

MERCATUS CENTER
GEORGE MASON UNIVERSITY

REGULATORY STUDIES PROGRAM

**Public Interest Comment on
the Food and Drug Administration and First Amendment Issues¹**

The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic scholarship to assess rulemaking proposals from the perspective of the public interest. Thus, this comment on the Food and Drug Administration's (FDA) Request for Comment on First Amendment Issues does not represent the views of any particular affected party or special interest group, but is designed to evaluate the effect of FDA's approach to the First Amendment on overall consumer welfare.

I. Introduction

The FDA was created at the turn of the last century with the directive to protect consumers from fraud. In order to fulfill this mission, the FDA has maintained that it must filter the information that reaches the consumers:

FDA has historically employed its authority to ensure, to the extent possible, that health care professionals and consumers receive accurate and complete information. The manner and substantive content of FDA's regulation of speech has important implications for public health. False or misleading claims concerning foods, drugs, biologics, medical devices, cosmetics, or veterinary medicines may harm individuals who rely on those claims. Truthful claims, by contrast, may improve public health.²

However, in several instances the FDA's methods in protecting the consumer from information have fallen afoul of the First Amendment provision: "*Congress shall make no law ... abridging the freedom of speech.*" In light of recent case history, the FDA has requested public comment on whether FDA regulations chill speech and ways in which the FDA could protect consumers' interest without violating the First Amendment. The FDA posed nine questions to guide those wishing to comment, three of which this comment addresses. They are: 1) "Is FDA's current position regarding direct-to-consumer and other advertisements consistent with empirical research on the effects of

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² 67 Federal Register 34942, 3943 (May 16, 2002).

those advertisements, as well as with relevant legal authority?” 2) “What arguments or social science evidence, if any, can be used to support distinguishing between claims made in advertisements and those made on labels? Does the First Amendment and the relevant social science evidence afford the Government greater latitude over labels?” 3) “Do FDA’s speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?”³ This comment addresses these questions by giving a brief overview of case law, followed by a discussion of how advertising and labeling practices affect the consumer, and the FDA’s handling of the trans fat labeling regulation, concluding with the recommendation of how the FDA should approach consumer protection in the 21st century.

II. The Current State of Case Law

In order to determine whether FDA policy consistently violates the First Amendment, it is necessary to review current case law on the topic. Historically, the First Amendment has protected commercial speech less than pure speech, but the protection that the First Amendment extends to commercial speech is nonetheless considerable. In *Central Hudson Gas and Elec. Corp. v. Public Service Comm’n*, 447 U.S. 557 (1980), the Supreme Court laid out a four part test to determine whether government regulatory policies chill commercial speech. First, commercial speech must “at least...concern lawful activity and not be misleading. Next, we ask whether the asserted government interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.”⁴

In several cases, courts have found that FDA regulation has violated this test. Most recently in *Thompson v. Western States Medical Center*, 122 S. Ct. 1497, U.S. (2002) the Supreme Court held that the FDA’s restrictions on pharmacists advertising their practice of compounding drugs violated the First Amendment.⁵ The Court determined that the FDA had overstepped its bounds by imposing speech restriction to achieve its ends when there were several other possibilities that could have been used to achieve the FDA’s objectives without having to restrain speech. In fact, the Court found that the FDA’s restrictions would have prohibited the pharmacists from engaging in useful and beneficial speech.

³ Id. at 34943, 3944

⁴ 447 U.S. 557, 566 (1980).

⁵ Compounding is the “preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner’s prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice or for the purpose of or as in incident to research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.” http://www.custompharmacy.com/co_def.html

Likewise in *Washington Legal Foundation v. Friedman* 13 F. Supp.2d 51 (1998) and *Washington Legal Foundation v. Henney*, 56 F. Supp.2d 81 (1999)⁶, the District Court found that the FDA had overstepped its bounds in preventing drug manufacturers from distributing to doctors independent journal articles that described off label uses of pharmaceuticals or medical devices (hereafter referred to as “drugs”).⁷ The court applied the test from *Central Hudson* and determined 1) the speech was neither unlawful nor inherently misleading; 2) the government had a substantial interest⁸; 3) the policies directly advanced the substantial government interest, but 4) that the means the FDA chose to advance its interest placed a substantial and unnecessary burden on speech, because there were less burdensome restrictions than curbing speech that could have been placed upon the manufacturer. In fact, the courts proposed more speech, not less, as a remedy. The court advised that manufacturers should engage in full and complete disclosure, particularly as

