Legal Backgrounder

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AN FDA Q&A:

HOW DOES THE FIRST AMENDMENT LIMIT ITS REGULATORY POWER?

by

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Sometimes a federal regulatory agency does something out of the ordinary, perhaps even constructive, in evaluating or reevaluating its regulatory authority. Such is the situation regarding the Food & Drug Administration's (FDA) Federal Register notice of May 16, 2002. Notice; Request for Comment on First Amendment Issues, 67 Fed. Reg. 34942 (May 16, 2002).

In the notice, FDA requests comment by interested parties "to ensure that its regulations, guidances policies, and practices continue to comply with the governing First Amendment case law" and do not impose "unnecessary restrictions on speech." Interested persons can submit comments until **September 13**. Responses to the submitted comments are due **October 28**.

The notice outlines nine questions relating to foods, dietary supplements and prescription drugs — for the latter, particularly direct-to-consumer (DTC) advertising and off-label communications. Interestingly, the FDA call for comments in some instances relates to more than "speech" issues. For example, the questions relating to DTC advertising call for data on its effects, both positive and negative, particularly as it may affect compliance. Some of these requests mirror prior agency calls for data in its various proposals concerning regulation of DTC using broadcast media. In other questions, FDA calls for social science data. Therefore, it seems clear that while the notice stresses speech issues, it is a major public initiative policy.

Reason for the Notice. The first key question is why did FDA issue the notice now? To some former FDA officials, the notice was so distressing that they felt it necessary to vehemently oppose this FDA request for comments in *The Washington Post*. William B. Shultz & Michael R. Taylor, *Hazardous Hucksters*, WASH. POST, May 28, 2002, at A17. These officials likely view FDA's efforts as blasphemous. To others, it was a long overdue recognition that even FDA regulation of advertising, promotional labeling, and other forms of medical communications had boundaries, a view the authors share.

While pure speculation, there are two possible reasons. First, the new FDA Chief Counsel, Daniel Troy has a professional reputation for respecting the First Amendment. Second, FDA has not faired well in recent court decisions concerning the agency's regulation of information. In a case involving dietary supplements, FDA restrictions on marketing were struck down on First Amendment grounds in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999). In a series of cases brought by the

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Washington Legal Foundation,[1] FDA regulation of the dissemination of "off-label" information contained in recognized medical textbooks and peer reviewed journal articles came under First Amendment attack. While FDA's actions were declared unconstitutional in a scholarly opinion by the Federal District Court, the agency was saved by a Court of Appeals which, too reticent to uphold the lower court, reversed the case solely on procedural grounds. Yet, interestingly, the Court of Appeals noted that its decision should not be viewed as critical of the lower court. Finally, in *Western States v. Thompson*, 122 S. Ct. 1497 (2002), the U.S. Supreme Court struck down the compounding provisions of the Food and Drug Modernization Act of 1997 primarily because of its prohibition of the advertising of drug compounding services.

Based on these cases, FDA's lawyers could quite properly become concerned about the agency's credibility before the federal courts on regulatory matters relating to communications. What better way to establish its credibility and an administrative record for future challenges than to seek public comment?

Questions posed. FDA asks nine groups of questions. The first concerns the distinctions between FDA's regulation of the promotion of dietary supplements, which is, at least by FDA standards, essentially unregulated at the present time, and its regulation of pharmaceutical promotion. The agency asks whether such a distinction makes sense, what its legal basis might be, and what sort of evidentiary record is necessary to sustain it. The agency also is seeking opinions on whether the kind of speech it allows depends on the audience. In other words, can some things be said to doctors that cannot be said to consumers?

The next set of questions is about DTC advertising, with the agency asking about the empirical effects of such advertising on patient compliance, physician visits, and prescribing habits. Interestingly, these questions do not focus on FDA's legal authority, but rather seek to build a record about DTC's actual effects that could support the agency in any congressional or judicial challenge to its policies.

The third set of questions mirrors the first, except that this time the agency is interested in whether it can or should have different standards for food and dietary supplement claims, given the different statutory schemes. In the fourth set, the agency asks about disclaimers, presumably but not explicitly, with respect to dietary supplements again, where disclaimers are a major issue. The fifth set of questions deals with label warnings, and whether any evidence exists on how such warnings might be best presented. It is interesting that the agency poses these questions at all, considering that there is likely extensive information already on these subjects in FDA's possession. The issue of disclaimers has been an ongoing one, warnings have already been debated as FDA revamps its drug labeling regulations, and the food/dietary supplement distinctions have been considered in the context of litigation.

