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HEALTH AND EDUCATION

JOINT ECONOMIC COMMITTEE

United States Senate

WASHINGTON, DC 20510-3903

July 16, 2002

PLEASE RESPOND TO:

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<http://reed.senate.gov>

Lester M. Crawford, D.V.M., Ph.D.
 Deputy Commissioner
 Food and Drug Administration
 HF-1
 5600 Fishers Lane
 Rockville, Maryland 20857

Dear Dr. Crawford:

I write about the Food and Drug Administration's (FDA's) Federal Register notice of May 16, 2002. As you know, FDA published a notice of request for comments on how to ensure that its regulations, guidances, policies and practices comply with recent First Amendment case law, which the agency claims has emphasized the need for not imposing unnecessary restrictions on speech.

The notice asks the public to comment on several aspects of FDA regulation and offers a series of questions that it says are meant to facilitate the public process. I am very concerned about the content of the notice. The questions are related to basic tenets and requirements of the Federal Food, Drug and Cosmetic Act (FDCA). Many of the questions posed in the notice require in-depth evaluation of empirical data. The notice, however, provides no discussion of what the FDCA actually requires of FDA and the regulated industry.

Importantly, the notice blurs the distinction between statutory requirements that are within the authority of Congress and the agency's regulations, which are meant to implement and interpret the law. Throughout the notice, the agency asks policy questions as though FDA has absolute discretion to make decisions in these areas. In discussing the impact of false and misleading claims as opposed to that of truthful claims and then referring to Supreme Court protection of commercial speech that is "truthful and not misleading," the notice implies that "truthful and not misleading" is the only standard for FDA's regulation of promotional material. Rather, central to the FDCA is the statutory requirement that companies demonstrate that drugs, biologics and medical devices are safe and effective for a particular use or uses intended by the manufacturer.

The determination of whether information is false or misleading or both constitutes a determination separate from that of a product's intended use or uses, which forms the basis for its approval and its labeling. Your notice would have the public believe otherwise. In addition, as Michael Taylor and William Schultz, former FDA officials,

note in their May 28, 2002 Washington Post editorial, information can be truthful and still be misleading in certain contexts.

The May 16 notice also poses questions about a range of issues, including direct-to-consumer advertising, off-label use, standards for regulation of different categories of products, impacts of warnings and other information. It is very misleading for FDA to pose the questions in the notice without providing any information about how FDA has addressed these issues in the past and without being clear that the agency has done extensive research in many of these areas or acknowledging that these are issues that are central to many of the decisions that the agency makes on an ongoing basis.

As you know, the agency's jurisdiction over manufacturer communications depends in part on whether a particular communication is considered labeling, as defined in section 201(m) of the Act, or advertising. Nor does the notice provide information on the differences among the kinds of speech granted protection by the First Amendment or about the differences in protection accorded different categories of speech. The notice makes reference to the recent Supreme Court ruling in Thompson v. Western States Medical Center, but does not explain the decision. That decision by the Court addressed section 503a of the Act, which prohibited pharmacists from advertising the compounding of specific drug products. The Court ruled that the provision was more restrictive than necessary to satisfy the government's interest in protecting the public health and that there were non-speech related means to achieve FDA's goal. While the Court held that the provision was unconstitutional, the notice does not make it clear that the decision was narrow and did not address the specific content of any particular ad or the issue of off-label use.

In 1999, the Court of Appeals for the District of Columbia Circuit vacated earlier decisions by the District Court for the District of Columbia holding unconstitutional section 401 of the Food and Drug Administration Modernization Act of 1997. Section 401 provides a means by which companies may, under certain circumstances, distribute certain kinds of material that describe unapproved uses for approved products. As FDA explained in its March 16, 2000 Federal Register notice, the agency interprets section 401 as a safe harbor for industry meaning that if a manufacturer follows the provisions of the section and its implementing regulations at 21 CFR Part 99, FDA may not use the information disseminated by the manufacturer as evidence that the product is intended to be used for a "new" or unapproved use. The provisions do not confer any independent legal or enforcement authority on the agency. The plaintiff in the litigation, the Washington Legal Foundation, agreed that FDA could proceed on a case-by-case basis under the agency's preexisting legal authority. The Circuit Court noted that a manufacturer could argue in any specific instance that FDA's use of a manufacturer's promotion of a "new use" of a product violates the First Amendment.

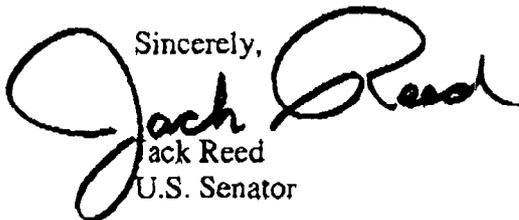
While the FDA should be encouraged to evaluate its policies in regard to this most central of issues, the agency has a duty to do so in a manner that provides the appropriate statutory and legal context for its history of product regulation and for policies that it has

developed over the years to implement its primary mission of protecting and promoting the public health.

The notice would also seem out of step with recently passed legislation. Indeed, section 522 of the recently approved Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes significant appropriations for each of the next five fiscal years for FDA's Division of Drug Marketing, Advertising and Communication because Congress believes that stringent regulation and oversight is essential as more and more drug companies use advertising as a means to inform the public about their products. The agency's recent notice has been perceived by many as a sign that FDA seeks to move away from more aggressive oversight in this area. I believe this would be a step in the wrong direction for America's healthcare consumers.

