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Happy Inconsistency: Health Claims Standards at the FTC and FDA

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We live in a society increasingly preoccupied with healthy food. Restaurant menus now include heart smart options, network news programs run segments on teenage vegetarians, consumer groups denounce our beloved movie popcorn, and people dead set against the metric system count fat grams in their light beers. At the same time, of course, the percentage of obese people in our country has reached bulging proportions. In the face of all this, enterprising manufacturers see a way to improve the general welfare—and make a decent profit—by providing healthier foods. Educating the consumer about the benefits of a better diet is necessary to open up new market niches. Health sells, and manufacturers have been understandably eager to seize the day.

The Federal Trade Commission and the Food and Drug Administration regulate the types of messages that food manufacturers can send in their efforts to capture the healthy food market. This paper will explore the relationship between the regulatory approaches at the FTC and FDA. The first section delves into the history of and statutory authority for each agency's approach. The second section compares the current official regulatory stance toward health claims at the FTC and FDA, and analyzes the recent rumblings for harmonization. The third section explores public statements by FTC officials that may reveal more practical policy. The fourth section analyzes whether recent enforcement actions reflect the drive toward harmonization. Finally, the fifth section examines the reasons for vestigial inconsistencies at the agencies, and argues for a

flexible approach.

I. Background

A. History, Statutory Authority, and Culture

The FTC derives authority to regulate product claims from § 5 of the Federal Trade Commission Act. Specifically, § 5 prohibits unfair or deceptive acts or practices in or affecting commerce.¹ §§ 14 and 15 of the FTC Act prohibit food advertisements, other than labeling, that are misleading in a material respect.² FDA, on the other hand, derives its regulatory authority from the Food, Drug, and Cosmetics Act. This statute broadly prohibits the misbranding of any food in interstate commerce³, then declares food to be misbranded if its labeling is false or misleading in any particular⁴. A food is also deemed to be misbranded if its label contains health-related information that fails to adhere to detailed agency regulations designed to contextualize it.⁵

The statutory language in the FTC Act seems to provide the Commission with a broad mandate, and in fact the early cases establish that both agencies could regulate food labeling claims under their respective statutes.⁶ In addition, food manufacturers making identical false claims on food labeling and in other advertising media are subject to concurrent attack by the FTC

¹15 U.S.C. § 45 (1988).

²*Id.*

³21 U.S.C.A. § 331 (1996).

⁴21 U.S.C.A. § 343(a) (1996).

⁵21 U.S.C.A. § 343(r) (1996).

⁶*Fresh Grown Preserve Co. v. FTC*, 125 F.2d 917 (2d Cir. 1942).

and FDA. The FTC could issue a cease and desist order while FDA pursued a seizure action.⁷

In 1954, the FTC and FDA entered into a Memorandum of Understanding regarding the regulation of food manufacturer claims. The FTC agreed to focus on food advertising, while FDA assumed responsibility for food labels.⁸ At times, this system of bifurcated oversight has led to significantly different standards for food product health claims on labels versus other advertising media. For example, the FTC has generally allowed manufacturers to promulgate reasonably substantiated health claims for their food products.⁹ FDA, on the other hand, has opted for a more rigid regulatory regime, one which requires a great deal of evidence before a health claim can be made.

To some extent, regulatory cultures at the FTC and FDA contribute to the divergence in food health claims standards. Differing statutory mandates in turn influence the cultures. The FTC is charged with preventing only deceptive or unfair advertising practices.¹⁰ The statutory language is prophylactic and reactive, and seems to contemplate egregious manufacturer representations. Accordingly, the Commission has traditionally eschewed the pre-clearance style of regulation in favor of post hoc enforcement. In the deregulatory heyday of the 1980s, the FTC began to encourage truthful and non-misleading health claims for food products.¹¹

⁷United States v. Various Quantities... Instant Alberty Food, 83 F.Supp 882 (D.C. 1973).

⁸Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) 9850.01 (1971).

⁹See, e.g., Peter Hutt, Government Regulation of Health Claims in Food Labeling, 41 FOOD DRUG COSM. L.J. 3 (1986) (hereinafter referred to as Hutt).

¹⁰15 U.S.C. § 45 (1914).

¹¹See Hutt.

FDA, on the other hand, declares itself responsible for ensuring that foods are safe, wholesome, and sanitary... and regulated products are honestly, accurately and informatively represented.¹² Recent legislation has also charged FDA with educating the public about health issues¹³, and indeed FDA itself has declared its intention to assist the media, consumer groups, and health professionals in providing accurate, current information about regulated products to the public.¹⁴ FDA's rigorous health claims standards reflect its vigilance in protecting the integrity of the food label. FDA surveys indicate that the level of consumer confidence in the honesty/integrity/truthfulness of the food label is very high¹⁵, and accordingly the agency takes pains to maintain its reliability.

B. Judicial Interpretations

Interestingly, the courts have used a wide variety of standards to determine whether a label or an advertisement is deceptive under the FTC Act or misleading under the FD&C Act. In actions brought under the FD&C Act, several judges have concluded that the purpose of the legislation is to protect the ignorant, unthinking, and the credulous.¹⁶ Any other construction, it was said, would open a loophole through which those who prey upon the weakness, gullibility, and superstition of human nature can escape the consequences of their actions.¹⁷ Others, however, have interpreted the FD&C Act to contem-

¹²FDA mission statement at www.fda.gov.

¹³Nutrition Labeling Education Act, 21 U.S.C.A. 343(r).

¹⁴FDA mission statement at www.fda.gov.

