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**Before the
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration**

**In re: Food Labeling: Health Claims;
Dietary Guidance**

Docket No. 2003N-0496

**COMMENTS OF LIFE EXTENSION FOUNDATION BUYERS' CLUB; DURK
PEARSON AND SANDY SHAW; JULIAN M. WHITAKER, M.D.; AND
AMERICAN LONGEVITY**

Life Extension Foundation Buyers' Club (LEF); Durk Pearson and Sandy Shaw (Pearson and Shaw); Julian M. Whitaker, M.D. (Dr. Whitaker); and American Longevity (AL) (collectively, the "Joint Commenters") hereby file these comments in response to the advance notice of proposed rulemaking, 68 FR 66040 (Nov. 25, 2003), in the above-referenced docket.

BACKGROUND OF THE COMMENTERS

Life Extension Foundation Buyers' Club (LEF): LEF is a Florida-based corporation involved in the research, development, manufacture, and marketing of dietary supplements since 1980. LEF, through its subsidiaries, sells approximately 136 different formulations of dietary supplements to consumers around the world via catalog and internet sales. LEF is pursuing a qualified health claim before FDA for omega-3 fatty acids and reduction in the risk of coronary heart disease.

Durk Pearson and Sandy Shaw: Pearson and Shaw are scientists residing in Nevada. They design dietary supplement formulations and license them to manufacturing and retailing companies. They are the authors of four books on aging and age-related diseases, including the number one, million-plus best seller *Life Extension: A Practical Scientific Approach* (1982). They have also published three other health

books, two of which were best sellers: *The Life Extension Companion* (1984); *The Life Extension Weight Loss Program* (1986); and *Freedom of Informed Choice—FDA v. Nutritional Supplements* (1993). Pearson and Shaw rely on qualified health claims to inform consumers about scientific findings concerning the products they license for sale to the public. Pearson and Shaw were named plaintiffs in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) (“Pearson I”) in which the Court of Appeals for the D.C. Circuit held unconstitutional under the First Amendment FDA’s ban on dietary supplement health claims that did not meet the agency’s “significant scientific agreement” standard. Pearson and Shaw were also named plaintiffs in Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001) (“Pearson II”) and Pearson v. Thompson, 141 F. Supp. 2d 105 (D.D.C. 2001) (“Pearson III”).

Julian M. Whitaker, M.D.: Julian M. Whitaker, M.D. is a physician licensed to practice medicine in the states of California and Washington. He graduated from Dartmouth College in 1966 with a B.S. degree and from Emory University in 1970 with an M.D. degree. He received additional training in surgery as a resident at the University of California Medical School. From 1975 to 1976 he worked as a physician at the Pritikin Institute in California. Since that time he has been the Clinical Director of the Whitaker Wellness Institute in Newport Beach, California. He is the author of five books: *Reversing Heart Disease* (1985), *Reversing Diabetes* (1987), *Reversing Health Risk* (1989), *Natural Healing* (1994), and *What Your Doctor Won’t Tell You About Bypass* (1995). Since 1991 he has been the editor of *Health and Healing*, a national single editor health newsletter. Dr. Whitaker also formulates and licenses dietary supplements. Dr. Whitaker has a direct stake in the outcome of these proceedings, as he

relies upon FDA’s allowance of qualified health claims to inform the consuming public of the potential for nutrients to reduce disease risk. Dr. Whitaker was a named plaintiff in Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002) (“Whitaker”), holding that a qualified health claim may not be suppressed unless the Government proves that (1) the claim is not backed by any scientific evidence and (2) no disclaimer can suffice to cure potential misleadingness. Id. at 10.

American Longevity (AL): AL, a California company, has been a leading marketer of human and animal dietary supplements and cosmetics for over six years. AL markets over 50 dietary supplement and personal care products ranging from vitamin and mineral supplements to skin care products. AL was a named plaintiff in the Whitaker case, cited supra. AL has also submitted several qualified health claim petitions to FDA and relies on the use of qualified health claims to inform AL customers of potential health benefits of their products.

COMMENTS

The Joint Commenters respond to FDA’s request for comments on alternatives for regulating qualified health claims in the labeling of conventional foods and dietary supplements and on other related issues. As discussed above, Pearson and Shaw; Dr. Whitaker; and AL have been plaintiffs in successful First Amendment suits against the agency and with them LEF have all been petitioners for qualified health claims. As such, they are uniquely qualified and situated to address with experience the issues presented in the advance notice.

In this proceeding, FDA explores the constitutional limits of its authority to regulate health claims. Statements on labels and in labeling that characterize the

relationship of a nutrient to a disease or health-related condition, i.e., health claims, come to the agency with a constitutional presumption in favor of their free communication. See, Pearson I, supra at 655. See also, Pearson III, 141 F. Supp. 2d at 112 (Court reiterates that Pearson I “established a very heavy burden which Defendants must satisfy if they wish to totally suppress a particular health claim”); Whitaker, 248 F. Supp. 2d at 7, 13 (Court holds that “the government must satisfy a heavy burden to prove that suppression of commercial speech is allowed under the First Amendment”). In light of that presumption, FDA has been ordered by our courts to rely on disclaimers as a less speech restrictive alternative to outright suppression. Id; See also, Pearson II, Pearson III, and Whitaker, supra. As explained below, the Joint Commenters believe that the current interim procedures and evidence-based ranking system approach (Option 1) furthers the core values of the First Amendment, fulfills the constitutional mandates of the federal courts to this agency, and best comports with the health claims provision of the Food Drug and Cosmetic Act, 21 U.S.C. § 343(r), provided that the evidence-based ranking system is modified to identify the B through D disclaimers as exemplary only and to make clear that disclaimers actually used will be tailored by FDA with precision to the individual claims presented. Only by carefully tailoring each disclaimer to each claim presented can FDA fully comply with the courts’ requirement that its disclaimers be “short, succinct, and accurate.” See, Pearson II, 130 F. Supp. 2d at 120; Pearson III, 141 F. Supp. 2d at 107.

I. ASSESSMENT OF THE REGULATORY OPTIONS

To understand which regulatory option or options are constitutional and are likely to yield constitutional outcomes, (1) the FDA should consider the basic informational

characteristics of the speech it proposes to regulate; (2) the FDA should consider the core values underlying the First Amendment that are implicated by its regulation of the speech in question; (3) the FDA should consider the extent to which each option avoids adverse effects on those core values; (4) the FDA should determine which regulatory option complies with the applicable First Amendment tests for assessing restrictions on the speech in question and is least likely to invite regulatory actions that could violate those tests in future; and (5) the FDA should determine which regulatory option comports with the health claims provision of the Food Drug and Cosmetic Act, 21 U.S.C. § 343(r), and would not require an amendment to that act as a condition precedent to agency implementation of the option.

A. INFORMATIONAL CHARACTERISTICS OF THE SPEECH IN ISSUE

The business of regulating qualified health claims is the business of government restriction of speech presumptively protected by the First Amendment to the United States Constitution. See, Pearson I, 164 F.3d at 655. As such, FDA cannot adopt any method for regulation unless that method is based on a clear understanding of the informational characteristics of the speech in issue and avoids transgressing First Amendment limits on government power.

Qualified health claims are, by definition, speech laden with scientific content, content that characterizes the potential relationship of a nutrient to a disease or a health related condition. 21 U.S.C. § 343(r). Qualified health claims differ from typical forms of commercial speech in that they do not convey price information. In and of themselves, they are not offers to sell but are, rather, health messages germane to the entire population or to a significant subgroup of the population. By alerting consumers to the

effects of nutrients on disease they enable consumers to modify their dietary habits in ways that can prevent disease, reduce the likelihood of disease, or increase longevity. The information conveyed by qualified health claims is quite often the same or substantially similar to information appearing in peer-reviewed scientific journals, government scientific publications, or other scientific publications. Although qualified health claims are vital, edifying consumers on nutrition science at the point of sale, the place at which consumers are most influenced in making ultimate purchasing decisions,¹ they are not the product of scientific certainty.

Little, if any, science is known with absolute certainty. Scientific information, including qualified health claims, may be said to rest on a continuum between a total absence of proof and a substantial quantity of it (approaching, but never achieving, certain knowledge). The vast majority of scientific information rests between these two extremes in areas of relative uncertainty where debate emerges, rages, disappears, reemerges, rages, and disappears in a redundant pattern that continues until an apparent consensus is achieved and will recur when that consensus is challenged. To be sure, a stable consensus is an extreme rarity in science, including nutrition science. Orthodoxies are, to a large extent, unscientific because they are supported by the notion that evolution in scientific understanding has come to an end. Debate is the norm in science because the kind of easy consensus that can be achieved through unquestioning acceptance cannot exist in an environment of searching and unending inquiry. Indeed, even when consensus is thought to be achieved, there is inevitably another way to perceive the supporting data or to appreciate the significance of the data. In a free scientific information market a

¹ See, e.g., Pearson I, 164 F.3d at 658, n.7 (citing, John E. Calfee & Janis K. Pappalardo, How Should Health Claims for Food Be Regulated (Bureau of Economics, Federal Trade Commission 1989)).

premium is placed on discovery, invention, and debate, so the exercise of faculties to challenge notions that gain widespread acceptance is commonplace.

Scientific debate is the best means by which truths (i.e., accurate descriptions of the current state of scientific uncertainty) are discovered. Questioning and challenging disabuses science of illogical elements or unfounded assumptions and reveals alternative explanations, forcing refinement and, oftentimes, greater accuracy in definition. What we may call scientific truth is nothing more than one of a series of competing, scientifically supportable, propositions that aim at defining a state of nature. In the area of nutrition science, scientific truth is one of a series of competing, scientifically supportable, propositions about the effects of a nutrient. Scientific truth is not absolute. It is grounded in empirical evidence (studies), but in the end it is an educated opinion concerning a *potential* effect. Nevertheless, consumers depend upon all manner of nutrient-disease information, from the possible to the probable, in exercising choice in the market. Because science concerning nutrients is largely incomplete, consumers *must* exercise choice in the food and dietary supplement markets with *less than* perfect information, i.e., in an environment of relative uncertainty. To do so in logical pursuit of his or her own self interest, each consumer must depend on current information and must try to determine whether that information has particular relevance to him or her.

There is much value in accurate, but uncertain, information. Nutrition science has not advanced to a point where we know the effects every, let alone most, constituents of a food have on the body, either individually or in combination with other nutrients. Consumers must do the best they can with the limited information available. Although some would still question the certainty of science supporting the folic acid-neural tube

defect health claim, it is quite helpful for consumers to appreciate the potential of folic acid to reduce the risk of neural tube defects in women of childbearing age. Likewise, it is quite helpful for consumers to appreciate that vitamins B6, B12, and folic acid lower homocysteine levels and, thereby, reduce the risk of vascular disease and that omega-3 fatty acids may reduce the risk of sudden death heart attacks. The very real potential of these nutrients to produce the aforementioned risk reducing effects and the fact that consumption of them at recommended levels entails little, if any, risk makes the benefit of information flow indispensable to furtherance of public health. Government suppression of nutrient-disease information creates a void in the market into which less reliable information can gain favor, including proveably false claims communicated with an intent to deceive.

In addition to aiding consumers in attaining self-fulfillment and greater autonomous control over their biological destinies, qualified health claims contribute greatly to scientific debate. If communicated widely, qualified health claims can engage far more minds in the questioning and challenging process that is science, thus fueling the search for truth. The universe of debate participants grows from a select few academics to the consuming public. While repression breeds ignorance, disclosure breeds discovery, enlightenment and freedom of choice.

