



The FDA & The FTC: An Alphabet Soup Regulating The Misbranding Of Food

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**The FDA & The FTC:
An Alphabet Soup Regulating The Misbranding Of Food**

Food & Drug Law

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Nicole Gerhart

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The FDA & The FTC:

An Alphabet Soup Regulating The Misbranding Of Food

Abstract: This paper will first look at the historical development of the division of regulation of food labeling by the Food and Drug Administration (FDA) and the regulation by food advertising by the Federal Trade Commission (FTC). Then the standards by which the agencies regulate misbranding will be compared, both generally and in regards to health claims specifically. Agency interaction will be emphasized.

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I.

Introduction

Pursuing through newspapers in the last month, headlines about the Food and Drug Administration (FDA) proclaim “F.D.A. Approves Allergan Drug for Fighting Wrinkles,”¹ “The Need to Test Drugs on Children,”² and “F.D.A. Warns About Powdered Formula.”³ While the role of the FDA in approving new drugs is a vital role for the protection of the health of Americans, it often overshadows another important aspect of the FDA, that of ensuring the dissemination of accurate and truthful information to the public.

Recent headlines about the Federal Trade Commission (FTC) broadcast “F.T.C. Plans to Challenge Libbey Purchase,”⁴ and “Sale of a Unit of Homestore Is Approved,”⁵ focusing on the antitrust activities of the agency, rarely mentioning the FTC as the guardian of advertising messages.

Food messages and claims barrage the average American consumer often and repeatedly. “One need not go back to the apple in the Garden of Eden to find false claims made for objects that, on the facts, do not live up to their touted status.”⁶ Surveys show that consumers have confidence generally in the FDA,⁷ and therefore consumers also have confidence in the accuracy of advertising claims, for if these statements were untrue, would not the FDA prevent these statements from being made?

Probably to many consumers’ surprise, the FDA does not have jurisdiction over food advertising claims.

There is a system of regulation; jurisdiction is just split between the FDA and the FTC.

¹Reed Abelson, *F.D.A. Approves Allergen Drug for Fighting Wrinkles*, N.Y. TIMES, Apr. 16, 2002, at C4.

²*The Need to Test Drugs on Children*, N.Y. TIMES, Apr. 7, 2002, § 4, at 14.

³*National Briefing Science and Health: F.D.A. Warns About Powdered Formula*, N.Y. TIMES, Apr. 13, 2002, at A15.

⁴*F.T.C. Plans to Challenge Libbey Purchase*, N.Y. TIMES, Apr. 4, 2002, at C4.

⁵*Sale of a Unit of Homestore Is Approved*, N.Y. TIMES, Mar. 29, 2002, at C6.

⁶JAMES T. O’REILLY, *FOOD AND DRUG ADMINISTRATION* §3.01 (2d ed. 1993).

⁷See Donald G. McNeil Jr., *Protests on New Genes and Seeds Grow More Passionate In Europe*, N.Y. TIMES, Mar. 14, 2000, at A1 (favorably comparing American confidence in the FDA with that of European regulators); *Food Safety: Survey Results for the U.S. Food and Drug Administration Remain Constant*, MEDICAL LETTER ON THE CDC & FDA, Jan. 28, 2001, at 5 – 6 (“The results of the second government-wide customer satisfaction survey released December 22, 2000, showed that consumers continue to be satisfied with the U.S. Food and Drug Administration’s (FDA) performance in food labeling and consumer alerts on food safety issues, and continue to have confidence and trust in the FDA to ensure food safety for consumers.”).

The Food Drug and Cosmetic Act (“FDCA”) generally prohibits misbranding, which is defined as using a false and misleading label or labeling, or having a label which does not contain the information specified in the act, such as directions for use of the product and warnings about potential health dangers.⁸ This paper will focus on the regulation of food misbranding generally, and not on the specific regulations concerning font size, placement, format, and other such specificities of the labels themselves although violations of these regulations will also result in a product being “misbranded.”⁹

The Federal Trade Commission Act (“FTC Act”)¹⁰ generally regulates advertising, as an “unfair trade or practice” of section 5, or under section 12 which explicitly provides that it is unlawful for anyone to disseminate any false advertising in connection with the purchase of foods or drugs.

This paper will proceed by first analyzing the historical roots of the divided jurisdiction of the regulation of food advertising and food labeling in Part II. Part III will then compare the misbranding standards by which the FTC and the FDA act in their respective sphere of regulation, in regards to food misbranding. Part IV will discuss the regulation of health claims specifically. Health claims regulation is an interesting subset of labeling and advertising regulation. The term “health claims,” as used herein, refers to claims about diet and health that links consumption of a food to the reduction of risk or delay in onset of a chronic disease. Health claims are distinguished from nutritional claims, which merely state the vitamin or mineral content of a particular food, without the next step – an invocation of why this content is important. Part V will evaluate of this divided system.

⁸Federal Food, Drug, and Cosmetic Act, c. 675, 52 Stat. 1040, (1938) (codified as amended at 21 U.S.C. §§ 301 – 392 (2000)).

⁹For a comprehensible guide to the current RDA regulations on size, placement, disclosure obligations, etc. of food labels, see FDA, A FOOD LABELING GUIDE (Sept. 1994, last revised June 1999), *available at* www.cfsan.fda.gov/~dms/flg-toc.html. The text of these regulations is available at 21 C.F.R. § 101.1 et. seq. (2002).

¹⁰Federal Trade Commission Act, ch. 311, 38 Stat. 717 (1914), (codified as amended at 15 U.S.C. § 41 – 64).

II.

History of Divided Jurisdiction

A.

The 1906 Act

In 1906, Congress enacted the Pure Food Law (“1906 Act”).¹¹ This Act generally regulated labeling by prohibiting false or misleading labels.¹² The issue of regulating advertising was apparently never contemplated during the Congressional discussions of this Act,¹³ nor was the FTC created yet. In implementing regulations under the 1906 Act, the Secretaries of the Treasury, Agriculture, and Commerce and Labor, defined the term “label” as used in section 8, as “any printed, pictorial or other matter upon or attached to any package of a food or drug product, or any container thereof subject to the provisions of this act.”¹⁴ Courts even further limited this definition, rather than broadly construing this Act to prevent abusive advertising claims. In *United States v. American Druggists’ Syndicate*, the district court judge held that an advertising circular, which was enclosed inside the carton with the product, was not within the intended scope of the Act.¹⁵

In the sphere of health claims specifically, if a food product made a health claim on its label, the product was regulated as both a food and a drug. Because of the Act’s inapplicability to advertising, health claims that could not be made on the label “could be made with impunity in the collateral advertising.”¹⁶ This lack of control over advertising “opened up methods for the perpetration of all kinds of fraud from petty

¹¹Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768.

¹²For the text of § 8 of the 1906 Act, see *infra* note 100.

¹³For example, see H.R. REP. NO. 59-2118, (1st Sess. 1905), which never discussed the issue of advertising vs. labeling.

¹⁴Regulation 17 (originally enacted Oct. 17, 1906, as amended by F.I.D. 84, Jan. 31, 1908), *available at* U.S. DEPARTMENT OF AGRICULTURE, FOOD AND DRUGS ACT 22 (1914).

¹⁵*United States v. American Druggists’ Syndicate*, 186 F. 387, 391 (C.C.E.D.N.Y. 1911). *See also* *United States v. 17 Bottles . . . of an Article of Drugs Labelled in Part “B. & M.”* 55 F.2d 264, 268 (D. Md. 1932)

¹⁶STEPHEN WILSON, FOOD & DRUG REGULATION 83 (1942).

deceptions to serious misrepresentations.”¹⁷ One example of such, in the area of drug products, was the advertising of *B. & M.*, a horse liniment.¹⁸ The government spent ten years and almost \$75,000 to force the removal of the claim that *B. & M.* cured tuberculosis off of the label. But the same claim could continue to be made “over the radio – in newspapers or magazines – on billboards – in booklets, circulars, letters, and all other advertising – the manufacturer may still make any claims that strike his fancy.”¹⁹

The potential for abuse was growing, as absolute advertising activity was dramatically increasing, as well as the form of advertising changing. One proponents of extending FDA’s jurisdiction to covering advertising focused on the changing technology. In 1936, Ruth deForest Lamb, an FDA Public Information official, wrote:

Thirty years ago, magazines and newspapers were published primarily for their editorial content, and radio—as we know it, anyway—was still undreamed of. To a great extent, manufacturers depended upon their labels rather than collateral advertising to sell goods. Requiring labels to tell the truth was thought to be ample protection against dishonest claims. It was, moreover, a decidedly radicals step for those days for the Government to try to regulate labels, let alone other advertising. In consequence, the manufacturer of today finds it possible to inflate the demand for his wares through wildly extravagant advertising wholly at variance with the truthful claims on his label.²⁰

Additionally, as evidence of the growing importance of advertising, between the years 1914 and 1929, general advertising activity in the United States doubled.²¹ Radio also soon became a medium by which manufactures

¹⁷*Id.*

¹⁸RUTH DEFOREST LAMB, AMERICAN CHAMBER OF HORRORS 53 – 61 (1936). Other products and their claims made during the reign of the 1906 Act include: Banbar and Healthagain as cures for diabetes, and Wilken’s Proprietary Medicine, Dr. Koch’s Synthetic Anti-Toxin, and Mixer’s Cancer and Scrofula Syrup as cancer cures. WILSON, *supra* note 16, at 83.

¹⁹*Id.* at 58.

²¹WILSON, *supra* note 16, at 86.

could advertise to a wide audience.²²

B.

The FTC Act

The FTC Act was enacted in 1914, establishing the FTC as an independent administrative agency.²³ Despite not having any express statutory authority to regulate food advertising, the FTC, from its inception, considered false advertising and misleading labeling as within the practices that violate section 5, and court decisions have supported the FTC's asserting of authority.²⁴ However, under the then-existing FTC Act, the FTC was unable to effectively regulate advertising in some circumstances, since section 5 only prohibited "unfair methods of competition in commerce." The Marmola case is illustrative of this weakness of the FTC Act.²⁵ Marmola was sold as an obesity cure, and this product in fact did lower weight, but with serious health consequences, potentially even leading to death. The FDA did not have authority to regulate the product,²⁶ and the FTC tried but failed. The FTC filed a complaint in 1928, ordering the company to

²²It was around 1928 when radio became a significant advertising medium. WILSON, *supra* note 16, at 86.

²³Federal Trade Commission Act, ch. 311, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. § 41 – 64).

²⁴In regards to FTC authority over false advertising, see, e.g., *Sears, Roebuck, & Co. v. F.T.C.*, 258 F. 307, 311 (7th Cir. 1919) (holding that the FTCA prohibition of unfair methods of competition included false advertising, for "[t]he commissioners, representing the government as *parens patriae*, are to exercise their common sense, as informed by their knowledge of the general idea of unfair trade at common law, and stop all those trade practices that have a capacity or a tendency to injure competitors directly or through deception of purchasers, quite irrespective of whether the specific practices in question have yet been denounced in common-law cases."). In regards to FTC authority over misleading labeling, see, e.g., *F.T.C. v. Good-Grape Co.*, 45 F.2d 70 (6th Cir. 1930) (upholding injunction issued by the FTC to prevent Good-Grape from implying that its product was natural grape juice on its labels); *Royal Baking Powder Co. v. F.T.C.*, 281 F. 744 (2nd Cir. 1922) (affirming the FTC order, finding petitioner engaged in an unfair method of competition by intentionally using labels for its new baking powder similar to the old baking powder, in an effort to mislead purchasers as to the contents of the new baking powder.).

²⁵LAMB, *supra* note 18, at 7 – 9.

²⁶The FDA could not prevent the sale of Marmola because it was not a "drug" within the definition of the 1906 Act, for the condition is was "intended to cure, mitigate or prevent," – that of obesity – was not a condition generally recognized as a disease. LAMB, *supra* note 18, at 9. During the years 1906 – 1938, the Post Office was the other government agency that had any success, albeit limited, in regulating advertising. This department can take action if the mails are used to defraud, but of course has no control over other forms of advertising. A Post Office prosecution against Marmola resulted in a \$5000 fine in 1914, but the company changed its name and location at least twice and just simply continued as before. See WILSON, *supra* note 16, at 84; LAMB, *supra* note 18, at 6 – 8.

stop advertising Marmola as safe and effective. The Sixth Circuit,²⁷ and later the Supreme Court,²⁸ determined that the FTC did not have the authority to act in that the FTC's powers were limited to protecting competition and not consumers, and the FTC failed to show that any competition existed. In so holding, the Supreme Court looked to the purpose of the act to protect competition.²⁹ Thus, FTC authority was limited to circumstances where there was at least one competitor who might be harmed by the offending advertisement. This decision was significant not only for preventing FTC action in certain circumstances, but also because it required the FTC to expend time and monetary resources in all cases to prove that there was injury to competition.

But despite this holding, the chairman of the Commission, Ewin Davis, defended the current Act as effective, arguing that the FTC was able in virtually all other cases to assert jurisdiction. He noted, “[I]t is the rarest case in the world, if it ever exists, where the consuming public is adversely affected by false or misleading advertisements that a competitor is not also affected, and consequently we would have the requisite showing of competition.”³⁰

²⁷Raladam Co. v. F.T.C., 42 F.2d 430 (6th Cir. 1930).

²⁸F.T.C. v. Raladam Co., 283 U.S. 643 (1931). For a criticism of this decision, see Note, *Scope of the Jurisdiction of the Federal Trade Commission Over False and Misleading Advertising*, 40 YALE L.J. 617, 629 (“Moreover a logical application of the court’s hypothesis would lead to anomalous results. It imports, for example, that although by the statute proceedings are to be instituted in the public interest, yet where the public alone is injured by a fraudulent practice, the Commission is not authorized to intervene. Again, if the deception is prevalent throughout an entire trade, it becomes impregnable; but when one honest competitor enters the field, the Commission’s jurisdiction is established. Finally, compliance with the court’s rule would compel the Commission in every case to try the legitimacy of the activities of competitors. It cannot be supposed that such incongruities were intended. Rather would it seem that the ‘unfair methods’ referred to in the Trade Commission Act include any policy of sales promotion which tends to deceive the public.”). See also Milton Handler, *The Jurisdiction of the Federal Trade Commission Over False Advertising*, 31 COLUM. L. REV. 527, 549 – 51 (1931).

²⁹F.T.C. v. Raladam Co., 283 U.S. at 647 – 48 (“The paramount aim of the act is the protection of the public from the evils likely to result from the destruction of competition or the restriction of it in a substantial degree, and this presupposes the existence of some substantial competition to be affected, since the public is not concerned in the maintenance of competition which itself is without real substance.”).

³⁰Note, *The FTC’s Injunctive Authority Against False Advertising of Food and Drugs*, 75 MICH. L. REV. 745, 758 n.79 (1977).

C.