¹⁵55 Fed. Reg. 5176, 5286 (February 13, 1990)

¹⁶U.S. v. 62 Packages... Marmola Prescription Tablets, 48 F.Supp. 878 (W.D. Wis. 1943); U.S. v. Article Consisting of 216 Cartoned Bottle... Sudden Change, 409 F.2d 734 (2d Cir. 1969)

¹⁷U.S. v. Sudden Change at 741.

plate a reasonable person standard for consumer confusion.¹⁸ Some courts interpreting the FTC Act have also adopted the ignorant, unthinking, and credulous consumer standard¹⁹ in determining whether an advertisement is deceptive or not. In fact, the 2nd Circuit declared that the remedial purpose of the Federal Trade Commission Act is sufficiently analogous to that of the Food, Drug and Cosmetics Act to justify the identical ignorant consumer standard.²⁰ Many courts, however, rely on something approaching the reasonableness standard. For example, one court acknowledged the traditional ignorant, unthinking and credulous standard, but warned that neither the courts nor the Commission should freely speculate that the... public will place a patently absurd interpretation on an advertisement.²¹ Another court analyzed an advertisers' claims under a commonsense net impression standard.²² Still another court have required that the advertisement mislead an appreciable segment of the public to be deceptive under the FTC Act.²³ Regardless of the consumer standard, it is settle doctrine that an advertisement susceptible of more than one interpretation is deceptive if any of the interpretations are false.²⁴

II. Current Agency Enforcement Regimes

¹⁸U.S. v. Pinaud, Inc., 1938-1949 FDLI Jud. & Admin. Rec. 526 (S.D.N.Y. 1949); U.S. v. Vrilium Products, Co., 1949-1950 FDLI Jud. & Admin. Rec. 210 (N.D. Ill. 1950).

¹⁹Aronberg v. FTC, 132 F.2d 165 (7th Cir. 1942); Charles of the Ritz Dist. Corp. v. FTC, 143 F.2d 676 (2d. Cir. 1944); Heinz v. Kirchner, 63 F.T.C. 1282, 1290 (1963), aff'd, 337 F.2d 751 (9th Cir. 1964).

²⁰U.S. v. Sudden Change at 741.

²¹Standard Oil of California v. FTC, 577 F.2d 653, 657 (9th Cir. 1978).

²²Removatron International Co. v. FTC, 884 F.2d 1489 (1st Cir. 1989).

²³Enurtone Co. v. FTC, 285 F.2d 879 (9th Cir. 1960).

²⁴Country Tweeds, Inc. v. FTC, 326 F.2d 144 (2d. Cir. 1963); Continental Wax Co. v. FTC, 330 F.2d 475 (2d Cir. 1964); Craswell, Interpreting Deceptive Advertising, 65 B.U. L. Rev. 658 (1992) (hereinafter Craswell).

While the courts have evinced some confusion about the extent of the protective mandate, the agencies have promulgated regulations and issued statements of policy that better reflect their own internal enforcement philosophies. Because the FTC and FDA wield so much discretionary power, and because so few cases are actually litigated under the applicable statutes, these declarations are far better indicators of the regime under which food manufacturers must operate.

A. The FDA Standard – Rigid but Detailed

In 1990 Congress passed the Nutrition Labeling Education Act, which added § 343(r) to the FDCA.²⁵ In addition to directing FDA to standardize and limit terms on food labels, this amendment also broadened requirements to disclose nutrition information. Congress intended that the new regulations educate consumers about healthy dietary practices.²⁶ § 343(r) tightens the regulatory screws in two major areas of food labeling: nutrient content claims and broader health claims.

1. Nutrient Content Claims

§ 343(r)(1)(A) of the NLEA forbids nutrient content claims that depart from the strict guidelines fleshed out in detailed FDA regulations.²⁷ Examples of nu-

²⁵21 U.S.C.A. § 301 et seq. (1988).

²⁶House Committee on Energy and Commerce, Nutrition Labeling and Education Act of 1990, H.R. Doc. No. 538, 101st Cong., 2d Sess. 9-10 (1990).

²⁷21 U.S.C.A. § 343(r)(1) (1996).

trient content claims include phrases like low sodium, contains 100 calories, high in oat bran, or healthy, contains 3 grams of fat.²⁸ Any nutrient content claim on a food label must be accompanied by a prominent referral statement, which directs the consumer to See [panel] for nutrition information.²⁹ Furthermore, FDA authorizes only a limited set of words (and reasonable spelling variations) for use in nutrient content claims.³⁰ Presumably, these measures minimize consumer confusion and further FDA's educational goals.

FDA prescribes a detailed series of metrics to validate absolute and comparative nutrient content claims. For example, claiming that a food is a good source of a particular nutrient is an absolute claim that requires that each serving of the food contain 10-19% of the RDI of that nutrient. Likewise, declaring that a food has more of a particular vitamin is a comparative claim that requires that each serving contain at least 10% more of the RDI for that vitamin than the reference food.³¹ A manufacturer making a comparative claim must specifically identify the reference food (e.g., Brand X) and include both absolute and percentage comparisons.

Manufacturers may draw from a short list of narrowly defined words in making their claims. These include more, less, reduced, added, extra, light, high, low, and a few others. In a meager effort to placate hamstrung marketers, FDA also allows manufacturers to use a few synonyms. For instance, manufac-

²⁸21 C.F.R. 101.13(b).

²⁹21 C.F.R. 101.13(g).

³⁰21 C.F.R. 101.13(b)(4).

³¹21 C.F.R. 101.54.

turers may substitute rich in or excellent source of for high.³²

FDA also places restrictions on implied nutrient content claims. These are defined as representations that (1) describe the food in manner that suggests the presence or absence of a particular nutrient (e.g., contains oat bran) or (2) suggest in connection with an explicit nutrient claim that the food may be useful in maintaining a healthy diet (e.g., healthy, contains 3 grams of fat).³³ Implied claims must not only comply with the general requirements for nutrient content claims, they must also satisfy the performance metrics laid out in the regulations. For instance, labeling claims that indicate a food contains oat bran are only allowed when that food qualifies as a good source³⁴ of dietary fiber. Similarly, marketers seeking to use any variation on the word healthy in the food label must ensure that the food meet FDA's standards for fats, saturated fats, sodium, cholesterol, and various vitamins and minerals. FDA's regulatory oversight in this area is astoundingly precise.

