alliance for natural health USA

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ANH Challenges FDA for Blocking Government-Backed Health Claims

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ANH Challenges FDA for Blocking Government-Backed Health Claims

ALEXANDRIA, VA; September 2. The Alliance for Natural Health USA (ANH), alongside industry partners Living Fuel International, Health Ranger Store, Inc., and Sanacor International, Inc. and Evolution Nutraceuticals, Inc. dba Cardio Miracle, has filed a petition with the U.S. Food and Drug Administration (FDA), challenging the agency's decades-long misapplication of federal law that has blocked consumers from accessing truthful information concerning how nutrients reduce the risk of disease.

At issue is FDA's 1998 guidance, which unlawfully imposed the **Significant Scientific Agreement (SSA) standard on health claims** based on "authoritative statements" issued by federal scientific bodies such as the National Institutes of Health, Centers for Disease Control and Prevention, and National Academy of Sciences. **Congress expressly exempted these claims** from SSA requirements in the 1997 Food and Drug Administration Modernization Act (FDAMA).

Instead, under FDAMA, such claims were to be made available immediately after FDA notification—unless the agency rescinded them through formal rulemaking. By ignoring the statute's plain language and congressional intent, FDA has unlawfully suppressed at least 118 nutrient-disease health claims backed by authoritative government science.

"Americans face unacceptably high rates of diet-related diseases—ranging from obesity and fatty liver disease to diabetes, high blood pressure, and cognitive decline," said Robert Verkerk, Ph.D., ANH's Executive and Scientific Director. **"One major reason is that consumers are denied at the point of sale access to accurate, government published information about how nutrients reduce disease risk. Our petition simply seeks to uphold the law, effectively allowing the republication of government speech, so that this vital information can reach consumers at the point of sale and help reduce disease burdens."**

The petition by ANH aims to open the marketplace to 118 health claims in a single instance, which, if successful would amount to a precedent-setting breakthrough in consumer access to truthful disease risk reduction information. It builds on ANH's long history of legal victories advancing consumer access to nutrient-disease information, including the **landmark Pearson v. Shalala (1999)** case spearheaded by Jonathan Emord, Esq., now ANH General Counsel, that established the right to use qualified nutrient-disease risk reduction claims for dietary supplements. Over the last two decades, ANH has helped secure claims for

nutrients such as folate, saw palmetto, omega-3 fatty acids, fiber, vitamin E, vitamin B, and selenium.

The legal landscape shifted dramatically in 2024 when the U.S. Supreme Court decided **Loper Bright Enterprises v. Raimondo**, overturning the Chevron doctrine that gave agencies broad deference in interpreting ambiguous statutes. Under this new precedent, FDA's 1998 guidance is now vulnerable, as its requirements contradict the clear text of FDAMA and Congress's express intent.

"For more than a quarter-century, the FDA has acted in open defiance of Congress, blocking the very health claims lawmakers required it to allow," said Jonathan Emord. **"With Chevron deference now gone, FDA must implement fully the FDAMA exception to FDA's significant scientific agreement prior restraint on speech. This petition is about restoring the rule of law, ending unlawful censorship, and opening the nutrient marketplace to truthful, science-based disease risk reduction information as never before. It will improve health, increase longevity, and save lives."**

With rates of preventable, diet-related diseases at alarming levels, ANH argues that FDA's unlawful censorship harms the public by keeping science-based information out of the market. The organization is seeking FDA compliance with the law to fulfil one key element of the MAHA agenda: access to critical health claims derived from authoritative government science.

END.

ABOUT THE ALLIANCE FOR NATURAL HEALTH USA

The Alliance for Natural Health USA is a nonprofit advocacy organization dedicated to protecting access to natural health options, promoting sustainable health freedom policies, and empowering consumers with truthful, science-based information to make informed choices about their health.

Find out more at: **www.anh-usa.org.**

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Backgrounder

Alliance for Natural Health Petition to Open the Market to Health Claims Based on Authoritative Statements

Overview

A longstanding legal and regulatory dispute centers on how the US Food and Drug Administration (FDA) interprets and applies health claim requirements for food and supplements under 21 USC § 343(r)(3)(C). At the heart of this case is the FDA's 1998 Guidance,[1] which imposed Significant Scientific Agreement (SSA) requirements on health claims made by the government itself that Congress explicitly intended to exempt from such scrutiny.

