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Dockets Management Branch
(HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Comments of the Competitive Enterprise Institute on
Promotion of FDA-Regulated Medical Products on the Internet
Docket #96N-0309
61 FR 48,707 (September 16, 1996)

Dear Sir or Madam:

The Competitive Enterprise Institute would like to file comments on some questions raised by the Food and Drug Administration regarding the advertising of medical products on the Internet. CEI is a non-profit, non-partisan free market research and advocacy group. We have long been involved with FDA regulatory issues,[1] as well as commercial speech issues.[2]

The potential of the Internet to do both good and evil is so widely acknowledged that it has become a cliché. The wealth of information available through this ever-developing

[1] See, for example, Kazman, Sam. "Deadly Overcaution: FDA's Drug Approval Process," *Journal of Regulation and Social Costs*, Vol. 1, No. 1, August 1990, p. 31-58. Also see "The Food and Drug Administration: A Modest Proposal," CEI Press Release, January 6, 1995. Also see DeFalco, Julie, "The FDA vs. Reform" Guest Editorial, *Investor's Business Daily*, June 7, 1996.
[2] See, for example, CEI v. Rubin (D.D.C.)(No. 1:96CV02476, Filed 10/29/96). Suit against the Bureau of Alcohol, Tobacco and Firearms challenging the agency's prohibition against truthful statements concerning the health benefits of moderate drinking on alcoholic beverage labels and advertisements.

technology means that Web surfers have the ability to find a cascade of data on any given topic. It is this fact which makes the Internet exhilarating to some – and a threat to others. It is also this fact which highlights the failure of the FDA's current policy on restriction of information about medical therapies to consumers.

The FDA has been able so far to (mostly) restrict the circulation of such information because much of it was in physical form – e.g. medical textbooks – and because much of it was not easily available to average consumers (for example, medical journal articles). Now that information is available quickly and in a fluid form, the FDA is increasingly unable to maintain its policies of keeping all but the most provisory and qualified information away from consumers. Tellingly, the FDA has solicited ways to impose the old order upon the new. The agency really should be asking how to make itself a valuable addition to the Internet.

The FDA's first set of questions deals with the manner in which companies present product information on their Web pages and related issues. It is important that the FDA keep in mind that not everything a company does needs federal input. Nor is it the FDA's duty to set itself up as a Web page design consultant. What is really at issue here is not compliance with the Federal Food, Drug and Cosmetic Act, but marketing strategy. Questions about the setup of the Web pages ought to be left to the companies and their advertisers, not to the sensibilities of a government agency.

The FDA asks, "Is it necessary to distinguish between promotion directed to health professionals and consumers on the Internet? If yes…., how should Websites clearly make the distinction between professional-directed and consumer-directed promotion?" The FDA, which has done everything in its power to obstruct the full circulation of information about medical products to doctors and patients (e.g. curtailing the distribution of medical journal studies showing possible secondary uses for a drug), is now concerned that the information presented to health professionals may confuse layman readers. In the words of the FDA, "many Internet users may not have the technical background to fully understand the language typically used in prescription drug, biological product, and medical device promotion."[3]

If that is truly the case, then obviously there is no need to mandate distinctions between promotions because the layman won't be able to understand the professional jargon used on the Web page. Yet the FDA has given no indication of any problems incurred or harm done due to confusion arising from these different types of promotion. Given that the companies with Web pages have a direct financial stake in showcasing as much information as possible, this is yet again not a question for the FDA to decide. If it turns out that readers are confused, the company can easily remedy the situation by labeling information differently.

The FDA's questions about the aesthetics of Web pages overlap the agency's questions about links from a regulated company's Website to other sites. These sites may contain

[3] 61 FR 48,709

information which the FDA believes should be kept from the public, lest it be misinterpreted. But the very existence of such sites shows that the public not only understands such information, but desires more of it. Indeed, a dedicated layman can look up all sorts of research, either on the Internet or in traditional venues, to obtain information about unapproved uses of drugs and medical devices from overseas Web pages. The Internet simply makes such research easier. These examples demonstrate that the FDA must re-think its approach to speech regulation – the Constitution does not allow it, and frankly, the FDA will not be able to regulate speech on the Internet to the extent it does in the non-virtual world.

The FDA's policy on the flow of information about off-label uses of FDA-approved drugs has always been inherently suspect. The First Amendment prohibits the federal government from keeping information from the public. For part of this century, there has been an exception to this law for what is known as "commercial speech," or advertising. In the past few years, however, the U.S. Supreme Court has re-emphasized the importance of consumer information and advertising.[4] As Justice John Paul Stevens wrote, "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."[5]

In a very real sense, the FDA's restrictions hurt consumers twice – they cannot get such information, and, in many cases, neither can their doctors. This has become a serious

[4] See especially Rubin v. Coors Brewing Co., 115 S. Ct. 1585 (1995) and 44 Liquormart Inc. v. Rhode Island, 116 S. Ct. 1495 (1996).
[5] 44 Liquormart, 116 S. Ct. at 1508.

health threat, as shown by two physician polls sponsored by CEI. When asked, "if a drug or medical device has already been approved for one use by the FDA, should the FDA restrict information about off-label uses, that is, other unapproved uses of that drug or device," 67 percent of cardiologists[6], and 76 percent of oncologists[7] surveyed answered with a resounding "No."

These policies are also harmful to public health because they make the job of these specialists harder. In the same polls, when asked "to what extent does this FDA policy of limiting information make it more difficult to you to learn about new uses for drugs or devices," 60 percent of both groups of physicians said the FDA made their job more difficult. In short, when it comes to protecting the public health, the FDA's advertising restrictions are a step backwards.

If the FDA is truly concerned about this issue, the wisest thing to do would be to create an "FDA seal of approval" which a company could voluntarily affix to its Web page or portions of it. By stamping a Web page "FDA certified," there would be no question in the minds of consumers reading that page that the information presented meets FDA criteria. Even if the stamp were voluntary, it is likely that many companies would use it as a way to increase trust with the public. This is similar to the notion of the FDA certifying therapies, as discussed in a recent paper by a George Mason University law professor.[8]

[6] A National Survey of Cardiologists Regarding the Food and Drug Administration, CEI, July, 1996.
[7] A National Survey of Oncologists Regarding the Food and Drug Administration, CEI, August, 1995.

Certification would also resolve some of the other issues raised, such as company information in chat rooms and information about therapies in other countries. The FDA should not in any way prevent true information about therapies to be disseminated on the Internet. The FDA should note that if companies simply labeled certain packets of information as "FDA approved" (or others as "not FDA approved"), consumers would be clear about the quality of information provides, and could see for themselves how the government views the appropriateness of information and factor that into their decisions. Such technology is already available and easily applied.

In short, the FDA ought to stay away from regulating the Internet and instead look at ways companies can voluntarily certify information. If FDA were to follow such a course, its credibility would derive from the quality of its work, not from government fiat.

Sincerely,

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[8]4 George Mason Law Review. Krauss, Michael. "Loosening the FDA's Drug Certification Monopoly: Implications for Tort Law and Consumer Welfare." p. 457, Spring 1996.