FDA's regulations also require manufacturers to disclose certain information if the food contains prescribed levels of risk-increasing nutrients. Foods containing specified levels of fat, saturated fat, cholesterol, and sodium must modify the mandatory nutrition panel referral statement to signal the dangerous nutrient level. For example, a food containing more than 13 grams of fat per serving must direct the consumer to See side panel for information about total fat and other nutrients.³⁵

³²*Ibid.*

³³21 C.F.R. 101.13(b)(2).

³⁴See *supra*, footnote 31.

³⁵21 C.F.R. 101.13(h).

2. Health Claims

§ 343(r)(1)(B) severely limits broad claims linking food nutrients to disease or other health-related conditions. If a food contains certain prescribed levels of a risk-enhancing nutrient (e.g., 4 grams of saturated fat), then its label will be disqualified from making any health claim whatsoever.³⁶ In addition, the food must contain at least 10% of the Reference Daily Intake or Daily Reference Value for a number of vitamins and minerals in order to promote any health claim on its label.³⁷ This is the so-called jelly bean rule, which no doubt intends to prevent manufacturers from loading their non-nutritive goodies with enough calcium, for instance, to declare them a bone-saving miracle.

In perhaps the most important provision of the NLEA, Congress indicated that FDA should only allow health claims about which there is significant scientific agreement based on the totality of publicly available evidence.³⁸ The standard is broad—some would say vague—but FDA explicitly refused to formulate parameters of scientific certainty in its regulations. The agency did cite a number of important factors in its analysis. It agreed to consider well designed clinical studies, animal studies, and epidemiological data, for instance, but, quite naturally, it declared a preference for human studies.³⁹ While FDA stopped short of requiring consensus or unanimity in the scientific community, it

³⁶21 C.F.R. 101.14(a)(5).

³⁷21 C.F.R. 101.14(e)(6).

³⁸21 U.S.C.A. § 343(r)(3)(B).

³⁹58 FR 2478 at 2506.

nevertheless cited NLEA legislative history indicating that the Secretary should have a high level of comfort that the claim is valid before approving it.⁴⁰ FDA also hinted that while proprietary research would not be ignored, findings in peer reviewed research journals may carry extra weight.⁴¹ Inevitably, FDA must take a case-by-case approach.

To date, FDA has approved ten health claims. These range from statements linking calcium-rich diets with the prevention of osteoporosis⁴²; diets low in cholesterol, saturated fats, and total fats with the reduction of the risk of heart disease⁴³; and, most recently, diets high in soluble fiber from whole oats with the reduction of heart disease.⁴⁴ In a recent full-page print advertisement, Quaker Oats characterized this last claim as the first authorization of a food specific health message.⁴⁵ Pursuant to the educational mandate outlined in the statute itself, FDA's regulations require that health claims indicate the value of the ingested substance as part of a total dietary pattern. In addition, the regulations suggest that if other non-dietary factors affect the disease or health-related condition, they may need to be addressed in the health claim.⁴⁶ The FDA regulation authorizing each specific claim offers model language to fulfill these requirements. For example, claims about calcium and osteoporosis must explain how gender, age, ethnicity, and exercise affect the relationship between

⁴⁰56 FR 60,537 at 60,547.

⁴¹*Ibid.*

⁴²21 C.F.R. 101.72.

⁴³21 C.F.R. 101.75.

⁴⁴Health Claims on Oatmeal May Be Made, *New York Times*, January 22, 1997, A10.

⁴⁵Now he has another reason to smile! (advertisement), *The New York Times* (January 23, 1997), A15.

⁴⁶21 C.F.R. 101.14(d)(2)(iii).

calcium consumption and osteoporosis.⁴⁷ Model language can be paraphrased, as long as mandatory elements are addressed.⁴⁸

The limited number of available health claims indicates that FDA is proceeding cautiously in this area. The agency must not only distinguish between substantiated health benefits and puffery, it must also distill sophisticated scientific relationships into information the public can comprehend. Undoubtedly, FDA's concerns about information overload and the integrity of the food label underlie its conservative approach in this area.

B. The FTC Standard – Harmonization Lite

While the FTC has traditionally encouraged substantiated health representations to educate consumers⁴⁹, in recent years the Commission has been pressured to harmonize its policy with that of FDA. The Center for Science in the Public Interest (CSPI), for instance, has repeatedly blasted the FTC for its unwillingness to implement harmonization.⁵⁰ In addition, some legislators have attempted to mandate a uniform standard—the more stringent FDA version—with regard to health claims across advertising and labels.⁵¹ The concerned parties evidently regard the barrage of health claims advertising spawned by

⁴⁷21 C.F.R. 101.72.

⁴⁸58 FR 2510.

⁴⁹Elisabeth Sachs, *Health Claims in the Marketplace: The Future of the FDA and the FTC's Regulatory Split*, 48 *Food & Drug L.J.* 263 (1993) (hereinafter *Health Claims in the Marketplace*).

⁵⁰See, e.g., John Donnelly, *Consumer Group Blasts Health Claims in TV Milk Ads*, *Food & Drink Daily* (March 6, 1995); *CSPI Hits FTC's Proposed Consent Order with Haagen-Dazs*, Vol. 3, No. 21 *Food Labeling News* (February 23, 1995).

⁵¹*Health Claims in the Marketplace* at 263-64.

FTC's mid-1980's policy as coercive and harmful to consumer health. They may also feel that differing standards across advertising media confuse consumers and potentially undermine the cherished integrity of the food label.

In response to these attacks, in 1994 the FTC issued a 28 page Enforcement Policy Statement on Food Advertising (hereinafter EPS).⁵² Ostensibly intended to create a consistent regulatory framework across the agencies, the EPS nevertheless stops short of adopting all of FDA's stricter standards. The document is a fascinating series of earnest deferrals and pointed reservations. Even the ringing words of cooperation in the introduction eventually subvert themselves: The Commission recognizes the importance of consistent treatment of nutrient content and health claims in food advertising and labeling and seeks to harmonize its advertising enforcement program with FDA's food labeling regulations *to the fullest extent possible under the statutory authority of the FTC Act*.⁵³ (emphasis added). From the outset the EPS carefully confines the scope of its action.

