COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE REGARDING THE CONSTITUTIONALITY OF THE FOOD AND DRUG ADMINISTRATION'S TREATMENT OF PRODUCT INFORMATION

67 FR 34,942 (May 16, 2002)

September 13, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

INTRODUCTION

The Competitive Enterprise Institute (CEI) is a non-profit public interest organization committed to advancing the principles of free markets and limited government. CEI has a longstanding interest in protecting and expanding consumer choice in the marketplace, and in opposing overregulation of commercial speech.

This request for comments represents a welcome departure from FDA's prior treatment of First Amendment concerns in the context of product advertising, labeling, and promotions. Over the past decade, FDA has aggressively restricted the information that can be disseminated by manufacturers regarding the health benefits of foods, drugs, and dietary supplements. In doing so, the agency has essentially ignored the substantial body of Supreme Court precedent protecting the commercial use of factually accurate information about products and services.[1] Manufacturers wishing to use unapproved health information were often forced to file suit in federal court.[2]

[1] *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council Inc.*, 425 U.S. 748 (1976); *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of N.Y.*, 447 U.S. 557 (1980); *In re R.M.J.*, 455 U.S. 191 (1982); *Bolger v. Youngs Drug Product*

FDA's policy has been less than satisfactory, both for manufacturers and consumers. Even after agency speech restrictions were found unconstitutional, FDA would continue to pursue its restrictive policies, either by devising new explanations for banning the speech at issue, or by refusing to undertake the court-ordered administrative actions in a timely fashion. These delaying tactics have necessitated years of litigation, which in some instances has continued long after the speech restrictions at issue were initially determined to violate the First Amendment.[3] Further, the agency has construed each decision to narrowly apply only to the specific speech at issue.

In effect, FDA had been content to flout the First Amendment, and continue banning a considerable volume of product information, defying the affected parties (manufacturers or consumers) to undertake the lengthy litigation necessary to vindicate their rights. The chilling effect of this policy has deprived the public of a wealth of potentially beneficial product information.

There is, however, a notable exception to this attitude—FDA's stand *against* mandating certain statements on bioengineered foods and related products. As described

---

Corp., 463 U.S. 60 (1983); *Zauderer v. Office Of Disciplinary Counsel*, 471 U.S. 626 (1985); *Posadas de Puerto Rico Associates v. Tourism Col Of Puerto Rico*, 478 U.S. 626 (1985); *Peel v. Attorney Reg. & Disciplinary Comm'n*, 496 U.S. 91 (1990); *Edenfield v. Fane*, 507 U.S. 761 (1993); *Ibanez v. Florida Dept. Of Business and Prof. Reg.*, 512 U.S. 136 (1994); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Greater New Orleans Broadcasting Ass'n v. U.S.*, 527 U.S. 173 (1999); *Lorillard Tobacco Co., v. Reilly*, 533 U.S. 525 (2001).

[2] *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (Pearson); *Washington Legal Foundation v. Freidman*, 13 F.Supp.2d 51 (D.D.C. 1998); *Thompson v. Western States Medical Center*, 122 S. Ct. 1497 (2002).

[3] In *Washington Legal*, FDA restrictions on medical studies regarding off-label uses of drugs were found unconstitutional in 1998, yet the issue was not settled until 2000. In *Pearson*, the agency restrictions on certain dietary supplement health claims were found unconstitutional in 1999, yet FDA's last motion to reconsider was denied in 2001.

below (pages 8-11), on many occasions, FDA has resisted petitions to require mandatory labels on such products. FDA's denials of these petitions have been based on scientific grounds; specifically, on FDA's view that the information at issue was not material. In fact the First Amendment adds further support to these agency actions. The First Amendment not only protects truthful speech; it also protects the right of manufacturers to be free from mandated speech unless there are compelling reasons for such mandates.

CEI applauds FDA's effort, through this request for comments, to proactively and comprehensively modify its policies to comply with First Amendment jurisprudence. As will be discussed below, this body of precedent requires several changes in FDA's treatment of manufacturer requests to use product information.