The Debate

Between the first efforts for revision and the 1938 enactments, consensus grew that more explicit controls over advertising were necessary. Once it was accepted that something needed to be done,³¹ the debate centered on what was to be the form of this regulation, and more specifically, what agency, as between the FTC and the FDA, was to have authority over this regulation.³²

Those supporting the FDA as having jurisdiction included President Roosevelt. In 1935, in a special message to Congress urging the adoption of a new Food and Drug Act, President Roosevelt emphasized the need for practical improvements, especially by extending the controls of the FDA that were formerly applicable only to labels to advertising also.³³

Those supporting extending the FDA's jurisdiction over advertising argued that the FTC was concerned primarily with economic issues, such as trade and competition, and not the protection of consumer health,³⁴ and that advertising regulation is a necessary corollary to labeling regulation.³⁵ Also argued was that the

³¹One of the first proposals for change dated to 1912, the Richardson Bill. If it had been enacted, it would have given explicit control over advertising to the predecessor of the FDA. WILSON, *supra* note 16, at 86. Consensus continued to grow; for example, in 1917, the United States Department of Agriculture Annual Report, identified a "serious limitation" in the effective control over the food supply was the lack of jurisdiction by the Bureau of Chemistry (which later became the FDA) over false or misleading claims not made on food labels. Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSMETIC L.J. 2 (1984).

³²For a detailed analysis of progress of the specific proposed bills and their amendments, David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROB. 2 (1939). What follows in this paper is a general analysis of the policy concerns discussed at this time, to enlighten the later discussion of the proper division of power between the FDA and the FTC now.

³³President Roosevelt Special Message to Congress, March 22, 1935, *available at* LAMB, *supra* note 18, at 332 – 34.

³⁴*See, e.g.*, WILSON, *supra* note 16, at 111.

³⁵*See, e.g.*, 83 CONG. REC. 566 (1938) (remarks of Rep. Mapes) ("If administration of half of the law goes to the Federal Trade Commission and the other half remains with the Pure Food and Drug Administration, it will simply cripple the enforcement of the law. It is not necessary to cast aspersions upon either the members of the Federal Trade Commission or the people responsible for the administration of the pure food and drug law to reach that conclusion. Plain common sense will cause anyone who considers the matter to reach that conclusion.").

FTC's enforcement powers and procedures would not effectively protect consumer interests,³⁶ especially since there were no direct penalties for violations of the FTC Act. The FTC only had the power to order cease and desist orders, which could only be enforced by court action, which necessarily involved delays,³⁷ thus allowing a deceptive advertiser the opportunity to benefit from his deception, and move onto a new form of deception before the Commission could restrain him.³⁸

Conversely, some Congressmen favored the FTC's remedial, as opposed to preventative, procedure as more appropriate to define the line between deception and puffery; that remedial action was more consistent with notions of fairness.³⁹ The FDA was also criticized for not having a formal adversary procedure by which to govern the agency's actions.⁴⁰ Representative Lea argued that the FDA is a "typical bureaucratic organization," and to effectively control advertising, a quasi-judicial body, like the FTC, was necessary.⁴¹

Many Congressmen were concerned that the FDA would harass honest businessmen, who would work in fear of action against an inadvertent statement.⁴² The FDA, at this time, had a reputation among some Congressmen as being arbitrary in its treatment of commercial interests.⁴³ Senator Howard W. Ambruster went further in his criticism of the FDA, asserting that the FDA selectively enforced the 1906 Act, for the FDA was afraid to attack large industry players.⁴⁴ He stated that extending FDA jurisdiction to include

³⁶See, e.g., 83 CONG. REC. 394 (1938) (remarks of Rep. Mapes).

³⁷See *The FTC's Injunctive Authority Against False Advertising of Food and Drugs*, *supra* note 30, at 757 – 763. Prior to 1938, the FTC had been required to petition the courts for enforcement of an order, which could only be done upon evidence that the order was being violated. Because of this system, an advertiser might actually have to repeat an offense three times before effective punishment: once by which to issue a cease and desist order, again to support a petition for enforcement, and a third time to justify imposition of court contempt sanctions. *Id.* at 758, n. 80.

³⁸See, e.g., 83 CONG. REC. 394 (remarks of Rep. Kenney); *id.* at 3287 (remarks of Sen. Copeland); Foods, Drugs, and Cosmetics: Hearings on S.5 Before the Senate Comm. On Commerce, 74th Cong. 360 (1935) (statement of W.G. Campbell, then Chief of FDA). Congress did respond to these alleged deficiencies in the Wheeler-Lea Act in 1938, by establishing civil penalties for violations of Commission cease and desist orders. For a discussion of the early debate concerning these provisions, see Mitchell Salem Fisher, *The Proposed Food and Drugs Act: A Legal Critique*, 1 LAW & CONTEMP. PROB. 74 (1933).

³⁹See, e.g., H.R. REP. NO. 75-1613, at 4 – 6 (1st Sess. 1937).

⁴⁰See, e.g., 83 CONG. REC. 410 (1938) (remarks of Rep. Lea); *id.* at 411 (remarks of Rep. O'Malley).

⁴¹*Id.* at 566 (remarks of Rep. Lea).

⁴²See, e.g., 83 CONG. REC. 401 (1938) (remarks of Rep. Halleck).

⁴³See 80 CONG. REC. 401 (1938) (remarks of Rep. McCormick).

⁴⁴HOWARD WATSON AMBRUSTER, WHY NOT ENFORCE THE LAWS WE ALREADY HAVE? HOW AND WHY INDUSTRIES' OUTLAWS ARE CRUCIFYING HARVEY WILEY'S PURE FOOD AND DRUG LAW, 49 – 53 (1935). In support of this assertion, Senator Ambruster compared the actions of the FTC and the FDA in controlling aspirin manufacturer's fraudulent claims that aspirin "does not depress the heart." The FTC has successfully forced Bayer Aspirin from using this claim in its advertisements, while the FDA

advertising “can only result in the immunity of jurisdictional conflict for all violators having funds to pay attorneys.”⁴⁵

Many Congressmen did not like the New Deal activists of the current Department of Agriculture, nor the Department’s current head, Rexford G. Tugwell, and were highly suspicious of the Roosevelt Administrations’ aggressive consumer protectionism.⁴⁶

Overall, the food and drug industry favored FTC jurisdiction.⁴⁷ Not surprisingly, the FTC favored retention of control.⁴⁸ On behalf of the FTC, Commissioner Ewin L. Davis advocated that the Commission retain authority, presenting the accomplishments of the Commission in suppressing fraudulent advertising thus far.⁴⁹ He also argued that the FTC adjudicatory process was the better process by which to regulate advertising, also noting that the FTC and the FDA have worked well together in the past.⁵⁰

In the course of the Congressional debates, one proposed compromise was nearly successful in resolving the issue. In 1936, both the House and the Senate had passed almost identical versions of a new food and drug bill, agreeing on all issues except for which agency was to have jurisdiction over food advertising.⁵¹ The Conference committee proposed a compromise that would have given the FDA jurisdiction only over food and drug advertising that affected health, leaving responsibility for all other violations with the FTC.⁵² This

had ignored this claim on the labels of the two largest violators, but attacked smaller manufacturers. *Id.* at 51 – 53.

⁴⁵*Id.* at 53.

⁴⁶CHARLES W. DUNN, FEDERAL FOOD DRUG & COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 26 (1938).

⁴⁷WILSON, *supra* note 16, at 111.

⁴⁸*See, e.g.*, WILSON, *supra* note 16, at 113; AMBRUSTER, *supra* note 44, at 50.

⁴⁹*See* AMBRUSTER, *supra* note 44, at 50 (quoting Commissioner Davis) (“Of course, . . . it is a matter for Congress to determine as to where it wants to place this jurisdiction, but I am simply reminding you that this Commission has had and has exercised this jurisdiction for 19 years, and there has grown up a long line of decisions. We have a trained personnel. We have field officers and investigators, and are prepared to conduct the field investigations. . . . [I]n the case of food and drugs, or cosmetics, or whether they cure or not, we have been calling upon the Department of Agriculture for their analysis and opinion . . . [T]he analysis of the technical experts of the Department of Agriculture are received before the Federal Trade Commission just like any other evidence.”).

⁵⁰AMBRUSTER, *supra* note 44, at 50 (quoting Commissioner Davis) (“The Commission sits there in a judicial capacity and undertakes to decide the case in accordance with the law and the facts; and in that connection, under The Federal Trade commission, has grown up a long line of precedents, not only in the Commission, but in the Court decisions. . . . The Pure Food and Drug division of the Department of Agriculture . . . have heretofore repeatedly referred to the commission false advertising upon which the Commission has proceeded to act.”)

⁵¹*See* 79 CONG. REC. 8356 (1935); 80 CONG. REC. 8356 (1936).

⁵²80 CONG. REC. 10514 – 10520 (1936).

compromise ultimately failed, due to the House’s unwillingness to expand the FDA’s jurisdiction to food advertising.⁵³

Ultimately, the FTC of the 1930s was more politically compatible with the House of Representatives than the New Deal leader of the Department of Agriculture,⁵⁴ and the House did not want to give too much discretionary power to an administrative agency. The FTC was considered procedurally fairer because of its adversarial administrative hearings and the enforcement of its orders was postponed until judicial review was completed.⁵⁵ At the end of the debate, in 1938, Congress declined to give FDA jurisdiction over advertising⁵⁶ and instead confirmed FTC authority over false and misleading advertising by passing the Wheeler-Lea Amendments,⁵⁷ which amended Section 5 of the Federal Trade Commission Act.⁵⁸ The final version of the new food law⁵⁹ made no reference at all to advertising, thus implicitly announcing that advertising jurisdiction would remain with the FTC.

⁵³80 CONG. REC. 10674 – 10680 (1936).

⁵⁴See O’REILLY, *supra* note 6, §24.02.

⁵⁵See *The FTC’s Injunctive Authority Against False Advertising of Food and Drugs*, *supra* note 30, at 766.

⁵⁶Congress has granted specific authority to regulate advertising to the FDA in a few circumstances: for prescription drugs under § 502(n) of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, and for vitamins and minerals under §§ 403(a)(2) and 707 of the Vitamin-Mineral Amendments of 1976, Pub. L. No. 94-278, 90 Stat. 410 (1976) (codified as amended at 21 U.S.C. §350). FTC does retain authority over regulating non-prescription drugs.

⁵⁷Wheeler-Lea Amendments, ch. 49, § 4, 52 Stat. 111, 114 (1938) (amending § 12 of the FTC Act) (codified at 15 U.S.C. § 45(a)(1)).

⁵⁸Section 5(a)(1), now provides that “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.” 15 U.S.C. § 45 (2000).

⁵⁹Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 – 392 (2000)).

D.

Current Division

Generally, the FDA has jurisdiction over labels and labeling. Under the FDCA, a label is on the package, and labeling is that which accompanies the package, including the label. Specifically, the term label is defined as “a display of written, printed, or graphic matter upon the immediate container of any article,”⁶⁰ and labeling is defined as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”⁶¹ The FDA and courts have given an expansive definition to “accompanying,” thereby maximizing FDA authority.⁶² Advertising is everything else, anything that lacks “immediate connection with sale of the product.”⁶³

The FTC has the authority to regulate advertising generally. While Section 15 defines “false advertisement” as excluding labeling, the FTC is still able to assert authority under Section 5’s general prohibition against unfair competition. The Second Circuit has specifically rejected the argument that a claim made only on a label was not within the FTC’s authority, and only within the authority of the FDA.⁶⁴ Thus the jurisdictions

⁶⁰21 U.S.C. § 321(k) (2000). The section continues, providing that “a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.” *Id.*

⁶¹21 U.S.C. § 321(m) (2000)

⁶²*See* Kordel v. United States, 335 U.S. 345, 350, *reh’g denied*, 335 U.S. 900 (1948), *reh’g denied*, 336 U.S. 911 (holding that even though the product and the circular were shipped in separate parcels, they nevertheless accompany each other within the meaning of the FTCA) (“One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.”); United States v. Urbuteit, 335 U.S. 355, 356 – 57 (1948) (holding that where product and leaflets explaining use were mailed separately, leaflet was part of the label); V. E. Irons, Inc. v. United States, 244 F.2d 34, 39 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957) (“It is clear that the term ‘labeling’ must be given a broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article. There is no doubt that the printed circulars, pamphlets, brochures and newsletters distributed by appellants in the present case constituted ‘labeling’ within the statutory definition, and thus may properly be received in evidence as proof of false or misleading statements.”); United States v. Guardian Chem. Corp., 410 F.2d 157, 160 – 61 (2nd Cir. 1969) (“In order to ‘accompany’ an article and thus constitute ‘labeling’ for it, printed pamphlets or brochures need not be shipped along with the article. They may be sent out either before or after the article and still ‘accompany’ it, as long as the distribution of the drug and the brochures are parts of an ‘integrated distribution program.’”).

⁶³United States v. 24 Bottles “Sterling Vinegar . . .,” 338 F.2d 157, 160 (2nd Cir. 1964).

⁶⁴Fresh Grown Preserve Corp v. F.T.C., 125 F.2d 917 (2nd Cir. 1942) (rejecting petitioner’s argument that a claim made only on a label was not within the FTC’s authority and could only be challenged by the FDA, for the definition of “false

of the FDA and of the FTC do overlap, for labeling is within the scope of advertising.⁶⁵

Because of this overlap the two agencies in 1954 agreed to a Memorandum of Understanding, under which the FTC has assumed primary responsibility for regulating food advertising, other than labeling, while the FDA has taken primary responsibility for regulating food labeling.⁶⁶ The purpose of this Memorandum is to reduce the duplication of regulation and conserve agency resources by eliminating confusion as to what agency regulated what.⁶⁷ Despite this Memorandum, it is possible that both agencies may proceed against the same defendant,⁶⁸ and this Memorandum is only an informal allocation of enforcement responsibility

advertisement” within Section 15 is limited to cases arising under Sections 12, 13, and 14, and not Section 5) (“Like false labeling, it may have been deceptive and have amounted to unfair competition under Sec. 5 and we need now be concerned with nothing more.”).

⁶⁵See also *Kordel v. United States*, 335 U.S. 345, 351 (1948) (“We have searched the legislative history in vain, however, to find any indication that Congress had the purpose to eliminate from the Act advertising which performs the function of labeling. Every labeling is in a sense an advertisement. The advertising which we have here performs the same function as it would if it were on the article or on the containers or wrappers.”); *United States v. Research Laboratories, Inc.*, 126 F.2d 42, 45 (9th Cir. 1942), *cert. denied*, 317 U.S. 656 (1942) (“Most, if not all labeling is advertising. The term labeling is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising. . . . It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled What is Arthritis. The power of the District Court [to] condemn misbranded articles is not impaired, diminished, or in any wise affected by the possibility that such misbranding may also be the subject of a cease and desist order or even by the fact, if it be a fact, that such an order has actually issued.”); *United States v. 250 Jars of U.S. Fancy Pure Honey*, 218 F. Supp. 208 (D.C. Mich. 1963), *aff’d*, 344 F.2d 288 (6th Cir. 1965); *United States v. Paddock*, 67 F. Supp. 819 (W.D. Mo. 1946) (“Advertising and labeling circulars may be the same and yet perform the two offices of advertising, and labeling.”)