Despite the dissembling, however, it is clear that the EPS intends to increase the level of harmonization between FDA and the FTC. FDA has characterized the document as establishing that food advertising will now be held to the same standards as food labeling.⁵⁴ This seems a bit overstated, though, because in many areas the EPS indicates that the FTC will depart from FDA's nutrient and health claim standards. The EPS does seem to acknowledge FDA's regulations as the baseline, however, by declaring that it is unlikely that the

⁵²1994 Policy Statement, 59 Fed. Reg. 28,388.

⁵³*Ibid.*

⁵⁴FDA Consumer, Sept. 1994.

Commission will take action under Section 5 and 12 of the FTC Act... if [the health claims] comply with FDA's regulations.⁵⁵ Perhaps this will encourage advertisers to rein in some of the more aggressive campaigns.

One indication that the EPS fails to harmonize agency policies is its explicit reliance on traditional interpretations of FTC statutory authority. In a section of the statement entitled Legal Framework for Commission Action, the Commission refers to its 1984 Deception Policy Statement (Deception Statement) and 1987 Statement on Advertising Substantiation (Substantiation Statement) as defining the principles for interpreting deceptive acts or practices under the FTC Act.⁵⁶ These documents were promulgated at the height of the deregulatory heyday at the FTC, during which the Commission visibly broke with FDA over the costs and benefits of a looser standard of substantiation for food product health claims.⁵⁷

The Deception Statement indicates that an advertisement will be unlawful if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material.⁵⁸ While claims involving health or safety are presumptively material⁵⁹, the Deception Statement clearly rejects the ignorant, unthinking, and credulous standard adopted by so many courts in early interpretations of both the FTC and FD&C Act. Rather than focusing on specific claims or

⁵⁵1994 Policy Statement, 59 Fed. Reg. 38,388.

⁵⁶*Ibid.*

⁵⁷Evidence of the FTC's regulatory stance can be found in the Comments of the Bureaus of Competition, Consumer Protection, and Economics of the FTC in Response to a Request for Public Comment on its Advance Notice of Proposed Rulemaking Regarding Food Labeling, Dkt. 85N-0061, 55 Fed. Reg. 5176 (Feb. 1990).

⁵⁸1994 Policy Statement, 59 Fed. Reg. 38,388.

⁵⁹*Ibid.*

taboo phrases, the FTC instead pursues a case-by-case approach that looks to whether the overall impression created by the ad is deceptive.⁶⁰

The Substantiation Statement requires that advertisers have a reasonable basis for making their health claims.⁶¹ The EPS declares that [a] reasonable basis consists of competent and reliable evidence.⁶² Interestingly, the EPS cites a series 1992 cases as defining the nature of competent and reliable. In this respect the FTC's new standard is in fact backward-looking and deferential to earlier FTC policies. The FTC further states:

Commission orders generally require that scientific evidence consist of tests, analyses, research, studies or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the relevant profession to yield accurate and reliable results. The substantiation must also be examined in the context of the entire body of relevant evidence, particularly if it produces results that are contrary to that body of evidence.⁶³

While this standard implies a good deal of rigor, in the past it has been interpreted as somewhat less stringent than FDA's significant scientific agreement standard. In any case, because the FTC and FDA lay out substantiation requirements in different language, clever lawyers have an opportunity to carve out distinctions in regulatory policy, whether or not those distinctions were intended.

1. Nutrient Content Claims

In spite of the EPS's deference to hoary FTC doctrine, in several specific

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² *Ibid.*

⁶³ *Ibid.*

circumstances the FTC explicitly adopts FDA's regulatory approach. For instance, the EPS states that the Commission will apply FDA's definitions for absolute nutrient content terms when those terms are used in the same context in advertising.⁶⁴ Concerned about consumer expectation that nutrient content terms are consistently applied, the Commission also indicated that it would continue to defer to FDA's scientific and public health determinations.⁶⁵ Given the historical discord regarding the regulation of semi-substantiated health claims, it is unclear just how much cooperation continued deference will engender.

In the arena of comparative nutrient content claims, the EPS cites FDA's guidelines as safe harbors from Commission action. This apparently reflects standard FTC policy since the passing of NLEA.⁶⁶ However, the Commission also states that a comparative advertising claim that is accurately qualified to identify the nature of a nutrient difference and to eliminate misleading implications may comply with Section 5, *even if the nutrient difference does not meet FDA's prescribed differences for purposes of labeling.*⁶⁷ (emphasis added) While declaring its intention to carefully scrutinize those claims that depart from FDA's guidelines, the EPS clearly authorizes appropriately qualified health claims. Rather than adopting FDA's bright line rules, the FTC stands fast with its traditionally broader test of whether the overall impression of the advertise-

⁶⁴*Ibid.*

⁶⁵*Ibid.*

⁶⁶See, e.g., Nestle Food Co., FTC Dkt. No. C-2265 (Jan. 21, 1992) (consent order) (permitting representations authorized by FDA's food labeling regulations).

⁶⁷1994 Policy Statement, 59 Fed. Reg. 38,388.

ment is deceptive.⁶⁸

The EPS offers a specific example of how its flexible standard provides food manufacturers the opportunity to differentiate their products:

[A]n advertiser may seek to signal to consumers that, while it has reduced total fat and saturated fat in its product by 25%, it has also achieved a small reduction in sodium compared with other products in that category. In these circumstances, a truthful claim that makes clear that the sodium reduction is less than the 25% reduction in other nutrients and does not overstate the significance of this incidental reduction is unlikely to mislead consumers.

While it is arguable whether consumers can adequately negotiate the maze of claims and disclaimers involved in this scenario, it seems plausible that consumers would benefit from information about nutrient disparities deemed insignificant under FDA's regulations. Over the course of a day's worth of servings, even small variations in nutrient intake can have a large cumulative impact.