This body of precedent may also require changes in FDA's interpretation of its underlying statutes. FDA states that it "intends to defend the [Food, Drug, and Cosmetic Act] against any constitutional challenges …." 67 FR 34,943. Nonetheless, FDA has a duty to construe that act in a manner that will avoid First Amendment issues to whatever extent possible. The Supreme Court has noted its "prudential desire not to needlessly reach constitutional issues and [its] assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority." *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers,* 121 S. Ct. 675, 683 (2001). FDA should do likewise.

I.
THE FIRST AMENDMENT SEVERELY LIMITS FDA'S AUTHORITY TO RESTRICT THE USE OF FACTUALLY SUPPORTED PRODUCT INFORMATION

A. FDA Must Meet A High Burden In Justifying Speech Restrictions

First Amendment jurisprudence makes clear that the burden is on FDA to justify any restriction on the use of product information. The "party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Bolger*, 463 U.S. at 71 n.20. The standard for agency review of commercial speech was first set out in *Central Hudson*:

> "At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must 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."

Id. at 566. The *Central Hudson* test has become the standard for reviewing government restrictions on commercial speech, and was most recently used by the Supreme Court to strike down FDA's ban on compounded drug advertising in *Thompson*. 122 S. Ct. at 1504.

B. Demonstrably Misleading Product Information Can Be Restricted, But Only If Empirical Evidence Demonstrates that It Cannot Be Cured By Reasonable Disclaimers

The *Central Hudson* test not only details the burden FDA or other agencies must meet in restricting commercial speech, but also makes clear that there is little or no deference afforded an agency's determination that it has met this burden. "The burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to

sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will alleviate them to a material degree." *Edenfield*, 507 U.S. at 507. A government restriction that rests on "anecdotal evidence and educated guesses" does not satisfy this test. *Coors*, 514 U.S. at 490.

This is particularly true of agency attempts to ban allegedly misleading speech. "The absolute prohibition on appellant's speech, in the absence of a finding that his speech was misleading, does not meet these requirements." *In re R.M.J.*, 455 U.S. at 207. "Given the complete absence of any evidence of deception . . . we must reject the contention that petitioners [speech] is actually misleading." *Peel*, 496 U.S. at 106.

The mere assumption that the public will be misled by product information does not satisfy this requirement. In *Pearson*, the U.S. Court of Appeals was unpersuaded by FDA's unsupported assertion that the dietary supplement claims at issue would mislead consumers:

> "health claims [FDA argues] are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous."

Id. 164 F.3d at 655

Nor do assertions that a claim is true but misleadingly incomplete justify keeping it off product labels and ads. The Supreme Court has noted that:

> "it seems peculiar to deny the consumer, on the ground that the information is incomplete, at least some of the relevant information needed to reach an informed decision. The alternative - the prohibition of advertising – serves only to restrict the information that flows to consumers. Moreover, the argument assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public.

> In any event, we view as dubious any justification that is based on the benefits of public ignorance."

Bates v. State Bar of Arizona, 433 U.S. 350, 374, 375 (1977). "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all." *Central Hudson*, 557 U.S. at 562.

Even if a particular health claim is demonstrably misleading, First Amendment court rulings make it clear that disclaimers, rather than outright bans, should be used whenever possible. "When government chooses a policy of suppression over disclosure – at least where there is no showing that disclosure would not suffice to cure misleadingness – government disregards a far less restrictive means." *Pearson*, 164 F.3d 658 (internal quotations omitted). This judicial insistence that, prior to the use of a ban, a disclaimer be *shown* to be ineffective, is important. It indicates empirical data may well be essential when an agency chooses to ban questionable speech rather than cure it through disclaimers.

When disclaimers are used, moreover, they must be reasonable given the space limitations inherent in labeling and advertising. They cannot be so lengthy that they serve as de facto bans.

