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Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To Whom It May Concern:

Please find enclosed comments on "Food Labeling: Health Claims; Dietary Guidance," prepared in response to the Department of Health and Human Services request for comment [Federal Register: January 27, 2004 (Volume 69, Number 17 at 3,868); Extension of Comment Period].

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge of regulations and their impact on society. These comments on the Department's proposed rule do not represent the views of any particular affected party or special interest group, but are designed to evaluate the effect of the proposal on the public interest generally.

The Regulatory Studies Program appreciates the opportunity to comment and we hope that consideration of these comments will enhance the quality and development of of Food and Drug Administration (FDA) policy and regulations.

Sincerely,

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Enclosure: a/s

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REGULATORY STUDIES PROGRAM

Public Interest Comment on
Food Labeling, Health Claims, and Dietary Guidance: Advance Notice of Proposed Rulemaking[1]

The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic scholarship to assess rulemaking proposals from the perspective of the public interest. Thus, this comment in response to the Food and Drug Administration's Advance Notice of Proposed Rulemaking (ANPRM) on qualified health claims in food labeling does not represent the views of any particular affected party or special interest group, but is designed to evaluate the effect of the FDA's proposals on overall consumer welfare.

I. Introduction

The Nutrition Labeling and Education Act of 1990 gave the Food and Drug Administration (FDA) authority to permit health claims on food labels. A "health claim" is any claim that a substance in the food affects disease or other health conditions. Initially, the FDA permitted only those health claims that the agency determined were supported by "significant scientific agreement." Several court rulings, however, directed the FDA to explore ways of permitting producers to make "qualified" health claims – claims for which there may be some scientific evidence, but not significant scientific agreement. Courts stated that instead of banning such claims outright, the agency should first determine whether such claims could be presented in a truthful and non-deceptive way, such as by including disclaimers.

On July 11, 2003, FDA issued a notice of availability of a Task Force report and two guidance documents regarding the evaluation of qualified health claims.[2] This ANPRM

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[1] Prepared by Jerry Ellig, Senior Research Fellow, Mercatus Center and Cindy Goh, Associate Director, Regulatory Studies Program, Mercatus Center. This comment is one in a series of Public Interest Comments from Mercatus Center's Regulatory Studies Program and does not represent an official position of George Mason University.

solicits comments on the procedures outlined in those documents. The FDA seeks comment on three options for permitting qualified health claims.[3] Under Option 1, a producer would petition the FDA for permission to make a specific claim, and the FDA would determine what the appropriate disclaimer by assessing the strength of the scientific evidence underlying the claim. Under Option 2, each health claim would be subjected to a full notice-and-comment rulemaking to determine whether the wording of the claim accurately reflected the underlying scientific evidence. Under Option 3, producers would be free to make qualified health claims without prior FDA approval, but the FDA would investigate suspect claims to ensure that they were not false or misleading. Thus, the first two options involve pre-market review of all qualified health claims, while the third option focuses on post-market enforcement. The first two options are consistent with the FDA's pre-market approval approach for new drugs, medical devices, and unqualified health claims on food labels. The last option is based on the Federal Trade Commission's (FTC) approach to preventing false or misleading claims in advertising – including advertising for products whose labeling is regulated by the FDA.

Based on the available information, Option 3 appears to be the alternative that best promotes consumer welfare by giving consumers the most access to truthful health claims while protecting them from false and misleading claims. In doing so, Option 3 also satisfies the courts' directive that the FDA should deal with qualified health claims in a manner less restrictive than an outright ban.

II. Genesis of the Current Rulemaking

The current rulemaking is the FDA's most recent attempt to square its regulation of qualified health claims with a series of court cases which found that previous FDA decisions to ban qualified claims violate the First Amendment. The policy debate sparked by this constitutional challenge is also informed by a stream of economic research assessing the impact of health claims and their regulation on consumer welfare.

A. FDA First Amendment Cases

The Supreme Court recognizes commercial speech[4] as a category of speech that is protected by the First Amendment.[5] In *Central Hudson Gas and Electric Corp. v. Public Service Comm'n*, 447 U.S. 557 (1980), the Court established a four-prong test for

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[2] The two documents are titled "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data" and "Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements." The documents are available at http://www.fda.gov/oc/mcclellan/chbn.html.

[3] The ANPRM also seeks comment on a wide variety of other issues. Our comments are confined to evaluation of the three options for permitting qualified health claims.

[4] Commercial speech is speech that "no more than proposes a commercial transaction." Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748 (1976).