Questions six through nine are more interesting from a legal perspective. Question six asks whether there is legal or empirical evidence which would support different approaches to the regulation of advertising or labeling. Question seven concerns the limits (if any) on FDA's ability to regulate speech about off-label uses, and whether permitting such speech would undermine FDA's regulatory scheme. And the final two questions invite comment on whether FDA's regulations advance the public health, whether less restrictive alternatives are available, and whether the First Amendment requires any change in government policies.

The questions the agency has asked are in some ways strangely grouped. They range from the very minor (what type size should be used for disclaimers) to the important, but impossibly vague (are there any practices FDA should change?). Within the group, however, there are some very significant issues, which must be addressed.

DTC Advertising. Especially significant are the rather extensive set of questions on DTC advertising. Some consumer groups and health care payers have attacked DTC as one of the driving forces for higher drug prices. According to critics, such advertising encourages patients to ask for drugs they do not need. Critics

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[1] *See Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). *See also*, *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) ("WLF IV"); *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999) ("WLF III"); *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) ("WLF II"); *Washington Legal Foundation v. Kessler*, 880 F. Supp. 26 (D.D.C. 1995) ("WLF I").

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further maintain that the high costs of advertising on television and radio are reflected in pricing decisions, encouraging consumers to pay more for drugs they do not need. To its credit, FDA has not shown any signs of being swayed by such arguments. Indeed, over the last decade, FDA has moved, sometimes slowly and grudgingly to be sure, towards a more First Amendment-friendly attitude towards DTC. Existing empirical data is considerable and unlikely to reverse this process.

Standard for Regulating Promotional Claims. Questions six through eight however, venture into areas where the agency's positions have not been so supportive of the First Amendment. FDA, for example, does not permit advertising to go beyond the product label information in any way. Thus, for almost any advertising claim, FDA requires substantial data usually consisting of two adequate and well-controlled clinical studies to support the claim. Yet, most advertising is regulated by the Federal Trade Commission (FTC) under a different standard, one that permits a claim for which a reasonable basis exists. There is no data that exists to show that the FTC standard would be inappropriate for pharmaceutical products. Indeed, Congress adopted the FTC standard in the Food and Drug Administration Modernization Act of 1997 concerning communications of "pharmacoeconomic" data by manufacturers to managed care and formulary committees. It is likely that FDA's position derives more from administrative convenience — it is far easier to show that an advertisement deviates from the label than to establish that it is false or misleading — than from any public health concern.

Off-Label Communication. With respect to question seven, FDA's position is well known. With very limited exception, no off-label speech is permitted except in response to unsolicited questions or in a very narrowly drawn "educational" context. FDA's stated rationale for its position varies from a public health concern to a concern over the undermining of its regulatory authority, to a legalistic view that the statute requires FDA to ban off-label speech. Until now, FDA has never taken a step back and asked what the First Amendment permits and what makes sense.

Clearly there is some tension between the dissemination of information about unapproved uses and the public health. Absolutely unregulated speech could lead to adverse public health consequences, since information, once disseminated, can never completely be recalled, even if later found to be false. And the consequences of false information about pharmaceuticals are likely to be much greater than the consequences of false information about a refrigerator or computer, for example. But there is a huge amount of space between unfettered and unregulated speech, and FDA's flat out prohibition on the discussion of off-label information, even if that information is true. And somewhere in that middle ground, there is an appropriate line to be drawn.

The Supreme Court, in *Central Hudson Gas & Electric Corp. v. Public Services Comm'n of N.Y.*, 447 U.S. 557 (1980), set out the test for determining whether regulation of speech complies with the First Amendment. Among those tests was whether a regulation was reasonable under the circumstances, or whether a lesser degree of regulation would be sufficient to meet the government's legitimate interests. As the Court noted in the recently decided *Western States* case, "If the First Amendment means anything, it means that regulating speech must be a last — not first — resort." 122 S. Ct. At 1507. FDA is to be commended for asking — at long last — whether lesser degrees of regulation might work. In deciding whether a policy change is in order, it would be useful for the agency to begin considering the application of different standards to different types of information. On the one hand, labels ought to be written much as they are now. Some additional flexibility should be permitted in advertising, perhaps involving application of the FTC standard to advertising claims. And some types of truthful material should be essentially beyond regulation.