While FDA authorizes only certain synonyms for nutrient content terms, the FTC's Enforcement Policy Statement rejects this approach. However, the Commission does caution that when express or implied claims suggest that a food product meets the standard for use of an FDA-defined term, advertisers should ensure that the food actually meets the relevant FDA standard.⁶⁹

For example,

[U]se of the phrases 'packed with' or 'lots of' to describe the level of fiber in a food could convey to some reasonable consumers that the food is 'high' in fiber. Because FDA's regulations define the terms 'good source' and 'high' with respect to fiber, consumer are likely to be misled if a 'high fiber' claim is implied by an ad for a food that is only a 'good source' of fiber.⁷⁰

Thus, while advertisers are free to experiment with synonyms under the

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

⁷⁰ *Ibid.*

FTC system, they risk regulatory action if their word smiths play fast and loose with FDA's language. As Commission precedent establishes, advertisements susceptible of both misleading and truthful interpretations by the reasonable consumer will be deemed misleading.⁷¹

Both FDA and the FTC employ a case-by-case approach to evaluating implied nutrient content claims. The Commission vows to analyze the overall context of the advertisement rather than prescribe or prohibit specific representations. For instance, in one case the FTC found that claims about the amount of milk in processed cheese slices were implied claims about calcium content.⁷² The FTC standard is vague only because the potential range of implied claims is vast. The FTC's broad discretion may paralyze the would-be advertiser or encourage clever health claim innuendo. Stating its commitment to harmonization, the FTC vows to give great weight to any FDA determinations concerning ingredient statements in analyzing the net impression conveyed by an ad.⁷³ In the end, though, it is likely that traditional regulatory philosophies will dictate practical policy in an area as hazy as this one.

In the area of nutrient content claim disclosures, the FTC explicitly breaks with FDA's approach. Stating that the educational goals of the NLEA... are beyond the scope of the Commission's law enforcement mandate, the EPS announces that the failure to provide nutrition information that consumers may find useful in improving their diet... is not necessarily subject to challenge un-

⁷¹See *supra*, footnote 20.

⁷²1994 Policy Statement, 59 Fed. Reg. 38,388.

⁷³*Ibid.*

der Section 5.⁷⁴ However, where an advertisement conveys the net impression that a food makes only positive contributions to a diet, the failure to disclose the presence of risk-increasing nutrients may be actionable.⁷⁵ In addition, the Commission also pledges to scrutinize advertising claims about cholesterol, saturated fat, and fiber to eliminate inappropriate inferences regarding the overall healthiness of the product.⁷⁶ This parallels FDA's special mandate to police labeling claims in these areas.⁷⁷

2. Health Claims

Perhaps the most interesting section of the EPS concerns the FTC's approach to health claims. In an effort to downplay years of disharmony among the agencies, the FTC first declares that the principles underlying FDA's significant scientific agreement standard for food health claims form the foundation of the Commission's well-established deception and advertising substantiation doctrines.⁷⁸ Later, the EPS again attempts to paper over historical regulatory discrepancies by insisting that [l]ike FDA, the Commission imposes a rigorous substantiation standard for... health claims for food products.⁷⁹

In the past, the FTC's competent and reliable evidence standard had been defined as tests, analyses, research, studies or other evidence based on the exper-

⁷⁴ *Ibid.*

⁷⁵ *Ibid.*

⁷⁶ *Ibid.*

⁷⁷ 21 U.S.C.A. § 343(r)(2)(A)(iii)-(v).

⁷⁸ 1994 Policy Statement, 59 Fed. Reg. 38,388.

⁷⁹ *Ibid.*

tise 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 accepted in the profession to yield accurate and reliable results.⁸⁰ In the abstract, it is difficult to compare this mountain of words to significant scientific agreement. In the real world, however, the FTC generally required a lower level of scientific consensus.⁸¹

With the promulgation of the EPS, however, the FTC appears to have taken a step closer to adopting FDA's health claims approach. For instance, the Statement declares that the 'significant scientific agreement' standard, as set forth in the NLEA and FDA's regulations, [is] the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim.⁸² Accordingly, the Commission admits that it is likely that it will reach the same conclusions as FDA regarding the adequacy of scientific evidence for unqualified health claims.

In keeping with its tradition of looser guidelines, however, the FTC recognizes that there may be certain limited instances in which carefully qualified health claims may be permitted under Section 5 although not yet authorized by FDA, if the claims are expressly qualified to convey clearly and fully the extent of the scientific support.⁸³ While preserving this loophole, the FTC cautions that [f]ood marketers should not expect to circumvent FDA's petition process for health claims simply by limiting the assertion of unapproved or unreviewed

⁸⁰ *Ibid.*

⁸¹ See *supra*, footnote 10.

⁸² 1994 Policy Statement, 59 Fed. Reg. 38,388.

⁸³ *Ibid.*

claims to advertising.⁸⁴ Recognizing the potential confusion that qualifications and disclaimers inevitably engender, the Commission also pledged to be especially vigilant in ensuring that qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community.⁸⁵

The EPS recognizes the merits of prohibiting health claims for foods that contain risk-increasing levels of total fat, saturated fat, cholesterol, and sodium. Accordingly, it states that the Commission will rely heavily on FDA's determination of the operative danger levels. As usual, however, the Commission also indicates that it will not necessarily prohibit all health claims for foods that contain such levels.⁸⁶ By way of illustration,

the Commission would not prohibit a truthful advertising claim that explains in a nondeceptive manner the health advantages of substituting meat or poultry items that are relatively low in fat or saturated fat for higher fat alternatives (e.g., a claim suggesting the merit of substituting skinless breast of turkey for hamburger). Such claims would assist consumers who are trying to improve their diets but who are unwilling to forgo all meat and poultry.⁸⁷

These claims would not be available under FDA's food labeling scheme, because turkey breasts themselves contain risk-increasing levels of fats. Once again, the FTC's tradition of cost-benefit analysis carries over into its harmonization effort.

Interestingly, even before the harmonization effort undertaken in the EPS, the FTC had attacked some unqualified health claims for foods that con-

⁸⁴ *Ibid.*, footnote 79.