Some question whether scientific information in the realm of uncertainty can have any practical utility. They contend paternalistically that it is better to deprive consumers of accurate but uncertain nutrition science for fear that consumers will misapprehend its relative importance and will choose unwisely, wasting dollars or time or both. They regard less than certain information as inherently misleading, a proposition (along with

the preference for keeping people in the dark purportedly for their own good) that our federal courts have repeatedly and soundly rejected.²

The view that consumers cannot be trusted with accurate but uncertain scientific information proceeds from a highly paternalistic premise contrary to the First Amendment onus in favor of free information exchange and individual decisionmaking. The view does not follow logically because the substances in question are ones commonly and lawfully consumed; people know foods and nutrients experientially. Without the information, consumption proceeds lawfully but, to a greater or lesser degree, ignorantly. With the information, consumption proceeds cognizant of facts that may alter choices in ways more reflective of the true desires of each consumer, integrating nutrition science information into consumer preferences. Knowing that, for example, trans fatty acids may increase the risk of heart disease and cancer may dissuade some (perhaps most) from eating certain foods laden with trans fats. That knowledge may cause others not to alter their consumption patterns one iota. The reasons for the differing decisions are numerous, and vary from person to person, but in the end allowance of free will to be exercised by each consumer reflects our greater national commitment to protect freedom of speech and freedom of choice. We must have the freedom to choose among lawful options based on accurate information, even if in so doing we may be perceived by others as making poor choices.

² See, Pearson I at 655; See also 44 Liquormart v. Rhode Island, 517 U.S. 484, 503 (1996) (“The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good”); Rubin v. Coors Brewing, 514 U.S. 476, 497 (1995) (citing Virginia State Board of Pharmacy v. Virginia Citizen’s Consumer Council Inc., 425 U.S. 748, 769-70 (1976)); See also Central Hudson Gas & Elec. Corp. v. Public Service Comm’n of New York, 447 U.S. 557, 562 (1980) (“Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all”) (citations omitted).

Qualified health claims are but an opening bid for consumer attention in the idea and information marketplace. Recognition of that fact is critical because it belies the hasty generalization that a qualified health claim must include all manner of information capable of apprising the public of every facet of the nutrient-disease relationship. That approach, which results in unreasonably lengthy qualified disclaimers, operates on the mistaken assumption that limited but truthful information is inaccurate information and should be suppressed. The Supreme Court has ruled to the contrary, however, reasoning: “Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.” Central Hudson, cited *supra*, 447 U.S. at 562. Limited information is useful to consumers if not inherently misleading; it need only alert consumers to the relative level of scientific support for an accurate nutrient-disease relationship; from there, the idea and information markets can be counted upon to do the vetting that will ultimately affect consumer choices.

A qualified health claim is not the end of discussion, it is the beginning. Consumers do not view qualified health claims in isolation, but as important fragments of information among several similar information offerings. Consumers tend to be highly skeptical of all claims made by marketers of goods and services. *See, e.g.,* Transparent Marketing: How to Earn the Trust of a Skeptical Consumer, www.marketingexperiments.com/transparent_marketing.cfm (last visited February 19, 2004). Foods and dietary supplements are no exception. *See*, Wansink, Brian, Steven Sonka, Michelle Morganosky, and Clare Hasler (2001), How Consumers Interpret Two-sided Claims, Food and Brand Lab, University of Illinois Working paper, Champaign, IL

at 2. In the end, so long as the product is lawfully on the market, it is better for the consumer to judge the relative worth of accurate but uncertain information than for the government to impose its preferences paternalistically by restricting or denying access to that information. Indeed, the Supreme Court has determined that this result is the command of the First Amendment. See, Virginia State Board of Pharmacy and 44 Liquormart, supra at n. 2.

If FDA policy denies access to accurate but uncertain information, useful in the exercise of choice, it not only robs consumers of their freedom at the point of sale, it also creates an information void that encumbers market processes, leads to misallocation of resources, allows uninformed prejudice about the utility of foods and dietary supplements to take hold, and enables charlatans to purvey fraudulent claims unchecked by contrary, accurate information. In the end, suppression of accurate but uncertain information influences consumer choice against rational pursuit of self interest, disabling consumers who lack information necessary to choose what they would otherwise perceive as in their own best interests, and adding to consumer search costs. It also distorts demand by causing foods and supplements that may not be preferred (were accurate but uncertain information about them available in the market) to remain the choice of the unwary.

In sum, based on the foregoing, the Joint Commenters urge FDA to recognize the following informational characteristics of qualified health claims: (1) uncertainty of proof is the norm in the nutrition science information market, as it is in the science information market generally; (2) health claims that accurately state the relative level of uncertainty in nutrition science provide the public with important information helpful in (and sometimes indispensable to) the exercise of informed choice in the purchase of foods and dietary

supplements; and (3) the exercise of choice is far more likely to be one of deliberate pursuit of self-interest and far less likely to be the product of fraud, misunderstanding, or prejudice if accurate qualified health claims are allowed to reach the market expeditiously.

B. THE CORE VALUES OF THE FIRST AMENDMENT IMPLICATED BY REGULATION OF THE SPEECH IN ISSUE

The freedom from government abridgement of speech that is the command of the First Amendment creates a private communications sphere in which the free exchange of ideas and information (without fear of government prior restraint or punishment after the fact) is the norm and in which any government intrusion into that sphere proceeds with a presumption against its constitutionality. Aspects of the free idea and information exchange protected by the First Amendment have been variously described as core values underlying the amendment or interests created by the amendment. Courts have examined the extent to which government acts have interfered with the operation of those core values and interests in evaluating the First Amendment validity of government acts. See, e.g., *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (“The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented”); *Virginia State Board of Pharmacy*, 425 U.S. 748, 762 (1976) (“Our question is whether speech which ‘does no more than propose a commercial transaction,’ is so removed from any ‘exposition of ideas,’ and from ‘truth, science, morality, and arts in general, in its diffusion of liberal sentiments on the administration of Government, that it lacks all protection. Our answer is that it is not”)

(citations omitted); Id. at 760 (Court reaffirms principle that the “relationship of speech to the marketplace of products or of services does not make it valueless in the marketplace of ideas”) (citing, Bigelow v. Virginia, 421 U.S. 809, 825-26 (1975)); Id. at 765 (“It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To that end, the free flow of commercial information is indispensable”); New York Times v. Sullivan, 376 U.S. 254, 270 (1964) (The First Amendment “presupposes that right conclusions are more likely to be gathered out of a multitude of tongues, than through any kind of authoritative selection. To many this is, and always will be, folly; but we have staked upon it our all”) (citing United States v. Associated Press, 52 F. Supp. 362, 372 (D. C. S. D. N. Y 1943)); Id. (Court considers case “against the background of a profound national commitment to the principle that debate on public issues should be uninhibited, robust, and wide-open, and that it may well include vehement, caustic, and sometimes unpleasantly sharp attacks on government and public officials”); Terminiello v. Chicago, 337 U.S. 1, 4 (1949) (“The vitality of civil and political institutions in our country depends on free discussion...it is only through free debate and free exchange of ideas that government remains responsive to the will of the people and peaceful change is effected. The right to speak freely and to promote diversity of ideas and programs is therefore one of the chief distinctions that sets us apart from totalitarian regimes”) (citing, De Jonge v. Oregon, 299 U.S. 353, 365 (1937)).

Free idea and information exchange cultivates intellect, inspires invention, and leads by varying degrees to the progress of mankind. That exchange exposes falsehood and confirms truth, causing scientific, political, economic, and social wisdom to evolve. The intellectual tradition which influenced James Madison and his contemporaries led

them to favor a prohibition on federal government abridgement of free speech and press, arising from a desire to protect against censorship the operation of a private communications sphere that included all manner of speech (commercial and political) indispensable to the functioning of idea and information markets. See 44 Liquormart, 517 U.S. at 496; see also 2 JOHN TRENCHARD & THOMAS GORDON, CATO'S LETTERS 296-300 (Leonard Levy, gen. ed., 1971) (Letter No. 100, *Discourse upon Libels* (1722))³; JOHN MILTON, AREOPAGITICA IN THE TRADITION OF FREEDOM 1, 28 (Mayer ed. 1957) (“And though all the winds of doctrine were let loose to play upon the earth, so Truth be in the field, we do injuriously by licensing and prohibiting to misdoubt her strength. Let her and Falsehood grapple; who ever knew Truth put to the worse, in a free and open encounter. Her confuting is the best and surest suppressing”); BENJAMIN FRANKLIN, AN APOLOGY FOR PRINTERS (Book Craftsmen Associates, Inc., ed. 1955) (1731); THOMAS JEFFERSON, *First Inaugural Address*, reprinted in THE COMPLETE JEFFERSON 385 (Padover ed. 1943) (“if there be any among us who would wish to dissolve this Union or change its republican form, let them stand undisturbed as monuments of the safety with which error of opinion may be tolerated where reason is left free to combat it”); Martin H. Redish, The First Amendment in the Marketplace: Commercial Speech and the Values of Free Expression, 39 Geo. Wash. L. Rev. 429 (1971). See also, 44 Liquormart, 517 U.S. at 495-96 (citing Benjamin Franklin, supra).

Scholarship defining the core values that underlie the First Amendment (i.e., beneficial by-products of the amendment's denial of government power over the private

³ These two English Whigs (part of the opposition political movement to the Hanoverian Kings), esteemed by the revolutionary Americans as embodying in their letters on liberty the American cause, wrote that it was “senseless to think that any Truth can suffer by being thoroughly searched, or examined into . . .” and explained that “Truth has so many Advantages above Error, that she wants only to be shewn, to gain Admiration and Esteem.” J. TRENCHARD & T. GORDON, CATO'S LETTERS (L. Levy, gen. ed.) 298-300.

communications sphere) largely arose in the twentieth century. See generally Kent Greenawalt, Free Speech Justifications, 89 Colum. L. Rev. 119 (1989). Various First Amendment scholars have argued that the amendment serves interests in democratic self-government (e.g., ALEXANDER MEIKLEJOHN, POLITICAL FREEDOM (1948)); in individual self-fulfillment (e.g., Martin H. Redish, The Value of Free Speech, 130 U. Pa. L. Rev. 591, 630-35 (1982)); in the free exchange of ideas in the marketplace (e.g., Mary B. Nutt, Trends in First Amendment Protection of Commercial Speech, 41 Vand. L. Rev. 173, 205 (1988)); and in the search for truth and in individual liberty (e.g., THOMAS I. EMERSON, THE SYSTEM OF FREEDOM OF EXPRESSION (1970); JOHN STUART MILL, *On Liberty*, in SELECTED WRITINGS OF JOHN STUART MILL 121 (M. Crowley ed. 1968) (1858)).

Self-Government. Democratic self-government depends on an informed electorate that has at its disposal all information potentially useful in discerning how best to evaluate the prudence of government men and measures, exercise the franchise, vote on referenda, and participate in the body politic. See Whitney v. California, 274 US 357, 375-77 (1927) (Brandeis, J., concurring); see also Vincent Blasi, The First Amendment and the Ideal of Civic Courage: The Brandeis Opinion in Whitney v. California, 29 Wm. & Mary L. Rev. 653, 679-83 (1988). Justices Stevens, Kennedy, and Ginsburg have indicated their preference for this core First Amendment value. In 44 Liquormart, 517 U.S. at 503, Justice Stevens' opinion (joined by Justices Kennedy and Ginsburg) recites that suppression of truthful information can never be permitted because such government actions "often serve only to obscure an 'underlying governmental policy'" and, in so doing, "impede debate over central issues of public policy."

General awareness of beneficial effects of nutrients on disease risk reduction has an obvious impact on the health of the population. That, in turn, tends to reduce reliance on public coffers, including those of the health agencies of the United States. Thus, public knowledge of nutrient-disease relationships necessarily influences decisionmaking on how best to expend public health dollars and direct public health initiatives. It also affects health legislation (e.g., the popular support for the passage of the Dietary Supplement Health and Education Act) and angst over FDA policy (e.g., the popular outcry against FDA suppression of the folic acid/neural tube defect claim). Thus, the self-government core value is adversely affected by any decision to deny consumers accurate qualified health claims.

Marketplace of Ideas and Information. Justice Oliver Wendell Holmes has been given greatest credit for popularizing what has become known as the “marketplace of ideas” core value of the First Amendment. See Abrams v. United States, 250 US 616, 630 (1919) (Holmes, J., dissenting).⁴ In Virginia State Board of Pharmacy, 425 U.S. at 763, the Supreme Court embraced the concept in the commercial speech context, finding the First Amendment presumption squarely in favor of free idea and information exchange, holding the benefits of free idea and information exchange essential to the functioning of our free enterprise economy. Id. (“[t]he particular consumer’s interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day’s most urgent political debate”); see also Red Lion Broadcasting Co. v.