[5] *Id.* However, no clear standard of scrutiny emerged from this case.

evaluating government regulations that affect commercial speech: First, the message must not involve illegal activity, and cannot be false or misleading. Second, the regulation must serve a substantial government interest. Third, if the first two tests "yield positive answers," the Court will then determine if the regulation "directly advances" the governmental interest. Lastly, the regulation must not be "more extensive than is necessary to serve that interest."[6] Since the *Central Hudson* test was established, FDA has faced several challenges to regulations that restrict commercial speech.[7]

By enacting the Nutritional Labeling and Education Act (NLEA) in 1990, Congress gave the FDA statutory authority to permit health claims on the labels of food products.[8] The approval of a health claim involves the notice-and-comment rulemaking process, and each health claim has to meet a "significant scientific agreement" standard before it is approved.[9] By 1993, the FDA approved seven health claims under this standard, but has only added three claims to the list in the past decade.[10] While the NLEA provided health claim approval authority to the FDA, it was silent on the issue of qualified health claims.

The agency was forced to re-evaluate its process for evaluating qualified health claims for dietary supplements when it was found to have overextended its power over commercial speech. Two cases in this area laid the groundwork for the FDA's effort to improve its conventional foods qualified health claims process.

In *Pearson v. Shalala*, 164 F.3d 650 (1999), the United States Court of Appeals for the District of Columbia Circuit applied the *Central Hudson* test and found that while the FDA had a substantial governmental interest, it failed to meet the last two prongs of the test when it declined to authorize the appellants' four claims characterizing the relationship between their dietary supplements and disease or health-related conditions.[11] The court ruled that because the FDA's restrictions fell under the doctrine of commercial speech, the agency lacked sufficient evidence to prove its claim that "consumers would be considerably confused by a multitude of claims with differing degrees of reliability." It also stated that a disclaimer would have been a less restrictive but equally effective way

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[6] *Central Hudson*, 447 US 557, 566 (1980).

[7] It was determined in Nutritional Health Alliance v. Shalala, 953 F.Supp. 526 (S.D.N.Y.1997), that health claims should be analyzed as commercial speech under the *Central Hudson* doctrine.

[8] 21 U.S.C. § 343(r)(3) (FDCA § 403(r) (3)). Health claims are defined as any claim made in a food label that characterizes the relationship of any nutrient on the label to a disease or health-related condition. 21 U.S.C. § 343(r)(1)(B).

[9] 21 U.S.C. § 343(r)(3)(B)(1).

[10] *See* 21 C.F.R. § 101.79-101.81.

[11] Pearson v. Shalala, 164 F.3d 650, 657-59 (D.C. 1999). Plaintiffs were dietary supplement marketers who asked FDA to authorize four separate health claims: (1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers." (2) "Consumption of fiber may reduce the risk of colorectal cancer." (3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease." (4) ".8 mg of folic acid in dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." *Id.* at 652.

of informing the consumer. In addition, it instructed FDA to provide a clearer explanation of the "significant scientific agreement" standard.[12]

The court also dismissed the FDA's assertion that "health claims lacking significant scientific agreement are inherently misleading" as "almost frivolous" because it suggests that "[the claims] would have such an awesome impact on customers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the customers were asked to buy something while hypnotized, and therefore they are bound to be misled." It also pointed out that the FDA's assumption that consumers were unable to think for themselves showed "a simplistic view of human nature or market behavior."

Pearson I, as the case came to be known,[13] was referred to extensively in *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (2002), in which the District Court for the District of Columbia granted the plaintiffs' motion for a preliminary injunction against the FDA's ban on the health claim for their dietary supplements because the FDA's prohibition was unconstitutional. However, it also held that an appropriate disclaimer was required before the plaintiffs could use a health claim on their product labels. The court instructed the FDA to submit suggested disclaimers.[14] In applying the *Central Hudson* test, the District Court stated that the Supreme Court has consistently "rejected the 'highly paternalistic' view that government has complete power to suppress or regulate commercial speech" in the name of consumer protection. It also indicated that if the government could achieve its interests "in a manner that does not restrict speech, or that restricts less speech, the Government must do so."[15]

The *Whitaker* court found that the plaintiffs' health claim was not inherently misleading, and that the FDA "failed to provide empirical evidence that consumers would be deceived by the use of the claim if accompanied by a disclaimer." The court also established that the plaintiffs were harmed by the FDA's suppression of their health claim because the "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury," especially since nine years had passed since the FDA first prohibited the health claim. Moreover, the public interest served by the health claim and the right to commercial speech outweighed the potential,

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[12] *Pearson*, 164 F.3d at 59. While the court did not make any conclusions regarding Pearson's Fifth Amendment argument that FDA's standards were "so vague as to deprive the producers of liberty...without due process," it agreed that "significant scientific agreement" was poorly defined.

[13] *Pearson II* is the name for the second case, Pearson v. Thompson, 130 F. Supp. 2d 105, 121 (DDC 2001), concerning another preliminary injunction against FDA prohibition of health claims concerning folic acid in dietary supplements. (The original defendant was Secretary of Health and Human Services, Donna Shalala, who was replaced by Secretary Tommy G. Thompson).