⁸⁵ *Ibid.*

⁸⁶ *Ibid.*

⁸⁷ *Id.* at footnote 85.

tained risk-increasing nutrient levels. In the Campbell's Soup case, for instance, the Commission required the manufacturer to disclose the high sodium content of its soups in advertisements making claims about heart disease and cholesterol.⁸⁸ While this may have been an egregious case that triggered the FTC's higher standard of deception, the Commission acknowledges in the EPS that FDA's treatment of health claims in labeling for any food containing a risk-increasing level of a nutrient... could well increase consumers' expectations... that the foods do not present any significant health risks.⁸⁹ This seems to imply that the FTC and FDA health claims policies may eventually converge.

The EPS pays obeisance to FDA guidelines regarding threshold levels of nutrients to qualify for certain health claims (e.g., high enough calcium levels to speak of the beneficent effects on osteoporosis) and minimum nutritional value to qualify for any health claim whatsoever (the so called jelly bean rule).⁹⁰ However, just as in the case of comparative nutrient content claims, the FTC recognizes the value of certain limited instances in which it is possible to craft a qualified, truthful, and nonmisleading claim comparing the relative health benefits of a food product to other products for which the food can be substituted.⁹¹ It appears the FTC will take a highly contextualized approach in evaluating borderline advertisements.

Finally, the FTC cites its limited mandate in declining to adopt FDA model language and disclosure requirements for health claims. As per usual,

⁸⁸Campbell, FTC. Dkt. No. 9223 (Aug. 18, 1992).

⁸⁹1994 Policy Statement, 59 Fed. Reg. 38,388 at footnote 90.

⁹⁰*Ibid.*

⁹¹*Ibid.*

the Commission seeks to prevent deceptive claims rather than ensure consistent ones. The EPS also establishes that omission of even valuable dietary information might not rise to the level of deception under the FTC Act.⁹² The Statement quite sensibly comments that in many forms of advertising it would not be feasible to include all nutritional information that may be of interest to consumers.⁹³ It is quite clear that the Commission is satisfied to let FDA, with its superior scientific resources, lead the way on consumer education about healthier diets.

III. Words to the Wise – Public Comments by the FTC

While the EPS lays out a number of harmonizing principles, its many reservations preserve a good deal of uncertainty in the regulatory scheme for food health claims. Perhaps the document is best understood as an issue-spotter for potentially aggressive advertisers, or maybe an admonition to stay off the thin ice. Like case law, the Statement is often ambiguous or fact-specific, and wary advertisers would do well to supplement its vague guidelines. The public comments of FTC officials, for instance, emphasize particular areas of concern.

In a recent speech before the National Infomercial Marketing Association, for instance, FTC Commissioner Roscoe B. Starek reiterated the traditional reasonable basis requirement for substantiation of advertiser representations. More specifically, he sought to dispel Myth #1 – If a Couple of Studies

⁹²*Ibid.*

⁹³*Ibid.*

Support Your Claim, It Is Substantiated.⁹⁴ In doing so, he urged manufacturers to consider not only contradictory studies and design flaws in successful research, but also whether studies are conducted in a sufficiently independent fashion. If the studies are conducted by persons who ha[ve] an incentive to obtain particular results, [the food manufacturer's] claim may not be substantiated.⁹⁵ While this admonition appears nowhere in the EPS, it has proven important in a recent high-profile regulatory action.⁹⁶

In an earlier speech before the National Food Processors Association, Mr. Starek emphasized the flexibility implicit in the EPS. Advertisers have a green light for claims approved by FDA and a series of clear red lights for non-approved claims, Mr. Starek declared.⁹⁷ He also declared that in areas where there are differences between advertising and labeling, or differences between FTC's and FDA's statutory authority, advertisers faced yellow lights, and should proceed with caution.⁹⁸ Starek further identified synonyms, comparative claims, and health claims as yellow light areas.

Another high level FTC official fleshed out practical administrative policy in a recent interview.⁹⁹ Anne Maher, Assistant Director of Advertising Practices at the FTC, reiterated the Commission's deference to FDA on scientific matters. However, she also stated that for unapproved health claims, FTC

⁹⁴Roscoe B. Starek III, Myths and Half-Truths about Deceptive Advertising, 11-14-96 WLN 12129 (text of prepared remarks by FTC Commissioner Roscoe B. Starek III).

⁹⁵*Ibid.*

⁹⁶See *infra*, Metagenics, Inc., FTC Dkt. No. 9267 (initial decision).

⁹⁷FTC's Ad/Label Policy Sends Clear Signals, Starek Says, 2 Food Labeling News No. 37 (June 16, 1994).

⁹⁸*Ibid.*

⁹⁹FTC Official Cites Close Cooperation with FDA in Monitoring Accuracy of Food Advertising, 4 Food Labeling News No. 46 (August 15, 1996).

might allow an advertiser to veer a little from the FDA regulations.¹⁰⁰ She also acknowledged that the FTC is increasingly concerned with the aggressive marketing of comparative claims, especially the large number of reduced-calorie and reduced-fat representations. Ms. Maher commented, I think it's important to make sure that they're not conveying 'low' claims to consumers.¹⁰¹ Ms. Maher's analysis implicitly recognizes that the FTC's looser standard for comparative claims may have diluted FDA's educational efforts in this area. In singling out regulation of comparative claims for comment, she may have intended to signal the industry to rein in its horses a bit.

Finally, in a recent *New York Times* article Lee Peeler, associate director for advertising practices in the commission's Bureau of Consumer Protection, stated that nutrition advertising claims for both food products and supplement products have been a high priority for us of late. The article also revealed that the FTC has settled 23 food advertising cases since 1990. It settled only two in the previous decade.¹⁰² Either the FTC has stiffened its enforcement policy, or advertisers have gone hog wild under the vague EPS regime.