⁶⁶Working Agreement Between Federal Trade Commission and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9850.01 (June 9, 1954) (as originally enacted); Updated FTC-FDA Liaison Agreement – Advertising of Over-the-Counter Drugs, 36 Fed. Reg. 18,539, 4 Trade Reg. Rep. (CCH) ¶ 9851 (Sept. 16, 1971). The 1971 Memorandum stated the division as follows:

In order to facilitate the purposes of this agreement, it is specifically agreed that:

a. With the exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics. In the absence of express agreement between the two agencies to the contrary, the Commission will exercise primary jurisdiction over all matters regulating the truth or falsity of advertising of foods, drugs, . . . devices, and cosmetics;

b. The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. . . . In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics.

⁶⁷*Id.* The stated purpose of the 1971 agreement is as follows:

It is agreed that the common objective of preventing injury and deception of the consumer requires that the statutory authorities and procedures, and the manpower and other resources available to each agency are so employed as to afford maximum protection to the consumer. This means joint planning of coordinated programs, exchange of information and evidence to the extent permitted by law, by the staffs of both agencies in appropriate undertakings and the careful selection of the procedure of either agency (or simultaneously by both) promising greatest benefit to the public.

Despite this agreement, the FTC found it necessary to issue a policy statement in 1994 concerning food advertising and health claims clarifying the use of health claims. See *infra* Part IV.C.

⁶⁸The Memorandum does contemplate both agencies proceeding against the same defendant, but states that it “shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings.” It defines a liaison

and therefore not a defense to an FTC action concerning food labeling.⁶⁹

In 1976, Congress added section 707 of the FDCA, which addresses the aforementioned overlap in jurisdiction, specifically when a claim made in a medium typically regarded as advertisement, falls within the definition of labeling.⁷⁰ Section 707(a) requires that the FDA notify the FTC before taking action itself if it suspects the advertising as causing the misbranding a food, with the notice outlining the reasons misbranding is suspected and accompanied by the evidence of such. If the FTC does not act or provide notice of its intent to act, within 30 days of the FDA's notice, the FDA may initiate action; if the FTC initially decides to pursue action, but fails to follow through within 60 days, then the FDA may pursue action.⁷¹ This notice requirement and 30 to 90 day holding period before FDA action represents the Congressional decision that in these scenarios where the authority is unclear, it would prefer the FTC to pursue enforcement proceedings.⁷² Not only do the definitions of labeling versus advertising control agency authority, but also does the definitions of food, versus drug, versus medical device. While this paper will focus only on the regulation of food, it is important to note that the FDA has jurisdiction over both the advertising and labeling of prescription drugs and restricted medical devices, per statute, thereby eliminating FTC from this arena.⁷³ The distinction

relationship is order to prevent dueling actions from occurring. *Id.* For examples of coordinated action, see *Warner-Lambert Co. v. F.T.C.*, 361 F. Supp. 948, 952 (D.D.C. 1973); *Warner-Lambert Co. v. F.T.C.*, 562 F.2d 749 (D.C. Cir. 1977); *United States v. 1 Dozen Bottles . . . Bonquet Tablets*, 146 F.2d 361 (4th Cir. 1944); *United States v. Research Laboratories, Inc.*, 126 F.2d 42 (9th Cir. 1942); *United States v. Various Quantities . . . "Instant Alberty Food,"* 83 F. Supp. 882 (D.D.C. 1949); *United States v. Paddock*, 67 F. Supp. 819 (W.D. Mo. 1946). While not a FDA-FTC conflict, the court in *Sunkist Growers* held that the Secretary of Agriculture did not have exclusive jurisdiction. *Sunkist Growers, Inc v. F.T.C.*, 464 F. Supp. 302 (C.D. Cal. 1979). *See also* *Friedlander v. United States Postal Service*, 658 F. Supp. 95 (D.D.C. 1987) (holding that the existence of FDA or FTC jurisdiction over fraudulent mailings does not prevent the Postal Service from proceeding).

⁶⁹JULIAN O. VON KALINOWSKI, *et al.*, ANTITRUST LAWS AND TRADE REGULATION § 5-14.1 (2nd ed. 2002).

⁷⁰Proxmire Amendments, Pub. L. No. 94-278, § 501(b), 90 Stat. 401, 412 (1976) (adding § 707 of the FDCA, codified at 21 U.S.C. § 378).

⁷¹21 U.S.C. § 378(b) (2000).

⁷²H.R. CONF. REP. NO. 94-1005, at 31 (1976), *reprinted in* 1976 U.S.C.C.A.N. 742, 755. This Report does not explicitly express any dissatisfaction with the current division of authority; in fact it specifically recognizes the 1954 Memorandum of Understanding, and encourages the FTC and FDA "to continue to coordinate their regulatory actions in a manner to avoid unnecessary duplication and waste." *Id.* The memorandum did not explicitly delineate jurisdiction between the two agencies when some method of promotion could be both advertising and labeling. The agreement did provide for the coordination and use of liaisons when the same or similar claims are found in both labeling and advertising, thus indicating when there was overlap, they would coordinate and decide on a case-by-case method. *See* Working Agreement Between Federal Trade Commission and Food and Drug Administration, *supra* note 66.

⁷³In the Drug Amendments of 1962, Pub. L. No. 87-781, §11, 76 Stat. 780 (codified in scattered sections of 21 U.S.C.) Congress enunciated that with regards to prescription drugs, advertisement of such are not subject to the FTC Act relating to false and misleading advertising of drugs, thus eliminating any overlap of jurisdiction whether the two agencies, as was

between a food and a drug is significant in the sphere of FDA/FTC jurisdiction because the FDA considers the use of any unapproved health claims on a food to cause that product to be deemed a drug, thereby under the enforcement authority of the FDA.⁷⁴ In the medical device arena, the FDA recently attempted, but failed,⁷⁵ to assert regulatory authority over tobacco products as restricted medical devices, so that the agency could exert control not only over their distribution and use, but over their advertising as well, thus attempting to usurp the authority of the FTC.⁷⁶

Thus, in regards to food, in practice the FDA monitors labeling, while the FTC monitors advertising. But this summary may have made the distinction between advertising and labeling seem more absolute than it really is. While these jurisdictional lines have been drawn, the Memorandum of Understanding is revocable by either agency with 30 days notice, thus the FTC could soon assert authority over labeling.⁷⁷ But these lines are interwoven even more, in that advertising and labeling do not act independently of each other; what advertising contains is relevant to what is said in labeling, for “advertising is the dictionary of the labeler.”⁷⁸

previously the case.

⁷⁴See *infra* Part IV.

⁷⁵FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) (holding that Congress had not granted the FDA jurisdiction to regulate tobacco products, looking to the FDCA as a whole, it was clear that Congress intended to excluded tobacco products from the FDA’s jurisdiction, for if so, the FDCA their removal from the market entirely; such a ban would contradict Congress’ clear intent as expressed in recent tobacco-specific legislation).

⁷⁶See Lars Noah, *Statutory “Smoke” and Mirrors*, 51 FOOD DRUG L.J. 481, 483.

⁷⁷See Working Agreement Between Federal Trade Commission and Food and Drug Administration, *supra* note 66.

⁷⁸Peter B. Hutt, *Questions and Answers*, 28 FOOD DRUG COSMETIC L.J. 138, 144 (1973) (noting that the FDA has taken this position in numerous lawsuits since 1938).

III.

Misbranding Standards

A.

Misbranding Under the 1906 Act

Congress enacted the United State's first comprehensive, national regulation of foods and drugs⁷⁹ with the 1906 Act.⁸⁰ Prior to the 1906 Act, Congress had enacted various statutes to control the adulteration of specific food products,⁸¹ of food sold in the District of Columbia,⁸² of exported and imported meat and cattle,⁸³ of drug products,⁸⁴ and later of imported products generally.⁸⁵ It was not until 1902 that Congress begun to address the issues of misbranding and mislabeling specifically, by prohibiting the sale of "any diary or food product which shall be falsely labeled or branded as to the State or Territory in which they are made, produced, or grown."⁸⁶

There were many attempts by the states prior to 1906, even in colonial times, to regulate adulteration.⁸⁷ The first state general food law was passed in Illinois in 1874. A model law was drafted and enacted in New York

⁷⁹For a history of governmental regulation of the integrity of the food supply from ancient times to 1985, see Hutt & Hutt, *supra* note 31.

⁸⁰Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768.

⁸¹*See* Act of Mar. 2, 1883, ch. 64, 22 Stat. 451, amended by Act of Mar. 2, 1897, ch. 358, 29 Stat. 604 (banning importation of adulterated tea); Act of Aug. 2, 1886, ch. 840, 24 Stat. 209 (regulating oleomargarine and authorizing monitoring for ingredients used that were "deleterious to the public health"); Act of June 6, 1896, ch. 337, 29 Stat. 253 (regulating filled cheese under oleomargarine scheme). The Board of Tea, and the Tea Importation Act of 1897 was repealed recently, see Federal Tea Tasters Repeal Act of 1996, Pub. L. No. 104-128, 110 Stat. 1198.

⁸²Act of Oct. 12, 1888, ch. 1090, 25 Stat. 549; Act of May 5, 1898, ch. 241, 30 Stat. 398 (prohibiting candy adulteration in the District of Columbia).

⁸³Act of Aug. 30, 1890, ch. 839, 26 Stat. 414; Act of Mar. 3, 1891, ch. 555, 26 Stat. 1089; Act of July 24, 1897, ch. 11, §25, 30 Stat. 151, 210.

⁸⁴*See* The Vaccine Act of 1813, ch. 37, 2 Stat. 806; Import Drugs Act of 1848, ch. 70, 9 Stat. 237.

⁸⁵Act of Mar. 1, 1899, ch. 325, 30 Stat. 947. *See also* WILSON, *supra* note 16, at 16. The efficacy of this act can be questioned in that in 1905, it was observed that ten times as much Vermont maple syrup was sold every year as that state could produce. *Id.* at 25.

⁸⁶Act of July 1, 1902, ch. 1357, 32 Stat. 632. For the report accompanying this enactment, see H.R. REP. NO. 56-872 (1st Sess. 1900).

⁸⁷Hutt & Hutt, *supra* note 31, at 35 – 44.

in 1881, and most states followed within the next 25 years.⁸⁸ But state legislation was inadequate because, by in acting independently, the states could not regulate interstate commerce. Additionally, standards across the states varied, making it impossible for a manufacturer to satisfy all the requirements.⁸⁹

Between 1879 and 1906, more than 100 Congressional bills had been introduced that attempted general legislation, yet none were enacted.⁹⁰ Of these proposals, the first bill aimed at protecting public health, rather than protecting American farmers, was introduced in 1891.⁹¹ But two developments were necessary in order to enable the passage of a truly successful, general, national legislation: first, the creation of large urban centers which led to the development of national commerce, which needed national regulation; and second, the acceptance of Congressional jurisdiction to regulate, rather than state or local governments.⁹²

Opposition to these bills was primarily from food and drug industries, as well as from newspapers and magazines.⁹³ The newspapers opposed the proposals because the bill would affect their largest advertisers, and advertising for most newspapers consisted of the majority of its revenue.⁹⁴ Leading up to 1906, public demand for federal protection increased, and industry opposition lessened when the reputable manufacturers realized that a national law was in their interests.⁹⁵ In 1905, President Roosevelt entered the debate in his annual message to Congress, calling for the enactment of a law regulating the adulteration and misbranding

⁸⁸WILSON, *supra* note 16, at 11.

⁸⁹WILSON, *supra* note 16, at 18 – 19.

⁹⁰VETTER, FOOD LAWS AND REGULATIONS 7 (1996). General and specific combined, between Jan. 20, 1879 – the first such bill – and June 30, 1906, exactly 190 measures were introduced in the House of Representatives that somehow protected food and drug consumers. 4 AMERICAN LANDMARK LEGISLATION 1 (Irving J. Sloan, ed., 1976). Of these, eight became law, six passed the House, 23 were reported on favorably by the relevant House committee, nine reported adversely, and 141 were never heard from again. *Id.*

⁹¹See WILSON, *supra* note 16, at 15. This bill, sponsored by Senator Paddock of Nebraska, was proposed in response to approximately 200 petitions from the public praying for the prevention of food adulteration. See LANDMARK AMERICAN LEGISLATION, *supra* note 90, at 3.

⁹²Hutt & Hutt, *supra* note 31, at 47 – 53.

⁹³Objections within congress were ostensibly argued upon the measures too broadly construing the commerce clause of the constitution, or too much delegation of power to the Secretary of Agriculture. See LANDMARK AMERICAN LEGISLATION, *supra* note 90, at 3 – 4. But often opponents never openly voiced their true objections, and delays were achieved on the arguments of “the need for discussing more pressing legislation, agreement with the principle but opposition to the construction of the bill, the desirability of permitting the states to handle their own problems, or the necessity of preventing hasty and ill-considered legislation.” *Id.* at 5.

⁹⁴WILSON, *supra* note 16, at 22 – 24.

⁹⁵See, e.g., WILSON, *supra* note 16, at 18 – 19; LANDMARK AMERICAN LEGISLATION, *supra* note 90, at 7 – 9.

of food and drugs.⁹⁶

In 1906, an act was finally passed.⁹⁷ The stated purpose of this act was “for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein.”⁹⁸ The Act declared it unlawful to manufacture and transport any food or drug that is adulterated or misbranded.⁹⁹ Section 8 defined misbranding generally as false or misleading labeling or branding.¹⁰⁰ The 1906 Act’s labeling provisions operated on the basic premise that if people are given accurate information about what they are consuming, they will be able to make safer choices. Prior to 1913, the 1906 Act did not contain any affirmative disclosure obligations, but the third provision under “in case of food” of section 8 was then amended to define any package that “the quantity

⁹⁶See LANDMARK AMERICAN LEGISLATION, *supra* note 90, at 7.

⁹⁷Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768.

⁹⁸Food and Drugs Act of 1906, ch. 3915, preamble, 34 Stat. 768, 768. The purpose, according to the Supreme Court, of the misbranding prohibition is “to make it possible that the consumer should know that an article purchased was what it purported to be; that it might be bought for what it really was, and not upon misrepresentations as to character and quality.” *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914).

⁹⁹Food and Drugs Act of 1906, ch. 3915, §§ 1 & 2, 34 Stat. 768. Section 2 does exempt from misbranded or adulteration classification any article that is intended for export, is indeed exported, and the preparation or packing does not conflict with the laws of the foreign country.

¹⁰⁰Section 8, as originally enacted, reads:

That the term “misbranded,” as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this Act an article shall also be deemed to be misbranded:

In the case of drugs: [omitted]

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fails to bear a statement on the label of the quantity or proportion of any morphine, opium. . . .

Third. If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package.

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. [If a mixture or compound is or becomes to be known by a distinctive name, that name can be used if accompanied on label with where the product was manufactured or produced.]

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word “compound,” “imitation,” or “blend,” as the case may be, is plainly stated on the package in which it is offered for sale. . . .