[14] Whitaker v. Thompson, 248 F. Supp. 2d 1 (2002). The FDA banned plaintiffs from including on their dietary supplements label the health claim that "consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer." The plaintiffs were individuals and companies with direct financial interest in and physicians who sold dietary supplements containing the antioxidant vitamins C and E. *Id.* at 2.

[15] *Id.* at 24 (quoting Thompson v. Western States Med. Ctr., 535 U.S. 357, 371 (2002)).

unsubstantiated claim of harm to the public. The court identified two scenarios in which a ban would have been appropriate: (1) when the FDA determined that no evidence supported the health claim and (2) when the evidence in support of the claim is qualitatively weaker than evidence against the claim or if the claim were only supported by one or two studies. Even in those two cases, the ban would only be justified if FDA could prove that a disclaimer would confuse consumers.

As a result of *Pearson I*, the FDA announced in the December 20, 2002 *Federal Register* that it intended to apply the *Pearson I* holding to conventional human food and to allow qualified health claims for such food. The FDA stated that it would allow a disclaimer if the claim were "potentially misleading." The FDA was also forced to incorporate the *Whitaker* court's suggestion for using "credible evidence" instead of "weight of the evidence" to evaluate submitted claims. However, it stated that it intended to continue to use the strength of the evidence as a criterion because of its limited resources and because it believed the "weight of the evidence" standard is still more beneficial to public health than the "credible evidence" standard.[16]

FDA Commissioner Mark B. McClellan also established a Task Force on Consumer Health Information for Better Nutrition.[17] The Task Force is part of the Consumer Health Information for Better Nutrition Initiative, which was established to achieve the following twin goals: "[T]o encourage makers of conventional foods and dietary supplements to make accurate, up-to-date, science-based claims about the health benefits of their products, and to help eliminate bogus labeling claims by pursuing marketers of human dietary supplements and others who make false or misleading claims about the health benefits or other effects of their products."[18]

B. Economic Research on Health Claims

Economic research suggests that permitting qualified health claims, as the First Amendment requires, would benefit consumers by allowing them to make more informed dietary choices. If consumers are concerned about the health effects of their diets, food producers have incentives to provide information about the health and nutritional attributes of their products. Of course, an individual producer may only explain the beneficial aspects of its product, but consumer skepticism, warranties, and competition from other producers help ensure that consumers receive a fairly accurate portfolio of information.[19] (For example, the producer of a "fat free" food that is also high in sodium might emphasize only the link between fat and health, but competition from producers of

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[16] Consumer Health Information for Better Nutrition Initiative, Task Force Report (July 10, 2003), available at http://www.cfsan.fda.gov/~dms/nuttftoc.html.

[17] *Id.*

[18] *Id.*

[19] Sanford J. Grossman, "The Informational Role of Warranties and Private Disclosure About Product Quality," *Journal of Law & Economics* 24 (Dec. 1981); Elise Golan, Fred Kuchler, and Lorraine Mitchell, *Economics of Food Labeling*, Economic Research Service, U.S. Department of Agriculture, Agricultural Economic Report No. 793 (Dec. 2000).

low-sodium foods would encourage consumers to consider the health effects of sodium consumption as well.) Food producers might not generate the "socially optimal" amount of information or complete disclosure.[20] Nevertheless, when producers can make health and nutrition claims, consumers can make more informed decisions, and they may well choose healthier products.[21]

There is substantial evidence that food producers do compete by providing health and nutrition information about their products when permitted to do so:

- A 2002 study of food advertising in major magazines by FTC economists found that liberalization of the FTC's approach to advertising health claims in the early 1980s, along with the FDA's 1987 proposal to permit health claims on labels, led to a significant increase in health and nutrition information available to consumers. Conversely, adoption of new, more restrictive, FDA and FTC rules and guidelines under the NLEA in the early 1990s was followed by large reductions in the number of advertised claims regarding the fat and nutrient content of foods. Health claims in ads for fats and oils, which were a significant dimension of competition in the late 1970s and 1980s, disappeared after 1994; the authors note, "competition on the health reasons to choose one fat over another has been eliminated in advertising."[22]

- Comparative health claims can play an especially important role in ensuring that consumers receive accurate information. The FTC food advertising study found that these claims increased significantly when regulation was relaxed in the 1980s, then fell after passage of the NLEA, which restricts comparative claims.

- In 1984, Kellogg introduced an advertising campaign informing consumers of the link between fiber consumption and reduced cancer risk, pointing out that its All-Bran cereal is high in fiber. This initiative was not only voluntary, but also violated the FDA's policy at the time. By 1988, virtually all cereals with more than a tiny amount of fiber included that information on the labels, even though no regulation required them to do so.[23]

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[20] Golan, Kuchler, and Mitchell (2000), p. 8.