IV. Recent Enforcement Actions

A. Harmonization – A Few Steps Forward

Recent enforcement actions also shed some light on the relationship between the FTC and FDA health claims standards. In many cases, the agen-

¹⁰⁰ *Ibid.*

¹⁰¹ *Ibid.*

¹⁰² Marian Burros, Eating Well – Enforcing Truth in Nutrition Claims, *The New York Times*, January 8, 1997.

cies have been in accord. Just after the FTC promulgated its EPS, for instance, it resolved the Stouffer Foods case,¹⁰³ in which the manufacturer had made a low sodium claim that failed to conform to FDA's definition. Explicitly relying on FDA's scientific judgment, the Commission found the advertisement per se deceptive.

In a recent consent decree, the FTC required Unilever United States, Inc., one of the nation's largest manufacturers of margarines and spreads, to alter its advertising campaign for Promise margarine to conform with many of FDA's labeling standards. The campaign used a Get Heart Smart slogan, included heart-shaped pats of Promise on pancakes, and displayed statements like Low in Saturated Fat and No Cholesterol.¹⁰⁴ The FTC decided that the campaign was a deceptive health claim, because Promise contained levels of total fat high enough to be disqualified from making any health claim under FDA's regulations. Furthermore, the FTC required the manufacturer to adhere to FDA's requirements for the low fat designation, and also called for disclosure of the total grams of fat in conjunction with any cholesterol claims.¹⁰⁵ An FTC official admitted that Promise margarine is probably healthier than butter, but attacked the campaign as insufficiently qualified. In this situation the Commission seemed willing to forsake its traditional encouragement of comparative claims in favor of a more harmonized, rigorous approach.

Three other FTC consent orders indicate a more harmonized standard.

¹⁰³Stouffer Foods Corporation (1994), FTC Dkt. No. D-9250 (September 26).

¹⁰⁴Promise Margarine's Get Heart Smart Campaign Targeted in FTC Deceptive Advertising Case, FDCH Federal Department and Agency Documents, FTC, November 7, 1996.

¹⁰⁵*Ibid.*

In the Mrs. Fields case, the FTC ordered the manufacturer to reclassify its low fat cookies because they failed to conform to FDA's metric for the low fat descriptor.¹⁰⁶ In the Good News Eggs case, the FTC forbade the manufacturer from making representations about the effect of its product on heart disease or serum cholesterol levels. The consent order allowed the manufacturer to reformulate its claims under FDA's standards.¹⁰⁷ Finally, just a few days ago the FTC signed a consent agreement with Uno's Pizzeria over its low fat thin crust pizza claims.¹⁰⁸ The order called for the manufacturer to adhere to FDA's low fat guidelines, i.e., 3 grams of fat per serving. The pizzas at issue contained anywhere from 14 to a whopping 36 grams of fat per serving.

One other recent enforcement action illustrates the rigor of the FTC's current scientific substantiation requirement. The FTC attacked Metagenics, Inc. for claiming that its calcium supplement (1) restores lost bone, (2) restores bone strength, (3) reduces or eliminates pain associated with bone ailments, (4) is more effective than other calcium supplements in treating bone ailments, (5) is more bioavailable than other forms of calcium, (6) builds bone or increases bone thickness, (7) halts or prevents bone loss or thinning, and (8) halts, prevents, or treats osteoporosis.¹⁰⁹ An FTC Administrative Law Judge (ALJ) upheld the FTC on the first five charges, yet found the final three claims to be adequately substantiated. Interestingly, the three accepted claims most closely con-

¹⁰⁶FTC, Mrs. Fields Settle Complaint about Fat Content of Cookies, Food Labeling News (March 7, 1996).

¹⁰⁷Good News Products Settles FTC Charges Over Egg Claims, The Food Institute Report (June 12, 1995).

¹⁰⁸Marian Burros, Pizza Chain to Withdraw Its Low Fat Claims, The New York Times, January 23, 1997, A21.

¹⁰⁹FTC Law Judge Finds Calcium Supplement Ads Misleading, 4 Food Labeling News No. 5 (October 31, 1996).

formed to FDA's regulations for calcium/osteoporosis representations.¹¹⁰ The ALJ decried the source of substantiation—published, peer-reviewed studies by Metagenics CEO Jeffrey Katke—as dubious.

B. Harmonization – A Few Steps Back

Despite the examples of harmonization, however, in many cases the FTC and FDA still diverge. A year after the FTC issued the EPS, for example, the Center for Science in the Public Interest (CSPI) criticized the Commission for failing to act against certain health claims in advertisements for whole milk.¹¹¹ The milk industry's television commercials had declared They say milk and simple exercise can help prevent osteoporosis. While it is doubtful that this claim hewed close enough to FDA's model message for osteoporosis, there is no question that it violated the agency's prohibition against health claims for products high in saturated fats and cholesterol.¹¹² The National Food Processors Association defended the advertisement as an appropriate use of limited space to impart one important piece of health information.¹¹³

Around the same time, CSPI again attacked the FTC over its consent agreement with Haagen-Dazs for its failure to fully integrate FDA fat disclosure rules. While the consent order did call for Haagen-Dazs to comply with the 3 fat grams low fat metric in its frozen yogurt bars, it neglected to require the

¹¹⁰21 C.F.R. 101.72.

¹¹¹John Donnelly, Consumer Group Blasts Health Claims in TV Milk Ads, *Food & Drink Daily* (March 6, 1995).

¹¹²21 C.F.R. 101.14(a)(5).

¹¹³See *supra*, footnote 106.

manufacturer to include a nutrition panel referral statement in direct proximity to the claim, as required by FDA. CSPI also called for the FTC to implement proactive guidelines a la FDA, rather than pursue its case-by-case retroactive approach.¹¹⁴ Given the time and space constraints of various advertising media, CSPI's complaints appear a bit blustery here.