...off label prescriptions, presently legal, do constitute the most effective treatment available for some conditions. Through the government’s well intentioned efforts to prevent misleading information from being communicated, a great deal of truthful information will also be embargoed. In this case the truthful information may be life saving information, or information than [sic] makes a life with a debilitating condition more comfortable.⁹

The court then pointed out that the solution of full disclosure also fits the Supreme Court’s preference for combating “potentially problematic speech with more speech.” The court had touched on this point earlier in the opinion when it chastised the FDA for claiming that the FDA had to curb speech to ensure that physicians weren’t misled.

If there is one fixed principle in the commercial speech arena, it is that “a State’s paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it.” *44 Liquormart*, 517 U.S. at 497...To endeavor to support a restriction upon speech for his or her own protection, which is the

⁶ *Henney* is the government’s motion to amend *Friedman*, but the name changed because the Commissioner of the FDA changed.

⁷ On appeal in *Henney*, the FDA states that the Food and Drug Administration Modernization Act (FDAMA) did not provide it with “independent authority to proscribe speech.” As the constitutional issue was thus negated by this admission, the appeal was dismissed, and the district court decision vacated in part, but as the opinion noted, due to the change in the government’s position, the appellate court’s decision did not reach the merits of the district court’s First Amendment holdings.

⁸ The court did note however that while the government’s general interest in these matters is “protecting and promoting the public health, an interest of particular importance to the FDA. For purposes of a *Central Hudson* analysis, however, a more narrow definition of interests is more helpful.” 56 F. Supp 2d 81, 86 (FN 6) (1999).

⁹ 13 F. Supp. 2d 51, 73 (1998).

gravamen of FDA's claim here, is practically an engraved invitation to have the restriction struck.¹⁰

In this case the court was particularly concerned with information that was being disseminated to the medical community. Usually, however, the FDA bases limits on commercial speech regarding food and drugs on the belief that consumers are poorly equipped to separate useful health-related information from biased or misleading information. On that premise, FDA presents itself as the protector of the public from its own ignorance and confusion, as well as the implied tendency of producers to play upon that ignorance and confusion. Indeed, as discussed above, restrictions on commercial speech *must* be predicated on a claim of advancing the public interest. However, as history shows us, the FDA's estimation of public confusion is likely to be in error. Also, there exist substantial checks on potential producer abuses, discussed below, suggesting that the FDA's regulation of commercial speech not only does not advance public health; it actually hampers it significantly.

III. The Case of Food Advertising

Prior to the mid 1980s, the FDA did not permit food producers to advertise the health features of their products.¹¹ The FDA maintained this restriction, on the basis that consumers might be misled by biased advertising or would otherwise be unable to process the health information properly, until the Kellogg Company (in concert with the National Cancer Institute) openly ignored the restriction by advertising the benefits of its high fiber cereal All-Bran in fighting cancer. This advertising campaign was the impetus for a full review of regulatory policies toward health claims in food advertising, triggering congressional hearings on the matter. Despite the possibility that the FDA would bring legal action against Kellogg, the company extended the advertising campaign to its other high-fiber cereals, and many other producers followed suit.

This *de facto* (and eventual formal) regulatory change provided a natural experiment to analyze how consumers process health information contained in advertisements. Pauline Ippolito and Alan Mathios¹² performed such an analysis in an event study regression framework. Their results indicated unambiguously that people do indeed process health information contained in advertisements and this ability to process information was not restricted to those individuals we would expect to be particularly adept at processing information.

¹⁰ 13 F. Supp.2d at 69, 70. *See also* 56 F. Supp. 2d 81, 86. ("The government however benign its motivations, simply cannot justify a restriction of truthful nonmisleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information.")