[21] As a matter of pure economic theory, improved information benefits consumers even if, as a result, they choose less healthy products, because economic value is subjective and defined by the decision-makers. Information makes consumers better off if it helps them better select or obtain whatever it is that they value; the real gain in consumer welfare occurs because the decision was better-informed, not because the consumer chooses what policymakers or health experts believe is "right." That said, the empirical literature suggests that many consumers do consider their health when making food choices, and provision of more information therefore leads to healthier consumption decisions.

[22] Pauline M. Ippolito and Janis K. Pappalardo, *Advertising, Nutrition, and Health: Evidence from Food Advertising, 1977-1997.* Bureau of Economics Staff Report, Federal Trade Commission (Sept. 2002), available at http://www.ftc.gov/opa/2002/10/advertisingexec.pdf. Quote is form page E-30.

[23] Pauline M. Ippolitto and Alan D. Mathios, "Information, Advertising, and Health Choices: A Study of the Cereal Market," *RAND Journal of Economics* 21:3 (Autumn 1990), pp. 461, 469.

More and better nutrition and health information about specific foods appears to prompt consumers to make more healthful food choices:

- A series of studies by the USDA's Economic Research Service found that individuals with greater knowledge about the link between specific nutrients and health problems and the nutrient content of specific foods consume less fat, saturated fat, and cholesterol.[24]

- A landmark 1990 study by FTC economists found that the market share and sales of high-fiber cereals increased significantly after the Kellogg flouted the ban on health claims and the ban was temporarily suspended. The average fiber content of cereals (weighted by market shares) increased by about 7 percent between 1984 and 1987, implying that 2 million additional households consumed high-fiber cereals as a result of the advertising. Analysis of individual consumption data suggests that the advertising was particularly effective in persuading "informationally disadvantaged" households to increase fiber consumption.[25]

- The legalization of health claims between 1984 and 1990 also appears to have reduced fat consumption. The scientific link between fat and heart disease has been well-known since the early 1960s, but between 1984 and 1990, food producers could advertise the relationship. Consumption of fat, saturated fat, and cholesterol fell at a much faster rate during this period than during the previous eight years.[26] Many advertising campaigns for fats and oils emphasized the danger of saturated fats (the "worst" fats), and saturated fat consumption from products in this category fell by 24 percent when such advertising was legal, compared to a 3 percent reduction for fats overall.[27]

- The cost/benefit analysis accompanying the FDA's mandatory nutrition labeling regulations under the NLEA assumed that consumers change their diets in response to nutrition information at the point of sale, based on a study that found fat and cholesterol consumption fell when nutrition information flags were placed on grocery store shelves.[28]

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[24] Lorna Aldrich, *Consumer Use of Information: Implications for Food Policy,* Economic Research Service, U.S. Department of Agriculture, Agricultural Handbook No. 715 (June 1999).

[25] Ippolito and Mathios (1990), pp. 464-78. "Informationally disadvantaged" households were defined as those less educated or less likely to be reached by the news media's discussions of general scientific information about the fiber-cancer link.

[26] Pauline M. Ippolito and Alan D. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990,* Bureau of Economics Staff Report, Federal Trade Commission (Sept. 1996).

[27] Pauline M. Ippolito and Alan D. Mathios, "Information and Advertising: The Case of Fat Consumption in the United States," *American Economic Review* 85:2 (May 1995), pp. 91-95

[28] Golan, Kuchler, and Mitchell (2000), p. 20.

Regulation of information may also affect consumer welfare indirectly by altering competition and incentives for innovation. If qualified health claims facilitate entry by new competitors or introduction of new products, then a regulatory process that increases the cost of or restricts producers' ability to make such claims could reduce competition or stifle new product introduction. The cereal market's experience with health claims advertising is instructive on this point; new cereals introduced when such advertising was legal were much higher in fiber than either existing cereals or new cereals introduced prior to the advertising.[29] Thus, regulation of information could deprive consumers of lower prices or new products, in addition to depriving them of useful information.

However, health claims could misinform consumers if they lead consumers to receive selective or biased information. Producers could disclose only the favorable characteristics of foods, masking unfavorable characteristics, or advertise true but in some sense irrelevant health benefits of generally non-nutritious products (such as, "low-sodium donuts help control your blood pressure.") Very little systematic study rigorously assesses the actual extent of such problems, but a few studies have found some interesting nuggets of relevant information. For example, while cereal manufacturers advertised the health benefits of high-fiber cereals, the sodium and fat content of these cereals steadily declined; consumers apparently continued to consider more than just the advertised health benefits of the cereal.[30] The 2002 FTC food advertising study examined whether producers of desserts, snacks, and soft drinks use health claims in their marketing. It found, "with a few trivial exceptions, health claims are never used in marketing foods from ... these categories."[31] This occurred even in the years when regulation of such claims was most lenient, suggesting that producers have little incentive to trick consumers with claims that "junk food is good for your health." The 1996 FTC staff study of advertising, fat, and cholesterol consumption concluded, "The available evidence is generally inconsistent with the alternative deception/confusion hypothesis, in which producer claims are hypothesized to undermine public health advice, leading to overall deteriorations in consumers' diets."[32]

The empirical economic evidence suggests, therefore, that the post-NLEA approach to health and nutrient claims deprives consumers of a significant amount of useful information that could help them make healthier food choices. Misleading, deceptive or fraudulent claims are of course always possible, but it is doubtful that they are a serious enough problem to justify banning either qualified or unqualified health claims. For these reasons, consumers should welcome the FDA's current initiative to revise its regulation of qualified health claims.