⁴ Justice Holmes’ famous dissent reads in pertinent part: “. . . [W]hen men have realized that time has upset many fighting faiths, they may come to believe even more than they believe the very foundations of their own conduct that the ultimate good desired is better reached by free trade in ideas—that the best test of truth is the power of the thought to get itself accepted in the competition of the market, and that truth is the only ground upon which their wishes safely can be carried out. That at any rate is the theory of our Constitution.” 250 US at 630.

FCC, 395 US 367, 390 (1969) (“It is the purpose of the First Amendment to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail”); Edenfield v. Fane, 507 U.S. 761 (1993); Thompson v. Western States Medical Center, 535 U.S. 357 (2002); Milkovich v. Lorain Journal Co., 497 U.S. 1 (1990).⁵

All consumers depend upon accurate health information to guide choices in the market. The answer to the question, “what’s for dinner?”, increasingly depends not just on one’s taste preferences but also on what nutrients foods contain. Likewise, the answer to “what supplement should I take?” depends on the potential effect of the nutrients contained in the supplement. Free exchange of accurate qualified health claims thus fills a vital niche in the market, one that provides food and supplement consumers information at the point of sale that can help them alter consumption patterns in ways that may reduce disease risk and extend longevity. When government suppresses accurate qualified health claims it creates market dislocation. It denies consumers information necessary to avoid a misallocation of funds and to avoid waste of time and resources on mistaken beliefs about the relative utility of foods and supplements. It renders consumers more prone to fraud by virtue of the lack of truth in the market to counter false claims.

Self-Fulfillment. In both Cincinnati v. Discovery Network, 507 U.S. 410 (1993), and in Edenfield v. Fane, *supra*, the Supreme Court identified the self-fulfillment core value of the First Amendment as one justifying protection of commercial speech.

Discovery Network, 507 U.S. at 420, n.17; Edenfield v. Fane, 507 U.S. at 766-767. Free information exchange is essential to discerning how best to achieve self-fulfillment.

⁵ The marketplace of ideas core value is in substance a law and economics theory. Aaron Director and Ronald Coase expound upon the indispensable role of free information exchange in a series of seminal works. See, e.g., Aaron Director, The Parity of the Economic Marketplace, 7 J.L. & Econ. 1, 1 (1964); Ronald H. Coase, Advertising and Free Speech, 6 J. Legal Stud. 1 (1977); Ronald H. Coase, The Market for Goods and the Market for Ideas, 64 Am. Econ. Rev. at 384 (1974).

Restriction of that exchange impedes or obstructs self fulfillment by making it more difficult to discern what is in one's own best interest and how to maximize the likelihood of achieving that best outcome.

Search for Truth/Liberty. In the early modern formulation of theories underlying freedom of speech, the search for truth core value featured prominently (See ZECHARIAH CHAFEE, FREEDOM OF SPEECH 179 (1920)) and became incorporated into First Amendment jurisprudence. Abrams v. United States, 250 U.S. 616 (1919). In ON LIBERTY, John Stuart Mill argued that the freedom to disseminate a wide range of ideas and information, as opposed to insistence on the creation and maintenance of official orthodoxy, would lead to idea and information contests out of which truth would emerge. JOHN STUART MILL, *On Liberty*, in SELECTED WRITINGS OF JOHN STUART MILL 164-65 (M. Crowley ed. 1968) (1859). Tried through the rigors of debate, exposed and broadly appreciated, truth would tend to win out over falsity. Hidden, through government suppression, truth would neither be discovered nor gain acceptance. Indeed, for all we know the presumed falsity that those in power may perceive as a basis for suppression could, if subjected to a fair and open inquiry in the marketplace, ultimately prove true.

According to Thomas I. Emerson, “to cut off [the] search for truth, or [a person’s] expression of it, is . . . to elevate society and the state to a despotic command and to reduce the individual to the arbitrary control of others.” Thomas I. Emerson, Toward a General Theory of the First Amendment, 72 Yale L. J. 877, 880 (1963). In Whitney v. California, 274 US 357, 375-376 (1927), Justice Brandeis, concurring, identified the search for truth and the individual liberty core values of the First Amendment as indispensable, writing:

Those who won our independence believed that the final end of the State was to make men free to develop their faculties; and that in its government the deliberative forces should prevail over the arbitrary. They valued liberty both as an end and as a means. They believed that freedom to think as you will and to speak as you think are means indispensable to the discovery and spread of political truth; that without free speech and assembly discussion would be futile; that with them, discussion affords ordinarily adequate protection against the dissemination of noxious doctrine; that the greatest menace to freedom is an inert people; that public discussion is a political duty; and that this should be a fundamental principle of the American government. They recognized the risks to which all human institutions are subject. But they knew that order cannot be secured merely through fear of punishment for its infraction; that it is hazardous to discourage thought, hope, and imagination; that fear breeds repression; that repression breeds hate; that hate menaces stable government; that the path to safety lies in the opportunity to discuss freely supposed grievances and proposed remedies; and that the fitting remedy for evil counsels is good ones. Believing in the power of reason as applied through public discussion they eschewed silence coerced by law – the argument of force in its worst form. Recognizing the occasional tyrannies of governing majorities, they amended the Constitution so that free speech and assembly should be guaranteed.

Qualified health claims are a catalyst to the discovery and spread of truth and to health freedom. To the extent that qualified health claims foster public inquiry and discussion on the role of specific nutrients in reducing the incidence of disease, they invite debate that may yield greater discoveries which, in turn, expand freedom of informed choice. When government suppresses accurate qualified health claims, it forecloses opportunities for public inquiry and, thus, reduces or eliminates that debate which may prove essential to greater discoveries and to greater freedom to choose.

C. THE EFFECT OF THE OPTIONS ON THE CORE VALUES IMPLICATED

Option 1. Under Option 1, FDA would codify the current interim procedures and evidence-based ranking system into a regulation, or codify a variation of these. In lieu of notice and comment rulemaking, the current interim procedures provide the substantive benefit of that process by making the requested qualified health claim and the data

supporting it available for public comment. The current procedures do not relieve parties of the need to file qualified health claims with FDA for review but do ensure a faster review than would be achievable were the qualified health claims required to undergo formal notice and comment rulemaking. The current procedures also rely on enforcement discretion (i.e., FDA’s exercise of discretion to avoid taking enforcement action against the qualified health claim) and issuance of enforcement discretion letters in lieu of regulations. That approach, as modified to ensure efficient review and to avoid codification of specific pre-set qualification language, furthers the core First Amendment values at stake, complies with the First Amendment strictures present (as explained infra at 26-28), and best comports with the health claims provision of the Food Drug and Cosmetic Act (as explained infra at 28-29).

Two aspects of this approach adversely affect the core First Amendment values implicated by FDA regulation of qualified health claims. First, while the process is more efficient than notice and comment rulemaking, it still results in a considerable delay between the time the petitioner proffers the qualified health claim and the time the agency issues its decision letter on allowance of the qualified health claim. Delays burden the speaker because they deprive the speaker of the opportunity to engage in timely information exchange, discourse, debate and truth-seeking arising from the claim.⁶ Moreover, delays deprive consumers of the opportunity to integrate the information into decisionmaking at the earliest possible moment. The resulting market dislocation may prove harmful to public health, as Congress found with FDA’s suppression of the folic

⁶ Delays on the right to free speech even for short periods are presumptively unconstitutional. See, e.g., Elrod v. Burns, 427 U.S. 347, 373 (1976) (Court holds that “[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury”); Lakewood v. Plain Dealing Publishing Co., 486 U.S. 750,758 (1988) (noting that “opportunities for speech,” if suppressed, “are irretrievably lost”).

acid/neural tube defect claim. See S. REP. NO. 103-410, at 7 (1994) (wherein Congress explained that the delay in approving the claim contributed to preventable neural tube defect births).

Second, the evidence-based ranking system prefers, but does not mandate, use of specific qualifications for claims. In its “Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements,” [Guidance for Industry and FDA (July 10, 2003), *available at* <http://www.cfsan.fda.gov/~dms/hclmgui3.html>], FDA presents the following model disclaimers:

- B: “Although there is scientific evidence supporting the claim, the evidence is not conclusive.”
- C: “Some scientific evidence suggests...however, FDA has determined that this evidence is limited and not conclusive.”
- D: “Very limited and preliminary scientific research suggests...FDA concludes that there is little scientific evidence supporting this claim.”

While useful as models, revealing examples of disclaimers that have been used and could be used in future, any attempt to codify the examples as either required or preferred offends the core values of the First Amendment by imposing a one-size fits all qualification regime on the entire diverse universe of potential qualified health claims, eliminating that degree of claim specific tailoring required to ensure maximum accuracy in claim qualification. To be sure, no two health claims are exactly alike and the evidence upon which each is based varies, often greatly. To ensure that qualifications are accurate, they must be tailored to each claim. Only by tailoring the language of the qualification to each claim can the FDA ensure that truly accurate information indispensable to furtherance of each core First Amendment value reaches the market. FDA should precisely tailor each disclaimer to the claim in issue in light of the evidence

presented for each claim. FDA cannot reasonably rely on a standardized class of disclaimers to disclaim the entire wide-ranging universe of qualified health claims. Indeed, use of such a standardized approach not only offends the First Amendment core values in issue, it also violates the constitutional requirement that disclaimers be “short, succinct, and accurate.” See, Pearson II, 130 F. Supp. 2d at 120; Pearson III, 141 F. Supp. 2d at 107. See also, In Re R.M.J., 455 U.S. 191, 203 (1982); see also Ibanez v. Florida Dep’t of Bus. And Prof’l Regulation, 512 U.S. 136, 144-46 (1994); Peel v. Attorney Registration and Disciplinary Comm’n, 496 U.S. 91, 99-111 (1990).

The Joint Commenters therefore recommend codification of Option 1 (1) on the condition that FDA adopt a time limit (100 days) on the review process that ensures efficient evaluation of the science and promulgation of a decision letter and (2) on the condition that FDA modify the evidence-based ranking system to define the qualifications listed as B through D in the Guidance as exemplary only and to require that FDA craft specific disclaimers for each claim presented, tailored to each claim in light of the claim’s specific language and the claim’s unique evidentiary basis.

Based on the experiences of the Joint Commenters in evaluating and presenting scientific literature backing health claims, the Joint Commenters believe the agency should adopt a 100 day maximum review time, including a 30 day period for public comment. The agency may, of course, in cooperative discussions with a particular petitioner extend the review time by mutual consent, as has been the current practice, to accommodate the unpredictable demands created by limitations of available agency resources or other exceptional circumstances.

Option 2. Under Option 2, FDA would require each qualified health claim to undergo the notice and comment rulemaking proceeding statutorily prescribed for food health claims, 21 U.S.C. § 343(r)(4)(A)(i). Under this approach, FDA would reinterpret the significant scientific agreement standard to apply to the claim and the disclaimer rather than to the substance-disease relationship (as is the agency’s current practice). Qualified health claims would only be allowable following an up to 540 day review period and only then upon actual promulgation of a regulation codifying the claim. Qualified health claims so codified could only be removed from the market if they were subsequently proven inherently misleading through FDA promulgation of a rule revoking the original codification.

Four aspects of this approach violate the core First Amendment values implicated by FDA regulation of qualified health claims. First, the statutory process is prescribed by Congress for instances in which FDA “authorizes” health claims, i.e., instances in which FDA places its official imprimatur behind the claims having found them to satisfy “significant scientific agreement.” 21 U.S.C. § 343(r)(3)(B)(i). Yet, as the Pearson court made clear, a determination that a claim is not authorized under the statutory scheme is not the same as a determination that the speech in issue is inherently misleading (i.e., is unprotected by the First Amendment). Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999). As the Pearson court found, speech that FDA deems not capable of authorization under significant scientific agreement may nevertheless be truthful or, at worst, only potentially misleading and, as to the latter, capable of being rendered nonmisleading through use of a reasonable disclaimer. See id. at 657. Thus, FDA suppression of a qualified health claim on the grounds that it failed FDA’s test for health claim

authorization invites constitutional challenge (as explained infra at 26-28) and violates the core First Amendment values favoring the marketplace of ideas, self-government, self-fulfillment, truth-seeking, and liberty. It does so by denying accurate nutrient-disease information access to the market.