The Alliance for Natural Health USA (ANH) contends that, for decades, the FDA has misapplied the law to prevent the public from accessing, at the point of sale, critical information about how foods and supplements impact health. This censorship is detrimental to public health, particularly at a time when preventable, diet-related diseases have reached alarming levels in children and adults.

Statutory Background

In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), codified at 21 USC § 343(r)(3)(C). FDAMA provides an avenue to allow health claims on food and supplement labels that are based on "authoritative statements" made by federal government scientific bodies with responsibility for nutrition research (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, the National Cancer Institute, and the National Academy of Sciences, and others).

Congress expressly exempted such claims from the burdensome SSA standard. Instead, it allowed the claims to be used immediately after FDA notification—unless or until the agency rescinded them through formal rulemaking.

[1] See "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body" (June 1998)

In the legislative history of FDAMA, Congress explained its rationale for exempting health claims based on authoritative statements from the SSA requirement. For example, the Senate Report[2] criticized the existing process—where health claims are only permitted after FDA approves each specific claim—as "inefficient" and failing to take full advantage of the careful, science-based deliberations conducted by authoritative public health bodies.

The Senate Report also made clear that the amendment aimed to prevent the kind of FDA obstruction and delay that arose from the agency's decade-long failure to authorize the CDC's folic acid/neural tube defect claim for dietary supplement labels (a claim won for the public in a suit filed by Jonathan Emord, now ANH's General Counsel, on behalf of ANH and other parties). That delay stemmed from FDA's rejection of the claim under the SSA standard, and then from prolonged inaction—even as Congress faulted FDA for preventable neural tube defect births occurred at the time.

Contrary to FDA's position, the statute exempts authoritative government statements about nutrients reducing the risk of disease from the SSA standard. The statute states that "notwithstanding the provisions" of 343(r)(B) (that is, the SSA standard)…a nutrient-disease relationship claim or health claim… ***shall be authorized*** and may be made with respect to a food" (emphasis added) if:

1. The claim is an official statement from a recognized federal scientific body responsible for public health or nutrition research.
2. The statement is accurately summarized and is from the agency itself (not an agency scientist acting in his or her individual capacity)

The FDA's 1998 Guidance and Its Controversy

Despite the plain meaning of the statute and Congress's intent, the FDA issued its guidance in 1998 requiring SSA preclearance for the very authoritative statements from other government health agencies that were statutorily exempt from SSA. That FDA misinterpretation effectively nullified the congressional exemption and kept in place high wall censorship barriers preventing the public from accessing nutrient-disease information at the point of sale.

[2] See U.S. Senate Report 105-43, 105th Cong., 1st Sess. (1997).

Impact of *Loper Bright Enterprises v. Raimondo*

In *Loper Bright Enterprises v. Raimondo* (2024), the US Supreme Court overturned the Chevron doctrine, which had long given federal agencies broad deference in interpreting ambiguous statutes. In that decision, the Court ruled that it is now the judiciary's sole responsibility to determine what the law means, significantly curbing agency power to reinterpret statutes beyond their text.

When Loper Bright is applied to the FDA's 1998 Guidance, it is vulnerable to attack. The Guidance, a misnomer because it functions as a rule, is in the ANH cross-hairs with its current petition. Its requirement for SSA preclearance contradicts the unambiguous language of 21 USC § 343(r)(3)(C), which Congress crafted specifically to eliminate that requirement for claims based on authoritative statements. Under *Loper Bright*, FDA must revise its treatment of authoritative government statements and allow them into the market to align with the plain statutory language.

Legal Precedent: *Pearson v. Shalala* and ANH's Role

This filing builds on the landmark First Amendment decision in *Pearson v. Shalala* (1999), a suit led by Jonathan Emord and brought on behalf of ANH (then the American Preventive Medical Association) and others. That ruling established the right to use qualified health claims for dietary supplements. In *Pearson*, ANH and co-plaintiffs were vindicated in their First Amendment right over FDA censorship to inform the public that folate containing dietary supplements during pregnancy could prevent neural tube defects. In *Pearson*, the court held that the FDA had to henceforth favor disclosure over suppression of nutrient-disease relationship claims that were backed by credible scientific evidence. But FDA has never fully implemented the *Pearson* decision, and its continuing suppression of FDAMA health claims is a prime example.