[29] Ippolito and Mathios (1990), p. 466.

[30] Ippolito and Mathios (1990), pp. 467-69.

[31] Ippolito and Pappalardo (2002), p. E-19.

[32] Ippolito and Mathios (1996), p. E-3.

III. Analysis of Alternatives

The three alternatives for regulating health claims could have different impacts on consumer welfare by altering information flows to consumers. Understanding these impacts is critical if the FDA is to promote consumer welfare in a manner consistent with the courts' constitutional directives.

A. FDA should adopt the *least* restrictive alternative that reasonably protects consumers from false or misleading claims

It is not completely clear whether the FDA will satisfy the courts by regulating qualified health claims in any manner that is less restrictive than an outright ban, or if the agency must in this case choose the least restrictive method that accomplishes its consumer protection goals. While the Supreme Court stated that *Central Hudson* does not impose a "least restrictive means" requirement, it does mandate a "reasonable" fit between means and ends.[33] However, it did not define the parameters for this subjective determination. The Supreme Court in *New York v. Fox* suggested that "the means need not be the single best disposition, but one whose scope is 'in proportion to the interest served.'"[34]

Some aspects of court decisions, however, suggest that the agency may have difficulty if it chooses a more restrictive means of accomplishing its goals when a less restrictive option is also available. The Court has held that a commercial speech restriction that burdens "substantially more speech than necessary" will fail the *Central Hudson* test.[35] The Supreme Court also demonstrated that when less restrictive options are available, the government regulation will inevitably fail the fourth prong of the *Central Hudson* test.[36] Both *Pearson I* and *Whitaker* reiterated this point, suggesting that disclaimers were the less restrictive options available to meet the FDA's goal of educating consumers with truthful information about the health consequences of their dietary choices, and so the FDA should pursue that path instead. The *Whitaker* court goes further than the Supreme Court, stating, "The First Amendment places the burden on the government to prove that its method of regulating speech is the least restrictive means of achieving its goals."[37]

While the general standard suggested by the courts uses the words "reasonable" and "less restrictive," courts seem loath to approve a more restrictive option if a less restrictive one could also accomplish the government's objective. Consequently, the FDA could minimize the potential for further constitutional litigation by choosing the least restrictive option that successfully protects consumers from false and misleading health claims

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[33] New York v. Fox, 492 U.S. 469, 486 (1989) (discussing *Central Hudson*, 447 U.S. at 564-66).

[34] *Id.* (quoting In re R.M.J., 455 U.S. 203 (1982)).

[35] U.S. v. Edge Broadcasting Co., 509 U.S. 418, 430 (1993) (citing Ward v. Rock Against Racism, 491 U.S. 781, 799 (1989)).

[36] Rubin v. Coors Brewing Co., 514 U.S. 476, 490-91 (1995).

[37] *Whitaker*, 248 F. Supp. 2d at 24.

Economic reasoning also suggests that if one or more alternative approaches accomplish the government's goal, then the one that restricts truthful information flows the least would benefit consumers the most. In this case, choosing the least restrictive alternative would protect consumers from false and misleading claims, but it would also offer producers the widest opportunity to make truthful health claims. Consumers would have access to the maximum possible amount of truthful information, and producers would have greater incentives to compete by offering healthier products. Since consumers are better off with more truthful information than with less, they are better off with the option that prevents false and misleading claims while permitting the most truthful information.

B. Which alternative is least restrictive?

A regulatory process can affect both the timing and amount of information that reaches consumers. If the process causes producers to convey information less rapidly than they otherwise would, then consumers have less information during the period of the delay. The *Whitaker* court apparently took a dim view of delay, noting that "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury."[38] The damage may be especially significant during periods when rapid advances in scientific knowledge or product innovation occur, because those are precisely the times when consumers most need up-to-date information.

Even if the regulatory process creates no delay, it may reduce the amount of information consumers receive by screening out some claims (even if truthful) or effectively putting some truthful claims on "hold" due to the regulated agency's resource constraints. Regulation can also reduce the amount of truthful information consumers receive by raising the cost of making claims; in the presence of these additional costs, producers may refrain from making claims that are truthful and useful to consumers, but only marginally profitable. In particular, smaller firms producing for niche markets may find that regulatory compliance generates a cost per unit of sales that makes some truthful claims unremunerative.