Second, the process prescribed for ascertaining whether a nutrient-disease claim is backed by significant scientific agreement requires the adduction of proof for the claim to a near certain degree. Consequently, the review to affirm a claim capable of agency authorization requires far greater time than one to determine whether a claim is backed by credible evidence consistent with Whitaker v. Thompson, 248 F. Supp. 2d 1, 11 (D.D.C. 2002). Thus, qualified health claims allowable under the constitutional precedent must be delayed for a far longer time than is necessary. The time delay maintains claim suppression for excessive periods. Delays burden the speaker because they deprive the speaker of the opportunity to engage in timely information exchange, discourse, debate and truth-seeking arising from the claim. Moreover, it deprives consumers of the opportunity to integrate the information into decisionmaking at the earliest possible moment. The resulting market dislocation may prove harmful to public health, as Congress found with FDA's suppression of the folic acid/neural tube defect claim. See S. REP. NO. 103-410, at 7 (1994) (wherein Congress explained that the delay in approving the claim contributed to preventable neural tube defect births). The Supreme Court is loathe to tolerate any delays. See, e.g. Elrod v. Burns, 427 U.S. at 373 and Lakewood v. Plain Dealing Publishing Co. 486 U.S. at 758 at footnote 6, supra.

Third, Option 2 fails to ensure that degree of flexibility in regulatory response required to cure promptly any defect in health claim qualification made apparent through

the functioning of the scientific information marketplace. Thus, if it comes to light that a qualified health claim once codified is misleading through omission of a material fact or representation of a fact since proven false, correction would require use of the rulemaking process to modify or revoke the codified rule. That delay will disserve the core values of the First Amendment which depend upon accurate information in the market.

Fourth, Option 2 improperly relies on a statutory system for FDA health claim authorization to accommodate qualified health claims that are ones not FDA authorized because they must be qualified to reveal the absence of that degree of scientific evidence statutorily prescribed for authorized claims. The effect will be to mislead and obfuscate, creating the impression that FDA places its official imprimatur of authorization behind claims that it has determined are accurate but backed by inconclusive science. The confusion is generated by the fact that a codified claim is one that the government communicates to the world as its official position whereas a qualified health claim under the interim procedures is recognized as a claim that the petitioner communicates to the world but that the government does not codify, authorize or endorse. The former is to a large extent the government's speech because through "authorization" the government effectively adopts an approved health claim as its own. The latter is the private petitioner's speech that FDA does not endorse or adopt as its own. The core First Amendment values are only served when accurate information is conveyed to the public and accuracy is disserved when the distinction between government endorsed or authorized claims, on the one hand, and unauthorized qualified health claims, on the other hand, are obscured. So long as the health claims provision, 21 C.F.R. § 343(r), remains part of the Food Drug and Cosmetic Act, FDA will be obliged to maintain this bifurcated

approach. The statute plainly contemplates FDA codification of a health claim following rulemaking applying SSA. Pearson plainly contemplates claim qualification and exercise of enforcement discretion when SSA is not satisfied.

Option 3. Under Option 3, FDA would not impose any advance review requirement on the use of qualified health claims but would instead rely on its power under Section 403(a)(1) of the Food Drug and Cosmetic Act, 21 U.S.C. § 343(a)(1), to police the market for false or misleading labeling on a postmarket basis. No aspect of this approach violates the core First Amendment, as explained infra at 26-28. Indeed, the Joint Commenters believe that this approach best advances the core values of the First Amendment due to its immediacy (i.e., no government barriers to market entry) and its narrow focus on suppressing, postmarket, only false and misleading claims. As explained infra at 28-29, however, this approach violates the health claim provision of the Food Drug and Cosmetic Act, 21 U.S.C. § 343(r)(1)(B) and (5)(D). It does so by excepting from advance review labeling statements that characterize the relationship of a nutrient to a disease or health-related condition. The statute requires all such statements to be filed with FDA for evaluation. 21 U.S.C. § 343(r)(4)(A). The statute does not require FDA to “authorize” every claim so filed, only those that satisfy “significant scientific agreement.” Pearson establishes that claims not FDA authorized may not be suppressed if they are capable of being rendered nonmisleading through the addition of a disclaimer. Pearson expressly does not stand for the proposition that the pre-market filing requirement (in 21 U.S.C. § 343(r)(3)(B) and 21 C.F.R. §§ 101.14 and 101.70) violates the First Amendment. Thus, without amendment to the statute to eliminate the premarket filing requirement for FDA evaluation of qualified health claims, FDA lacks

discretionary authority to eliminate that requirement unilaterally. Accordingly, the Joint Commenters urge FDA to seek congressional authorization of an amendment to the Food Drug and Cosmetic Act to codify an exception to the premarket review requirement for qualified health claims.⁷ With such an exception in place, Option 3 would be viable and, among the three options, the best in furtherance of the core First Amendment values present and an obvious less speech restrictive alternative to the present regime, thus rendering it preferable under the First Amendment precedent.

D. THE REGULATORY OPTIONS WHICH SURVIVE FIRST AMENDMENT SCRUTINY

Of the three regulatory options, only Options 1 and 3 can survive First Amendment scrutiny. The Pearson and Whitaker cases apply the three part Central Hudson test. Under that test, the government must possess a substantial state interest in regulating the speech in question. Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York, 447 U.S. 557, 566 (1980). As in Pearson, so too here, there can be no question but that FDA has a substantial state interest in avoiding fraud and protecting public health and, thus, it satisfies that requirement.

Under Central Hudson, the government must establish that its chosen means further its chosen ends in a direct and material way. See, e.g. Edenfield v. Fane, 507 U.S. 761, 767 (1993); Western States Medical Center, supra, 535 U.S. 357. The courts have said that the government must show that the harms it recites “are real” and that the government’s chosen means advances the government’s interest “to a material degree.” Ibanez v. Florida Dep’t of Bus. and Prof’l Regulation, 512 U.S. 136, 143 (1994);

⁷ Option 3 is an obvious, less speech restrictive alternative. Because, as explained above, it appears not allowed by the statute, it raises questions as to the First Amendment validity of the statute as applied to qualified health claims. That underscores the importance of FDA seeking a change in the FDCA to exempt qualified health claims.

Edenfield, 507 U.S. at 770-71; see also Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 648-49 (1985). Options 1 and 3 clearly satisfy the means-ends fit test because they respond to Pearson and its progeny by avoiding the taking of enforcement action against health claims that do not satisfy the “significant scientific agreement” (“SSA”) test but can be reasonably qualified to avoid misleadingness. They thus directly satisfy the goal of avoiding fraud and protecting public health without violating the First Amendment. Option 2, however, does not further the goal in a direct and material way. That is because health claims that may be rendered nonmisleading through the addition of a disclaimer may nevertheless lack the level of scientific proof FDA requires for health claim authorization (i.e., SSA). See Pearson I at 653. In Pearson, the harm of misleadingness was held not present when claims were, at worst, only potentially misleading and were capable of being disclaimed to guard against that potential. Pearson v. Shalala, 164 F.3d at 655. Far from eliminating misleadingness, Option 2 actually creates it (1) by suppressing all claims that do not satisfy SSA, including those that are accurate representations of inconclusive scientific evidence and (2) by erasing the distinction between FDA authorized claims and FDA allowed claims, forcing all claims to be codified and, thus, to become official positions of the agency.

Under Central Hudson, government may not restrict speech if there are obvious less speech restrictive alternatives to the regulation. See, e.g., Thompson v. Western States Medical Center, 535 U.S. at 371 (“In previous cases addressing this final prong of the Central Hudson test, we have made clear 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”); Rubin v. Coors, 514 U.S. 490-91; 44 Liquormart, 517 U.S. at 507. Options 1 and 3 do not *per se* invite a conclusion that there are obvious less speech restrictive alternatives. Each constitutes a direct response to the constitutional mandates of the Pearson and Whitaker courts. See Pearson I; Pearson II; Pearson III; and Whitaker, cited supra. Option 2, however, fails under this final prong of Central Hudson because there are obvious less speech restrictive alternatives to the speech and time burdens imposed by this option. Options 1 and 3 are obvious, less speech restrictive alternatives to Option 2 because each permits use of qualified health claims without requiring proof to the level of SSA, resting instead on the constitutional standard that the speech in issue not be inherently misleading and, if potentially misleading, be allowed with disclaimers to avoid misleadingness. Option 3 is less speech restrictive than Option 1, however, and, thus, should be preferred. But Option 3, unlike Option 2, is prohibited by statute, and, thus, FDA should ask Congress to exempt qualified health claims from the pre-market filing requirement in 21 U.S.C. § 343(r)(3)(B) and 21 C.F.R. §§ 101.14 and 101.70 to permit Option 3 to replace Option 2. See discussion, infra, at 29-30.

E. THE REGULATORY OPTIONS WHICH COMPLY WITH THE FOOD DRUG AND COSMETIC ACT, 21 U.S.C. § 343(r)

The health claim provision of the Federal Food Drug and Cosmetic Act requires that every labeling statement that characterizes the relationship of a nutrient to a disease or health-related condition be filed with FDA before it enters the market. 21 U.S.C. § 343(r)(1)(A). The provision further provides that FDA may only “authorize” health claims that it finds backed by SSA. Under Pearson I, its progeny⁸, including Whitaker, a health claim not backed by SSA must be “allowed” by FDA (i.e., permitted to be made

⁸ See also, Pearson II and Pearson III, cited supra.

despite FDA's conclusion that it fails SSA) so long as the claim can be rendered nonmisleading through the addition of a reasonable disclaimer. Thus, not every health claim that enters the market need be FDA authorized, but none of these cases stands for the proposition that a health claim need not be filed with FDA, as required by 21 U.S.C. § 343(r)(1)(A).

Under the extant statutory and constitutional schemes, only Option 1 complies. Option 2 fails because it violates the First Amendment requirements of Pearson and Whitaker, as explained above. Option 3 fails because it violates the health claims provision's statutory requirement that every labeling statement that characterizes the relationship of a nutrient to a disease or a health-related condition be filed with FDA before entering the market. As explained above, the Joint Commenters believe Option 3 the best alternative (i.e. an obvious, less speech restrictive alternative to Options 1 and 2) were it not for the statutory impediment. Thus, while they urge FDA to adopt Option 1, as modified by their recommendations, they also urge FDA to seek congressional amendment to the health claims provision to except from its premarket filing requirement all qualified health claims with the end in view of adopting Option 3 as soon as the statute is thusly changed.

F. CONCLUSION: OPTION 1, AS MODIFIED, IS THE BEST LAWFULLY AVAILABLE REGULATORY ALTERNATIVE

As explained above, Option 1 is the best legally available regulatory alternative when modified to specify a review time limit of 100 days, including a 30 day public comment period, and when modified to make the B through D qualifications of the Guidance exemplary only and to require FDA to develop specific, tailored, succinct disclaimers for each claim). The Joint Commenters therefore urge FDA to adopt Option

1 as modified consistent with their recommendations. They find Option 3, however, to be the best were it not for the statutory requirement in the health claims provision that all statements characterizing the relationship of a nutrient to a disease or a health-related condition be filed premarket with FDA. They therefore urge FDA to seek congressional amendment of the health claims provision to except from the premarket filing requirement all qualified health claims and thereby permit adoption of Option 3.

II. ISSUES IN THE TASK FORCE REPORT

The Joint Commenters address each of the topic areas arising from the Task Force Report.

A. Data and Research on a Substance/Disease Relationship, Including Incentives for SSA

Under this heading, the FDA requests comments on (1) how to provide incentives for manufacturers to develop the data needed to obtain SSA approval for unqualified claims. FDA also requests comments on (2) how to more effectively develop public-sponsored research on substance/disease relationships.

