



October 28, 2002

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

RE: Request for Comment on First Amendment Issues
Docket No. 02N-0209
67 Fed. Reg. 34942 (May 16, 2002)

Dear Sir or Madam:

AARP appreciates the opportunity to respond to the first round of comments submitted in this docket concerning the impact of recent court cases involving the First Amendment on FDA authority to regulate product labeling and advertising.

We would like to first address a number of general, crosscutting issues raised by some of those commenting, and then discuss two product-specific labeling and advertising requirements raised in the comments.

General Issues

As a threshold matter, we agree with other commenters that FDA should reject a broad interpretation of court decisions limiting restrictions on commercial speech in lieu of narrower interpretations that would preserve FDA authority. We raised the very same concern in our initial comments.

Second, we agree with the suggestion that FDA hold a public meeting to discuss the issues raised in this docket. These issues are complex and any decision to revise FDA's approach to labeling and advertising regulations could have far-reaching effects.

02N-0209

D
C 89

Third, we agree with other commenters that weakening current restrictions could erode public health protections afforded under the Federal Food Drug and Cosmetic Act (FFDCA). As two former FDA officials noted in a recent op-ed, “the right to advertise without restriction needs to be balanced against the need to promote the public health.”¹ The op-ed noted that to protect the public, “[d]rug and other health product companies should be required to demonstrate safety and effectiveness of their products *before* they promote them.” With food products, for which effectiveness need not be proven, they said manufacturers should be required to present rigorous scientific evidence that a food can help prevent disease *before* making such a claim. We agree that only by maintaining these requirements will the public health be adequately protected.

Fourth, a number of commenters argued that the First Amendment prevents the government from compelling individuals to express certain views, specifically to disclose certain information in labeling and advertising about products. In support of this argument, one of the commenters cited two court cases: *United States v. United Foods, Inc.*² and *International Dairy Foods Ass’n v. Amestoy*.³ However, the holdings in these two cases are not applicable to FDA rules requiring disclosures.

In *United States v. United Foods*, the Supreme Court held that a federal law compelling fresh mushroom handlers to pay assessments used primarily to fund advertising promoting mushroom sales violated the First Amendment. The question was whether the government could underwrite and sponsor speech with a certain viewpoint using special subsidies exacted from a designated class of persons, when some of these persons objected to the ideas being advanced.

The compelled advertising at issue in *United Foods* differed substantially from the type of assessments found to be permissible in *Glickman v. Wilemann Brothers*.⁴ As the Court noted in *United Foods*, the assessments in *Glickman* were part of an expansive set of marketing orders and rules that exempted fruit producers from antitrust laws. The FDA’s authority to control product labeling and advertising is also permissible because it is part of a broad regulatory scheme comparable to the expansive program at issue in *Glickman*.

¹ William B. Schultz and Michael R. Taylor, *Hazardous Hucksters: When it Comes to Public Health, Some Limits on Advertising are Necessary*, WASHINGTON POST, May 28, 2002, at A17.

² 533 U.S. 405 (2001).

³ 92 F. 3d 67 (2d Cir. 1996).

⁴ 521 U.S. 457 (1997).

The Court in *United Foods* also clearly distinguished the circumstances of the case from those in another prior decision, *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*.⁵ In *Zauderer*, the Court specifically noted that disclosure requirements necessary to prevent consumer deception do pass constitutional muster. The Court invalidated a number of restrictions on voluntary advertising by licensed attorneys, but did permit a rule requiring that attorneys who advertised by their own choice and who referred to contingent fees disclose that clients might be liable for costs.

The disclosures required by FDA – such as the disclosure of possible side effects in a direct-to-consumer advertisement for prescription drugs or the disclosure of trans fatty acid content on a food label – do not constitute the type of “compelled” speech that violate the First Amendment. They are, instead, the type of disclosures that the Supreme Court in *Zauderer* determined did not violate the First Amendment because they are intended to prevent consumer deception.

The disclosure law invalidated in *Amestoy* also is clearly distinguishable from the type of disclosure requirements now mandated by FDA. In *Amestoy*, the Second Circuit struck down a Vermont law requiring that labeling had to disclose whether recombinant Bovine Growth Hormone (“rGBH”) was used in milk or a milk product. The Vermont law was found to violate the First Amendment rights of dairy manufacturers because it did not satisfy the test for permissible regulation of commercial speech established in *Central Hudson*.⁶ The Court found that the Vermont rGBH-labeling law was not based on health and safety concerns, but rather, on a more general “strong consumer interest” and “the public’s “right to know.”