1. Timing

Each of the FDA's proposed options has different effects on the timeliness with which producers can make health claims.

Option 1 hampers producers' ability to convey information in a timely manner by subjecting qualified health claims to pre-market review. The producer would need to devote time to preparing a petition, then "usually" wait as long as 270 days for an FDA decision – unless the FDA decided there is "good cause" to extend the period by 30-60 days.[39]

[38] *Whitaker*, 248 F. Supp. 2d at 43.

[39] ANPRM, p. 66042; Interim Procedures, Sec. III.B.8 and III.B.9.

b. Resource constraints

FDA, like all federal agencies, has limited resources. Given this constraint, the different options may have different effects on truthful information flows to consumers depending on the resources required to implement them.

The FDA implicitly acknowledges resource limitations in its current Guidance outlining the evidence-based ranking system, which Option 1 would continue. The system requires that the FDA assess the completeness of each petition for a qualified health claim, request public comments, undertake scientific review of the supporting data, and consult with other federal agencies as appropriate.[42] Due to limited resources, the Guidance notes that FDA will prioritize based on a large number of factors.[43] If this process is finalized in a rule, it is not clear what would happen to low-priority petitions for qualified claims. The ANPRM pledges that under Option 1, claims would "usually" be processed within 270 days. But if resource limitations require FDA to prioritize petitions, then some petitions may not be processed within this deadline. These low-priority petitions would then incur even greater delay, or perhaps find themselves on "indefinite hold." Consumers would either have less truthful information, or less timely truthful information, as a result.

It is not clear whether resource constraints would create a similar result under Option 2. Nevertheless, it is highly unlikely that a notice-and-comment rulemaking, together with the required analysis of evidence, would require fewer FDA resources than a petition under Option 1. Option 2 would therefore likely constrain truthful information flows by at least as much as Option 1, and perhaps more.

The FDA offers resource constraints as the principal argument against Option 3.[44] However, agency resource constraints have different effects on truthful information flows under pre- and post-market review. If the FDA must conduct pre-market review, resource constraints can reduce the flow of truthful information to consumers. If the FDA opts for post-market review, resource constraints would limit the number of unqualified claims the agency could investigate, but not the number of truthful claims that producers could make. Because of this difference, Option 3 restricts truthful information less than Options 1 or 2.

c. Costs

Each of the three regulatory options imposes costs on producers who want to make qualified health claims. If the cost of making qualified health claims increases, then fewer qualified health claims will be made. As a result, consumers receive fewer truthful claims.

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[42] Interim Procedures, Sec. III.B.1, 3, 4, 6.

[43] Interim Procedures, Sec. III.B.2.

[44] ANPRM, p. 66043.

Different options impose different costs. Pre-market review under Options 1 or 2 imposes an up-front cost on any producer seeking to make a qualified health claim. The producer must shoulder the legal, scientific, and other costs associated with marshalling evidence and presenting a petition, and it must also forego the additional profit it expects from the claim while the petition is under review. Each health claim incurs this cost, regardless of whether it is absolutely truthful, absolutely baseless, or somewhere in between. The cost associated with notice-and-comment rulemaking is likely higher than the cost associated with petitioning, and so Option 2 likely would restrict truthful claims more than Option 1 in this regard.

Option 3 imposes no up-front regulatory cost, but it imposes a cost nevertheless. Each time a producer makes a claim, that producer assumes some risk that the claim will be investigated and found misleading. The investigation creates both direct costs (e.g., legal bills) and indirect costs (e.g., damaged reputation and credibility). A negative outcome creates additional costs. Interestingly, under Option 3, the producer's *expected* regulatory costs — in other words, the costs of an investigation multiplied by the probability of an investigation, and the costs of a negative outcome multiplied by the probability of a negative outcome — would vary with the veracity of the claim. A claim that accurately reflects the strength of the scientific evidence would face a relatively low probability of investigation and rejection. A highly inaccurate claim would face a higher probability of investigation and rejection. For this reason, Option 3 has the highly desirable property of imposing higher expected regulatory costs on the claims that are most likely to mislead consumers. In regard to regulatory costs, Option 3 would constrain the flow of truthful information less severely than either Option 1 or Option 2.

Taking effects on both the timing and volume of information into account, the FDA's Option 3 is the alternative that least restricts the flow of truthful information available to consumers. Option 1 is the next least restrictive, and Option 2 is the most restrictive.

C. Which is the least restrictive option that protects consumers from false or misleading claims?

Since Option 3 is the least restrictive alternative, the FDA should first consider whether Option 3 adequately protects consumers from false or misleading claims.