Food and Drugs Act of 1906, ch. 3915, §8, 34 Stat. 768.

of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count” as misbranded.¹⁰¹

While the 1906 Act defined misbranding, the courts were ultimately responsible for the interpretation and application of the Act. The courts imprecisely defined the terms false and misleading. One court defined these terms as: “False means, of course, untrue. Misleading means calculated to deceive, actually tending to deceive.”¹⁰² The same judge in another case seemingly eliminated an inaccurate, but non-misleading statement as violating the statute, by stating that as regarding the word “false” and the word “misleading” as used in section 8,

[T]he two words are of the same import and one or the other or both may be indifferently used. The appropriate meaning of the word ‘false’ as extracted from the dictionary is ‘adapted or intended to mislead,’ and the word ‘misleading’ means ‘tending to lead astray, deceptive.’ I perceive no difference in these significations for the purpose of the statute in question.¹⁰³

Comparatively, while an inaccurate, but non-misleading statement may not violate the 1906 Act, early cases established that a literally true statement may also violate the Act. For example, the Supreme Court ruled that the statement “Made from selected apples” was deceptive when the vinegar was in fact made from chopped dried apples.¹⁰⁴ The court, in so holding, emphasized the conjunctive “or,” stating:

¹⁰¹Gould Amendment, Act of Mar. 3, 1913, 37 Stat. 732.

¹⁰²United States v. Von Bremen, Notice of Judgment No. 1949 (C.C.S.D.N.Y. 1910), *in* U.S. DEPARTMENT OF AGRICULTURE, *supra* note 14, 347, at 347.

¹⁰⁴United States v. Ninety-Five Barrels, More or Less, Alleged Apple Cider Vinegar, 265 U.S. 438 (1924)

The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.¹⁰⁵

To find a violation of the 1906 Act, there must be intent to deceive, further limiting the potential scope of the Act. In requiring evidence of intent, the Eighth Circuit relied on the purpose of the act, that of “to prevent the injurious deceit of purchasers.”¹⁰⁶

In defining misleading, “[t]he question is whether this label is calculated by its wording or nature to deceive the public,” the public being “reasonable members of the body of citizens who are entitled to know so far as labels can tell you what it is you are eating.”¹⁰⁷ In *United States v. Ten Barrels of Vinegar*, a district court held that in evaluating whether a label is misleading, and therefore misbranded, should be judged as that of a consumer’s first impression, even if “a deliberate reading of the label might correct such impression.”¹⁰⁸

The court based its reasoning upon the “common observation” that the average consumer does not carefully analyze labels, but “contents himself with a hasty glance or cursory examination.”¹⁰⁹

¹⁰⁶*Hall-Baker Grain Co. v. United States*, 198 F. 614, 617 (8th Cir. 1912), *overruling* *United States v. Hall-Baker Grain Co.*, Notice of Judgment No. 1135, in U.S. DEPARTMENT OF AGRICULTURE, *supra* note 14, at 452. The Eighth Circuit was unclear on whether its factual ruling was based on a factual finding on the lack of intent to mislead on the part of the manufacturer (since the cause of the false label was by the actions of a third party), or that the deceit did not cause injury, or that by law an invoice accompanying the product was not a label, therefore there was no violation.

¹⁰⁷*United States v. Von Bremen*, Notice of Judgment No. 1949 (C.C. S.D. N.Y. 1910), in U.S. DEPARTMENT OF AGRICULTURE, *supra* note 14, at 347, 348 – 49.

¹⁰⁸*United States v. Ten Barrels of Vinegar*, 186 F. 399, 401 (E.D. Wisc. 1911). *See e.g.* *United States v. Harper*, Notice of Judgment No. 25, at 4, in U.S. DEPARTMENT OF AGRICULTURE, *supra* note 14, at 163, 164.

¹⁰⁹*U.S. v. Ten Barrels of Vinegar*, 186 F. at 401. In the context of drug misbranding, this standard was limited in an opinion

The first case to be decided by the Supreme Court under the 1906 Act severely limited the scope of section 8's prohibitions on misbranding. The Court held that section 8 was "aimed not at all possible false statements, but only at such as determine the identity of the article."¹¹⁰ The Sherley Amendment later filled this gap by amending section 8, in the case of drugs, by adding a third paragraph stating that an article is deemed misbranded if "its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent."¹¹¹

The Act provided that the enforcement of the law should begin on Jan. 1, 1907, thus giving six months to formulate the necessary rules and regulations.¹¹² It also provided that the Bureau of Chemistry, the predecessor of the modern FDA,¹¹³ was to be the enforcing agency of the Act, but regulations could only be established by the joint action of the Secretaries of the Treasury, Agriculture, and Commerce, thus ensuring that regulations would be slow in the creation, and compromised when finally promulgated.¹¹⁴ Nevertheless, on Oct. 17, 1906, the Secretaries of the Treasury, Agriculture, and Commerce and Labor adopted forty "Rules and Regulations for the Enforcement of the Food and Drugs Act, June 30, 1906."¹¹⁵

The implementation of the 1906 Act was "embroiled in controversy" almost from its enactment.¹¹⁶ Fostered

written by Judge Hand, as a district court judge in New York, in which he held that in determining misbranding, the audience to whom the product was intended is relevant. In this case, the label was "intended to be read and to be understood by men who were in the drug business, and so you must consider whether within commercial meaning" whether the label was misleading. *United States v. J.L. Hopkins & Co.*, Notice of Judgment 1881, at 9 (1912), *in* U.S. DEPARTMENT OF AGRICULTURE, *supra* note 14, at 528, 536.

¹¹⁰*United States v. Johnson*, 221 U.S. 488, 497 (1911).

¹¹¹Act of August 23, 1912, ch. 352, 37 Stat. 416. Note that the same amendment was not made as regarding the misbranding provision for food, since by the definition of drug, any "substance or mixture of substances intended to be sued for the cure, mitigation, or prevention of disease" was a drug and not a food, Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, therefore any such health claims transformed the product into a "drug." *See infra* Part IV.

¹¹²Federal Food and Drugs Act of 1906, ch. 3915 § 13, 34 Stat. 768.

¹¹³The Bureau of Chemistry administered the 1906 Act until the Food, Drug, and Insecticide Administration was established in 1927, which was renamed in 1930 as the FDA. Hutt & Hutt, *supra* note 31, at 49 n.386.

¹¹⁴C.C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 Law & Contemp Probs. 3 (1933); Lauffer T. Hayes & Frank J. Ruff, *The Administration of the Federal Food and Drugs Act*, 1 Law & Contemp. Probs. 16 (1933).

¹¹⁵A copy of these regulations as amended by 1914, appear in U.S. DEPARTMENT OF AGRICULTURE, *supra* note 14, at 17 – 31.

¹¹⁶Hutt & Hutt, *supra* note 31, 55 – 57.

by the lobbying of food producers, the Department of Agriculture’s policies and goals conflicted with those of its underling, the Bureau of Chemistry,¹¹⁷ resulting in “the fundamental principles of the Pure Food Law hav[ing] been strangled.”¹¹⁸ The lack of judicial precedent to guide agency action, and the length of time necessary to have a court issue an interpretation further exacerbated these problems.¹¹⁹

B.

Misbranding under the FDCA

The FDCA, enacted in 1938, did not change the basis of the 1906 Act standards¹²⁰ – the adulteration and misbranding of food were still prohibited – and these statutory prohibitions are currently still the same.¹²¹ But the 1938 Act unquestionably expanded the power and authority of the FDA. Specifically, in regards to labeling, the 1938 Act removed the burden from the FDA of proving knowledge or intent in misbranding cases.¹²²

The FDCA as enacted, in terms of misbranding, is almost the same today as in 1938.¹²³ Most simply, under

¹¹⁷For a detailed account of the “abrogation of the Food Law” by the Chief of the Bureau of Chemistry until his resignation in 1912, see HARVEY W. WILEY, HISTORY OF A CRIME AGAINST THE FOOD LAW 98 – 153 (1929). *See also* Hayes & Ruff, *supra* note 114, at 21 – 23.

¹¹⁸From the Rocky Mountain News, March 21, 1912, available in WILEY, *supra* note 117, at 95.

¹¹⁹WILSON, *supra* note 16, at 56. Relatively few cases interpreting the 1906 Act ever reached the Supreme Court, leaving unanswered some conflicting decisions from lower federal courts. *Id.* Wilson also noted that at least in one instance the decisions of district courts within the same circuit were also inconsistent. The exact same product with the same label was held misbranded in *United States v. Scanlon*, 180 F. 485 (N.D. Ohio 1908) and not misbranded in *United States v. 68 Cases of Syrup*, 172 F. 781 (E.D. Ill. 1909). *Id.*

¹²⁰For a discussion of some of the proposed amendments concerning labeling requirements prior to the passage of the 1938 act, see Hutt & Hutt, *supra* note 31, 58 – 59.

¹²¹Federal Food, Drug, and Cosmetic Act, c. 675, §§ 301(a), (b), (g), 52 Stat. 1040, 1042 – 43 (1938); 21 U.S.C. §§ 331(a), (b), (g) (2000).

¹²²This change has been criticized, as “thereby theoretically giving the FDA the right to tyranny.” SCOTT LUCAS, THE FDA 4 (1978). Intent is still relevant in felony prosecutions under § 303(b) of the FDCA, 21 U.S.C. § 333(b) (2000). *See* U.S. v. Arlen, 947 F.2d 139, 141 – 43 (5th Cir. 1991) (holding that intent under § 303(b) does not necessarily only mean the intent to defraud or mislead the purchaser, but can include the intent to mislead a government agency).

¹²³Federal Food, Drug, and Cosmetic Act, c. 675, §§ 201(k), (m), (n), 52 Stat. 1040, 1040 – 42 (1938) (codified as amended at 21 U.S.C. § 321(k), (m), (n)(2000)). In 1976, “or advertising” was inserted after “labeling” wherever appearing within subsection (n), in order to extend the application of the factors to consider in regards to misbranding to drugs, corresponding with the 1962 amendments that authorized the FDA to regulate drug advertising. Act of Apr. 22, 1976, Pub. L. No. 94-278,

section 403(a), a food is misbranded if “its labeling is false or misleading in any particular,”¹²⁴ or if it does not contain certain information on its label or in its labeling.¹²⁵

Under the FDCA, the term “false” has its usual meaning of “untruthful,” while the term “misleading” has become a term of art.¹²⁶ Misbranding still reaches not only false claims, but also those claims that might be technically true, but still misleading.¹²⁷ If any one representation in the labeling is misleading, then the entire food is misbranded, nor can any other statement in the labeling cure another misleading statement.¹²⁸

Misleading is judged in reference to “the ignorant, the unthinking and the credulous.”¹²⁹ It is not necessary

§ 502, 90 Stat 401.

¹²⁴21 U.S.C. § 343(a) (2000).

¹²⁵Additionally, a food is misbranded if:

- (1) If it is offered for sale under the name of another food,
- (2) If it is an imitation of another food and is not labeled as such,
- (3) If the container is misleading (i.e., as to sizing),
- (4) If the label does not identify the supplier, the statement of quantity, either as weight, measure, or numerical count [see 21 C.F.R. §§ 101.5 & 101.7],
- (5) If any disclosure required is not placed prominently and conspicuously [see 21 C.F.R. § 101.15],
- (6) If there is a standard of identity, it must so comply,
- (7) If it is represented to be a standard of quality as per regulations,
- (8) If the food is not represented by a standard of identity, then the label must have the common or usual name of the food, and a list of ingredients if fabricated from two or more ingredients [see 21 C.F.R. §§ 101.3 & 101.4],
- (9) If the food claims to be for special dietary uses, the label must have certain information according to the regulations [see 21 C.F.R. § 105],
- (10) If artificial flavorings, artificial colorings or chemical preservatives are used but not so labeled [see 21 C.F.R. § 101.22], and
- (11) If the label fails to bear the specific information that the FDA requires.

21 U.S.C. § 343(b) – (k), (q) (2000). There are additional requirements for specific products. For example, saccharin must be labeled with a congressionally negotiated cancer warning; the absence of such is a misbranding violation. 21 U.S.C. § 343(o)(1). For a summary of what is affirmatively required on the label, and details on size and placement of this information, see VETTER, *supra* note 90, at 67 – 108; FDA, A FOOD LABELING GUIDE, *supra* note 9.

¹²⁶*See, e.g., V. E. Irons, Inc. v. Unites States*, 244 F.2d 34, 43 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957) (“[A] representation may be ‘misleading’ from the very fact of overemphasis and exaggeration, even though the product in question may be helpful, and in some circumstances useful, though not really indispensable to good health.”).

¹²⁷*See, e.g., V. E. Irons, Inc. v. Unites States*, 244 F.2d at 42 (“Bearing in mind the broad remedial purposes of the Act in preventing deception, the Congress must be taken to have meant to strike not only at palpably false claims but also at clever indirection and ambiguity in the creation of misleading impressions.”).

¹²⁸*See, e.g., U.S. v. Hoxsey Cancer Clinic*, 198 F.2d 273, 281 (5th Cir. 1952), *cert. denied*, 344 U.S. 928 (1953) (rejecting the defendant’s argument that the booklets as a whole disclaim any specific claim of efficacy) (“It was not necessary for the Government to prove that each and every representation in the booklet was false or misleading.”).

¹²⁹*See, e.g., United States v. Strauss*, 999 F.2d 692, 696 (2nd Cir. 1993) (“It also is irrelevant that a reasonable consumer reading the labels would realize that all Professional Choice varieties, and indeed all other dog foods, contain roughly the same ingredients and that the artificial flavoring adds no nutritional value to the dog food. We have construed section 343 broadly, since the test is not the effect of the label on a reasonable consumer, but upon ‘the ignorant, the unthinking and the credulous’ consumer.”); *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62 (9th Cir. 1951) (“The Act as a whole was designed primarily to protect consumers from dangerous products; its purpose is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze.”). *Compare V. E. Irons, Inc. v. Unites States*, 244 F.2d at 39 – 40 (“In determining whether such labeling contained ‘false or misleading’ statements, we must be careful not to read the literature with the eyes either of experts in nutrition or of overly skeptical buyers. What is

to prove anyone was actually mislead.¹³⁰

Overall, the FDA has pursued a high standard of consumer protection under the FDCA,¹³¹ and courts have generally upheld this standard.¹³² Additionally, courts often defer to the FDA in defining the terms “false” or “misleading.”

In implementing the 1938 Act, there was an initial emphasis at the FDA on preventing economic adulteration – the reduction in value of a food by using a less valuable material in the composition of the food, such as diluting orange juice with water.¹³³ But economic adulteration was not that easy to define in practice, especially with advances in food science and technology. Thus, the misbranding provisions took the lead position in how the FDA chose to monitor economic adulteration, allowing consumers to protect themselves by relying on truthful labeling.¹³⁴

As the public became more aware of the connection between diet and health, nutrition labeling became a priority of the FDA.¹³⁵ In response to this new consumer interest, the food industry started developing “healthier” products, and enhancing the labeling to emphasize the health benefits of a certain product. At this time, there were no standard definitions of terms such as “low” and “free,” thus necessitating more FDA

pertinent is the effect the claims would have on those to whom they are addressed, namely, prospective purchasers and actual customers of appellants, who cannot be presumed to have special expertness or to be unduly cautious, but who are more likely than not to be persons who are pathetically eager to find some simple cure-all for the diseases with which they are afflicted or who are susceptible to luridly painted scare literature as to the prospect of being disease-ridden unless they consistently partake of the vaunted drug product.”).

¹³⁰See, e.g., *United States v. An Article of Food Labeled Nuclomin*, 482 F.2d 581, 584 (8th Cir. 1973).

¹³¹Samia N. Rodriguez, *Food Labeling Requirements*, in *FUNDAMENTALS OF LAW AND REGULATION* 254 (Robert P. Brady et al. eds, 1997).

