not be the same standard of approval for drugs as currently exists, he noted. Finally, Samp cited the interest the government has in preventing the over-prescription of drugs, especially as it bears an increasing burden of drug costs in the U.S.

The FDA, argues Samp, runs into difficulties when defending these interests. First, it is difficult to determine whether speech *is* misleading in the first place. Recent decisions, says Samp, demonstrate that courts will not allow the FDA to be the arbiter of whether commercial speech is misleading. The fact that FDA has not verified a claim's truthfulness cannot, Samp argues, be enough for it to prohibit the speech. The interest in promoting regulatory compliance is a valid one, acknowledged Samp. But, it will often be difficult for the government to show that the substantial interest at hand will be directly promoted by the regulation. Finally, Samp predicted that the government's interest in preventing over-prescription will be rejected by courts as "paternalism."

Former FDA Assistant Commissioner Schultz recalled the incident with DES, a drug once promoted by doctors at the Harvard Medical School as a wonder drug for preventing miscarriages. It was so successful, they believed at the time, that *all* pregnant women should have it administered – not just those at risk of miscarriages. In fact, the drug had no beneficial effects and horrible side effects, including cancer and reproductive complications in the daughters of those women who had taken DES. Congress's reaction included the 1962 Kefauver amendments to the Food Drug and Cosmetic Act, which required that drug companies prove "substantial evidence" of a drug's efficacy prior to its being allowed on the market.

Such regulation finally provided drug companies a substantial incentive to conduct research on the drugs doctors were giving patients, said Schultz.

Schultz then addressed arguments being advanced to weaken regulation of off-label uses. When he was at the FDA, he related, he was sympathetic to the idea that distributing research on drugs to doctors should be allowed so that they could determine for themselves whether such secondary use was wise. A discussion with a former drug representative, however, changed his mind. She related to him how handing out such things as journal articles actually suppressed in-depth research because doctors tended to take them on faith without substantial, further inquiry.

Turning to the question of advertising, Shultz noted arguments that there should be a lower standard for advertising than labeling. In other words, rather than meeting the "substantial evidence" test, some argued, drug companies should be allowed to make advertising claims until government regulators proved them false. Such a rule, however, would vitiate the labeling requirements because what patients and even doctors knew about drugs was more likely to be derived from advertising than labels, contended Shultz.

Finally, Shultz argued that, in fact, courts had not been as sympathetic to First Amendment arguments as some had claimed. Although one district court case had, Shultz acknowledged, held that there was a right to distribute journal articles regarding unapproved uses, that decision had been vacated by the Court of Appeals. Next, the Court in *Pearson* had explicitly stated that its rationale should *not* be applied to drugs, its rationale being limited to dietary supplements.

Pfizer's Friede responded that the FDA *had* amassed a poor track record in recent cases. The FDA's request for comments on the legality of various uses of its power was more appropriately seen as a way to avoid what Friede characterized as the fate of the Federal Communications Commission in terms of losing credibility with the courts, rather than as an attempt to undermine its mission as some congressional critics had alleged.

Friede summarized Pfizer's response to the FDA's call for comments. First, Pfizer stressed the useful benefits that consumer information has on informed decision making. Critics have, Friede noted, have alleged that too much information could actually have negative effects on consumer health. Friede drew upon First Amendment cases in other contexts to suggest that the courts could evaluate FDA regulations on the claims of drug makers under a more benign standard, while still extending First Amendment protections. The FDA should be commended for thinking about the First Amendment implications of its regulations, regardless of their views on Pfizer's own position, Friede concluded.

Regulation, not the First Amendment, has had more efficacy in providing consumers with useful information CSPI's Bruce Silverglade begun. He cited the example of the Nutrition Labeling Education Act, which requires that food labels provide nutritional information. The same law gave dietary supplement makers the right to make claims about their products' benefits. Silverglade was concerned that the public might not be able to tell the difference between FDA *approve*d health claims and FDA *authorized* claims. Silverglade noted that such over-reaching claims by supplement manufacturers have actually led to a decrease in sales, as the ability to make unsubstantiated claims has led consumers to doubt the efficacy of even those supplements whose claims were proven. He wondered why attorneys for the drug industry would try to gain the same "freedoms" via First Amendment litigation.

The FDA's solicitation of comments on the applicability of the First Amendment was actually an attempt to hide a deregulatory agenda behind the First Amendment, continued Silverglade. He noted that former FDA Chairman David Kessler, who had once been a Republican Senate staffer, had voiced similar views.

Silverglade said that the campaign to expand the commercial speech doctrine in general would "turn free speech into a license for quackery." Companies should be careful to ensure that First Amendment jurisprudence creates what Silverglade called "a level of First Amendment protection that creates a level, competitive playing field." The alternative, according to Silverglade, would be "a marketplace free-for-all."