ANH followed *Pearson* with a series of additional lawsuits spearheaded by Emord that expanded access to qualified health claims for nutrients such as saw palmetto, omega-3 fatty acids, fiber, vitamin E, vitamin B, and selenium. These cases laid the legal foundation for challenging the FDA's ongoing suppression of credible, government-backed health information.

While these were landmark victories that secured health claims, ANH's current filing aims to open the marketplace to some 118 health claims in a single instance—a precedent-setting breakthrough in consumer access to truthful health information.

A Fight for Health Access

This case highlights critical issues at the intersection of public health, regulatory overreach, and free speech. With diet-related diseases on the rise and the current administration advancing initiatives like MAHA (Make America Healthy Again), it's more important than ever to help the public understand that some food ingredients—especially nutrients—can offer significant health benefits. Yet current FDA policy blocks access to truthful, science-based claims about these benefits—even when the source of the information is the government itself.

The filing brings attention to FDA censorship that keeps us ill and sacrifices lives. It vindicates First Amendment rights, as FDA's policy is restricting truthful, non-misleading speech. Ultimately, this is about restoring access to credible health information that can help people make better choices for their health. It is part of a broader ANH initiative to restore legal protection for the basic American right to receive truthful nutrient-disease information at the point of sale.

September 2, 2025

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NOTIFICATION OF HEALTH CLAIMS
BASED ON AUTHORITATIVE STATEMENTS

Alliance for Natural Health USA ("ANH") together with Living Fuel International, Inc., Health Ranger Store, Inc., and Sanacor International, Inc. and Evolution Nutraceuticals, Inc. dba Cardio Miracle (collectively, the parties) hereby submit this Notification for Health Claims Based on Authoritative Statements pursuant to 21 USC 343(r)(3)(C) in accordance with the filing instructions contained in FDA, "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (June 1998)" (hereinafter, 1998 Guidance). Correspondence to the parties concerning this notice should be addressed to the undersigned lead counsel. Under the provisions of 21 USC 343(r)(3)(C)(ii), the agency must act on this notice no later than 120 days from the date of submission, i.e., on or before December 31, 2025.

As explained below, if the FDA chooses not to approve the claims requested under 21 USC 343(r)(3)(C), it must allow them as a matter of constitutional right under the First Amendment to the United States Constitution because the FDA lacks authority to deny private parties the right to communicate on labels and in labeling the very same information it communicates to the public concerning the nutrient-disease associations at issue here.

Analysis under each of these legal constraints on FDA authority is required without deference to prior agency interpretation following the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo,* 603 U.S. 369 (2024).

Summary

Each of the 118 noticed health claims (Exhibit 1) for use on the labels and in the labeling of the foods specified herein (Exhibit 1) are claims subject to the provisions of 21 USC 343(c)(3)(C) because they are based on authoritative statements of scientific bodies of the United States Government with official responsibility for public health protection or research directly relating to human nutrition. The authoritative statements in Exhibit 1 have been made and published by the National Institutes for Health (NIH) and the Centers for Disease Control and Prevention (CDC). The relevant, published science relied upon by these agencies in support of the authorities' respective publications of these authoritative statements is included in the references (URLs) to the agency publications containing the authoritative statements from which the respective health claims are derived (Exhibit 2).

In its 1998 Guidance, FDA interpreted 21 USC 343(r)(3)(C) at odds with the plain meaning of the statute's terms, the legislative history underlying that section of the code, and the canons of statutory construction. In the Guidance, FDA required health claims based on authoritative statements to be subjected to the requirements of 21 USC 343(r)(3)(B)(i) (hereinafter, Significant Scientific Agreement standard or SSA) when Congress in Section 343(r)(3)(C) plainly intended claims based on authoritative statements to be exempt from the SSA requirement. The agency's interpretation contradicts the statute which exempts health claims based on authoritative statements from SSA review in advance of market entry and permits continuous use of the claim in the market until such time, if ever, when the Secretary promulgates a rule following notice and comment rulemaking that modifies or revokes the claim or a federal court in an enforcement action acts against the claim. *Contrast* 21 USC 343(r)(3)(C) ("a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) ***shall be authorized and may be made with respect to a food*** if—") *with* 21 USC 343(r)(3)(D) ("A claim submitted under the requirements of clause (C) may be made ***until***—") (Emphasis added).