¹³²See, e.g., *U.S. v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (“[R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health.”); *United States v. An Article of Food Labeled Nuclomin*, 482 F.2d 581, 584 (8th Cir. 1973) (recognizing the overriding purpose of the FDCA, the court held that the FDA has authority to condemn a product for a misleading label, even though the label was technically accurate); *United States v. An Article of Food . . . “Manischewitz . . . Diet Thins,”* 377 F. Supp. 746 (E.D.N.Y. 1974); *United States v. An Article of Food Consisting of 432 Cartons . . . Candy Lollipops*, 292 F. Supp. 839 (S.D.N.Y. 1968).

¹³³See VETTER, *supra* note 90, at 11.

¹³⁴*Id.*

¹³⁵This new public interest in the relationship of diet and health was due to a number of factors: advances in nutrition and medical research; the White House Conference on Foods, Nutrition, and Health in 1969 recommendation for producers to fortify foods; the publication of the 1977 Report on Dietary Goals for the United States by the Senate’s Select Committee on Nutrition and Human Needs. *Id.* at 13 – 16.

interference, since the marketplace “became a jungle again,”¹³⁶ with the proliferation of claims for healthier products. In the early 1970s, the FDA refocused its approach away from case-by-case law enforcement in the courts, which predominated prior to the 1970s, to rulemaking.¹³⁷ In October 1977, Commissioner Donald Kennedy also announced that the FDA would seek tighter controls on labeling and advertising, not just through stricter regulations, but also by seeking additional legislation.¹³⁸

Despite this announcement, there was much criticism of the FDA and its enforcement policy, or lack of enforcement policy. Even industry participants did not take FDA seizure threats very seriously. For example, in the early 1990s, under Commissioner David Kessler, the FDA threatened to seize thousands of cases of Proctor & Gamble’s Citrus Hill orange juice, for being misleading because the word “fresh” appeared on the label, although the juice was made from concentrate.¹³⁹ Proctor & Gamble did not respond, for, as in the past, it believed the FDA would simply send a regulatory letter. Commissioner Kessler, newly appointed to his post, said “[t]he time has come to end the din of mixed messages and partial truths on food labels,”¹⁴⁰ thus signaling the new focus of FDA enforcement actions against mislabeling.

To aid the FDA’s goal of a stricter policy, the Nutrition and Labeling Education Act (NLEA) was enacted in 1990, which established additional affirmative requirements for labeling and more strictly regulated nutrient claims.¹⁴¹ Congress’s goal was that of enabling consumers to make informed decisions from accurate

¹³⁶*Id.* at 15.

¹³⁷LUCAS, *supra* note 122, at 122 – 26.

¹³⁸*See* LUCAS, *supra* note 122, at 38.

¹³⁹*See* HERBERT BURKHOLZ, THE FDA FOLLIES 179 – 82 (1994).

¹⁴⁰Warren E. Leary, *Citing Labels, U.S. Seizes Orange Juice*, NEW YORK TIMES, April 25, 1991, at A18.

¹⁴¹Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified in part at 21 U.S.C. § 343). For a discussion on how the NLEA affected health claims, see *infra* Part IV.

information.¹⁴² The major changes of the NLEA are as follows:¹⁴³ (1) The NLEA added § 403(q), which requires nutrition labeling for virtually all FDA regulated food products in a uniform format; (2) The NLEA added § 403(r), which prohibits the use of a “nutrient descriptor” or “nutrient content claim” – a claim that characterizes the level of a nutrient present in a food such as “low calorie” or “high fiber” – unless the FDA has defined it and the use conforms with that definition; (3) Section 403(r) also prohibits disease prevention claims – such as a claim that a product “helps to reduce the risk of heart disease” – in food labeling unless it conforms with a regulation promulgated by the FDA. If an unapproved health claims is used, even if truthful, then the article is deemed misbranded.¹⁴⁴

The stricter controls sought by the FDA in the early 1990s were minimized by the enactment of the Food and Drug Administration Modernization Act of 1997 (FDAMA).¹⁴⁵ The FDAMA allowed certain nutrient content claims to be made if based on an “authoritative statement,”¹⁴⁶ thus again expanding the freedom of labelers.

¹⁴²See VETTER, *supra* note 90, at 18. A prior amendment of the FDCA was the Fair Packaging and Labeling Act of 1966. Its stated purpose was similar to that of the NLEA, to prevent deceptive and unfair business practices by requiring honest and informative labeling in consumers commodities generally. Fair Packaging and Labeling Act of 1966, Pub. L. No. 89-755, §2, 80 Stat. 1296, (codified as amended at 15 U.S.C. § 1451 *et seq.* (2000)). Section 2 provides that:

Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons. Therefore, it is hereby declared to be the policy of the Congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods.

But the only provision not already applicable to food under the 1938 Act was the uniform location requirement on the principal display panel in a specified type size of the net quantity of contents.

¹⁴³See, *e.g.*, PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 200 – 203 (2nd ed. 1991).

¹⁴⁴The effect of the NLEA on health claims is discussed *infra* Part IV.A.

¹⁴⁵Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325.

¹⁴⁶“Authoritative statements” are defined further *infra* Part IV.B.

C.

Misbranding under the FTC Act

In 1938, the FTC Act was amended. Before then, the FTC could only protect consumers indirectly by protecting competitors, since the FTC Act section 5, as originally enacted in 1914, only prohibited “unfair methods of competition in commerce.” While the definition of “unfair or deceptive acts or practices” was left generally to case law, in 1938 section 12 was also added, providing that the dissemination of any false advertising in connection with the purchase of foods or drugs is an unfair or deceptive act or practice within section 5’s prohibition.¹⁴⁷ Section 15(a) contains the definition of false advertisement for the purposes of section 12, limiting section 12’s application to “an advertisement, other than labeling, which is misleading in a material respect.”¹⁴⁸ The distinction between sections 5 and 12 of the FTC Act was originally based upon the remedy available. Section 12 provided for injunctive relief. Statutory amendments in 1973 provided the FTC with general injunctive powers, thus eliminating the need to rely on section 12.¹⁴⁹

The terms “unfair” and “deceptive” of section 5, although similar, are not identical, and there are no statu-

¹⁴⁷Section 12 “False advertising; dissemination prohibited,” provides as follows:

(a) Unlawfulness. It shall be unlawful for any person . . . to disseminate, or cause to be disseminated, any false advertisement

— (1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of foods, drugs, devices, services, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce of food, drugs, devices, services, or cosmetics.

(b) Unfair or deceptive act or practice. The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 5.

15 U.S.C. § 52 (2000).

¹⁴⁸Section 15(a)(1) provides:

The term “false 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 (among other things) 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.

15 U.S.C. § 55(a)(1) (2000).

¹⁴⁹Trans-Alaska Pipeline Authorization Act, Pub. L. No. 93-153, §408, 87 Stat. 591 (1973) (codified at 15 U.S.C. §§ 45(1), 45 (m), 53(b), 53(c)).

tory definitions as to either. The legal standards used by the FTC concerning deception are fairly well established, while the standards for unfairness are still in a comparatively recent state of development. The basic approach by the FTC for evaluating food advertising claims is that claims must be (1) adequately substantiated, and (2) not deceptive.

Adequate Substantiation. The FTC requires a “reasonable basis” to adequately substantiate advertising claims, and the absence of a reasonable basis has been held to violate section 5 under both deception¹⁵⁰ and unfairness¹⁵¹ theories. Implied representations must also be adequately substantiated.¹⁵²

What constitutes a reasonable basis depends on a number of factors “relevant to the benefits and costs of substantiating a particular claim.”¹⁵³ These factors include: (1) the type of product advertised, (2) the type of claim, (3) the benefits of a truthful claim, (4) the ease of developing substantiation for the claim, (5) the consequences of a false claim, and (6) the amount of substantiation that experts in the field believe is reasonable.¹⁵⁴ The issue of adequate substantiation is considered separately from the technical accuracy of the claim.¹⁵⁵

The advertiser must be able to prove that ex ante, he had a reasonable basis prior to the advertisement. This is not an easy evidentiary burden, but a written report, drafted in good faith prior to marketing, setting

¹⁵⁰The deception is the implicit representation of prior objective verification, and the absence of such verification is misleading. See, e.g., *Firestone Tire & Rubber Co. v. F.T.C.*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973); *National Commission on Egg Nutrition*, 88 F.T.C. 89 (1976), *enforced as modified*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978).

¹⁵¹See, e.g., *In re Pfizer, Inc.*, 81 F.T.C. 23, 72 – 73 (1972).

¹⁵²See, e.g., *F.T.C. v. Figgie Int’l, Inc.*, 994 F.2d 595, 603 – 04 (9th Cir. 1993) (“Figgie frequently argues that some of the representations that the Commission found false or misleading were implied, not express. This is a distinction without a difference. Figgie can point to nothing in statute or case law which protects from liability those who merely imply their deceptive claims; there is no such loophole.”). Substantiating implied claims can become circular, for example, when scientific studies are cited in an advertisement as a basis for one claim, but no studies are cited for another technical representation, the FTC could argue that the advertisement contains a materially misleading implication that adequate substantiation exists for all of the claims made. See, e.g., *Crown Central Petroleum Corp.*, 84 F.T.C. 1493 (1974), *aff’d, per curiam by unpublished order of the court*, (D.C. Cir. 1976).

¹⁵³FTC Policy Statement Regarding Advertising Substantiation, 49 Fed. Reg. 30,999, 104 F.T.C. 648, 839 (1984) (appended to *Thompson Medical Co., Inc.*).

¹⁵⁴FTC Policy Statement Regarding Advertising Substantiation, *supra* note 153.

¹⁵⁵The existence of substantiation for a claim will not shield the advertiser from liability if additional substantial evidence proves the claim nevertheless to be false. *National Dynamics Corp.*, 82 F.T.C. 488 (1973), *aff’d on other grounds and remanded*, 492 F.2d 1333 (2nd Cir.), *cert. denied*, 419 (U.S. 993) (1974).

forth the evidentiary basis, should aid in proving such.¹⁵⁶ The subjective good faith is not conclusive, for the reasonableness of the advertiser's reliance on the substantiating data will be measured against the degree of substantiation reasonably consumers would expect.¹⁵⁷

Deception.¹⁵⁸ In the early 1980s, the FTC issued a new policy statement outlining its standards for determining when an advertising claim will be found to be deceptive.¹⁵⁹ Prior to then, the deception standard was that any statement that had the tendency and capacity to mislead or deceive a prospective purchaser was a deceptive practice within the meaning of the FTC Act prohibitions.¹⁶⁰ The FTC reconsidered this definition, for it found this definition to be “circular and therefore inadequate to provide guidance on how a deception claims should be analyzed.”¹⁶¹ The revised standard will find an act or practice deceptive if, “first, there is a representation, omission, or practice that, second, is likely to mislead consumers acting reasonably under the circumstances, and, third, the representation, omission, or practice is material.”¹⁶² Thus the focus shifted from advertising that had a “tendency and capacity to deceive” to advertising that is “likely to mislead,” from simply “consumers” to “consumers acting reasonably under the circumstances,” and to include a requirement of materiality.¹⁶³

¹⁵⁶In re Pfizer, Inc., 81 F.T.C. 23, 72 – 73 (1972) (“[R]espondent made no written report setting forth the actions which were taken to support the existence of a reasonable basis for its advertising claims. Such a report, if made in good faith prior to marketing, if reasonable in scope and approach, and if reasonably clear as to the evidentiary basis for the specific claims in question (be they scientific tests, specified medical references, or specific clinical evidence), would certainly have, in itself, gone a considerable distance in demonstrating the existence of a reasonable basis for their affirmative product claims.”).

¹⁵⁷See Firestone Tire & Rubber Co., 81 F.T.C. 398 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).

¹⁵⁸See generally *FTC's Authority Over Deceptive Advertising: Hearing Before the Subcomm. for Consumers of the Senate Comm. on Commerce, Science, and Transportation*, 97th Cong. 2d Sess (1982); *Deception: FTC Oversight: Hearing before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 98th Cong, 2d Sess (1984).

¹⁵⁹FTC Policy Statement on Deception, 103 F.T.C. 110 (1984) (appended to Cliffdale Associates, Inc.). The Cliffdale Associates decision was the first case applying the new deception standard and thus the policy statement was appended to the decision, but the new policy was first articulated in a letter to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives, dated Oct. 14, 1983.

¹⁶⁰See *Chrysler Corp. v. F.T.C.*, 561 F.2d 357, 363 (D.C. Cir. 1977); *F.T.C. v. Algoma Lumber Co.*, 291 U.S. 67 (1934); *Charles of The Ritz Corp. v. F.T.C.*, 143 F.2d 676 (2nd Cir. 1944).

¹⁶¹FTC Policy Statement on Deception, *supra* note 159, at 164.

¹⁶²*Id.* at 164 – 65.

¹⁶³For cases under this new policy, see generally, *F.T.C. v. Pantron I Corp.*, 22 F.3d 1088 (9th Cir. 1994), *cert. denied*, 115 S. Ct. 1794 (1995); *Kraft, Inc. v. F.T.C.*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993); *F.T.C. v. Silueta Distrib., Inc.*, 1995-1 Trade Case (CCH) ¶70,918 (N.D. Cal. 1995); *Stouffer Foods Corp.*, 5 Trade Reg. Rep. (CCH) ¶23,686 (1994).

The advertiser's intent to deceive is not relevant, for the FTC Act is concerned with protecting the public from deception rather than punishing the violator.¹⁶⁴ The omission of material information, even if the representations are entirely truthful, may be determined to be deceptive and therefore a violation of section 5.¹⁶⁵ Advertisements are viewed from the vantage of a consumer, and that of the ordinary consumer. While courts have held that the audience will be assumed to include "the ignorant, the unthinking and the credulous,"¹⁶⁶ the FTC has softened this approach in enforcement, requiring consumers to act reasonably in the circumstances.¹⁶⁷ Misleadingness is judged on the entirety of the ad, and not based upon a particular claim.¹⁶⁸ Puffing is allowed, but the dividing line between puffing and misleading claims is not bright: puffing is permitted as long as the manufacture speaks generally of his product's high quality, but not as to specific claims. The deception of an actual consumer need not be proved, just that that the advertisement

¹⁶⁴See, e.g., *F.T.C. v. Algoma Lumber Co.*, 291 U.S. 67 (1934); *Porter & Dietsch, Inc. v. F.T.C.*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980); *Regina Corp. v. FTC*, 322 F.2d 765, 768 (3d Cir. 1963).

¹⁶⁵See, e.g., *Simeon Management Corp. v. F.T.C.*, 579 F.2d 1137, 1145 (9th Cir. 1978) ("Failure to disclose material information may cause an advertisement to be false or deceptive within the meaning of the FTCA even though the advertisement does not state false facts."); *Bristol-Myers Co. v. F.T.C.*, 738 F.2d 554, at 563 (2d Cir.1984); *Katharine Gibbs School v. F.T.C.*, 612 F.2d 658, 665 (2nd Cir. 1979); *Firestone Tire & Rubber Co.*, 81 F.T.C. 398 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973); *In re Stupell Enters.*, 67 F.T.C. 173 (1965); *In re Universe Co.*, 63 F.T.C. 1282 (1963), *aff'd, sub nom.*, *Kirchner v. F.T.C.*, 337 F.2d 751 (9th Cir. 1964); *In re Novel Mfg. Corp.*, 60 F.T.C. 1748 (1962); *In re Nuclear Prods. Co.*, 49 F.T.C. 229 (1952); *In re Fisher & Dertis*, 49 F.T.C. 77 (1952).