As a final point, Silverglade mentioned a recent National Academy of Sciences report that concluded that claims about nutrient-disease relationships were "more easily made than scientifically supported." As an example, he cited beta-carotene, which was supposed to have a positive effect on lung cancer, according to an article in the *New England Journal of Medicine*. Subsequent further research, including research published in the New England Journal, ultimately revealed that beta-carotene actually increased risks of lung cancer, according to Silverglade.

Former FDA Counsel Cooper posed a "thought test" to the panel's audience. The test's purpose, Cooper said, was to test the audience's commitment to two emerging principles in commercial free speech law. The first was that truthful speech couldn't be suppressed on the grounds that it will lead to bad decisions. The second was that the answer for bad decision-making was more speech rather than less.

Suppose, Cooper posited, we had a regime under which the FDA would create "official labeling" for every approved drug. Inside each package would be inserted its government-approved instructions on when to prescribe the drug and how much to prescribe. This language would be inserted into the Physician's Desk Reference. Cooper analyzed such official instructions as "government speech." The pharmaceutical company would have no ownership of it.

The pharmaceutical company would be allowed, Cooper continued, to make its own claims in advertise-

ments, medical journals, detailing pieces left with practitioners, or in booths at professional meetings, etc. This speech could offer different views on uses, dosage, or anything else about the drug. Such speech would not need to be based on adequate and well-controlled studies. It would simply need to qualify as "truthful and non-misleading," as defined by the FDA. Further, the company would need to disclose when such claims were not established under the adequate and well-controlled studies standard.

This would give doctors the option of being either conservative (by restricting their dispensation to the government's approved instructions) or to take greater risks when they thought appropriate (by relying on broader claims issued by the maker). This would test the value of the FDA's imprimatur, and the extent it was worth the company's attempts to get FDA approval rather than relying on the company's reputation for competence and integrity.

Cooper addressed some concerns he had about the FDA's power to test the drug company's claims. He proposed that it could send an inspector to the company to investigate the claim. If it were not satisfied, it could denounce the company's claims, sue it for misbranding, or even pull the product off the shelf, depending on its view of the seriousness the company's claims posed to the public's health. Cooper asked the audience to evaluate such a regime by asking whether the scenario was plausible and realistic? Was it constitutionally required? Finally, even if it were not, was it a good idea anyway, Cooper inquired.

During the question and answer period, Silverglade addressed the latter question, observing that such a regime would amount to "regulation through press release," which he deemed "a horrible way to regulate." Such an approach was after the fact, which meant, "people have already been injured. People have died already." Press releases only affect the information mix for so long, he noted. "If you didn't read the paper that day, you can miss the message and you can die the next day."

After Cooper's presentation, the panel hosted questions from the audience. One participant opened by asking Silverglade whether he thought the FDA's renewed sensitivity to free speech had yet resulted in the marketing of unsafe dietary supplements. Silverglade said that it had, but the news really had not gotten out yet. The newspapers began to carry stories about the hazards of dietary supplements only months after courts started to get involved in considering such arguments. Cooper noted that it was interesting that the FDA had shown concern about First Amendment issues, despite never having lost an enforcement action due to a First Amendment defense.

Another participant raised the issue of why speech, rather than use, was regulated. If something is not authorized for a particular purpose, why not just outlaw its use for that purpose rather than outlawing speech advocating that it be used for that purpose? Pfizer's Friede answered that Pfizer had not pushed that approach in its comments, but it *had* taken the view that unapproved uses ought to be freely discussed without hindrance. "We understand that the statute prohibits promotion for off-label uses. We endorse that. But that's a far cry from saying any dissemination whatsoever automatically becomes an overt promotion." Such speech, he theorized, should be treated as "scientific speech" rather than "commercial speech."

Cooper added that it would be impracticable to ban off-label uses for drugs. "There are many…off-label uses that are critical to health care and that are the standard of care for treating certain conditions," he observed. While current law prohibited manufacturers from speaking about off-label uses of their own drugs, Cooper added, such speech by others *was* allowed. Samp added that exceptions were allowed where information was solicited from the manufacturer, which only adds further to the confusion.

The virtues of the Internet for health information research were the subject of one question. Friede noted the Internet provided a "wealth of information." The problem was that, while some sites were "very, very good," others were "very, very poor." The widespread publication and availability of health related information on the Internet revealed that at least one of the government's assumptions was invalid, Friede noted, namely that it could control the information pool by regulating one small channel of information.

The full text of the voluminous comments filed in response to the FDA's request can be read on-line at: http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n0209.doc.

Footnotes

[1] See *Washington Legal Foundation v. Friedman*, 13 F. Supp.2d 51 (1998) and *Washington Legal Foundation v. Henney*, 56 F. Supp.2d 81 (1999).

[2] *Thompson v. Western States Medical Center*, 122 S. Ct. 1497 (2002).