The 1998 Guidance also contradicts the legislative history on point, which confirms that 21 USC(r)(3)(C) was meant to be an alternative to, not a subset of, SSA statutory review. See H.R. Rep. No. 105-399, 105th Cong., 1st Sess. (1997); S. Rep. No. 105-43, 105th Cong., 1st Sess. (1997).

Moreover, FDA demands that conditions precedent beyond those listed in the statute be satisfied before a health claim filed under subpart (C) can be authorized, yet neither the statute nor the legislative history gives FDA authority to impose those additional conditions. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 144 S.Ct. 2244 (2024), the *ultra vires* doctrine, and the canons of statutory construction, FDA has no statutory authority to require conditions be satisfied beyond those specified in the statute. See, e.g., *United States v. Great Northern Ry.,* 287 U.S. 144, 154 (1932); Unif. Statute & Rule Construction Act § 19 (1995) ("*Primacy of Text.* The text of a statute or rule is the primary, essential source of its meaning"); Justinian's Digest 32.69 (*A verbis legis non est recedendum*) ("Do not depart from the words of the law").

For the reasons explained in this submission, the parties ask FDA to adhere to the plain and intended meaning of the statute in accordance with the command of *Loper Bright Enterprises*, the *ultra vires* doctrine, and the canons of statutory construction in assessing this notification and to avoid application of the 1998 Guidance requirements that exceed and contradict the statute. In the context of noticed claims pursuant to 21 USC 343(r)(3)(C), FDA lacks the authority to require SSA compliance before authorizing the claims for entry into the market. *Contrast* 21 USC 343(r)(3)(C) ("a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—") *with* 21 USC 343(r)(3)(D) ("A claim submitted under the requirements of clause (C) may be made until—"). FDA also lacks the authority to demand satisfaction of conditions beyond those required by the statute because Congress did not delegate to FDA authority so to do. See *Loper Bright Enterprises* overturning *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 468 U.S. 837 (1984).

In the advent of *Loper Bright Enterprises*, FDA is no longer entitled to judicial deference in favor of agency interpretations that fail to track the plain and intended meaning of statutory language or that impose requirements beyond those required by the statute. Instead, in reviewing this notification, FDA must adhere to the plain and intended meaning of the statute and abide by the applicable canons of statutory construction. *Loper Bright Enterprises,* 144 S.Ct. at 2268 ("It . . . makes no sense to speak of a 'permissible' interpretation that is not the one the court, after applying all relevant interpretive tools, concludes is best").

In this submission, the parties satisfy the statutory requirements for market entry of the health claims noticed herein, as prescribed by 21 USC 343(r)(3)(C). Accordingly, the agency must authorize all of the health claims specified in Exhibit 1 to enter the market on the labels and in the labeling of the corresponding dietary supplements and foods identified.

By taking the requested action, FDA will enable consumers at the point of sale to make food purchasing decisions based on label claims concerning the effect of nutrients at levels in the dietary supplements and foods on reduction in the risk of disease. Consumers who make dietary supplement and food choices based on that information may reduce disease occurrence, extend healthy lifespans, lower burdens on health care resources, and expand individual control over their biological destinies. These ends are in ultimate fulfillment of purposes underlying the First Amendment. See, e.g., *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council,*

Inc., 425 U.S. 748, 765 (1976) ("So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end the free flow of information is indispensable.").

There is an enormous pent-up demand among health-conscious consumers for trusted, authoritative scientific information about nutrients and other natural substances that have been scientifically demonstrated to reduce the risk of disease. Were it not for barriers to market entry erected previously by FDA, consumers would presently be equipped at the point of sale with authoritative information about nutrient-disease risk reduction. Such information, published by scientific bodies of the United States federal government, would be widely known, and would help U.S. consumers make health enhancing choices in the food market, with a reasonable expectation that such choices would result in a reduction in the incidence of disease. Those barriers, inefficiencies, and acts of suppression were the subject of criticism of this agency in the legislative history underlying 21 USC 343(r)(3)(C) and gave rise to the authoritative statement notice exception to the SSA requirement.