¹⁶⁶See, e.g., *F.T.C. v. Standard Educ. Soc'y*, 302 U.S. 112, 116 (1937) ("The fact that a false statement may be obviously false to those who are trained and experienced does not change its character, nor take away its power to deceive others less experienced. There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. The best element of business has long since decided that honesty should govern competitive enterprises, and that the rule of caveat emptor should not be relied upon to reward fraud and deception."); *F.T.C. v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2nd Cir. 1963) ("Unlike that abiding faith which the law has in the 'reasonable man,' it has very little faith indeed in the intellectual acuity of the 'ordinary purchaser' who is the object of the advertising campaign.") quoting 1 CALLMAN, UNFAIR COMPETITION AND TRADEMARKS § 19.2(a)(1), at 341-44 (1950):

The general public has been defined as 'that vast multitude which includes the ignorant, and unthinking and the credulous, who, in making purchases, do not stop to analyze but too often are governed by appearances and general impressions.' The average purchaser has been variously characterized as not 'straight thinking,' subject to 'impressions,' uneducated, and grossly misinformed; he is influenced by prejudice and superstition; and he wishfully believes in miracles, allegedly the result of progress in science.... The language of the ordinary purchaser is casual and unaffected. He is not an 'expert in grammatical construction' or an 'educated analytical reader' and, therefore, he does not normally subject every word in the advertisement to careful study.

¹⁶⁷FTC Policy Statement on Deception, *supra* note 161.

¹⁶⁸See, e.g., *F.T.C. v. Standard Educ. Soc'y*, 302 U.S. 112, 116 – 17 (1937); *Food Motor Co. v. F.T.C.*, 120 F.2d 175 (6th Cir.), *cert. denied*, 314 U.S. 668 (1941); *Sterling Drug, Inc. v. F.T.C.*, 317 F.2d 669, 674 (2nd Cir. 1963) ("It is therefore necessary in these cases to consider the advertisement in its entirety and not to engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately. 'The buying public does not ordinarily carefully study or weigh each word in an advertisement. The ultimate impression upon the mind of the reader arises from the sum total of not only what is said but also of all that is reasonably implied.'").

in question was likely to mislead.¹⁶⁹ Nor is the fact that in actuality the majority of consumers were not deceived a defense.¹⁷⁰

Recently, the FTC has increasingly used consumer surveys and such objective evidence as proof of the likelihood to mislead.¹⁷¹ But the determination is ultimately one the Commission makes, based on its own visual inspection and interpretation of the advertising.¹⁷² Overcoming an adverse FTC determination on the likelihood to mislead is a fairly high hurdle. Courts often give great deference to the FTC's judgment on whether an advertisement contains representations or omissions that might be deceptive, on what representations are explicitly and implicitly conveyed, and if these representations are material.¹⁷³ This deference is partially

¹⁶⁹ See, e.g., *F.T.C. v. Algoma Lumber Co.*, 291 U.S. 67 (1934); *Beneficial Corp. v. F.T.C.*, 542 F.2d 611, 617 (3rd Cir. 1976), *cert. denied*, 430 U.S. 938 (1977) (“[T]he FTC has been sustained in finding that advertising is misleading even absent evidence of that actual effect on customers, the likelihood or propensity of deception is the criterion by which advertising is measured. . . . At the same time, evidence that some customers actually misunderstood the thrust of the message is significant support for the finding of a tendency to mislead.”); *National Commission on Egg Nutrition v. F.T.C.*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); *Sterling Drug, Inc. v. F.T.C.*, 317 F.2d 669, 674 (2nd Cir. 1963) (“In order best to implement the prophylactic purpose of the statute, it has been consistently held that advertising falls within its proscription not only when there is proof of actual deception but also when the representations made have a capacity or tendency to deceive, i.e., when there is a likelihood or fair probability that the reader will be misled.”); *Charles of the Ritz Distributors Corp. v. F.T.C.*, 143 F.2d 676, 680 (2nd Cir. 1944).

¹⁷⁰ See, e.g., *Firestone Tire & Rubber Co. v. F.T.C.*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).

¹⁷¹ See, e.g., *Kraft, Inc. v. F.T.C.*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993); *In re Thompson Medical Co., Inc.*, 104 F.T.C. 648 (1984); *Stouffer Foods Corp.*, 5 Trade Reg. Rep. (CCH) ¶23,686 (1994). Advertisements directed to a specific segment of consumers will be judged with respect to that group, including advertising directed to children. See, e.g., *ITT Continental Baking Co., Inc. v. F.T.C.*, 532 F.2d 207 (2nd Cir. 1976); *Wand Labs., Inc. v. F.T.C.*, 276 F.2d 952 (2nd Cir.), *cert. denied*, 364 U.S. 827; *In re Topper Corp.*, 79 F.T.C. 681 (1971). For a comparison of the FTC use of consumer surveys with the FDA's apparent lack of use, see Manoj Hastak, et. al, *The Role of Consumer Surveys in Public Policy Decision Making*, JOURNAL OF PUBLIC POLICY & MARKETING 170 (2001). According to this article, the FTC relies on surveys sometimes to assess whether an advertising or marketing practice is deceptive, and as evidence during litigation. The FTC frequently uses surveys when an implied claim is at issue, the FTC does not typically use surveys when it believes that the claims are express. In these cases, the FTC usually relies on a marketing expert to evaluate the deceptiveness. Contrast this with the FDA, which rarely uses survey evidence, relying instead on its expertise to make a determination as to a claim's misleadingness. *Id.*

¹⁷² See, e.g., *F.T.C. v. Colgate-Palmolive Co.*, 380 U.S. 374 (1965) (sustaining the findings of fact of the Commission that rested on inferences that could reasonably be drawn from the commercials themselves); *ITT Continental Baking Co. v. F.T.C.*, 532 F.2d 207 (2nd Cir. 1976); *Kraft, Inc. v. F.T.C.*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993) (“[T]he Commission may rely upon its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear from the face of the advertisement.”)

¹⁷³ See, e.g., *F.T.C. v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965) (“This Statutory scheme necessarily gives the Commission an influential role in interpreting § 5 and in applying it to the facts of particular cases arising out of unprecedented situations. Moreover, as an administrative agency which deals continually with cases in the Area, the Commission is often in a better position than are courts to determine when a practice is ‘deceptive’ within the meaning of the Act. This Court has frequently stated that the Commission’s judgment is to be given great weight by reviewing courts. This admonition is especially true with respect to allegedly deceptive advertising since the finding of a § 5 violation in this filed rests so heavily on inference and pragmatic judgment.”); *Beneficial Corp. v. F.T.C.*, 542 F.2d 611, 617 (3rd Cir. 1976), *cert. denied*, 430 U.S. 938 (1977) (“Whether particular advertising has a tendency to deceive or mislead is obviously an impressionistic determination more closely akin to a finding of fact than to a conclusion of law.”); *F.T.C. v. Figgie Int’l, Inc.*, 994 F.2d 595 (9th Cir. 1993); *Kraft, Inc. v. F.T.C.*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993); *Sterling Drug, Inc. v. F.T.C.*, 741 F.2d

based upon the accumulated agency expertise.¹⁷⁴ Additionally, advertisements that might be found to be misleading, “should be construed against the advertiser.”¹⁷⁵

D.

Comparison of the FDA & FTC Standards and Interagency Action

The definition of misleading advertising in section 15(a)(1) of the FTC Act is nearly identical to the definition of misleading labeling in section 201(n) of the FDCA. The conference report accompanying the FDCA enactment indicates that the two sections were intended to have the same meaning.¹⁷⁶ However, there are a few statutory differences. Misbranding under the FDA is easier to prove in that the FDCA only requires the labeling to be “false or misleading *in any particular*,” while the FTC must show that misleading statement is *materially* misleading.¹⁷⁷

1146, 1154 (9th Cir. 1984), *cert. denied*, 470 U.S. 1084 (1985) (“It is within the Commission’s expertise to determine what inferences consumers may draw from such representations. . . . We defer to that expertise and affirm the conclusion that Bayer was advertised to have scientifically established therapeutic superiority.”). Compare Robert Pitofsky, Beyond Nader: Consumer Protection and the Regulation of Advertising, 90 HARV. L. REV. 661, 677 – 79 (1977) (explaining the “virtually unreviewable” discretion of the FTC in interpreting advertisements because of the “administrative inconvenience of alternative approaches” rather than because of the FTC’s expertise).

¹⁷⁴Simeon Management Corp. v. F.T.C., 579 F.2d 1137, 1145 – 46 (9th Cir. 1978) (“The Commission has been engaged in making such determinations since 1938, when its jurisdiction was extended to include the prevention of unfair or deceptive acts or practices in commerce. As a result, the Commission has accumulated extensive experience and is therefore generally in a better position than the courts to determine when a practice is deceptive within the meaning of the FTCA.”).

¹⁷⁵Resort Car Rental Systems, Inc. v. F.T.C., 518 F.2d 962, 964 (9th Cir.), *cert. denied*, 423 U.S. 827 (1975). See also United States v. Ninety-Five Barrels, 265 U.S. 438 (1924); Giant Food, Inc. v. F.T.C., 322 F.2d 977 (D.C. Cir. 1963); *cert. dismissed*, 376 U.S. 967 (1964).

¹⁷⁶H.R. REP. NO. 75-2139, at 3 (3rd Sess. 1938). See also 83 CONG. REC. 3255 (daily ed. Mar. 11, 1938) (statement of Sen. Wheeler).

¹⁷⁷See, e.g., United States v. An Article of Food Consisting of 432 Cartons . . . Candy Lollipops, 292 F. Supp. 839, 840 – 41 (S.D.N.Y. 1968) (“[W]e recognize that the statute [FDCA] does not provide for much flexibility in interpretation. . . . Since it requires only that the labeling be false or misleading ‘in any particular.’ This represents a stricter substantive standard than that applied with respect to false advertising, which in order to be prohibited must be ‘misleading in a material respect.’”). For comparison, in one case recently under the felony provisions of the FDCA, 21 U.S.C. § 333(a)(2), the Ninth Circuit held that the “intent to mislead” requirement of the felony provisions also requires proof of materiality. U.S. v. Watkins, 278 F.3d 961, 966 – 69 (“[O]ne still cannot ‘intend to mislead’ another by means of a misrepresentation without having an expectation that the recipient would actually or reasonably rely on it.”). Compare U.S. v. Jorgensen, 144 F.3d 550 (8th Cir. 1998) (addressing

For the most part, the agencies have pursued similar definitions of misbranding. But the FDA holds labeling to a higher standard than the FTC, for the FDA attempts to protect the ignorant, the unthinking and the credulous from being misled, while the FTC, under its enforcement policy, will only protect the consumers who are acting reasonably under the circumstances.

The method by which these agencies act is also different. The FTC acts primarily by adjudication, rather than rulemaking.¹⁷⁸ The FDA's current focus is on rulemaking, even though it has the power to seize misbranding articles and pursue policy individually.

Despite these differences, there is a high-level of interaction between the FTC and the FDA. The FTC has traditionally used the expertise of the FDA when evaluating advertising claims for FDA-regulated products.¹⁷⁹ The FTC often relies on an advertiser's compliance FDA labeling regulations when it determines whether advertising claims are false or deceptive.¹⁸⁰ Additionally, the FTC also specifically allows the use of "safe-harbor" provisions in certain circumstances, which affirmatively allows a manufacturer to make claims that are sanctioned by other governmental agencies.¹⁸¹ This reliance on regulations is not always the FTC relying on FDA regulations. In *United States v. Strauss*, the Second Circuit rejected the argument that the FDCA criminal provision prohibiting mislabeling was not unconstitutionally vague as applied to dog food sold sellers, notwithstanding the lack of FDA guidelines or regulations governing dog food labeling, since the

a similar felony misbranding provision of the Federal Meat Inspection Act, 21 U.S.C. §§ 601 – 695, that requires an "intent to defraud," and holding that the statute does not require the false or misleading statements to be material.)

¹⁷⁸A treatise on the Law of Advertising has notes that "the Federal Trade Commission indicated that it would consider proposing regulations governing food advertising after the publication of the FDA's final rules on food labeling" but as of yet, these regulations have not materialized. *ROSDEN & ROSDEN*, *supra* note 153, at 26 – 41 n.39.

¹⁷⁹Working Agreement Between Federal Trade Commission and Food and Drug Administration, *supra* note 66 at ¶ 9850.01.

¹⁸⁰*Simeon Management Corp. v. F.T.C.*, 579 F.2d 1137, 1145 – 46 (9th Cir. 1978) (upholding the FTC determination that the failure to disclose that the drug involved lacked FDA approval for such use renders the advertisement deceptive and therefore in violation of section 5); *Removation Int'l Corp. v. F.T.C.*, 884 F.2d 1489 (1st Cir. 1989); *Thompson Medical Co. v. F.T.C.*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Bristol-Myers Co. v. F.T.C.* 738 F.2d 554 (2nd Cir. 1984), *cert. denied* 469 U.S. 1189 (1985); *American Home Products Corp. v. F.T.C.* 695 F.2d 681 (3rd Cir. 1982).

¹⁸¹*See, e.g.*, *Gracewood Fruit Co.*, [1993-1997 Transfer Binder] Trade Reg. Rep. (CCH) ¶ 23,359 (1993) (proposed consent) (safe harbor provisions allows health claims made for consuming grapefruit that are permitted on labels by the FDA under the NLEA); *Clorox Co.* [1987-1993 Transfer Binder] Trade Reg. Rep (CCH) ¶23,269 (1992) (consent) (order prohibiting misrepresentations regarding fat and cholesterol content of salad dressing did not prohibit claims specifically permitted by the FDA in labeling).

FTC had promulgated regulations expressly prohibiting misrepresentations of a dog food's suitability for a particular purpose.¹⁸²

At times, the FTC adopts the findings of the FDA to reach its own finding that an ad was false or deceptive.¹⁸³ There is some concern at the FTC, though, of relying too much on the FDA. In Commissioner Owen's dissent to a proposed consent order, she stated that "In taking this action today, I believe that the Commission has essentially ceded its authority to the FDA."¹⁸⁴

FTC enforcement has recently become more important to the FDA as the resources of the FDA are depleted. The FDA's budget has been persistently too minimal, and Congress has not authorized sufficient funds for the FDA to fully police this area.¹⁸⁵ Recently, the sale of misleadingly labeled products has been downplayed at the FDA due to budgetary constraints, and the FDA has increasingly been forced to rely upon the FTC to combat minor-scale fraud in otherwise traditionally FDA-regulated fields.¹⁸⁶

¹⁸²United States v. Strauss, 999 F.2d 692 (2nd Cir. 1993). The FTC has subsequently revoked these regulations.