1. How to Provide Incentives for Data Needed to Obtain SSA for Unqualified Health Claims

The agency's first inquiry is necessarily based on the presumption that the SSA standard is well enough defined so that the regulated class can perceive with a reasonable degree of certainty what level, degree, quantity, and quality of scientific evidence FDA will require to grant SSA approval. That presumption is in error. It is the Joint Commenters' experience that no one (indeed not even the highly qualified scientists hired by the Joint Commenters to evaluate research) can reasonably anticipate in advance how FDA will react to specific scientific evidence supporting the existence of a nutrient-

disease relationship. The agency's guidance on the topic, Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (1999), is unhelpful in that regard because it merely explains FDA's general views on the relative weight or significance of individual studies and does not explain precisely how FDA will assess overall, and cumulatively weigh, studies of varying significance. Four years after the Pearson Court equated the vagueness of FDA's SSA standard with that of the Supreme Court's obscenity standard (i.e., in the words of Justice Stewart, "I know it when I see it," Pearson I, 164 F.3d at 660 (quoting Jacobellis v. Ohio, 378 U.S. 184, 197 (1964))), the regulated class is still largely unable to discern what FDA expects of it to satisfy SSA. The regulated class cannot predict with reasonable certainty how CFSAN will evaluate scientific evidence in any particular case.

There appear to be seven principal reasons for this uncertainty. First, nutrition science supporting a nutrient-disease relationship is typically complex and capable of multiple interpretations. Second, differences in scientific opinion concerning the relative weight and merits of any particular study often vary widely. Third, the agency's focus—contrary to the plain language of 21 U.S.C. § 343(r)—is on the extent to which SSA supports the existence of a nutrient-disease relationship rather than the extent to which SSA supports the actual claim in issue. Fourth, there appear to be disincentives at work within CFSAN against grant of SSA authorization, (1) arising from an apparent fear that grant of SSA for any nutrient-disease relationship claim may cause FDA to condone a risk of public harm (no matter how remote or speculative) from increased nutrient ingestion and (2) arising from an apparent fear that grant of SSA authorization for certain accurate nutrient-disease relationship claims may blur the distinction between foods and

drugs. Fifth, even in the presence of actual agreement among leading authorities in the field that a relationship has been established, the agency has in the past determined there to be a lack of SSA. To date, FDA has never admitted error in the calculus or provided specific corrective instructions to CFSAN on any claim denial subsequently reversed to prevent recurrence of the same error (e.g., the approximately 2,500 preventable neural tube defects per year that could have been averted if a health claim concerning the relationship between folic acid and neural tube defects were allowed by the agency when first considered). See, S. Rep. No 103-410 at 7. Sixth, the agency spends over a year and a half before it grants SSA approval. That delay in getting authorized health claims into the market creates a tremendous institutional disincentive for the filing of health claim petitions. The food and dietary supplement markets are highly competitive and ever-changing, unlike the far more stable drug markets. That is due largely to the fact that, unlike in the drug market, in the dietary supplement market there are no legal barriers to market entry. Companies have considerable difficulty in justifying the amount of money required to prepare and file health claim petitions when the potential claim may not be available for 540 days. Most companies cannot predict consumer behavior, interests, and needs that far in advance and, so, often abandon pursuit of a health claim when informed of the length of the process. Seventh, FDA's recent decision to characterize as a drug claim any claim of a nutrient's effect on an existing disease, CFSAN, Letter, Dietary Supplement Claim for Saw Palmetto Extract and Benign Prostatic Hyperplasia: Denied (May 26, 2000), eliminates from the realm of health claims an enormous body of nutrition science concerning the effects of nutrients on disease, thereby reducing industry interest in pursuing health claims.

To provide an incentive for manufacturers to develop data needed to obtain SSA for unqualified health claims, FDA should change agency policy and culture in the following respects. First, FDA needs to recognize frankly that each study supporting a relationship is capable of multiple interpretations and should be equally frank in demanding a reversal of a CFSAN internal bias against supportive interpretations and in favor of negative ones. The tendency within CFSAN is to presume scientific evidence not supportive when a study can be interpreted either as supportive or as not of a nutrient-disease relationship. CFSAN should reverse that bias and favor a supportive interpretation whenever a supportive interpretation is reasonable.

Second, under the existing SSA guidance, Guidance for Industry, supra, CFSAN evaluates whether there is SSA supporting the underlying nutrient-disease relationship, rather than the claim itself. That practice is contrary to the plain language of the statute, 21 U.S.C. § 343(r)(3)(B), which focuses on the existence of SSA supportive of the “claim,” and not the underlying nutrient-disease relationship. It is entirely possible for a carefully worded claim to be one for which there is SSA among experts, yet were one to focus instead on the underlying nutrient-disease relationship, there may not be SSA. That is because a claim can be worded (i.e., qualified) in less than conclusive terms and be perceived by most experts to be backed by significant scientific agreement, but significant scientific agreement of the nutrient-disease relationship’s existence requires proof to a near certain degree that nutrient “X” prevents disease “Y.” For example, proof that the following claim is backed by SSA, “Nutrient X may reduce the risk of cancer,” requires less definite proof than establishing to a near certain degree the underlying nutrient-disease relationship (i.e., that Nutrient X prevents cancer). Accordingly, shifting

to a claim-based SSA system will create an incentive for more companies to file health claims, because proof of a nutrient-disease claim is often less onerous than proof of a nutrient-disease relationship.

Third, concerns within CFSAN about the potential adverse effects that may arise from increased ingestion of nutrients following SSA approval of a health claim should only result in a denial of SSA when empirical evidence establishes the nutrient (either in a dietary supplement or in a particular food) to be adulterated within the meaning of 21 U.S.C. § 342 at the recommended levels of ingestion. In all other instances, CFSAN should grant the claim and rely on the following mechanisms to guard against potential adverse effects. If the adverse effect is known to exist at certain levels of ingestion beyond those recommended (or if there are adverse effects known to exist for identified subpopulations), the agency should require use of a succinct and accurate warning statement on labels and in labeling to alert the public of the potential adverse effect. If the adverse effect is not known to exist but is thought possible based on reasonable inferences from the evidence, the FDA should encourage, but not require, use of a warning statement and should post on the FDA website, and issue as part of a press release simultaneous with the grant, a warning to the public of the possible adverse effect. In short, CFSAN should favor disclosure of more information, not claim suppression, as its remedy for perceived risks to the public arising from ingestion of nutrients beyond recommended levels following SSA approval of a health claim.

Fourth, the Nutrition Labeling and Education Act's exception of health claims from the drug definition has never been popular within CDER. The institutional bias within that center has long been against health claims because the Center perceives health

claims to diminish its regulatory control over articles intended for use in the prevention of disease (i.e., drugs).⁹ It may well be that no internal FDA system for evaluation of health claims can escape the pervasive bias against health claims that is part of the agency's institutional culture and history. See, e.g. S. Rep. No. 103-410, cited supra; Nutritional Health Alliance v. Shalala, 144 F.3d 220, 224 (2nd Cir. 1998); Pearson v. Shalala, 164 F.3d 650, 654 n.3 (D.C. Cir. 1999). To counteract the effects of FDA's internal bias against health claims, FDA should create independent outside expert SSA review panels, each comprised of a half dozen leading scientific authorities from outside the federal government who have not previously worked in a consulting capacity or otherwise for the FDA or DHHS or any DHHS subagency. FDA should establish a legal presumption in favor of a panel's determination on the existence of SSA, should make public each panel's determination, and should only overrule panel determinations upon proof of specific and substantial contrary evidence. Reliance on, and deference to, the scientific judgment of an outside independent expert SSA review panel in the assessment of each nutrient-disease relationship claim (limited in their review to a discrete time prescribed by regulation, e.g., 90 days) would do much to counteract disincentives for approval of unqualified health claims arising from institutional bias.

Fifth, the Pearson Court instructed FDA that it could define SSA either by telling the regulated class what SSA is or by telling the regulated class what SSA is not. Pearson I, 164 F.3d at 660-61. In other words, while it may be quite difficult for FDA to agree

⁹ Whether the agency agrees that there exists such a bias is not important, FDA knows from comments received in Docket No. 95N-0304 (Ephedrine Alkaloids: Report of Adverse Events; Availability) and in Docket No. 99D-5424 (Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Availability) that there is a widespread perception that the bias exists. The best way to overcome that perception is to institute measures, such as the independent outside expert SSA review panel, recommended herein.

internally on a definition of (i.e., the meaning of) SSA such that the regulated class can discern what elements must be present for FDA to find SSA in a particular case, it can certainly explain on a case-by-case basis precisely what evidence FDA would have needed in the case in order to find SSA. Moreover, in instances where it has reversed course and granted SSA after first finding SSA not present, it should explain in detail its own evaluative errors and use that explanation as precedent to educate FDA reviewers on illegitimate grounds for rejecting sound science. In that regard, FDA would do well to revisit its folic acid/neural tube defect SSA rejection and explain where it erred in the assessment of the evidence. FDA should admit error in its initial rejection of SSA for the folic acid/neural tube defect claim and explain precisely what evaluative errors it made that resulted in that unfortunate ruling so those same errors do not recur. Doing so would educate both the regulators and the regulated on the limits of agency discretion in evaluating SSA claims.

Sixth, FDA would do well to limit the time it spends on evaluation of unqualified health claims to 180 days. The present 540 days is far too long for most companies to endure in this highly competitive market. While the Nutritional Health Alliance Court, 144 F.3d at 228, thought a decision within 540 days not an unreasonable prior restraint, in practice it works as one, causing many parties to engage in self-censorship rather than pursue claim approval over such a long duration. Most companies cannot predict consumer interests and needs that far into the future and prefer not to risk the resources needed to prepare and file a health claim petition in light of the extraordinary time

required for review. Cutting the time for review to 180 days would create a significant new incentive for the filing of health claims and for adduction of data to support them.¹⁰

Seventh, many companies are dissuaded from filing health claims because the claims they wish to file concern the effects of nutrients on existing disease. The FDA presently takes the position that any such claim is a “drug” claim ineligible for health claim approval. The effect of that decision for unpatentable nutrients is to banish numerous accurate claims from the market to the detriment of manufacturers and consumers alike. Were FDA to allow such claims (or to define the term “treatment” very narrowly and thereby expand the number of permissible health claims), it would create an incentive for the filing of health claims by many who are now locked out of the information marketplace by FDA’s treatment claim ban. The overall effect would be to transform the supermarket, drug store, health food store, and vitamin shop into places where consumers could receive accurate information on the best foods and nutrients to ingest when ill. So, for example, the sellers of antioxidant-rich fruits, vegetables, and fruit juices could then supply consumer information in stores on the wisdom of consuming those substances for those who have seasonal colds or the flu. There is today a market dislocation created by government health claim suppression, consumers who need to know what foods and nutrients to ingest to minimize the duration, frequency, or symptomology of illnesses are not able to acquire that information at the point of sale. They must then either abandon the search (something common for the ill and infirm who are most apt to lack the energy and resources for a lengthy search) or incur greater costs

¹⁰ Because most single nutrients are unpatentable, there is no economic incentive to perform costly clinical trial research in the dietary supplement field. Hence, it is unrealistic for the agency to expect dietary supplement companies to pursue lengthy and costly clinical trials of their own in the ordinary course rather than to rely on the publicly available peer-reviewed scientific literature.

in time and money to obtain the information they need. Far from serving the public health, FDA's ban on treatment claims harms public health and creates a major disincentive for companies to file health claim petitions with the agency.

2. How to More Effectively Develop Public-Sponsored Research on Substance/Disease Relationships

The Joint Commenters believe current public sponsorship for research on substance disease relationships often misdirected because it does not necessarily match the industry's or the consumers' informational needs. Without public input, a select few scientists employed by the government direct how public funds are spent on research. They may misperceive the nutrients of greatest present interest and potential. They may also misperceive the diseases for which the nutrients are thought to be most effective in averting. A better approach would be to invite public comment on nutrient-disease relationships from the industry and the public that are believed to hold the greatest potential. Private sector scientists who advise food and dietary supplement companies and consumers are often the first to discover apparent benefits of foods and dietary ingredients. Informed of popular interest through public comment, public dollars could be better spent to discover with greater scientific exactitude the utility of foods and nutrients in reducing the risks of specific diseases. The Joint Commenters therefore urge FDA to solicit public comment on those nutrient-disease relationships thought to hold greatest potential and to encourage sister agencies to direct public dollars to research in the most popular and potentially fruitful areas of inquiry. This approach holds the greatest promise for adducing information that companies will disseminate and that consumers will desire to receive.