Unlike the Vermont rGBH labeling law, the labeling requirements established by FDA are grounded in health, safety or other interests that are clearly delineated in the FFDCAs. In fact, unlike the state of Vermont, FDA has repeatedly refused to recognize a “consumer right to know” and has rejected requests that it base any of its labeling and advertising restrictions on such a right. For example, in commenting on assertions that mandatory labeling of all genetically engineered foods is within the concept of consumers’ right-to-know, FDA stated that:

⁵ 471 U.S. 626 (1985).

⁶ 447 US 566. The standard for assessing the constitutionality of commercial speech restrictions established in *Central Hudson* requires a court to determine whether (1) the speech is lawful and not misleading and, therefore, protected by the First Amendment; (2) the government interest in restraining the speech is substantial; (3) the governmental interest is directly advanced by the regulation; and (4) the regulation is not more extensive than necessary to serve the governmental interest.

The United States has long supported the inclusion in food labeling of information related to dietary guidance (such as nutrient values) and information relating to economic value (such as quantity of contents). However, under current United States' laws and policy, consumers' right-to-know does not automatically extend to mandatory disclosures on food labels beyond relevant information on health, safety, altered nutritional composition, required handling, and conditions of use.⁷

We are troubled by the fact that, on the one hand, some industry members argue that the First Amendment prohibits FDA from banning certain information on labels and in ads and, on the other hand, prevents the agency from requiring that companies include disclosures along with the desired information. The goal of the disclosures is to eliminate any misleading impression created by the information that otherwise would have been banned but for the inclusion of the disclosures. As we argue above, disclosures that are intended to prevent consumer deception are not the type of compelled speech that the Court has found violates the First Amendment.

Finally, we devoted a significant portion of our initial comments in this docket to a discussion of the effectiveness of disclaimers and disclosures in remedying deceptive labeling and advertising. The comments filed by staff members of various Bureaus at the Federal Trade Commission also addressed this central issue. After discussing the importance of carefully crafting disclosures to eliminate deception, the FTC comment acknowledges that FDA may ultimately determine that certain claims cannot be adequately qualified by disclosures,⁸ and therefore, should not be allowed on labels and in advertisements. We remind FDA that disclosures are not an all-purpose solution to remedying deception and that this approach must, therefore, be considered on a case-by-case basis where it is permissible under the law.

Specific Requirements

Many of those commenting used this proceeding as an opportunity to complain about the specific labeling or advertising requirements that FDA currently applies to their particular products. We address two of these issues below:

⁷ See, e.g. United States of America, Implications of Biotechnology for Food Labeling (Additional Comments), Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labeling, 24th Sess. (May 17, 1996) at 2.

⁸ Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission at 16-17 (Sept. 13, 2002).

Direct-to-Consumer (DTC) Advertising of Prescription Drugs

A number of those commenting took issue with FDA's requirement that DTC advertising include a "brief summary" of specific side effects and contraindications. AARP believes strongly that a DTC ad is misleading unless it includes information about the advertised drug's risks along with its benefits.

However, we agree with many of those commenting that the "brief summaries" that currently accompany most print DTC ads are neither "brief" nor "summary," and they fail to provide consumers with key information in a "consumer-friendly" format. As we have recommended in previous comments, we urge FDA to revise its "brief summary" requirement for print DTC ads to ensure that the information on risks and benefits of the drug is useful, understandable, and readable for consumers. We believe that FDA should revise its regulation governing "brief summaries" to be consistent with the voluntary guidelines adopted for consumer-oriented "Medguides." The resulting summaries would be a vast improvement over the ones that currently appear in ads.

Health Claims for Food

Many of those commenting urged FDA to apply the approach governing health claims for dietary supplements to such claims made about conventional foods. This would allow health claims on labels of conventional foods that are supported by less than "significant scientific agreement," if the claim is accompanied by a "disclosure" describing the nature and extent of the scientific support.

We reject this approach because it is clearly inconsistent with the governing law. Health claims for dietary supplements and conventional foods are treated differently under the FFDCA. When it enacted the Nutrition Labeling and Education Act (NLEA) in 1990 to amend FFDCA, Congress specified that labels of these foods may only state claims supported by "significant scientific agreement." The law does not allow claims that fail to meet this standard to appear on food labels, even if those claims are accompanied by language intended to ensure that they are not misleading.

By contrast, in the FFDCA, Congress granted to FDA authority to determine appropriate standards and procedures for health claims for dietary supplements. FDA chose to apply the "significant scientific agreement" standard to claims for these products, and the D.C. Circuit in *Pearson v. Shalala*⁹ found that this standard, when applied to dietary supplements, violated the First Amendment.

⁹ 164 F.3d 650 (D.C. Cir. 1999).