V. The Attainable Ideal – A Happy Inconsistency

The gaps and inconsistencies between health claims regulation at the FTC and FDA have spawned a great deal of debate. Which approach better serves the public health? As is probably clear from the cases mentioned, CSPI is outraged by the FTC's failure to adopt the NLEA and FDA's consequent regulations. Calling the ESP a Recipe for Consumer Confusion, CSPI has attacked FTC flexibility on comparative nutrient content claims, disclosures, and health claims for comparatively healthy substitutes (e.g., chicken for beef).¹¹⁵ As evidence, a high level CSPI official has cited a survey indicating that 76% of consumers believe too many foods already claim to be healthy.¹¹⁶ CSPI evidently believes that lower substantiation standards dilute the authority of more valid claims.

Other commentators have declared the EPS a loophole bigger than the Washington beltway.¹¹⁷ In Congress, Representatives Al Swift (D-Wash.)

¹¹⁴CSPI Hits FTC's Proposed Consent Order with Haagen-Dazs, 3 Food Labeling News 21 (February 23, 1995).

¹¹⁵CSPI Asks Congress to Look at Loopholes in FTC Harmonization Policy, 2 Food Labeling News No. 36 (June 9, 1994).

¹¹⁶Food Marketing Institute, Shopping for Health (1995), Washington, D.C.

¹¹⁷Angela Shah, FTC to Require Food Ads to Follow FDA Label Guides, Wall Street Journal

and John Moakley (D-Mass.) have applauded the EPS as a good faith effort to achieve harmonization, but have also pledged to pursue further legislation should the FTC fall short of meeting the goals of the NLEA.¹¹⁸ These Congressmen have been working closely with CSPI.

Despite the shrill cries of protest, there are solid reasons for the FTC to maintain its more flexible regulatory standards. First, there is some evidence that the relaxed health claims standards of the 1980's contributed to significant reductions in average fat consumption during that period. From 1977-1990, men's fat consumption fell from 112.8 grams per day to 92.6 grams per day, and women's consumption fell from 73.3 grams per day to 62.1 grams per day.¹¹⁹ Researchers also found that consumers make better choices when companies can compete on nutritional characteristics. The results of this study illustrate the value of the market as an information-forcing mechanism and refute CSPI's concerns about oversimplification of health claims and deception of consumers.

Affording manufacturers an outlet for comparative health claims is another good reason for maintaining inconsistent regulatory approaches at the FTC and FDA. While one might not wish to sully the integrity of the food label with less substantial claims, surely print or television media are an appropriate place for a nutrition war. Just as incremental price slashing often yields a hefty cumulative discount over a very short time, so might marginal fat reductions soon create the guiltless hot fudge sundae. Under the strict FDA

(May 16, 1994), A6.

¹¹⁸Reps. Support FTC Ad/Label Policy, Promise to Monitor it Closely, 2 Food Labeling News No. 13 (October 13, 1996).

¹¹⁹Study Links Decrease in Fat and Cholesterol to Rise in Nutrition Labeling, Advertising, 2 Food Labeling News 5 (October 17, 1996).

approach, manufacturers have no incentive to implement marginal changes. For some products, immediate wholesale changes may be impossible, or at least inconceivable. Why penalize the sure-footed tortoise in favor of the unreliable hare?

The FTC's looser standard for affirmative disclosures is another area where inconsistency makes sense. By requiring disclosure only when an advertisement would otherwise be deceptive, the FTC sets up a flexible scheme that promotes creative packaging of health messages while reserving broad authority to act. The FTC's style of oversight recognizes that the simplest messages are the most effective. Disclaimers and other clutter confuse more than inform, and television and radio media are particularly unsuited to accommodate a broad range of disclosures. Provided they adhere to a truthful and nonmisleading standard, uncluttered advertisements best accomplish the NLEA's educational mission.

Some might feel that the FTC's flexibility on FDA model language and restricted synonyms sets up a framework for mixed messages to consumers. Many worry that advertisers will take the proverbial mile and disseminate wild and disparate claims, with the net result that consumers will elevate marketing form over nutritional substance. However, one must remember that the FTC always reserves authority to prohibit deceptive claims. In addition, by allowing the marketers to develop effective messages on their own, the FTC unleashes the awesome creative power of the market. There is little doubt that food indus-

try slogans will disseminate health information more effectively than a bland bureaucratic pronouncement. For instance, the National Food Processors Association (NFPA) has criticized FDA's model health claim on vegetables and cancer for being written at a grade 13.8 reading level. The NFPA advocates attention-getting bursts or slogans, such as heart healthy, be cancer smart, or helps reduce risk of brittle bones.¹²⁰ Obviously, there is a fine line between appropriate education and inappropriate persuasion, but one must rely on the FTC to police the border scrupulously.

Finally, the FTC's encouragement of relatively healthy food substitutions is a welcome loosening of FDA's good food/bad food paradigm. FDA's jelly bean rule prevents consumers from receiving valuable dietary information and inhibits responsible decision making. Not everyone will substitute an apple for a brownie, but many may choose to switch to a non-nutritive compromise like jelly beans. Likewise, many consumers benefit from receiving comparative health messages for products like pork and chicken. America will not become a nation of vegetarians overnight, but we devour fewer burgers if responsible comparative claims continue to be allowed.

VI. Conclusion

The rhetoric of the FTC Enforcement Policy Statement is conciliatory, compromising, and deferential to FDA and its NLEA mandate. Beneath the sooth-

¹²⁰Health Claims Rule 'Excessively Restrictive', May Violate Freedom of Speech, Food Manufacturers Say, 4 Food Labeling News No. 43 (July 25, 1996).

ing words, however, lie some nagging controversies. Differing statutory mandates and jurisdictional authorities have led to conflicting regulatory philosophies in a few areas. Each agencies' special pride in its turf may also contribute to the failure to completely harmonize the regulatory approach to food health claims. Instead of asking Which policy better protects public health?, perhaps we should ask Which policy better protects public health without sacrificing other important values? These might include First Amendment values, free market values, administrative discretion values, and a whole host of others. Undoubtedly, these values are susceptible to *one* defining interpretation and regulatory implementation. Just as one can eventually force a square peg into a round hole. The agencies have operated under an uneasy truce since 1954, arguably converging despite different agendas. Why not stay the course of flexible harmonization? Why not render unto each agency its own?