¹¹ For a detailed discussion of the FDA's policy in this area at the time, see P.B. Hutt, "Government Regulation of Health Claims in Food Labeling and Advertising," *Food, Drug, and Cosmetic Law Journal*, 41(1986): 3-73.

¹² P.M. Ippolito and A.D. Mathios, "Information, Advertising, and Health Choices: A Study of the Cereal Market," *The RAND Journal of Economics*, 21(1990): 459-480.

Specifically, Ippolito and Mathios estimated that advertising caused a statistically and practically significant increase in the consumption of high-fiber cereals. Further, while this increase was observed for all categories of consumers, Ippolito and Mathios's results "suggest that advertising effects would be concentrated among informationally disadvantaged portions of the population."¹³ That is, all things equal, those individuals we would expect to exhibit the greatest deficiencies in processing health information received the greatest benefits from the advertising.

However, this begs a question often raised by supporters of advertising restrictions: since advertisers are likely to publicize only the health benefits of their products, consumers might be led to ignore the potentially harmful effects of the product. Ippolito and Mathios's study illuminates this issue as well. They analyzed the effect of the fiber advertising on individuals' intakes of fat and sodium from cereals and found no increase.¹⁴ That is, even though consumers were induced to consume more fiber in their cereals, they generally stayed clear of those cereals that were high in fat and/or sodium.¹⁵

Direct empirical studies of the effect of health information on consumer choice are few in number due to difficulties in quantifying information. Despite this dearth of research, the FDA simply assumes, without evidence, that health information is too complex for consumers to process effectively. Though there is room for debate, as the investigation of cereal advertising demonstrates, the existing research¹⁶ does suggest that consumers can make informed decisions and are not blinded by advertising undertaken by producers in self-interest.

The experience of restrictions on health claims in food advertisements should give the FDA pause in its desire to protect consumers by limiting advertising for other classes of goods, such as pharmaceuticals and dietary supplements. As was shown in the case of food advertising, the FDA's concerns about consumers being confused and misled might be exaggerated. Also, as indicated in the research on health-related advertising for food, the FDA might well be impeding individuals' access to important information on the health benefits of various drugs and supplements.

¹³ Ibid, 476.

¹⁴ In fact, in some specifications, there was actually a statistically significant decrease in consumption of fat and sodium.

¹⁵ Their regression analysis excludes the possibility that this effect was due entirely to high-fiber cereals containing relatively low amounts of fat and sodium. That is, even among high-fiber cereals, consumers still chose low-fat, low-sodium products. Effectively, consumers were not blinded to negative health consequences by the advertising touting health benefits.

¹⁶ Another interesting study that implements the same methods as the cereal research is P.M. Ippolito and A.D. Mathios, "Information and Advertising: The Case of Fat Consumption in the United States," *The American Economic Review*, 85(1995): 91-95. In this article, the authors describe how once advertising restrictions were lifted and producers began promoting the health benefits of their low-fat products, consumers were induced to improve their fat intake.

IV. Advertising vs. Labeling

Both of the Ippolito and Mathios studies cited above also provide an interesting insight into the relative value of information contained in product labeling and that contained in advertisements. Specifically, in both the case of advertising related to the value of fiber in preventing cancer and the advertising promoting the coronary benefits of a low fat diet, the underlying research¹⁷ had existed well before advertising was allowed. Further, although food labeling provided data on the fiber content and fat content of various foods, it was not until companies were permitted to advertise the value of their products specifically, in light of the underlying health research, that individuals were induced to change their consumption behaviors. That is, the existence of information in the form of medical research and nutrition label data was not enough to generate improved health habits. Advertising was necessary to inform consumers.

In that sense, advertising is more consequential than labeling *per se*. However, it is unclear what the source of this relative disparity in the importance of advertising versus labeling is. Perhaps if producers received greater latitude to advertise the specific benefits of their products on labels, labeling would take on greater importance with respect to consumer behavior. This is an empirical issue that has not been investigated sufficiently to draw any conclusions. However, one inference from Ippolito and Mathios's work that cannot be ruled out is that advertising's value comes from explicitly communicating the link between health research and a given product. If that were the case, making health claims on a label directly would presumably have qualitatively similar results to advertising. Unless the FDA can present evidence or a plausible argument as to why the effects of health claims on labels differ from the effects of health claims in advertisements, the presumption should be for more latitude in a producer's decision to make health claims on its labels.

