

First Amendment Implications of Labeling And Advertising Restrictions

**COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION
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“Whoever would overthrow the liberty of a nation must begin by subduing the freeness of speech.”

–Benjamin Franklin

“Restriction of free thought and free speech is the most dangerous of all subversions. It is the one un-American act that could most easily defeat us.”

– Supreme Court Justice William O. Douglas

“The First Amendment is often inconvenient. But that is beside the point. Inconvenience does not absolve the government of its obligation to tolerate speech.”

– Supreme Court Justice Anthony Kennedy

I. First Amendment

“Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances.”

A. Basic Commercial Speech Doctrine

1. Commercial speech is:

- a) Speech that “[does] no more than propose a commercial transaction.” Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations, 413 U.S. 376, 385 (1973).
- b) “[E]xpression related solely to the economic interests of the speaker and its audience.” Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n, 447 U.S. 557 (1980).

A. Basic Commercial Speech Doctrine (cont.)

- c) Speech that constitutes an advertisement, refers to a specific product, and is disseminated by a company with an economic motivation for disseminating it. Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 67-68 (1983).

A. Basic Commercial Speech Doctrine (cont.)

2. Under Central Hudson, commercial speech that is neither misleading nor related to unlawful activity may not be restricted by law unless the government can demonstrate that:
 - It has a substantial interest in regulating the speech;
 - The restriction directly advances that interest; and
 - The restriction is no more extensive than necessary to serve that interest.

B. First Amendment protects the right not to speak, as well as the right to speak

1. United States v. United Foods, Inc., 121 S. Ct. 2334, 2338 (2001): “Just as the First Amendment may prevent the government from prohibiting speech, the Amendment may prevent the government from compelling individuals to express certain views.”
2. Int’l Dairy Foods Ass’n v. Amestoy, 92 F.3d 67 (2d Cir. 1996): Compelled product or package labeling constitutes compelled commercial speech.

II. FDA and the First Amendment

A. Recent cases favor curtailment of FDA laws and policies that infringe on First Amendment rights

A. Recent cases favor curtailment of FDA laws and policies that infringe on First Amendment rights (cont.)

1. Thompson v. Western States Medical Center, 122 S.Ct. 1497 (2002): Struck down section 503A of the Federal Food, Drug, and Cosmetic Act (FDC Act), which, among other things, prohibited pharmacies from advertising what types or classes of drugs they could compound. “[S]ection 503A’s provisions regarding advertisement and promotion amount to unconstitutional restrictions on commercial speech.” Slip Op. at 2.

A. Recent cases favor curtailment of FDA laws and policies that infringe on First Amendment rights (cont.)

2. Watchtower Bible & Tract Society of New York v. Village of Stratton, No. 00-1737, Slip Op. (S. Ct. June 17, 2002): Supreme Court struck down on First Amendment grounds an ordinance regarding door-to-door advocacy without first obtaining a permit, rejecting the argument that the licensing requirement served to prevent fraud: “[to] require a censorship through license which makes impossible the free and unhampered distribution of pamphlets strikes at the very heart of constitutional guarantees.”

A. Recent cases favor curtailment of FDA laws and policies that infringe on First Amendment rights (cont.)

3. Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999): FDA may not deny approval of a “health claim” simply by stating that the agency does not believe that there is “significant scientific agreement” to support the claim without a sufficiently-detailed explanation. FDA must consider approving “health claims” that incorporate qualified representations or “disclaimers”: “.... [W]hen 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.’”

A. Recent cases favor curtailment of FDA laws and policies that infringe on First Amendment rights (cont.)

4. Washington Legal Foundation v. Friedman, 13 F. Supp.2d 51 (D.D.C. 1998) (WLF I): Section 401 of the FDAMA, which prescribes a regulatory procedure for use of off-label use information, was held unconstitutional in violation of the First Amendment by U.S. District Judge Royce Lamberth. Although this holding was essentially vacated in a subsequent proceeding, the information at issue – off-label use information – was deemed by the Court to be worthy of constitutional protection.

B. FDA has called for public comments “to ensure that its regulations, guidance, policies, and practices continue to comply with the governing First Amendment case law.” 67 Fed. Reg. 34942 (May 16, 2002). A sample of issues with potential First Amendment implications includes:

B. FDA has called for public comments. . . (cont.)

1. Cosmetics: Although not specifically mentioned in FDA notice, aspects of the cosmetic labeling regulations may be vulnerable to a First Amendment challenge.
2. OTC drugs:
 - a) OTC labeling rule, prescribed content and format, 64 Fed. Reg. 13254 (Mar. 17, 1999) (codified at 21 C.F.R. Parts 201, 330, 331, 341, 346, 355, 358, 369 and 701) – e.g., effect of OTC labeling rule on marketing of small package products, placement and nature of warnings required, disclaimers required to be in certain size font

B. FDA has called for public comments. . . (cont.)

- b) OTC monographs – mandatory language in labeling, only FDA-designated alternatives permitted
- c) restrictions on highlighting the presence of desirable inactive ingredients

3. Foods/Dietary supplements

- a) Health claims
- b) Compelled speech in the form of DSHEA disclaimer

4. Prescription drugs:

- a) limitations on content of press releases and statements to investors and the financial community

B. FDA has called for public comments. . . (cont.)

- b) dissemination of information on off-label uses
- c) preclearance of promotional materials for Subpart H (accelerated approval) drugs
- d) limitations on statements concerning investigational products
- e) direct-to-consumer advertising

B. FDA has called for public comments. . . (cont.)

5. Devices:

- a) limitations on content of press releases and statements to investors and the financial community
- b) dissemination of information on off-label uses
- c) regulation prohibiting representation that device is 510(k)-cleared
- d) limitations on statements concerning investigational products

C. “Misleading” speech is not protected by First Amendment

1. Under the FDC Act, FDA is authorized to take enforcement action against products that contain false or misleading labeling.
 - Foods: 21 U.S.C. § 343(a)(1)
 - Drugs and devices: 21 U.S.C. § 352(a)
 - Cosmetics: 21 U.S.C. § 362(a)

C. “Misleading” speech is not protected by First Amendment (cont.)

2. When determining whether labeling or advertising is misleading, FDA considers “not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal [material] facts.” 21 U.S.C. § 321(n).