As to this last category, the agency might well consider the district court opinion in the WLF case as a good starting point. Certain kinds of truthful information, such as peer reviewed journal articles, continuing medical education, and legitimate medical textbooks deserve a high degree of protection under the First Amendment; it is difficult to think of any circumstances under which their dissemination should be prohibited. Prohibition is not only bad law under the Constitution, but bad policy. FDA should be seeking to foster discussion of the latest good scientific information rather than restricting it. As an alternative to prohibition, the agency might require reasonable disclaimers to accompany the material. It might also strictly enforce the law regarding false and misleading information, provided that "false" and "misleading" are given their dictionary definitions, and not interpreted to mean any information that FDA has not approved.

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FDA's final question is a sort of catch-all, designed to elicit comments that fail to fall neatly into one of the other questions. Perhaps this is the place to suggest some questions that FDA did not ask, questions that might provide some interesting insights into the agency's thinking about the First Amendment. While FDA does ask, for example, whether its existing regulations on off-label dissemination advance the public health, it does not ask the converse. It would be interesting, and instructive, if the agency sought comment on whether the dissemination of off-label material might itself advance the public health. Certainly in the area of oncology, where the majority of drug use is off-label, it would seem that dissemination of journal articles and textbooks would greatly benefit the treating physician and cancer patient. Undoubtedly there are other areas with similar treatment models.

Other Alternatives for FDA to Consider. While FDA is reviewing its procedures, it might also take a look at whether the agency should have to meet some threshold burden of proof before it sends letters to companies complaining about promotional practices. Until recently, letters could issue without any review outside the Division of Drug Marketing, Advertising and Communications (DDMAC). Now at least the chief counsel's office is reviewing the letters for legal sufficiency, and that is progress. But shouldn't there be some sort of due process for a manufacturer before a letter goes out? Perhaps an informal hearing and opportunity to respond to FDA's allegations? It is true that FDA's workload would increase under such a scheme, but so would fairness to the regulated industry, and so would the quality of decision-making.

Another policy FDA should examine involves its interpretation of the Court of Appeals decision in the WLF case. The agency has said that the use of an off-label peer reviewed journal article is not alone the basis for an enforcement action. But, according to FDA, such journal articles can be used as evidence of intent to promote off-label if the company is engaging in other activities that are seen as encouraging off-label use. One would strongly suspect that this policy has a chilling effect on the dissemination of journal articles. Most companies, when faced with the possibility that a journal article might come back to haunt them in an enforcement proceeding, will take the position that sending the article out is just not worth the risk. FDA should be seeking empirical data on whether or not its policies have had such a chilling effect.

Interestingly, on a more specific policy, FDA has said nothing in these questions about the Internet, and yet the Internet has become one of the principal promotional and educational tools in current use. Over the years, FDA has been all over the map on Internet issues, first stating that it would issue a comprehensive guidance, then backing off and saying no guidance was necessary because existing rules could be applied. Asked by Washington Legal Foundation to decide whether Internet materials were labeling, and subject to FDA regulation, or advertising, which, except for prescription drugs, would be subject to FTC regulation, the agency waffled, and simply said, "it depends," without giving any guidance on what the decision depended on.

FDA should provide adequate guidance to the regulatory industry concerning Internet communication. It is true that many FDA rules can apply to Internet materials, but rules designed in the 1960s for medical journal advertising are a poor fit in many respects. Does FDA want to regulate all Internet promotions as labeling? Should it? Is it willing to provide any guidance at all regarding issues that are peculiar to the Internet, such as links, or international access to web sites?

Finally, at the most basic level, FDA should seek some input on what constitutes promotion. Under its regulatory scheme, FDA has authority over promotion, but not over educational activities. FDA has defined educational activities very narrowly, to give it maximum regulatory control. Perhaps it is time to revisit the existing definitions. It is not the case that every time a company exercises some control over material it disseminates, that company is *promoting* its product rather than *educating*. FDA's current rules make enforcement easier, but stifle company-sponsored educational initiatives. Companies have an incentive to educate physicians and patients about diseases treated by their drugs. FDA should be encouraging them to do so rather than placing impediments in the way. Obviously, changes in policy here have to be carefully thought out, but FDA should at least be asking whether change is possible and advisable.

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