V. Checks on Producer Abuses

The foregoing analysis claims that consumers are capable of processing health information from advertisements. In fact, the analysis suggests that consumers are more likely to gain useful information from advertisements than they are from the mere existence of medical research and raw product data. Also, there is evidence that individuals are not likely to be duped into consuming something that is, on net, relatively harmful when presented with advertisements that selectively impart health information.

However, even if these empirical results could not be generalized, there are substantial market forces that limit a producer's ability to deceive its customers through false or

¹⁷ With respect to the fiber-cancer relationship, Ippolito and Mathios document that the research establishing the health benefits had been published in the 1970s, and there were no new major studies released during the period directly preceding the lifting of the advertising ban. As for the coronary implications of fat consumption, "the basic scientific information linking diet to heart disease was well-established by the early 1960s (Ippolito and Mathios, 1995)." This has two important implications: 1) The results indicating the benefits of advertising are unlikely to be artifacts of slowly disseminated health research through non-advertising mechanisms; and 2) Health research and product data alone are likely to be insufficient to convey useful information to consumers, adding importance to the role of advertising.

misleading advertisements. First, it is in the interest of a firm's competitor to provide advertisements exposing misleading statements. Second, customers themselves will often have recourse against a dishonest producer through a breach of warranty or tort claim, which can impose high costs for misrepresentations. Even in the absence of a legal claim, firms have the incentive to develop reputations for providing useful, non-misleading information. If they do not cultivate that reputation, consumers are likely to discount the firm's advertising or abandon the product altogether. Lastly, in reference to the claims of certain products being "too complex" for a consumer to understand and process information in advertisements, there are a number of complex products on the market that face relatively few advertising restrictions. Often with such products, consumers look to disinterested third parties for direction. It is not at all clear why the products falling under the FDA's purview are any different.¹⁸

All of these forces limit any producer's ability to mislead consumers. Therefore, the claim that the FDA's restriction on commercial speech is necessary to protect the public interest appears to be untenable in reality as in law.

VI. Who guards the guardians?

The FDA's claim of guarding the public health and protecting the public interest is particularly untenable when one considers the case of trans fatty acids.

In 1999, the FDA proposed to revise its nutrition labeling requirement to include information about the presence of trans fatty acids in food products. Trans fatty acids (trans fats) were to be listed on the label as saturated fats. A footnote would designate what percentage of the "saturated" fats were actually trans fatty acids, and trans fatty acids would be considered as saturated fats in the daily value calculation of nutrients in one's diet. Additionally the proposed regulation would lump trans fats in with saturated fats in most cases where the amount of saturated fats would affect the regulatory status of a health claim. Essentially, the labels required by the rule would have led consumers to believe that the FDA viewed trans fats as a subcategory of saturated fats.

However, trans fats are *not* saturated fats. They have a different chemical structure, and, because of this different structure, they have different biological effects than saturated fats do. The FDA recognized this fact, but nevertheless proposed to require that trans fats be incorrectly labeled "saturated" fats because it appeared to be an expedient way to convey that they are "bad fats."

Saturated fats may be "bad fats," but trans fats are arguably worse. Like saturated fats, trans fats appear to increase the low density lipoprotein (LDL) cholesterol concentration, a contributory factor for coronary artery disease. Unlike saturated fats however, trans fats may also decrease the levels of high density lipoprotein (HDL) cholesterol

¹⁸ Automobiles are just one example. While most drivers presumably know relatively little about car mechanics or safety, information sources such as consumer magazines find it profitable to fill this information gap.

concentration, creating another contributory factor for heart disease that saturated fats do not possess.¹⁹

The FDA knew this was the case, yet it still proposed to label trans fats as saturated fats, because it feared that consumers wouldn't understand the nature or significance of trans fats. Instead of taking the trouble to educate consumers, the FDA sought a "free ride" on the consumers' belief about saturated fats being "bad."²⁰ In doing so, the FDA violated the very standards it expects producers to meet. If a producer had tried to present trans fats on a label as the FDA proposed to present them, a court would have struck down the labeling for failing the first prong of the *Central Hudson* test, for this speech would have been misleading.²¹ Yet the FDA persists in asserting that it is the guardian who will protect the health of the public by deciding what information the public should receive.