Claims that are totally unsupported are in all likelihood inherently false and may be banned per se. For claims that are supported, however, the range of underlying evidence may vary greatly. A specific claim might be supported by only the slimmest of evidence, by preliminary evidence, by significant evidence, or by a preponderance of evidence. There is justifiable concern that claims falling into the first two (and possibly three) categories do not mislead the public into believing that they are scientifically

"proven". Clearly, however, disclaimers may well be able to alleviate this concern. FDA should expeditiously attempt to formulate a series of standard disclaimers that succinctly reflect its own assessments of the scientific support for various types of claims. While such disclaimers may be unprecedented in FDA's experience, their utility must be examined empirically, and not by conjecture.

C. Commercial Speech Restrictions Must Be Narrowly Tailored To Serve A Substantial State Interest

The final two steps of the *Central Hudson* test require that restrictions on speech directly serve a legitimate state interest, and be no more extensive than necessary. 446 U.S. at 556. These steps "basically involve a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends." *Coors*, 514 U.S. at 486. A commercial speech "restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective of remote support for the government's purpose." *Central Hudson*, 447 U.S. at 564.

Thus, even if a restriction on speech serves a legitimate purpose, the restriction must be narrowly tailored to directly serve that purpose. This is why, as discussed above, only demonstrably misleading speech may be restricted, and why the use of disclaimers is preferred over outright suppression. "The free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Zauderer*, 471 U.S. at 646.

Perhaps more importantly, the requirement of a reasonable means-end fit obligates regulatory bodies to first consider ways to achieve its objectives that do not restrict speech. For example, the Supreme Court has twice struck down alcoholic

beverage advertising restrictions that purport to advance legitimate state interests in promoting temperance, in part because "alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal . . ." *44 Liquormart*, 517 U.S at 507; see also *Coors*, 514 U.S. at 490-91.

In *Thompson*, the Supreme Court was similarly unimpressed with FDA's assertion that it needed to ban advertising of compounded drugs in order to prevent manufacturers from exploiting the less onerous regulatory requirements imposed on such drugs. The Court noted that "several non-speech related means … might be possible here," and that "the government has not offered any reason why these possibilities, alone or in combination, would be insufficient to prevent compounding from occurring on such a scale as to undermine the new drug approval process." 122 S. Ct. at 1506-7. The Court concluded that "if the First Amendment means anything, it means that regulating speech must be a last – not first - resort." *Id*. at 1507.

Thus, the high standard with which First Amendment restrictions are judged requires that all non-speech options be considered and found to be inadequate before FDA may regulate commercial speech.

II.
THE FIRST AMENDMENT SUPPORTS FDA'S POLICY AGAINST MANDATING NON-MATERIAL LABELING OF BIOENGINEERED PRODUCTS

Notwithstanding the above, there is one area in which FDA has admirably respected First Amendment rights: its regulation of whole foods, food additives, and other bioengineered food ingredients produced with recombinant DNA techniques. Ever since these products first became commercially available, FDA has received repeated requests that it mandate label statements indicating that they were derived from

genetically engineered materials. FDA determined, however, that there is no inherent, material difference between the products of bioengineering as a class and the products of conventional modification. Consequently, FDA has consistently found that it does not have authority under the Federal Food, Drug and Cosmetic Act to mandate such labeling.

Two federal court cases have affirmed this determination. One of these cases further held that, where bioengineered products do not differ materially from their conventional counterparts, mandating special labeling would violate the First Amendment as well.

In 1992, FDA published its "Statement of Policy: Foods Derived from New Plant Varieties," explaining its interpretation of the act with respect to foods derived from new plant varieties, including those developed with recombinant DNA techniques.[4] This policy, which is still in effect, holds that the "regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use." Consequently, foods developed from new plant varieties must be labeled if, and only if, their composition differs "significantly" from their conventional counterparts. Such differences may include, but are not limited to, the introduction of genes that create proteins (or other added substances, such as fatty acids and carbohydrates) that differ substantially in structure or function from other substances typically found in the food supply, the reduction in nutrients from what would be expected of the new plant's conventional counterpart, or the introduction of an allergen not present in the new plant's conventional counterpart. Heightened scrutiny would apply if the transferred genetic material is suspected to be a human allergen, and

[4] 57 FR 22,984 (1992).

particular attention would be paid to proteins derived from foods known to contain allergens, such as milk, eggs, wheat, fish, or nuts.