As the FDA acknowledges, Option 3 is based on the enforcement procedures the FTC uses in its regulation of advertising for foods, dietary supplements, and other products whose labeling is regulated by the FDA. Like the FDA, the FTC's goal is to prevent false or deceptive claims. Unlike the FDA, the FTC does not require producers to submit claims for pre-market approval. Instead, firms are free to make claims without prior approval, but the FTC investigates suspect claims and, when a claim is found to be deceptive, seeks to craft remedies that provide consumers with more information rather than less. Commenting in a previous FDA proceeding, the FTC staff noted, "The Commission has a long and successful history of bringing enforcement actions against deceptive advertising claims, including numerous actions challenging false and

unsubstantiated advertising claims about the efficacy and safety of food products, dietary supplements, over-the-counter drugs, and medical devices."[45] The FTC staff acknowledges that its approach does not stamp out all false or misleading claims, noting that case-by-case enforcement has not yet reduced deceptive weight loss claims. Nevertheless, the FTC's approach appears to be a good method for combating deception in food advertising, and so it merits consideration for food labeling as well.

The principal disadvantage of Option 3, from the FDA's perspective, is that the FDA lacks the administrative subpoena power that the FTC possesses for these types of investigations. When the FTC investigates a suspect claim, it can compel the party making the claim to turn over the evidence that the party relied upon to substantiate the claim, and the FTC can then assess that evidence. The FDA argues that, because it lacks administrative subpoena power, it would have to do more work than the FTC must do when it investigates advertising claims under FTC jurisdiction. To build a case against a deceptive, misleading, or unsubstantiated claim, the FDA would, on its own initiative, have to review literature, consult with experts, and perhaps test how consumers interpret claims.[46]

This need not be a fatal defect in Option 3, for four reasons: (1) Some firms will cooperate voluntarily; (2) Elimination of pre-market screening frees up significant resources; (3) Consumer benefits may justify increasing enforcement resources; and (4) the FDA could obtain subpoena power from Congress.

1. Some firms will cooperate voluntarily

The FDA can expect a certain amount of voluntary cooperation from producers whose claims are questioned. Many producers have strong reputational incentives to make claims that hold up under scrutiny. If a regulatory agency challenged their claims, their most likely response would be to furnish information that they relied upon in making the claims. The FDA could then use this evidence as a starting point for its investigation.

Of course, not all companies would be so cooperative, especially if they "pushed the envelope" in making questionable claims or consciously intended to mislead consumers. An FDA investigation of such a company's labeling claim could require more resources than an FTC investigation of a similar advertising claim. Since some companies would cooperate, though, it is likely that only some FDA investigations would be more resource-intensive than similar FTC investigations. As a result, the resource problem may not be as significant as the ANPRM's description of Option 3 might lead one to assume.

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[45] "Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission," In the Matter of Request for Comment on First Amendment Issues, Docket No. 02N-0209 (Sept. 13, 2002), pp. 13-14.

[46] ANPRM, p. 66043.

2. Elimination of pre-market screening frees up significant resources

If the FDA does not have to conduct pre-market review of qualified health claims, it could have adequate resources to investigate the subset of post-market claims that may be suspect. Therefore, a comparison of resources required for individual FDA and FTC investigations sheds little light on the effectiveness of Option 3. Option 3 could well require fewer total resources, because it requires the FDA to review only those qualified claims that the agency suspects are false or misleading. Options 1 and 2 require the agency to review all qualified claims that producers want to make. To do a conscientious job under Options 1 or 2, the FDA would have to review literature, consult with experts, and perhaps understand how consumers interpret claims – precisely the activities identified as requiring significant resources in the ANPRM's discussion of Option 3.[47] If the agency believes it has adequate resources to adopt either of the other two options, then it cannot logically rule out Option 3 without demonstrating that Option 3 requires more total resources than Options 1 or 2.

To see whether Option 3 requires more agency resources than the other two options, one must compare the amount of enforcement activity required to protect consumers adequately from misrepresentation with the total amount of resources available for post-market enforcement. Unfortunately, the number or nature of claims that might have to be investigated is not known. Anecdotes and hypotheticals abound, but we know of no systematic study that measures or predicts the extent of deceptive qualified health claims that would occur if claims were not subject to pre-market approval. Rigorous studies that have touched on the issue find little evidence that health claims confuse or mislead consumers.[48] One cannot rule out Option 3 due to resource constraints without knowing or estimating the amount of enforcement activity that would be necessary. It is quite possible that the FDA could adequately police post-market claims with an amount of resources equivalent to that which would be used for pre-market screening under Options 1 or 2. In that case, Option 3 would qualify as the least restrictive alternative that protects consumers from false or misleading claims

3. Consumer benefits may justify increasing enforcement resources

Even if post-market enforcement under Option 3 requires more FDA resources than either of the pre-market review options, consumers may benefit on net from adoption of Option 3. Consumers benefit under Option 3 because it permits more truthful information to reach them more quickly. These consumer benefits may more than offset the value of the additional resources the FDA might require to conduct post-market enforcement. If so, then Option 3 would qualify as the least restrictive alternative that protects consumers from false or deceptive claims

[47] ANPRM, p. 66043.