VII. Conclusion

Recent events indicate that the FDA regulations regarding advertising and labeling are not only contrary to constitutional principles, but may be internally inconsistent, and may actually harm public health. As summarized in this comment, the courts have determined that the FDA's current regulatory approach chills speech. Further, FDA's proposal to require that trans fats be labeled incorrectly as saturated fats ran counter to the standards it expects producers to maintain. And, perhaps most importantly, studies suggest that the FDA's long practice of not letting food producers advertise the health benefits of their products has kept valuable information from consumers. These points suggest that the FDA should change its regulatory course.

If the FDA wishes to be responsive to consumers' needs and the First Amendment, it should follow the Supreme Court's suggestion and embrace more speech not less, permitting full disclosure from producers as to the effects of their products, be they pharmaceuticals, nutritional supplements, or foods. By encouraging the free flow of information, the FDA will provide a valuable service. It will be empowering those most affected, the consumers, to make informed decisions about their needs.

¹⁹ Letter Report on Dietary Reference Uptakes for *Trans Fatty Acids*, Institute of Medicine (2002). [http://www.iom.edu/iom/iomhome.nsf/WFiles/TransFattyAcids/\\$file/TransFattyAcids.pdf](http://www.iom.edu/iom/iomhome.nsf/WFiles/TransFattyAcids/$file/TransFattyAcids.pdf). While the IOM report is from this year, the research that revealed the effects of trans fats of HDL and LDL was available before the FDA published its report, in fact some of the research was cited in the FDA's proposed rulemaking. See 64 Federal Register 62746 et seq.

²⁰ Howard J. Beales, *Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*, Mercatus Center (April 13, 2000.)

²¹ Not that a producer could label the trans fat content without FDA approval. 21 CFR 101.9(c) limits what nutrients may be included on the nutrition label. Trans fats are not on the list of nutrients that one may put on the label.

**APPENDIX I
RSP CHECKLIST**

Element	Agency Approach	RSP Comments
1. Has the agency identified a significant market failure?	FDA has not identified a market failure that necessitates its regulation of advertising and labeling.	On the contrary, research suggests that allowing market forces to work would permit competing companies to provide valuable health-related information to consumers through different avenues.
2. Has the agency identified an appropriate federal role?	The agency identifies its role as protecting the public health as well as promoting free and open communication.	Courts have held that while the FDA may have an appropriate role, it must be narrowly defined to meet the specifics of the case. The paternalistic view that the State needs to limit information because consumers wouldn't understand the information is unacceptable.
3. Has the agency examined alternative approaches?	The purpose of this notice was to request suggestions for alternative approaches to current policy.	FDA should permit producers to engage in full disclosure of information rather than limiting disclosure, thus equipping consumers to make an informed decision.
4. Does the agency attempt to maximize net benefits?	N/A	Available studies suggest FDA could improve public health benefits and lower costs if it allowed advertising/truthful labeling.
5. Does the proposal have a strong scientific or technical basis?	N/A to the proposal per se, but the FDA has, without evidence, assumed that health information is too complex for consumers to process effectively, despite the fact that direct empirical studies of the effect of health information on consumer choice are few in number due to difficulties in quantifying information.	Though there is room for debate, as the investigation of cereal advertising demonstrates, the existing research does suggest that consumers can make informed decisions and are not blinded by advertising undertaken by producers in self-interest.

Element	Agency Approach	RSP Comments
6. Are distributional effects clearly understood?	The FDA has not examined the distributional impacts of its policies.	Research has suggested that, all things equal, those individuals we would expect to exhibit the greatest deficiencies in processing health information received the greatest benefits from the advertising.
7. Are individual choices and property impacts understood?	The FDA's existing regulations appears to be based on the notion that consumers are not equipped to make their own choices, without government guiding them in the "proper" direction.	The agency has limited individual choice by withholding information from consumer, but is now seeking ways to address that past fault.