In 1993, when FDA approved the animal drug recombinant bovine somatotropin (rbST), mandatory labeling advocates again petitioned the agency to require that all dairy products from cows treated with rbST be labeled as "genetically engineered" or "contains rbST." The agency concluded that "there was no significant difference between milk from treated and untreated cows" and consequently determined that it did not have authority under the act to require labeling.[5] When FDA declined the request to mandate labeling, these advocates turned their efforts toward litigation and state-level lobbying state legislatures, with variable degrees of success.

In *Stauber v. Shalala*, 895 F. Supp. 1178 (W.D. WI, 1995), a group of consumers challenged FDA's approval of rbST as a veterinary drug. They also argued that its decision against mandatory labeling of dairy products from rbST-treated cows allowed those products to be falsely and misleadingly labeled. The court found that there was no material difference between milk from treated and untreated cows, and it upheld FDA's determination that mandatory labeling was not authorized by the act. The court further ruled that, because the dairy products in question did not significantly differ from conventional dairy products, "it would be misbranding to label [them] as different, even if consumers misperceived [them] as different". *Id*. at 1193.

In Vermont, the state legislature enacted a law requiring that, "[i]f rbST has been used in the production of milk or a milk product for retail sale in [Vermont], the retail

[5] 58 FR 59,946 (1993); 59 FR 6,279 (1994).

milk or milk product shall be labeled as such."[6] In *International Dairy Foods Association, et al. v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996), the court found the statute and its accompanying regulations unconstitutional, noting that the labeling mandate was grounded in consumer perception rather than in the diary products' measurable characteristics. The court held that producers cannot be forced to engage in involuntary speech simply because some people would like to have the information: "The right not to speak inheres in political and commercial speech alike … and extends to statements of fact as well as statements of opinion". *Id.* at 71.

Applying the *Central Hudson* test, the court found that Vermont could not demonstrate that its interest in compelling acknowledgment of rbST use represented anything more than satisfying consumer curiosity. Thus, Vermont could not compel milk producers to include that information on product labels:

> "We are aware of no case in which consumer interest alone was sufficient to justify requiring a product's manufacturers to publish the functional equivalent of a warning about a production method that has no discernable impact on a final product. … Absent some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it."

Id. at 74.

These judicial rulings indicate that FDA's policy on labeling requirements for food products produced with the aid of recombinant DNA techniques are not only scientifically defensible, but are also constitutionally compelled. FDA should not only maintain this position, it should extend it, where appropriate, to other regulated products as well.

[6] Vt. Stat. Ann. tit. 6, § 2754(c).

CONCLUSION

FDA should be commended for its recognition that there are growing conflicts between its current practices and First Amendment jurisprudence. FDA should begin immediately to reexamine and, to the extent possible, revise its interpretation of the Food, Drug and Cosmetic Act in order to minimize such conflicts. It should also begin to develop a set of succinct disclaimers that will allow it to readily communicate, to the public, its view of product claims that are based on less than conclusive scientific evidence.

At the same time, FDA should recognize that recent First Amendment rulings add support to its current stand on the labeling of bioengineered food products. FDA has, on scientific grounds, refused to require that such products carry statements regarding their bioengineered status unless there is a material difference between those products and their conventional counterparts. That position, it turns out, is supported, and very likely mandated, by First Amendment considerations as well.

September 13, 2002

Respectfully submitted,

_____

Ben Lieberman
Greg Conko
Sam Kazman

Competitive Enterprise Institute
1001 Connecticut Ave. NW,
Suite 1250
Washington, DC 20036

(202) 331-1010