In light of the serious concerns that this notice has raised, I would urge you to issue a second notice clarifying the issues presented in the request for public comment. The deadline for comments should be delayed accordingly. In addition, I request that FDA hold a public meeting to discuss the issues. The agency should invite members of a variety of organizations, including consumer groups and physician groups, who offer a range of experiences with advertising and risk information, as well as individuals or organizations with expertise in the First Amendment implications of the Act and the agency's regulations. Further, I would request that the agency submit to the Congress, prior to making any final determination on them, a report of the meeting proceedings with any recommendations that the agency seeks to make with regard to changes in the statutory requirements concerning labeling, advertising and other aspects of communication by regulated industry.

Please direct any questions to Lisa German Foster on my staff. She can be reached at 202-224-4642. Thank you for your attention to this request. I look forward to your prompt attention to these issues and concerns.

Sincerely,

Jack Reed
U.S. Senator



AUG 12 2002

The Honorable Jack Reed
United States Senate
Washington, D.C. 20510-3903

Dear Senator Reed:

Thank you for your letter of July 16, 2002, regarding the notice and request for comments on First Amendment issues the Food and Drug Administration (FDA or the Agency) published in the *Federal Register* on May 16, 2002. The notice is the first step in our process of evaluating, with full public participation, the potential effects of First Amendment principles on FDA regulations, guidance documents, policies, and procedures. We believe this evaluation will help us give full recognition to recent legal decisions while helping assure that FDA retains the overall legal credibility necessary for us to accomplish our important public health duties.

FDA is committed to enforcing, within constitutional and statutory boundaries, the full range of legal and regulatory requirements applicable to advertising and promotional labeling for foods, drugs, biologics, medical devices, and cosmetics. These requirements include many that restrict or prescribe the content of promotional labeling and advertising disseminated by or on behalf of manufacturers of FDA-regulated products. Much of this communication is commercial speech that, as the Supreme Court has repeatedly held, is subject to protection under the First Amendment. This protection is substantial. For example, as you know, in April 2002, the Supreme Court struck down on First Amendment grounds a provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that authorized FDA to restrict advertising of particular compounded drugs. *Thompson v. Western States Med. Ctr.*, 122 S. Ct. 1497 (2002). All nine members of the Court assumed the First Amendment applied to FDA, and a majority thought Congress had gone too far in restricting speech about compounded drugs, even though FDA contended that this provision was necessary to preserve the integrity of the drug approval process.

The *Western States* decision is of particular concern not only because it struck down a provision of the FD&C Act under the First Amendment, but also because of the potential breadth of the Supreme Court's rationale. The Court held that although the government interest underlying the statutory provision was substantial, it was not permissible under the First Amendment for FDA to pursue that interest by imposing advertising restrictions because non-speech-restrictive alternatives were available.

02N-0209

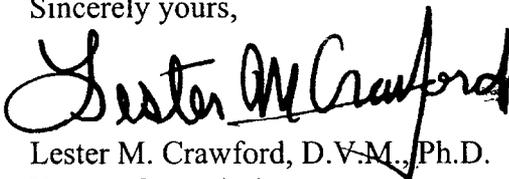
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Consequently, FDA determined to evaluate whether its regulations, guidance documents, policies, and procedures might impose speech restrictions of the type the Supreme Court found impermissible in *Western States* and other cases. FDA's objective in conducting this evaluation is two-fold. First, FDA hopes to facilitate the dissemination of truthful, nonmisleading health information to consumers, health professionals, and others. Second, FDA wishes to minimize the risk of lawsuits challenging on constitutional grounds the validity of its regulations, guidance documents, policies, and procedures. This will facilitate the execution of our public health mission by preserving FDA's credibility to the public, before Congress, among regulated firms, and in the courts.

FDA believes that its evaluation will benefit from input from a range of individuals and organizations. The Agency, therefore, published the May 16 notice in the *Federal Register* summarizing the pertinent First Amendment case law and posing several specific issues to stimulate analysis and provoke debate. FDA published a second *Federal Register* notice extending the deadline for filing comments by 45 days, to afford as much opportunity as possible for those wishing to participate in this proceeding to do so. See 67 FR §45,742 (July 10, 2002). After the initial comment period closes on September 13, 2002, there will be an additional period - until October 28, 2002 - to review comments and submit responsive comments. We have not yet decided whether to hold a public meeting or series of meetings on these issues, although that idea is certainly worth considering. Let me assure you that any proposals for changes to FDA regulations, guidance documents, policies, and procedures could and would be implemented only in accordance with the notice and comment and other administrative procedures prescribed by law. Any proposals for changes to FDA's statutory authority would, of course, have to be directed to Congress.

On behalf of FDA, I wish to thank you for your interest in our assessment of the impact of First Amendment principles on our activities. Your further comment on the May 16 notice, or on any other aspect of the Agency's implementation of its public health mission, would be most welcome.

Sincerely yours,

A handwritten signature in black ink that reads "Lester M. Crawford". The signature is written in a cursive style with a large, prominent "L" and "C".

Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner

cc: Dockets Management Branch, HFA-305
(Docket No. 02N-0209)