¹⁸³Simeon Mortgage Corp. v. F.T.C., 579 F.2d 1137, 1143 (9th Cir. 1978) ("The FTC did not independently determine that HCG is a new drug when used for the treatment of obesity. It merely declined to challenge the FDA determination because the record before it lacked substantial evidence that HCG is effective for such use. Petitioners do not, and indeed could not, dispute the fact that the FDA has declared HCG to be a new drug when used for the treatment of obesity. The Commission's acceptance of the FDA determination is supported by the applicable legal precedents and substantial evidence on the record as a whole, and hence cannot be set aside."); Chesebrough-Pond's, Inc. [1983-1987 Transfer Binder] Trade Reg. Rep. (CCH) ¶ 22,313 (1985) (finding of FDA substantiated respondent's comparative advertising claims).

¹⁸⁴Metagenics, Inc., [1993-1997 Transfer Binder] Trade Reg. Rep. (CCH) ¶ 23,650 (1994) (dissent criticizing the Commission actions because "on balance, it runs contrary to the public interest. I fear that the breadth of the allegations in the administrative complaint may convey the wrong message to the public and thereby discourage not only truthful and nondeceptive claims about calcium supplements but, ultimately, their use.").

¹⁸⁵See O'REILLY, *supra* note 6, §24.02 & §10.08.50 (cumulative supplement).

¹⁸⁶*Id.*; FTC Consent Order with Karr Preventative Medical Products Inc., 44 Fed. Reg. 39191 (July 5, 1979). *See also*, Dahlberg, Inc., [1993-1997 Transfer Binder] Trade Reg. Rep. (CCH) ¶ 23,536 (1994) (investigation of hearing aid manufacturer's claims coordinated with FDA).

IV.

Health Claims

“Health claims” refer to a claim that a food is effective in the prevention, cure, mitigation, or treatment of any disease or symptom, as distinguished from general information on nutrition. The sphere of regulation of health claims is one in which the contrast between the styles and personalities of the FDA and the FTC is most evident.

A.

The NLEA and The FDA

As society’s understanding of the relationship between food, diet, and health changed, so did the need for governmental regulation to change form and substance.¹⁸⁷ Before the 1980s, health claims for food products were prohibited, for any such claim would turn a food item into a drug, under the statutory definition of drugs.¹⁸⁸ In 1973, the FDA issued regulations using a “vague prohibition”¹⁸⁹ against false or misleading statements to regulate health messages in labeling. These regulations provided that “a food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its labeling represents, suggests, or implies: That the food because of the presence or absence of certain

¹⁸⁷For a comparison of how the United Kingdom, Japan, and the United States have chosen to regulate health claims, see Center for Science in the Public Interest, *Functional Foods: Public Health Boon or 21st Century Quackery* (Mar. 1999), at www.cspinet.org/reports/functional_foods/index.html.

¹⁸⁸In dictum, in a 1908 case under a Kentucky inspection act, a district court judge espoused his view that a product can be both a food and a drug:

[B]ut the act is not prevented from covering that which is a food because it is a medicine also. Conceivably an article may be a food and a medicine both, and that when used in the same way, i.e., when taken internally. Such an article is covered by the act notwithstanding its medicinal quality.

Savage v. Scovell, 171 F. 566, 566 – 67 (C.C. E.D. Ky. 1908).

¹⁸⁹Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L.R. 63, 67 (1995).

dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.”¹⁹⁰

In 1987, the FDA proposed a change to its prior policy and began allowing health claims for conventional foods without premarket approval.¹⁹¹ This proposal would allow health claims to be made on food labeling, as long as certain criteria were met. The basic criteria was that the information on the labeling must be truthful and not misleading, based on and consistent with valid, reliable, scientific evidence that is publicly available, and the label must include a description of the role of this food or ingredient in total dietary pattern, and must comply with the nutrition labeling requirements.¹⁹² If these criteria were met, the agency announced that it would not consider the food to be a drug within the definition of the FDCA solely because the labeling contains a health-related message.¹⁹³

Before the publishing of the 1987 proposed regulations, the FDA had already changed its enforcement policy. In 1984, the Kellogg Company began to sell its All-Bran cereal with a label that recommended to help prevent cancer, consumers should “eat high fiber foods, eat foods low in fat, eat fresh fruits and vegetables, eat a well-balanced diet and avoid being overweight.”¹⁹⁴ The FDA never took any action against Kellogg,

¹⁹⁰38 Fed. Reg. 2128 (1973). The regulation currently reads: “A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies: (1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and part 101, subpart E.” Nutrition Labeling of Food, 21 C.F.R. § 101.9(k) (2002).

¹⁹¹Public Health Messages on Food Labels and Labeling, 52 Fed. Reg. 28,843 (proposed Aug. 4, 1987). Responses to this proposed regulation varied highly. The Attorney Generals of 34 states advocated the absolute bar on health claims by food manufacturers, arguing, inter alia, that health claims have an immense capacity to deceive. Comments of Attorneys General On FDA Proposal Regulating Health Claims by Food Marketers, Docket Number 89N-0226, *available at* GEORGE ERIC ROSDEN & PETER ERIC ROSDEN, *THE LAW OF ADVERTISING*, at § 13C-3 (2001). They also note that any regulations issued should consider the role of the FTC in monitoring advertisements, specifically stating that:

In the health claims arena, FTC enforcement has not been as forceful as it should be. Under the new Chair of the FTC, it is hoped that the FTC will seriously and vigorously enforce the FTC Act with respect to claims of this nature. This must happen, if health claims are to be allowed at all. If the FDA limits health claims on labeling as suggested herein, only to find that the FTC permits a much broader type of claim to be made in consumer advertising, valuable protections against misinformation will be lost.

Id. at § 13C-8.

¹⁹²*Id.*

¹⁹³*Id.* at 28,849.

¹⁹⁴For a narrative of these events, see *United States v. Undetermined Quantities of . . . “Exachol,”* 716 F. Supp. 787, 790 (S.D.N.Y. 1989). For a scathing critique, see BURKHOLZ, *supra* note 139, at 159 – 66 (“But if the agency’s lackluster performance in the field of food was generally dues to an absence of resources and authority, its performance in the case of the Kellogg’s

despite acknowledging the violations of both the food and drug provisions of the act in a draft letter, which was never mailed.¹⁹⁵ This lack of action was a signal to the food industry that these claims would not be challenged; Kellogg itself made additional health claims for its other cereals, followed by General Mills, Quaker Oats, and countless others.¹⁹⁶

Subsequently, products claiming to cure every ailment flooded the market.¹⁹⁷ Even before this change in policy, Herbert Burkholz, a member of FDA's public affairs staff, attributed the increased number of questionable health claims to "a supine FDA and an OMB dedicated to the preservation of business interests."¹⁹⁸ Congress responded with the Nutrition Labeling and Education Act of 1990 ("NLEA"),¹⁹⁹ and the 1987 proposed regulations were revoked.²⁰⁰

The NLEA added section 403(r), which prohibits disease prevention claims unless it conforms with regulations to be promulgated by the FDA. This section specifically addressed the standard by which the FDA is to promulgate regulations that approve health claims, stating:

All-Bran label was nothing less than abdication or responsibility.").

¹⁹⁵United States v. Exachol, 716 F. Supp. at 790.

¹⁹⁶See BURKHOLZ, *supra* note 139, at 167 – 68.

¹⁹⁷See Ilene Ringel Heller, *Functional Foods: Regulatory and Marketing Developments*, FOOD & DRUG L.J. 197, 200 (2001). See also BURKHOLZ, *supra* note 139, at 184; Zachary Schiller et al., *The Great American Health Pitch: Have Food Companies Gone Overboard In Adopting That Old Parental Refrain: 'Eat It, It's Good For You'?*, BUS. WK., Oct. 9, 1989, at 114 (noting that "[f]ully 30% of the \$3.6 billion in annual U. S. food advertising now includes some type of health message."). Schiller also reported on a survey conducted by Lempert Co., an ad agency, that found that "74% of Pepsi drinkers said they would switch to Coke if it had oat bran in it," concluding that if a health claim will sell a product, companies will use it, for "[c]ompetitive pressures in the slow-growth food industry are likely to drag into the game even those marketers who have misgivings about health pitches." *Id.*

¹⁹⁸BURKHOLZ, *supra* note 139, at 184. Burkholz, while recognizing structural weakness in the bureaucracy, ultimately blamed the Reagan and Bush administrations for this decline in the efficacy of the FDA. *Id.* at 13 – 20. Specifically,

The pro-industry bias of the FDA during the Reagan-Bush administrations was never more evident than in the area of food labeling. Responsible for regulating the truth of claims made on those labels, the agency during most of the 1980s demonstrated a distinct reluctance to antagonize industry, coupled with an attitude toward the needs of the consumer that came close to callous indifference. Some of this attitude was generated from within the FDA itself; more of it was forced on the agency from the White House through an Office of Management and Budget (OMB) that was fervently devoted to free-marketeering. But whatever the source, the FDA during those years conformed to the ethics of the time, which dictated that nothing must be allowed to get in the way of making a buck.

Id. at 159. Robert Higgs, in defending the Republican administrations, has attacked this opinion one-sided, and based upon a "starry-eyed view of the agency in earlier days." Robert Higgs, *The FDA Follies*, REASON, Oct. 1, 1994, at 70.

¹⁹⁹Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified in part at 21 U.S.C. § 343(i), (q), and (r)).

²⁰⁰Health Messages and Label Statements, 55 Fed. Reg. 5176 (Feb. 13, 1990).

Based on the totality of publicly available scientific evidence (including evidence from well designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.²⁰¹

The FDA, in applying this language, implemented a rigid standard in evaluating health claims for approval.²⁰² As authority for this rigid standard, the FDA looked to Congressional intent in passing the NLEA.²⁰³ Under 21 C.F.R. § 101.14(c), “health claims must be supported by the totality of publicly available scientific evidence, and there must be significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims that this support exists.”

In applying this standard, the FDA has pre-approved twelve claims based on the relationship between a food and the risk of disease or health-related condition.²⁰⁴

In using these pre-approved health claims, the claim must “be stated in a manner so that the claim is an

²⁰²General Requirements for Health Claims for Food, 58 Fed. Reg. 2478 (Jan. 6, 1993) (codified as amended in scattered sections of 21 C.F.R. pt. 101).

²⁰³General Requirements for Health Claims for Food, 58 Fed. Reg. 2478 (Jan. 6, 1993) (citing to H.R. Rep. No. 101-538, at 19 (2nd Sess. 1990)); *id.* at 2505 (stating that the act requires “that there be significant scientific agreement about the support for the claim and the mandate provided in the legislative history of the 1990 amendments that FDA have ‘a high level of comfort that the claim is valid’”); *id.* at 2503 (“Congress intended the scientific standard to be ‘strong.’”).

²⁰⁴These are:

- (1) Calcium and osteoporosis,
- (2) Dietary lipids and cancer,
- (3) Sodium and hypertension
- (4) Dietary saturated fat and cholesterol and coronary heart disease,
- (5) Fiber containing grain products, fruit, vegetables, and cancer,
- (6) Fiber containing grain products, fruit, vegetables, and coronary heart disease,
- (7) Fruit and vegetables and cancer,
- (8) Folate and neural tube defects,
- (9) Sugar alcohols and non-development of tooth decay,
- (10) Soluble fiber from certain foods and coronary heart disease,
- (11) Soy protein and risk of coronary heart disease,
- (12) Plant sterol/stanol esters and coronary heart disease

Specific Requirements for Health Claims, 21 C.F.R. §§ 101.72 – 101.83 (2002).

accurate representation of [the claim] . . . so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.”²⁰⁵

In addition to these pre-approved disease relationship claims, the FDA has promulgated regulations establishing a procedure by which a manufacturer may petition to establish new allowed claims or modify existing ones.²⁰⁶ Otherwise, the FDA intends to proceed on a case-by-case basis in pre-approving further health claims.²⁰⁷

The FDA has used the statutory grant of power to ban “implied” health claims as well, arguably exercising more than its statutorily delegated power.²⁰⁸ The FDA identifies an implied health claim by looking to the “statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.”²⁰⁹

B.

The FDAMA and The FDA

During the period 1990 – 1994, misleading claims practically disappeared, replaced by ‘an orderly’ system for approving claims.²¹⁰ In 1994, Congress passed the Dietary Supplement Health and Education Act, which

²⁰⁵21 U.S.C. § 343(r)(3)(B)(iii) (2000).

²⁰⁶Petitions for Health Claims, 21 C.F.R. § 101.70 (2002).

²⁰⁷General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2506 (Jan. 6, 1993).

²⁰⁸58 Fed. Reg. 2482 – 2488 (Jan. 6, 1993); 21 C.F.R. § 101.14(a) & (e) (2002).

²⁰⁹21 C.F.R. § 101.14(a)(1) (2002).

²¹⁰Heller, *supra* note 197, at 200.

changed the rules for health claims for products that fit within the definition of “dietary supplements.”²¹¹ As a result of these developments, misleading claims again appeared in the marketplace on those products that could now be marketed as dietary supplements.²¹²

Then, the Food and Drug Administration Modernization Act (FDAMA) was enacted on Nov. 21, 1997.²¹³ The FDAMA, inter alia, allows manufacturers to use health claims based on authoritative statements published by a scientific body of the U.S. government.²¹⁴ While FDA approval is not required, the claims must still be authorized by the agency, which is presumed if after 120 days of notice, the FDA has not issued an interim final regulation prohibiting the claim.²¹⁵

Since these statutory changes, the FDA has issued a guidance document for the industry on how to use the new authorization avenue.²¹⁶ This guide outlines the procedures for using this new authorization procedure, and lists the qualified scientific bodies whose authoritative statement can be relied on. This guide also expands upon what constitutes an authoritative statement. The FDAMA itself states that an authoritative statement must be “about the relationship between a nutrient and a disease or health-related condition,” “published by the scientific body,” “currently in effect,” and “shall not include a statement of an employee

²¹¹Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325. The DSHEA was unique in that it limited the power of the FDA for the first time since the FDA’s creation.

²¹²Heller, *supra* note 197, at 200. “Foods” are distinguished from “dietary supplements,” in that to be a supplement, it must not be represented for use as a conventional food, and is not a sole item of a meal or of the diet. 21 U.S.C. § 321(ff). For an analysis of what is required under DSHEA, see Jeffrey A. Crossman, *Mark McGwire Does It, So Why Can’t I? High School Student Use of Dietary Supplements and the Failure of DSHEA*, 28 CAP. U. L. REV. 617, 635 – 55 (analyzing and evaluating the regulation of dietary supplements advertising).

²¹³Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2295.

²¹⁴Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 303, 111 Stat. 2295, 2351, amending 21 U.S.C. § 343(r)(3)(C).

²¹⁵Specifically, the FDA must be given 120 days advance notice of marketing a product with the claim. With this notice, a manufacture must demonstrate that the claim is based on an authoritative statement of a scientific body “with official responsibility for public health protection or research directly relating to human nutrition,” and must submit a balanced representation of the scientific literature on which the claim is based. The claim can be made if within the 120 days the FDA has not issued interim final regulations prohibiting the claim, or the FDA has successfully brought a lawsuit against the company. 21 U.S.C. § 343(r)(3)(C).