B. Revised Claim Language for Unqualified Health Claims

The agency wants to know whether removing the requirement for the word “may” from unqualified health claims would assist consumers in identifying the level of science supporting health claims and whether there are reasonable alternatives to this change. As in the calcium/osteoporosis example given in the ANPR, the typical unqualified health claim associates a nutrient with reduction in the risk of disease (“calcium may reduce the risk of osteoporosis”). An unqualified health claim is only granted upon a finding of the existence of near conclusive scientific evidence that the nutrient in question reduces the risk of the disease in question. While it is undoubtedly true that diet is but one factor affecting disease (albeit it is sometimes the most important factor), it is also true that the science supporting an unqualified health claim reveals it to affect disease risk in the general population and is not meant to convey the effect of the nutrient in a specific individual. Therefore, it is an accurate statement to say that calcium reduces the risk of osteoporosis, because while it may not reduce that risk in a particular case, population wide it undoubtedly reduces the risk. When the word “may” is removed, the remaining phrase, “reduce the risk of osteoporosis,” does not convey to the reader that the product will cure osteoporosis or will actually prevent osteoporosis onset in an individual person. Rather, it plainly conveys that the product reduces osteoporosis *risk*. The point of ambiguity arises if the consumer presumes that his or her own risk of osteoporosis will necessarily be reduced by ingesting the nutrient—a circumstance that may or may not happen because the proof concerns effects on the population as a whole.

The problem is one of claim interpretation, and the solution is the provision of more information. The information lacking from all FDA authorized health claims is that

the risk reduction effect is one that occurs population wide and may not necessarily occur in an individual case. The present required use of the word “may” does not convey the population wide limitation and reasonably leads to consumer reflection, as explained in the ANPR, on the relative worth of the science supporting the claim.

The Joint Commenters agree that the word “may” should be eliminated from unqualified health claims. They believe the agency should rely on press releases announcing claims and on information on its web sites to explain that unqualified health claims granted by the agency pertain to population wide disease risk reduction and not to the effect in an individual case. While it is always the case that the vagaries of language, education levels, and human experience invite differing perceptions of the meaning and utility of claims, FDA promotion of the population wide basis for the claim is best achieved through ordinary mass media and through education over its web site on the meaning of unqualified health claims. In this instance, any misperception of the extent to which the unqualified health claim pertains to risk reduction in an individual case will be of no serious physical consequence to the individual because the claim itself pertains to risk reduction and no person could reasonably conclude that the product was an absolute disease preventive. Thus, exclusive reliance upon it as a means to prevent the disease in question is unlikely and agency reliance on defining the population-wide meaning through the media and its web site should suffice over time to correct misperception.

C. Interim Final Rules for Unqualified Health Claims

The agency requests comments on whether it should continue to use the Interim Final Rule Process (IFR) for authorizing unqualified health claims upon publication of the proposed unqualified health claim in the Federal Register. The agency seeks

comment on the balance between the priorities of timeliness and of comprehensiveness in FDA's review of unqualified health claims. The agency asks if there are specific circumstances when IFRs should or should not be considered appropriate for health claims that meet the SSA standard.

The Joint Commenters believe that the agency should adopt as a general rule reliance on IFRs to ensure prompt introduction of unqualified health claims to the market. The First Amendment interests in avoiding claim suppression are powerful and the legal presumption lies in favor of the most expeditious removal of regulatory restraints on the communication of accurate information. See, Elrod v. Burns, 427 U.S. at 373 and Lakewood v. Plain Dealer Publishing Co., 486 U.S. at 758, at footnote 6, supra. While claims may later be tailored based on information received in comments, the need for avoiding suppression at the earliest possible moment exceeds the need for assuring the most accurate expression of the claim. Moreover, each unqualified health claim is an introduction of new information into idea and information markets. Those markets operate to vet the science and the claims, as explained above. They ferret out weaknesses and truths inherent in the claim and help educate the public in ways that editing of the language can never achieve. It is therefore less imperative that the claim be the most accurate articulation (if, indeed, that is linguistically achievable) than that the market-vetting process commence at the earliest possible moment and that the public be given the chance to experience the health benefits that can accrue from incorporating the nutrients into the daily diet.

There are specific circumstances in which it may be inadvisable to permit an unqualified health claim to enter the market through an IFR. If the evidence reveals that

the nutrient in certain foods (or when consumed at certain levels obtainable from ordinary dietary practices) could produce serious adverse effects to a population subgroup and when the precise nature of those adverse effects is uncertain without the benefit of public comment, then the FDA would be well advised to receive full comment on the effects before crafting an appropriate warning statement to accompany the claim into the market.

D. Use of Phrases Such as “FDA Authorized” in Qualified and Unqualified Health Claims

Under 21 U.S.C. § 343(r), when FDA determines that a claim is backed by SSA, it “authorizes” the claim. Thus, it is a truthful and nonmisleading statement to inform the public when using an unqualified health claim that FDA has authorized it. It is therefore axiomatic that FDA has no lawful authority under the First Amendment to prevent use of any of the following kinds of truthful statements in connection with an unqualified health claim: “FDA has authorized use of the following health claim;” “FDA has determined that . . .;” or “FDA has found that . . .” In each case, the representation is true. If there is a potential for confusion, FDA should again rely on dissemination of more information to discourage misperception. For example, in its press releases announcing the grant of unqualified health claims or on its website, FDA may explain that statements in association with unqualified health claims on labels and in labeling concerning its authorization of those claims should not be construed to be endorsements of specific products.

Under Pearson, when FDA allows a qualified health claim, it does not “authorize” it pursuant to 21 U.S.C. § 343(r). Thus, it is misleading to inform the public when using a qualified health claim that FDA has authorized it. Accordingly, FDA may prohibit use of such language in association with qualified health claims. The Pearson Court invites

the agency to include disclaimers to the effect that the agency does not approve qualified health claims. See Pearson I, 164 F.3d at 659.

E. Consumer Education

The agency properly recognizes that, “even when the scientific evidence for substance/disease relationships does not meet the standard of SSA, there may be considerable evidence of a relationship between the substance and the disease, and consumers may find this information useful in planning their diets.” The Joint Commenters agree with this view. Consumers must cope with the reality that very little in the field of science, including in the field of nutrition science, is known with near certainty. Common foods and supplements that we ingest daily contain ingredients that affect us in ways that science has only begun to explain. As that science emerges, the public has a right, indeed a need, to know of it. While it will be uncertain, it is nevertheless informative and, so long as accurately conveyed, can be integrated by each of us, individually, into that thought matrix which guides us in choosing one food or supplement over another. Each person’s choice will be based on differing factors, but that choice will more likely mirror each person’s own self interest if well enough informed.

The agency asks for comment on how it could best educate consumers about the role of qualified health claims in food labeling, and how such claims may be used by consumers to advance their own understanding of diet and health matters. The Joint Commenters believe that the FDA can perform an indispensable role in promoting public awareness of qualified health claims and of the scientific evidence concerning them. In that regard, the Joint Commenters recommend that the agency issue press releases

whenever a qualified claim is allowed, describing it and the agency's reasons for finding it backed by credible evidence. Likewise, the agency should explain its disclaimer in the press release. The press release should be posted on the agency's web site, and the agency should also post, with consent, the petitioner's petition and the agency's letter granting the claim. FDA might also hold press conferences to coincide with the release of qualified claims, allowing FDA representatives to elaborate on press release contents and inviting scientists for the claim proponents to appear, address the media, and respond to questions. Those conferences could be transmitted by FDA to the public at large in real time video, via the Internet, helping maximize public access and understanding.

FDA should also hold annual or bi-annual national conferences, inviting scientists from the private and public sectors to present papers on emerging information on nutrient-disease relationships and inviting all in the regulated class to send representatives to attend the conferences. The conferences could include interactive discussion seminars on the most promising new information and could encourage industry leaders to invest in research or to work with the government on research to investigate the nutrient-disease relationships. Seminar papers, related materials, and interactive seminars could be transmitted by FDA to the public at large in real time video via the Internet, helping maximize public access and understanding. Those same papers, related materials, and seminar transcripts could then be posted on the agency's website as evidence of emerging science on nutrient-disease relationships, edifying the industry and the public about potential new associations. These vehicles for the dissemination of information can help the public acquire more knowledge about the qualified claims and can help increase public awareness and understanding of the realistic potential and limits

of nutrient-disease associations. It could also help encourage investment and research in investigations of nutrient-disease relationships. It can help complete the transformation of FDA from a substance-disease information barrier into a substance-disease information provider. Edification of the public through these means can help improve consumer understanding and help render consumers more impervious to fraud in the food and dietary supplement markets.

F. Evaluations of Outside Scientific Groups

The agency asks whether the evaluations of scientific evidence by non-governmental groups, like the American Heart Association or the American Dietetic Association, should be given weight in evaluating health claims. If so, the agency asks how the weight should be determined. The Joint Commenters believe that there should be no preference of any kind established, no special weight given, for non-governmental organizations' scientific reviews. The agency must strive to be objective and it must also preserve its independence in order for the regulated class and the public to trust the agency's impartiality in the decisionmaking process. Assigning any preference or weight to the views of particular nongovernmental organizations creates a bias that will deny petitioners and the public confidence in the agency's objectivity. It will also afford those groups greater influence and power over decisionmaking involving claims not of their own creation. The principles of objectivity and independence are critical for the agency to maintain. Instead of assigning a special preference or weight to non-governmental groups, the agency currently considers, and rightly should consider, any person or group's scientific submissions or opinions in the course of evaluating qualified and unqualified health claims. The peculiar merits of each such submission should determine

its relative weight, not the identity of the petitioner.

G. Competent and Reliable Scientific Evidence

The agency requests comment on the meaning and/or relevance of the FTC’s “competent and reliable scientific evidence” standard (used by that agency in assessing whether claims of health benefit in advertising are deceptive under 15 U.S.C. §§ 45 and 52 of the Federal Trade Commission Act) for supporting qualified health claims.

The FTC’s standard applies to assess whether a claim of health benefit in advertising is substantiated such that a reasonable consumer reading the claim would not be deceived by it. See, e.g. FTC Bureau of Consumer Protection, Dietary Supplements: An Advertising Guide for Industry (1998). The standard focuses on the extent to which substantiation proffered by the advertiser in support of the claim has “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.” It focuses on the method of evaluation principally and it aims to determine whether that method is in accordance with scientific principles and procedures accepted in the relevant profession as yielding accurate and reliable results.

The FTC’s competent and reliable scientific evidence standard differs from the “credible evidence” standard in several material respects, making reliance by FDA on the FTC’s standard inappropriate.¹¹ First and foremost, unlike FTC’s “competent and reliable scientific evidence” standard, the FDA’s “credible evidence” standard is the product of federal court constitutional mandates to this agency that apply in the prior

¹¹ Indeed, the FTC itself has stated that the “competent and reliable scientific evidence standard has limited relevance under the evidence-based ranking system...” Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission, In the Matter of Food Labeling: Health Claims; Dietary Guidance Docket No. 2003-0496 at 8, fn. 18 (January 26, 2004) (“FTC Comments”).

restraint context. By contrast, FTC's standard applies in the post-publication context. In Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002), the federal court defined the "credible evidence" standard not by reference to FTC's "competent and reliable evidence" standard but by reference to FDA's burden of proof under the First

Amendment:

Specifically, Pearson I identified two situations in which a complete ban would be reasonable. First, when the "FDA has determined that no evidence supports [a health] claim," it may ban the claim completely. [Pearson v. Shalala, 164 F.3d 650, 659-660 (D.C. Cir. 1999)... Second, when the FDA determines that "evidence in support of the claim is qualitatively weaker than evidence against the claim—for example, where the claim rests on only one or two old studies," it may impose an outright ban. Id., 164 F.3d at 659 n.10... Even in these two situations, a complete ban would only be appropriate when

the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Court] suggested above ["The evidence in support of this claim is inconclusive" or "The FDA does not approve this claim"] would bewilder consumers and fail to correct for deceptiveness.