[48] See discussion on page 7 and studies cited there.

4. FDA could obtain subpoena power from Congress

Finally, if Option 3 creates insurmountable resource problems, the FDA could provide consumers with the benefits of Option 3 by asking Congress to give it administrative subpoena power for investigation and enforcement of health claims in the labeling of conventional foods and dietary supplements. Rulemaking does not occur in a vacuum, and rulemaking proceedings often identify modest changes in law that would permit an agency to better protect the public. The present rulemaking may be one of those situations. The consumer benefits of Option 3, together with the FTC's favorable enforcement experience, suggest that this option deserves serious consideration.

III. Conclusion and Recommendation

Consumers should welcome the Food and Drug Administration's initiative to permit qualified health claims. Legalizing qualified health claims would give consumers access to more truthful information, encouraging them to make healthier food choices. Consumers would also benefit because food producers have stronger incentives to develop healthier products when they can make qualified health claims.

The FDA offers three options that would allow producers to make qualified health claims: (1) Make permanent the current interim procedures, which allow producers to petition the FDA for enforcement discretion and require the FDA to "grade" the health claim based on the strength of the underlying scientific evidence; (2) Subject all proposed qualified health claims to a full notice-and-comment rulemaking; or (3) Eliminate requirements that FDA approve qualified health claims before producers make them, but investigate and penalize producers who make false or misleading claims.

The available evidence suggests Option 3 would restrict truthful commercial speech the least and benefit consumers the most. There are strong reasons to believe that the resource problems associated with Option 3 are smaller than imagined, and they can be solved. In the absence of substantial evidence to the contrary based on rigorous empirical study, Option 3 appears to be the least restrictive alternative that protects consumers from false or misleading claims

At a minimum, Option 3 deserves a temporary trial period. The trial period should include careful and rigorous assessment of the amount of resources required for enforcement, the extent of deceptive claims, and the extent of consumer harm created by deceptive claims.

If, despite all of these considerations, the FDA determines that Option 3 should not even receive a temporary trial, then Option 1 is preferable to Option 2. Both options give the FDA access to a producer's evidence in support of its qualified health claims; thus, both remedy the principal problem that FDA enunciated with Option 3. Option 1, however, restricts the flow of truthful information less than Option 2. It is therefore superior to Option 2 from the perspective of both First Amendment jurisprudence and consumer welfare.

APPENDIX I
RSP CHECKLIST

Element	Agency Approach	RSP Comments
1. Has the agency identified a significant market failure?	The FDA seeks to permit qualified health claims while protecting consumers from false or misleading claims. Grade: B	False or misleading claims can be a source of market failure. Their incidence and extent of consumer injury will depend in part on countervailing market forces, such as the competitiveness of the market and firms' incentives to protect their reputation for truthfulness. The ANPRM formulates the policy objectives well, but does not indicate the incidence of false or misleading claims or the amount of harm to consumers.
2. Has the agency identified an appropriate federal role?	The ANPRM is a result of court rulings stating that the FDA must find a less restrictive way than an outright ban to prevent false and misleading qualified health claims. Grade: A	Preventing false or misleading claims is an appropriate governmental function. There is a federal role here because most food products are sold in interstate commerce.
3. Has the agency examined alternative approaches?	The FDA presents 3 options. Grade: A	The FDA traditionally follows a pre-market approval model for both products and health claims. To its credit, the FDA offers an option modeled on the FTC's approach to advertising regulation, which does not require pre-approval of claims.

Element	Agency Approach	RSP Comments
4. Does the agency attempt to maximize net benefits?	The FDA asks for comments on strengths and weaknesses of each option. Grade: B	It is not clear if FDA is seeking to maximize net benefits for consumers, or just seeking to identify an option that will pass muster with the courts even if it does not maximize consumer welfare. Nevertheless, the ANPRM gives the FDA the opportunity to select the approach that maximizes net benefits.
5. Does the proposal have a strong scientific or technical basis?	All three options anchor evaluation of health claims in scientific evidence. Impetus for ANPRM is recognition that truthful health information benefits consumers. Grade: A	The FDA Task Force that developed the three options clearly sought to promote informed consumer choice and encourage producers to compete by developing healthier products. These objectives are consistent with economic research on the effects of health claims.
6. Are distributional effects clearly understood?	Not addressed. Grade: D	Two key distributional effects should be kept in mind. (1) Research shows that health claims disproportionately benefit less educated, informationally disadvantaged consumers; (2) Fixed costs of obtaining approval under Options 1 and 2 disproportionately disadvantage firms with small product volume – new entrants or niche producers. The ANPRM omits these issues.
7. Are individual choices and property impacts understood?	The FDA enunciates twin goals of providing consumers with truthful, science-based health information and preventing deception. Grade: A	The purpose of the ANPRM is to facilitate consumer choice based on accurate information.