C. “Misleading” speech is not protected by First Amendment (cont.)

3. Some FDA cases involving labeling and advertising alleged to be misleading:

- United States v. An Article of Drug . . . Acnotabs, 207 F.Supp. 758 (D.N.J. 1962)
- United States v. 47 Bottles . . . Jenasol RJ Formula ‘60’, 320 F.2d 564 (3rd Cir. 1963)
- United States v. An Undetermined No. of Shipping Packages . . . Vitasafe Formula M, 226 F.Supp. 266 (D.N.J. 1964)
- United States v. An Article of Device . . . Diapulse Mfg. Corp., 389 F.2d 612 (2nd Cir. 1968)
- United States v. Sene X Eleemosynary Corp., 479 F.Supp. 970 (S.D. Fla. 1979)

III. FTC and the First Amendment

A. Under the Federal Trade Commission Act, the FTC has broad authority to enjoin unfair or deceptive advertising

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1. Statutory provisions

a) Section 5, 15 U.S.C. § 45(a)(1): “[U]nfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.”

A. Under the Federal Trade Commission Act, FTC has broad authority. . . (cont.)

- b) Section 12, 15 U.S.C. § 52(a)-(b): “It shall be unlawful...to disseminate, or cause to be disseminated, any false advertisement (1) conveying the “purchase of food, drugs, devices, services, or cosmetics.” See Federal Trade Comm’n v. Pantron I Corp., 33 F.3d 1088 (9th Cir. 1994).
- c) Section 13, 15 U.S.C. § 53: Power of Commission to seek injunction barring dissemination within meaning of section 12.

A. Under the Federal Trade Commission Act, FTC has broad authority. . . (cont.)

d) Section 15, 15 U.S.C. § 55(a):

“‘[F]alse advertisement’ means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account. . . not only representations made or suggested by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.”

A. Under the Federal Trade Commission Act, FTC has broad authority. . . (cont.)

2. Substantiation policy statement, appended to Thompson Medical Co., 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987).

a) FTC and the courts have concluded that advertisers must have a “reasonable basis” upon which to base their claims

b) nature of prior substantiation required

(1) express claims – need at least the represented level of substantiation (e.g., “tests show,” “five out of six doctors recommend”)

(2) implied claims – need amount and type of substantiation that is communicated to the consumer, based on the reasonable consumer perspective

A. Under the Federal Trade Commission Act, FTC has broad authority. . . (cont.)

3. “Deception” policy statement, appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984). FTC will find an ad to be deceptive when
 - a) ad contains a claim likely to mislead consumers;
 - b) the ad will be examined from the perspective of a consumer acting reasonably under the circumstances;
 - c) the representation or claim is a “material” one.

B. Courts have traditionally resisted findings that FTC proscription of deceptive or misleading advertising violates the First Amendment

1. National Commission on Egg Nutrition v. FTC, 88 FTC 89, enforced in part, 570 F.2d 157 (7th Cir. 1977): Court upheld an FTC order to cease dissemination of advertisements claiming no connection between eating eggs and an increased risk of heart disease on grounds that First Amendment did not preclude restraint of false, misleading or deceptive advertising.

B. Courts have traditionally resisted findings. . . (cont.)

2. Sears, Roebuck and Co. v. FTC, 676 F.2d 385 (9th Cir. 1982): “...[T]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the Act, without offending the first amendment.”
3. Novartis Corp. v. FTC, 223 F.3d 783 (D.C. Cir. 2000): Claim of special ingredient not present in other OTC analgesics was an implied deceptive claim; FTC order for corrective disclaimer in future advertisements was held by Court to not impermissibly infringe company’s First Amendment rights.

C. Given the changing state of First Amendment jurisprudence in the FDA context and the trend toward a greater flow of information to consumers, FTC may find itself increasingly vulnerable to First Amendment challenges in connection with its regulation of advertising

IV. Lanham Act

- A. Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), provides a cause of action for private parties injured by a competitor's advertising.
- B. Plaintiff must demonstrate that 1) there has been a false, misleading or deceptive statement of fact by a defendant about either party's product, 2) the statement has a tendency to deceive the audience, and 3) the statement is likely to result in injury to the plaintiff.

IV. Lanham Act (cont.)

- C. American Home Products Corp. v. Johnson & Johnson, 654 F. Supp. 568 (S.D.N.Y. 1987); Towers Financial Corp. v. Dun & Bradstreet, Inc., 803 F. Supp. 820 (S.D.N.Y. 1992) (holding that business information report that was false or misleading was not protected by First Amendment and could be restrained under the Lanham Act).
- D. A statement is misleading wherein, although literally true, it implies something that is false. Mead Johnson & Co. v. Abbott Laboratories, 209 F.3d 1032, 1034 (7th Cir. 2000).