Id., 164 F.3d at 659-660. . . [T]he Court indicated that it was "skeptical" that the government would be able to provide such evidence. Id.

Whitaker v. Thompson, supra at 10-11.

Second, the FTC's standard focuses on the extent to which evidence proffered in support of the claim is of a kind generally accepted in the relevant profession as yielding accurate and reliable results. The FDA, by contrast, substantively evaluates the bona fides of each study supplied in support of a qualified claim to determine for itself the extent to which each study constitutes credible evidence in support of the claim and in relation to an underlying, discrete nutrient-disease relationship. While the FTC's focus under "competent and reliable scientific evidence" is upon whether the procedures used in the studies are generally accepted in the relevant profession as yielding accurate and

reliable results, the FDA's focus is on whether the studies are by design, methodology, and results credible evidence in support of the claim in relation to an underlying, discrete nutrient-disease relationship.

Third, the FTC standard applies to marketed claims of health benefit that lack government-mandated disclaimers or qualifications. It is an enforcement mechanism for the evaluation of advertising that is believed to be deceptive. The FDA "credible evidence" standard specifically invites the government to create disclaimers or qualifications as a means (less speech restrictive than suppression) to avoid misleadingness. It is a pre-publication mechanism designed to identify and correct for potential misleadingness. It is consistent with FTC policy under the "competent and reliable scientific evidence standard" to defer to the judgment of the FDA when it vets scientific evidence, drafts a disclaimer to avoid misleadingness, and then allows that qualified health claim to enter the market. See, Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971) (outlining liaison agreement between the agencies whereas FDA exercises jurisdiction over the regulation of product labeling and FTC exercises jurisdiction concerning advertising claims). Thus, an FDA-allowed qualified health claim by operation of law satisfies FTC's "competent and reliable scientific evidence" standard.

Fourth, were FDA to employ FTC's "competent and reliable scientific evidence" standard in addition to, or in place of, the court-mandated "credible evidence" standard in the evaluation of scientific evidence supporting qualified health claims, it would unnecessarily create analytical confusion in the law and would invite legal challenge in light of the different meanings and applications of those standards. FDA's primary

purpose (and duty) in performing a qualified health claim analysis is to ensure compliance with the First Amendment by requiring use of disclaimers that correct for potential misleadingness, as ordered by the federal courts. FTC performs no such function with its “competent and reliable scientific evidence” review which aids FTC in post-publication enforcement. It is critical for FDA to fulfill its constitutional mandates directly, under the credible evidence standard established by the court, and to avoid use of differing standards that could constitute legal error in fulfillment of the courts’ mandates. The Joint Commenters therefore urge FDA not to employ the FTC’s “competent and reliable scientific evidence” standard in the evaluation of qualified health claims.

H. Dietary Guidance Statements on Foods

The agency explains that dietary guidance statements focus on general dietary patterns, practices, and recommendations that promote health and may be made on conventional foods and dietary supplements without advance FDA review. The agency provides the following as an example of a dietary guidance statement: “Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases.” The agency explains further that a dietary guidance statement may make reference to a disease or substance, but not both, explaining that a “substance” is a specific food (expressly or impliedly a substance within the food) or component of food, whether in conventional foods or dietary supplements. See, e.g., 68 Fed. Reg. 66040; See also, CFSAN, Office of Nutritional Products Labeling and Dietary Supplements, [FDA’s Implementation of “Qualified Health Claims”: Questions and Answers](#) (August 27, 2003).

The agency asks for comment on an appropriate definition of “dietary guidance” for labeling purposes. In particular, FDA requests comment on how the “substance” element of the definition can be clarified. The agency asks whether General Mills, Inc.’s FDA-approved health claim, “Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers,” refers to a substance (as would be required for a health claim) or to a broad category of food (as would be appropriate for a dietary guidance statement). The agency seeks comment on the usefulness of statements that expressly include the substance that is the basis for the health claim (citing as an example, “calcium-rich foods, such as yogurt may reduce the risk of osteoporosis”) versus those that are food specific (citing as an example, “yogurt may reduce the risk of osteoporosis”). The agency seeks comment on whether dietary guidance statements should include recommendations for making food or substance “substitutions” or “replacements.” The agency asks how it may ensure that such statements are made in clear and nonmisleading ways that will enhance and benefit public health. FDA explains that, unlike with health claims, with dietary guidance statements, it may not be able to ensure that the statements fit within the context of a healthy diet and contain adequate amounts of the substance of interest and seeks comment on how it may regulate to avoid misleading statements. FDA also seeks comment on whether it would be desirable for the agency to provide a list of dietary guidance statements that FDA recommends for inclusion on food labels. Finally, FDA presents the following three topics for comment: (1) whether and how the agency should engage in partnership relationships with other Federal agencies to identify and agree upon recommended dietary guidance statements for food labeling, (2) the appropriate criteria

for evaluating the scientific validity of dietary guidance statements that appear on products in the marketplace, and (3) whether and how the agency should address dietary guidance statements from non-federal sources (e.g., States, trade associations, professional associations, etc.).

The Joint Commenters respond to each of the agency's inquiries. The Joint Commenters believe the current definition of dietary guidance ambiguous, making it difficult for the regulated class to discern which claims are health claims and which are dietary guidance statements. To help clarify the meaning of dietary guidance and minimize the risk of overlap, they recommend that the agency expressly recognize that 21 U.S.C. § 343(r) pertains to "nutrient" disease relationship claims, not to claims associating whole foods, broad categories of foods, herbs in general, botanicals in general, or broad categories of herbs or botanicals with disease or to claims associating broad nutrient categories, such as "vitamins", "minerals", and "amino acids," with disease. The definition of the term "dietary guidance" should be revised to make this clear. The term "substance" should be limited to discrete nutrients (when identified expressly or by clear implication) (consistent with 21 U.S.C. § 343(r)); it should exclude whole foods, broad categories of foods, herbs in general, botanicals in general, broad categories of herbs or botanicals, and broad nutrient categories, such as "vitamins"; "minerals"; and "amino acids." Thus, a dietary guidance would not be permissible for discrete nutrients, so defined, unless the dietary guidance made no reference to a disease. The present regulatory definition of disease may remain unchanged. Using the Joint Commenters' definition of "substance" would allow whole foods, herbs in general, botanicals in general, broad categories of herbs or botanicals, and broad categories, such

as “vitamins,” “minerals,” and “amino acids,” to be associated with diseases without falling within the definition of a health claim. The dietary guidance statements would still be subject to agency action if they were false or misleading in violation of 21 U.S.C. § 343(a).

The Joint Commenters believe General Mills, Inc.’s FDA-approved health claim is properly viewed as a dietary guidance statement. The diets in question are not specific foods or components of foods and, thus, do not meet the present definition of a “substance.” There is no material difference between the example of a dietary guidance statement given by the agency in the advance notice and General Mills, Inc.’s FDA-approved health claim.

To the extent that a claim includes a specific reference to a nutrient (e.g., “calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis”), the claim is one associating a nutrient with a disease and, thus, a claim that satisfies the statutory definition of a health claim in 21 U.S.C. § 343(r). While “calcium-rich foods” is a broad category, it is defined in the sentence by the presence of calcium which then is linked to reduced risk of osteoporosis (precisely a nutrient-disease relationship claim that meets the statutory definition of a health claim). The claim that “yogurt may reduce the risk of osteoporosis” differs fundamentally because it does not identify a specific nutrient. Yogurt is a complex food containing many nutrient ingredients, none of which is in this sentence associated with reduction in the risk of osteoporosis. It is thus not a nutrient-disease relationship claim within the plain meaning of 21 U.S.C. § 343(r) and should instead be considered a dietary guidance statement.

The agency asks for comment on whether dietary guidance statements should

include recommendations for making food or substance “substitutions” or “replacements.” The agency asks how it may ensure that such statements are made in clear and nonmisleading ways that will enhance and benefit public health. FDA has no constitutional power to suppress or prevent dietary guidance statements from including recommendations for making food or substance substitutions or replacements, so long as those statements are not inherently misleading. Truthful statements of this kind are very helpful to consumers because they can aid them in avoiding consumption of substances that may be less healthful or actually deleterious to the health of certain subpopulations. The agency should recognize the existence of several market incentives that militate against the making of false claims. First, most firms in this highly competitive marketplace depend upon brand loyalty and consumer trust to retain market share. They thus have a natural incentive to communicate truthful information. Second, substitution and replacement claims immediately implicate the market value of competitors. Competitors thus have an incentive to evaluate the claimed propriety of the substitution claim. If the claim is false, competitors can rely on counterspeech or can complain to non-governmental policing bodies, such as the National Advertising Division of the Council of Better Business Bureaus, or to the FDA and/or FTC that such claims are false. Third, the FDA retains power under 21 U.S.C. § 343(a) to take enforcement action against any party that engages in false or misleading labeling. Accordingly, there are many mechanisms available to help guard against false dietary guidance statements without resort to a prior restraint on such speech.

The agency seeks comment on how it may regulate to ensure that dietary guidance statements fit within the context of a healthy diet and contain adequate amounts

of the substance of interest to have beneficial effects. This issue is in part satisfied by the definition of “dietary guidance” and is in part resolvable by resort to enforcement under 21 U.S.C. § 343(a). Because the typical dietary guidance statement involves a whole food, category of foods, or category of nutrients, it will often involve reference to complex, multi-nutrient substances within the context of a healthy diet. Because 21 U.S.C. § 343(a) forbids the making of false and misleading claims, any use of a dietary guidance statement on foods or dietary supplements lacking adequate amounts of the substance of interest would be unlawful. As explained above, market forces militate against such false statements, but in instances where false statements are made, the agency has the power to take enforcement action against the offending parties under 21 U.S.C. § 343(a). To assist the regulated class in avoiding inadvertent or unintentional misuse of dietary guidance statements on products lacking adequate amounts of the substance of interest, the agency could invite parties to provide the agency with dietary guidance statements they intend to use or are using along with the quantitative amounts of the substances of interest recommended for consumption. The agency could then evaluate the information and provide advisory opinions on the minimum amount of the substances of interest needed to support use of the claim. In instances where the institutional knowledge within the agency and publicly available scientific evidence would not permit a clear answer, the agency could invite public comment on minimum levels necessary to support the dietary guidance statement and then determine based on the comments and the publicly available scientific evidence what minimum levels of the substance of interest would be necessary to support the dietary guidance statement.

The agency asks whether it would be desirable for it to provide a list of dietary

guidance statements that FDA recommends for inclusion on food labels. The Joint Commenters believe such a recommended list would aid the regulated class and would encourage use of dietary guidance statements to the benefit of consumers. The creation of such a list would give the regulated class confidence that using the statements would not likely engender adverse regulatory action. Many companies avoid use of any statements linking foods with disease in part because of the ambiguity in the definition of dietary guidance but also because of a fear that doing so will increase regulatory scrutiny. The creation of an FDA recommended list would tend to eliminate those fears and give the regulated class confidence that use of the dietary guidance statements will not engender adverse regulatory action.

The agency asks for comment on three topics: The first, whether and how the agency should work with other federal agencies to identify and agree upon recommended dietary guidance statements for food labeling. The Joint Commenters believe that the agency should invite public and private entities to file with the agency dietary guidance statements now in use and capable of use along with the corresponding listing of the substances in issue. FDA could then begin its evaluative process, determining which of the dietary guidance statements it intends to recommend. The evaluation could be aided through solicitation of public comment. The second topic concerns what criteria should be employed for assessing the scientific validity of dietary guidance statements. Because dietary guidance statements are quite similar in their usefulness to health claims and qualified health claims, before FDA may suppress them it must establish that they are lacking in credible evidence consistent with the test in Whitaker v. Thompson, 248 F. Supp. 2d at 10-11. The third topic concerns whether and how the agency should address

dietary guidance statements from non-federal sources (e.g., states, trade associations, professional associations, etc.). The agency should assess dietary guidance statements from non-federal sources in the same manner it does those from all other private sector sources. It has statutory authority to require that the statements not be false and misleading. It may reasonably demand that each non-federal source avoid use of any false and misleading dietary guidance statement.