²¹⁶Guidance for Industry: Notification of Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body and Agency (June 11, 1998), *available at* www.cfsan.fda.gov/~dms/hclmguid.html.

of the scientific body made in the individual capacity of the employee.”²¹⁷ The FDA further expands upon this, requiring that the authoritative statements “reflect a consensus within the identified scientific body if published by a subdivision of one of the Federal scientific bodies, and be based on a deliberative review by the scientific body of the scientific evidence,” relying on the legislative history of the FDAMA as the basis for its expanded requirements.²¹⁸ The guide goes on to assert that the FDAMA upholds the significant scientific agreement standard for health claims, as under the NLEA.²¹⁹

C.

FTC and Health Claims

Building upon the policies discussed earlier, the FTC encouraged “nondeceptive disease prevention claims” that appeared in food advertising during the mid-1980s, as long as these claims complied with the substantiation and deceptive policy guidelines.²²⁰

After the passage of the NLEA in 1990, the FTC reviewed its advertising policy in regard to foods, and announced on May 13, 1994, a policy to promote consistency in the regulation of food advertising and food labeling claims.²²¹ The stated goal of this policy was to eliminate the confusion from the different standards employed by the FTC and the FDA. The FTC Enforcement Policy Statement provides that the FTC will generally look to the FDA’s labeling regulations in evaluating nutrient content and health claims made in food advertising, acknowledging the specific scientific expertise of the FDA.²²² But the FTC did not com-

²¹⁷21 U.S.C. § 343(r) (2000).

²¹⁸Guidance for Industry: Notification of Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body and Agency (June 11, 1998), *available at* www.cfsan.fda.gov/~dms/hclmguid.html.

²¹⁹*Id.*

²²⁰*See* HUTT & MERRILL, *supra* note 143, at 187. For a good history of FTC regulation of health claims until 1990, see Richard M. Cooper et al., *History of Health Claims Regulation*, 45 FOOD DRUG COSM. L.J. 655, 667 – 77 (1990).

²²¹Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388 (Jun. 1, 1994).

²²²*Id.* at 28,388 – 28,389 (“the Commission also recognizes the scientific expertise of FDA in this area. The Commission has traditionally accorded great weight to FDA’s scientific determinations in matters of nutrition and health and will continue to

pletely accept FDA policy, in that any claim not affirmatively allowed by the FDA will not be presumptively banned, but will be carefully scrutinized for deceptiveness according to the deceptive policy statement.²²³

The FTC announced it would examine health claims on a case-by-case basis.

There is no pre-clearance of advertising claims by the FTC, even if they are health claims. As discussed earlier, the FTC requires that an advertiser should have a reasonable basis that substantiates its claim from the time that the claim is first made. To substantiate a food health claim, the advertiser must have competent and reliable scientific evidence, which has been specifically defined as “tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally adopted in the profession to yield accurate and reliable results.”²²⁴ This is a high standard of substantiation. “In recent years, the Commission has rejected studies, including university studies, that were offered by manufacturer as substantiation for claims, but that the Commission concluded were of insufficient quality.”²²⁵

do so. In addition, as a general matter, it is unlikely that the Commission will take action under Sections 5 and 12 of the FTC Act regarding nutrient content and health claims if they comply with FDA’s regulations.”).

²²³Douglas W. Hyman, *The Regulation of Health Claims in Food Advertising: Have the FTC and the FDA Finally Reached a Common Ground?*, 51 FOOD & DRUG L.J. 191, 191 (1996). See also McNamara, *supra* note 225, at 435 (summarizing that “if a company has sufficient data to substantiate other types of health-related claims that it has used on its labels or in other labeling, so that if questioned by FDA the company can demonstrate that the claims are not false or misleading in any particular, the company is likely thereby also to be in possession of sufficient substantiation to satisfy FTC”).

²²⁴See Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388, at 28,393 (Jun. 1, 1994) (citing to Gracewood Fruit Co., FTC Dkt. No. C-3470 (Oct. 29, 1993) (consent order); Pompeian, Inc., FTC Dkt. No. C-3402 (Oct. 27, 1992) (consent order)).

²²⁵Stephen H. McNamara, *So You Want to Market a Food and to Make Health-Related Claims – How Far Can You Go? What Rules of Law Will Govern the Claims You Want to Make?*, 53 FOOD DRUG L.J. 421, 435 (1998) (citing to *In the Matter of Viobin Corp.*, 108 F.T.C. 385 (1986)(consent)). See also C. Lee Peeler & Susan Cohn, *The Federal Trade Commission’s Regulation of Advertising Claims for Dietary Supplements*, 50 FOOD DRUG L.J. 349 (1995).

D.

Comparison of the FDA & FTC Health Claims Standards

According to the FDA, the “reasonable basis” standard of the FTC conflicts with the FDA’s scientific proof for labeling claims. In withdrawing its 1987 proposal to allow health claims, the FDA explicitly rejected this “reasonable basis standard,” stating that:

FDA is not convinced that this standard is adequate for determining the appropriateness of claims on the food label. As several comments pointed out, it is important that consumers maintain confidence in the food label. Consumers view food labeling as more reliable and trustworthy than food advertising.²²⁶

The FDA also explicitly rejected using the FTC’s substantiation standard when amending its regulations on health claims on dietary supplements, arguing that their statutory mandates are different; that the FDA is a scientific agency protecting the public health while the FTC protects the economic interests of consumers.²²⁷

The FTC does not consider its standards that different from the FDA’s, in that both the FTC’s “competent and reliable evidence” standard and the FDA’s “significant scientific agreement” do not require full consensus among scientists.²²⁸ The FTC concludes that “its is likely that the Commission will reach the same conclusion as the FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food or health-related condition is adequately supported by the scientific evidence” and “[t]he absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission’s assessment of the adequacy of substantiation for the claim.”²²⁹

Health claims represent a unique aspect of regulation in that the FDA is attempting to limit the flow of truthful information to consumers,²³⁰ based upon the concept that even though a health claim might be truthful, it is inherently misleading. The FTC policy seems to be more focused on preventing unsubstantiated claims, while the FDA is taking a more paternalistic stance. While the merits of both standards can be debated, often overlooked is the consumption of agency resources, since many of the same claims are used in both advertising and labeling, or when advertising is also labeling. In these circumstances, the claim will often be evaluated twice, under standards that are highly similar, if not identical.

V.

Conclusion: The Effect of the Dual Agency Structure

Thus, generally, the FTC regulates food advertising, and the FDA regulates food labeling. There is no doubt that the debate over the proper allocation of authority will continue, for it has persisted since the early 1900s.²³¹

The early Supreme Court case *Raladam*, concerning the obesity cure Marmola, implicitly acknowledged one weakness of the dual agency structure. In holding that the FTC did not have jurisdiction to pursue an

²³⁰For an analysis of government regulation of the disclosure of truthful information to consumers and the First Amendment implications, specifically discussing the first Supreme Court commercial speech decision to directly address product labeling controls, *Rubin v. Coors Brewing Co.*, 115 S. Ct. 1585 (1995) (holding that federal regulations prohibiting the disclosure of alcohol content in the labeling of malt beverages violated the First Amendment's protections for commercial speech), see Noah & Noah, *supra* note 189, at 73 – 105. Generally, to survive a First Amendment challenge to commercial speech, there must be a substantial government interest that is directly advanced by the regulation, and the regulation must not be more extensive than necessary to serve that governmental interest. *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

²³¹For a recent article arguing that the FDA should have authority over food advertising, see Roger E. Schechter, *The Death of the Gullible Consumer: Towards a More Sensible Definition of Deception at the FTC*, 1989 U. Ill. L. Rev. 571, 580 n.53 (1989) (“[O]ne should distinguish between products that are intrinsically harmful to consumers, such as dangerous toys, and those where the risk of physical harm flows from deception, such as useful medicinal products which can be harmful when advertisements deceive consumers into using the products in excessive quantities. When products fall in the former category, a more appropriate legal response may be to regulate or ban the sale of the product, not to insist that the manufacturer advertise the harmful item in a different fashion. Thus, agencies like the Consumer Products Safety Commission and the Food and Drug Administration should have primary responsibility in cases of this sort rather than the FTC.”).

action against the manufacturer because the existence of competition was not proven, the Court stated that “[w]hether the respondent, in what it was doing, was subjecting itself to administrative or other proceeding under the statute relating to the misbranding of foods and drugs we need not now inquire, for the administration of that statute is not committed to the Federal Trade Commission.” While the barring circumstance in this case was soon corrected by the 1938 statutory enactments, this case demonstrates the weakness of the dual enforcement structure, in terms of agency and court resources, as well as costs to the public because of delays and inefficiencies. This company, whose product by all accounts was causing deaths, was not enjoined until 1942, 14 years after the first complaint by the FTC.²³²

The coordinated action concept has worked well in many instances. For example, the FDA has withdrawn claims in order not to prejudice a possible future proceeding by the FTC under section 5.²³³ On another occasion, the FTC charged a defendant with falsely advertising the effectiveness of a product, and at the same time, the FDA filed a seizure and condemnation action, thus effectively blocking all sales of the product. The defendant ultimately reached a settlement with both the FTC and the FDA.²³⁴

In practice, the liaison has been less formal than intended by the Memorandum of Understanding, with informal contacts continuing between agency members.²³⁵ The FTC has often used the specialized scientists at the FDA to help with the analysis of the truthfulness of advertising claims. However, sometimes the FTC carries some rulings beyond the point at which the FDA can scientifically agree with.²³⁶

²³²F.T.C. v. Raladam Co., 62 S.Ct. 966 (1942).

²³³See, e.g., United States v. An Article of Drug ... Ova II, 414 F. Supp. 660 (D.N.J. 1975).

²³⁴Federal Trade Commission Press Release (Dec. 13, 1991); United States v. Various Articles of Device.. which include Sporidicin, 1992-1 Trade Cas. (CCH) ¶ 69,768 (D. Md. 1992). Other example of FDA and FTC cooperation can be found at Novartis Corp., FTC Dkt 9279, Trade Reg. Rep. (CCH) ¶ 24,399 (March 19, 1998) (over-the-counter drug efficacy claim); In re Levey, FTC Dkt C-3459, Trade Reg. Rep. (CCH) ¶23,415.

²³⁵See O'REILLY, *supra* note 6, §24.02.

²³⁶*Id.*

There are also legal ramifications of the dual agency structure. Early cases held that a decision in a prior FDA action was *res judicata* in a following FTC action.²³⁷

But there is another side to this dual structure. While the agencies have coordinated enforcement action, the honest manufacturers who want to comply with the law must understand this division of labor and how the misbranding standards might differ. Not only are there consumed resources on the agency-side in this dual system, but the manufacturers must evaluate their claims and try to anticipate both the FDA's and FTC's reaction to any proposed claims. By regulating advertising and labeling, the government changes businesses' costs of providing market information.²³⁸

Both the FTC and the FDA justify the differences in their misbranding standards as being required by the FTC Act and the FDCA respectively, with the FDA asserting that it is obligated to be highly protectionist in its standards. Comparatively, the FTC views its purpose as to ensure accurate and non-misleading information is presented to the public, but it does not consider protecting consumers from themselves within this purpose.

But how protectionist *should* the FDA and FTC be? Should the FTC adopt the more paternalist standards of the FDA? In a recent article on market manipulation, Jon Hanson and Douglas Kysar noted:

²³⁷See, e.g., *United States v. Willard Tablet Co.*, 141 F.2d 141 (7th Cir. 1944) (holding that the facts found by the FTC are conclusive and binding upon this action by the FDA); *George H. Lee Co. v. F.T.C.*, 113 F.2d 583 (8th Cir. 1940). See also *Sekov Corp. v. United States*, 139 F.2d 197 (5th Cir. 1943) (declining to invoke *res judicata* since the issues in the earlier FTC case were different than those in this FDA case); *United States v. Five Cases . . . Capon Springs Water*, 156 F.2d 493 (2nd Cir. 1946). However, asserting *res judicata* as a defense against a FTC action under section 5 is complicated since the FTC is an independent agency, and not a part of the executive branch, thus privity might not exist between the FTC and other governmental agencies. See *F.T.C. v. Wilcox*, 926 F. Supp. 1091, 1101 – 02 (S.D. Fla. 1995) (action by Postal Service involving the same facts does not act as *res judicata* barring FTC relief); *ROSDEN & ROSDEN*, *supra* note 153, at § 18-99. See also Scott E. Bohon, *Res Judicata as a Weapon of Enforcement of the Federal Food, Drug, and Cosmetic Act*, 9 FOOD DRUG & COSMETIC L.J. 256 (1954); Note, *Res Judicata and Two Coordinate Federal Agencies*, 95 U. Pa. L. Rev. 388 (1947).

²³⁸For a discussion of the economics of food advertising and labeling, in terms of usefulness to the consumer see LORNA ALDRICH, *CONSUMER USE OF INFORMATION: IMPLICATIONS FOR FOOD POLICY* (1999), available at <http://www.ers.usda.gov/epubs/pdf/ah715/>.

Manufacturers of food products, for instance, have learned that labeling a food product seventy-five percent non-fat instead of twenty-five percent fat can greatly increase sales. If consumers behave rationally with respect to product risk attributes, then sales figures would be unchanged regardless of the frame that marketers used to present nutritional information. Nonetheless, consumers do not behave rationally in this respect – frames do matter in product perceptions – and manufacturers are well aware of that fact.²³⁹

Should the FDA and FTC have the same standards for misbranding? While the FDA and the FTC have made significant progress towards cohesive regulation, their differing views on their statutory purpose currently prevents this from happening. But these agencies must change as the world around them changes. As in the last 96 years of federal regulation of the food supply, the market’s demand for information will continue to evolve.²⁴⁰

The next generation of food sales is upon us: the Internet. The FDA has stated that “[m]arketing on the Internet is subject to regulation in the same way as promotional materials (labeling or advertising) in any other media. FDA and FTC are currently engaged in discussions on how to appropriately apply each agency’s authority to sale of products such as vitamins on the Internet.”²⁴¹

And so the debate will continue.

²⁴⁰Betty Campbell, then director of the Office of Food Labeling of the FDA, stated in December of 1999, “The market is moving faster than we can sit down and think things through.” Heller, *supra* note 197, at 198 (citing to a speech by Campbell, to the FDLI annual meeting in December 1998, in FDA Labeling Policy Established Through Enforcement, FOOD REG. WKLY., Jan. 4, 1999, at 4.)

²⁴¹U.S. Food and Drug Administration, *Answers to Stakeholders’ Questions*, at www.fda.gov/oc/fdama/fdamawebcast/stakeholdersquestions/food (Apr. 28, 1999). The FDA has indicated that it will proceed on a case-by-case method in regulating “labeling” on the Internet, since “any rule or guidance on this issue would be quickly outdated due to the ongoing rapid changes in the Internet and its use.” Letter from Margaret M. Dotzel, Associate Commissioner for Policy of the FDA, to Daniel J. Popeo and Paul D. Kamenar, Washington Legal Foundation (Nov. 1, 2001), *available at* www.cfsan.fda.gov/~dms/labwww.html. In this letter, the FDA specifically refused to define absolutely information “presented or available on a company’s Internet website, including hyperlinks to other third party sites” as either labeling or advertising, stating that the “FDA believes that, in certain circumstances, information about FDA-regulated products that is disseminated over the Internet by, or on behalf of, a regulated company can meet the definition of labeling in section 201(m) of the FDCA.”