I. Future Analysis of Benefits and Costs

To aid the agency in evaluating benefits and costs of its regulatory options for qualified health claims, the agency seeks comment in response to the following questions: (1) what effects do health claims have on consumer purchases of foods and dietary supplements? What effects do health claims have on the total daily diet? (2) Is there a difference between consumers' willingness to buy products with qualified health claims and consumers' willingness to buy products with health claims based on SSA? (3) What effects would the different qualifying phrases described in the interim procedures for qualified health claims guidance and the Task Force report have on the willingness of consumers to buy the products containing the claims? Is there evidence that consumers would find the differences among qualifying phrases to be substantial? (4) What types of foods and dietary supplements are most likely to use qualified health claims in their labeling? What types of claims are most likely to be used by those products? (5) What types of existing products will manufacturers re-formulate in order to be able to make qualified health claims? What types of claims are most likely to lead to re-formulation? (6) What new products might be developed in response to qualified health claims? (7) Would any of the regulatory options discussed in the ANPRM have a significant effect on

small businesses or other small entities? (8) What additional research would FDA, other government agencies, or other organizations sponsor to answer these questions?

As an initial matter, the Joint Commenters urge the agency not to rely on survey evidence as a means to determine whether proposed qualified health claims and disclaimers are misleading. Qualified health claims, like health claims in general, are pre-market statements, unlike those FTC routinely evaluates. Moreover, as explained above, they convey scientific information, often of a complex character, that comes to be understood by the public only through the workings of the idea and information marketplace. Consequently, it is likely that upon their first introduction in the market they will be met with varying interpretations, varying levels of appreciation, and higher levels of misunderstanding than after they have been vetted in the idea and information markets. Testing consumer understanding before market entry and the free market vetting process will thus produce unreliable results. At best, it will produce an accurate picture of a surreal circumstance—a claim as it is understood upon first contact with consumers and shorn of related labeling and competitor and public commentary.¹²

Moreover, the First Amendment rights involved are those of the speaker. The listeners' rights are to receive the speaker's desired message, not to edit that message in aid of comprehension. As we know from Pearson and its progeny, the First Amendment protects the speech in issue so long as it is true or, at worst, only potentially misleading, regardless of its complexity. Pearson I, 164 F.3d at 657. Arguments that qualified health claims were beyond the ken of average consumers or were too complex for the public to

¹² The FTC explains that based on its market research the context in which a health claim appears in the market is a vital factor in consumer understanding of the claim. See FTC Comments at 10 (“...[T]he impression that consumers take away from a claim sometimes varies based on the context in which it is made...”).

understand were rejected by the Pearson court. Id. at 655 (Court rejects government’s argument that “health claims lacking ‘significant scientific agreement’ are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous”). To the extent that a qualified health claim is true, or only potentially misleading, it is protected speech and the FDA must rely on disclaimers as a less speech restrictive alternative to outright suppression. Id., citing Peel v. Attorney Registration and Disciplinary Comm’n of Illinois, 496 U.S. 91, 110 (1990); In Re R.M.J., 455 U.S. 191, 206 n.20 (1982); Shapero v. Kentucky Bar Association, 486 U.S. 466, 478 (1988). Our First Amendment precedent protects the right of the speaker to communicate a message and the right of the listener to receive that message. See, Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 756 (1976) (“Freedom of speech presupposes a willing speaker. But where a speaker exists...the protection afforded is to the communication, to its source and to its recipients both”). The First Amendment does not permit government restriction of speech on the basis that the listener does not understand the message communicated. Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 74 (1983) (Speech cannot be abridged solely on the level of understanding of the listener, as “the level of discourse in reaching a mailbox simply cannot be limited to that which would be suitable for a sandbox.”). The First Amendment protects the right of the speaker to communicate even complex messages (even messages that no one understands but the speaker him or herself). Id.; Butler v. Michigan, 352 U.S. 380, 383 (1957) (Court

holds that the government may not “reduce the adult population...to reading only what is fit for children”). The protection extends to the speech so long as it is not inherently misleading. If true, or potentially misleading, but comprehensible only to a very few, it still commands First Amendment protection. See, e.g. Bolger, supra; Pearson II, 130 F. Supp. 2d at 120 (Court holds that proposed health claim at issue “is only potentially misleading, and therefore subject to First Amendment protection”); See also, Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557, 562 (1980) (“Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all”). The Court has rejected attempts to restrict the speaker’s rights based on a supposed need for the listener to receive other or different information. See Miami Herald Pub. Co. v. Tornillo, 418 U.S. 241 (1974) (The Supreme Court, rejecting the notion that listeners have an independent First Amendment right to edit speech to suit their interests or needs, struck down a Florida right of reply statute as an abridgement of the speaker’s First Amendment rights); See also, National Association for the Advancement of Colored People v. Jones, 131 F.3d 1317, 1322 (9th Cir. 1997) (“While both the speaker and the listener have the right to assert First Amendment rights, no precedent exists that the listener’s rights are greater than those of the speaker.”).

Accordingly, were FDA to conduct a survey evaluating a claim and to presume from that evidence that the content of the speech had to be revised to enable listeners to understand the speakers’ message, it would engage in precisely that kind of restriction on the rights of the speaker that the Supreme Court has rejected as unconstitutional in the past. See, Tornillo, supra. FDA may rely on survey evidence to determine how best to

craft its own disclaimers (i.e., its own speech) but may not change the petitioner's claim based on that evidence.

Moreover, as explained above, survey evidence obtained before market vetting of a qualified health claim is of dubious value. It is at best but a snapshot in time, a sliver of a rapidly changing reality. As explained above, as soon as a qualified health claim enters the market, it becomes the source of attention, evaluation, and comment. Comprehension of it changes from the first introduction forward because communication about it fuels greater understanding, debate, and evolution in thinking. To be sure, even the science underlying the claim evolves, introducing new bits of information through the peer reviewed media and, in variously condensed forms, in the popular media. The best means for FDA to assist consumer understanding is through greater dissemination of information to the public about the qualified health claim and the evidence supporting it. As explained above, FDA can best aid this process by issuing press releases, holding press conferences, and relying on its web site to present information concerning the claim and the nutrient-disease relationship. Public education concerning the claim is the best means of maximizing public understanding, not claim suppression, claim restriction, or lengthy disclaimers.

Empirical evidence compiled by the Federal Trade Commission (FTC) suggests that consumers are influenced at the point of sale in favor of a purchase by information about the disease risk reducing effects of nutrients. See Dennis Murphy, et al., A Generic Copy Test of Food Health Claims in Advertising (1998); See also, E. Calfee & Janis K. Pappalardo, fn. 1, *supra*. Purchases of cereal containing bran accompanied by colon cancer risk reduction claims resulted in increased sales of the cereals and an apparent

shift in purchases away from non-bran containing cereals. See, Pauline Ippolito and Alan Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market* (1989). It can be reasonably anticipated that similar kinds of changes in the marketplace for other foods and for dietary supplements will occur with greater consumer awareness about the disease risk reducing effects of nutrients.

There appears to be no direct empirical evidence on the effect of health claims on the total daily diet. It is difficult to know whether, on average, consumers tend to add health claim containing foods and nutrients to their diets without substituting them for less health enhancing foods or tend to substitute health claim containing foods and nutrients for less health enhancing foods. Without question, the issue is affected by far more information inputs than health claims, depending on all manner of media inputs, interpersonal communications, and experiential factors and depending heavily on the variable interpretations of those inputs, communications, and factors by each person.

There appears to be no direct empirical evidence assessing consumer willingness to make a purchase depending on whether the claim in issue is a qualified health claim or an unqualified health claim. Given the great variability in the nutrients that are the subject of both kinds of claims and the variability in claim structures, it is highly unlikely that any clear difference would exist. Moreover, it would be virtually impossible to attribute any perceived difference to the claims themselves because purchasing decisions are complex and influenced by a great many factors that vary from person to person, only one of which would likely be the content of a health claim, whether qualified or unqualified.

There appears to be no direct empirical evidence assessing consumer reaction to each of the different qualifying phrases (described in the interim procedures for qualified health claims) on consumer willingness to buy the products in question. Empirical evidence of that kind would be very difficult, if not impossible, to obtain because consumer willingness to buy a product is affected by many factors and inputs, only one of which would be the claim and only one of which would be the disclaimer. Media inputs, interpersonal communications, and experience are weighty factors not easily discerned that undoubtedly weigh in any buying decision.

There appears to be no limit to the kinds of foods and dietary supplements that could potentially be eligible for qualified health claims and no limit to the interest from food and dietary supplement companies in use of qualified health claims. Food and supplement companies of all kinds have a keen interest in the process and would likely make more use of qualified health claims in the market were the disincentives for qualified health claims, explained above, removed. The kinds of claims likely to be used are ones that can be articulated in simple terms (i.e., in an expression containing few words such that the claim can readily appear on a product label and an expression that is not the subject of a disclaimer akin to those listed as “C” and “D” in the evidence-based ranking system).¹³

To the extent that popular demand shifts in the market in response to a qualified health claim, companies can be counted upon to reformulate products to permit use of the claim. For example, the prospect of a succinct qualified health claim for omega-3 fatty

¹³ That is not to say that “C” and “D” qualified health claims are useless to the industry. To the contrary, even claims backed by the most preliminary and inconclusive research do, from time to time, interest the regulated class. That is because early public consciousness of the potential association can lay a foundation for ready public awareness of the association if later evidence yields a “B” or an “A” claim. Moreover, even a slight potential of a nutrient to reduce disease risk may interest the industry and consumers.

acids on foods and supplements has already engendered considerable interest among those who sell omega-3 containing products to be sure that the quantitative amounts present in the foods and in the supplements will match any level the FDA determines to be appropriate. Many of those companies will reformulate existing products to ensure appropriate levels. Moreover, many foods and dietary supplements that could be fortified with omega-3 fatty acids may well become so in response to an FDA determination to allow a succinct qualified health claim for that nutrient. Any qualified health claim concerning a nutrient that can be added to a wide variety of foods without affecting the taste, aroma, texture, and appearance of the food and concerning a life-threatening disease that affects the general population (e.g., heart disease and cancer) are ones likely to result in the most widespread product reformulations and in the greatest use of the qualified health claim. To the extent that qualified health claims become more prolific, there will likely be a wide variety of new products on the market that capitalize on the health enhancing nutrients for which claims are allowed. This is likely in light of FTC findings following FDA allowance of a bran-cancer risk reduction claim. See, Ippolito and Matios, supra.

Small businesses would largely be locked out of the process if the FDA were to adopt Option 2. That is because the length of the process and the cost of participating would likely exceed the economic abilities of most small companies. Options 1 and 3 are feasible for small business, particularly in the case of Option 1, if the agency acts to reduce the time for review, as requested above.

FDA, like FTC and other government agencies, could conduct post-market research on qualified health claims to assess changes in product formulations and changes

in consumer demand linked to those claims. Information of that kind must be viewed with a good degree of skepticism, however, because it is largely impossible to discern precisely why consumer demand changes. Perhaps the best barometer of the change, and one that can be viewed without the extraordinary expense associated with consumer response surveys, can come from observing changes in purchasing patterns for foods and dietary supplements. Reformulated products that succeed in the market are the best evidence of a change in consumer consumption patterns and are indicative, albeit not conclusive, evidence of the persuasive effect of health claims. Interviews conducted of corporate executives can provide further confirmation of the corporate perception of the importance of the claim in product formulation and in generating product demand.

III. CONCLUSION

The Joint Commenters respectfully urge the agency to adhere to their recommendations presented above. Doing so will help the agency remain true to the First Amendment and to its public health mission, exercising its authority squarely within constitutional limits and maximizing freedom of informed choice in food and dietary supplement markets.

Respectfully submitted,

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