Survey data confirms that the label and labeling of foods and dietary supplements is the primary source for consumers in making decisions about which foods to buy. See, e.g., Muhammad Zeeshan Zafar, et. al., "The Impact of Interpretive Packaged Food Labels on Consumer Purchase Intention: The Comparative Analysis of Efficacy and Inefficiency of Food Labels," *Int. J. Environ Res. Public Health*, 2022 Nov; 19 (22): 15098 ("The primary source of communication between consumers and organizations is food labeling, which often influences consumers' purchase decisions," citing M. J. Moreira, et. al., "Evaluation of food labeling usefulness for consumers," *Int. J. Consum. Stud.* 2019; 43: 327-334; J. L. Pomeranz, et. al., "Mandating front-of-package food labels in the US – What are the First Amendment obstacles?" *Food Policy*, 2019: 85: 101722. Consequently, there is an urgent need for release of the health claims sought here so consumers may make better informed choices conducive to better health outcomes, taking into account statements heretofore made elsewhere by the government concerning foods and dietary ingredients but never allowed into the market itself by speech barriers erected by this agency.

Moreover, grant of this petition will be in substantial fulfillment of the Make America Healthy Again (MAHA) agenda, supported by a Presidential Executive Order issued on February 13, 2025, namely "Establishing the President's Make America Health Again Commission". There is a general consensus in the scientific community that dietary choices affect the risk of disease and longevity as much as, if not more than, any other environmental choice a person can make (Willett WC, Stampfer MJ. Current evidence on healthy eating. *Ann. Rev. Publ. Health* 2013; 34:77–95).

To achieve the goal of reversing the chronic disease epidemic in the United States, consumers must be armed with information at the point of sale in food and dietary supplement markets to exercise informed choice in favor of better health outcomes. Conversely, maintenance of the regime of prior restraint now regnant at FDA will postpone indefinitely, if not prevent altogether, complete achievement of the Make America Healthy Again (MAHA) agenda.

This petition seeks approval of 118 health claims, which if allowed will enable a broad diffusion of essential health information to reach consumers as never before in American history. That extraordinary infusion of health information is likely to have the most profound effect on the exercise of healthy choice food and dietary supplement options by consumers, redounding not only to individual benefit in lessened incidence in disease and greater longevity but to the overall benefit of the nation as reduced dependency on drugs, hospitalization, and health care will reduce demand on public resources and better position the nation to achieve MAHA health goals.

FDA's denial of the parties' use on labels and in labeling of the very information the government publishes violates the parties' First Amendment rights. The speech burden is content-based (affecting all nutrient-disease relationship claims that arise in publications of scientific bodies of the United States Government with official responsibility for public health protection or research directly relating to human nutrition) and is speaker-based (affecting all non-government speakers who are regulatees of FDA). As explained below, as a content-based and speaker-based ban on the parties' free speech, the agency's burden on the communication of health claims based on authoritative statements is presumptively unconstitutional under the First Amendment. The very fact that the government itself has published the information to the public concerning the nutrient-disease association belies any contention by this agency that the information is inherently misleading and suppressible at FDA's whim or caprice or that somehow consumers are either too ignorant or too gullible to comprehend the information. In the end, the First Amendment is more than a prohibition against government enactment of laws restricting protected speech, it is a guarantee of individual sovereignty, entrusting to each American citizen, not government, the power to decide what is in his or her own best interests. As the Supreme Court reasoned in *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996) (quoting *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 423 U.S. 748, 765 (1976):

> There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. If they are truly open, nothing prevents the 'professional' pharmacist from marketing his own assertedly superior product, and contrasting it with that of the low-cost, high-volume prescription drug retailer. But the choice among these alternative approaches is not ours to make or the Virginia General Assembly's. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.

Based on the statutory and constitutional reasons explained in detail below and the notification supplied herein, the parties ask the FDA to act as soon as possible to authorize each of the 118 health claims sought herein to enter the market on food labels and in food labeling.

The Parties

Alliance for Natural Health USA is a 501(c)(4) non-profit organization that works nationally to both promote sustainable and regenerative health care and protect individual freedom

of choice through proactive policy advocacy and public education. ANH protects access to healthcare by lobbying Congress and state legislatures; acting as a government watchdog; filing comments in rulemakings; educating the public, press, and decision-makers about threats to consumer access to healthcare options, and initiating suits to ensure access.

Living Fuel International, Inc., founded in 2001 and headquartered in Tampa, Florida, is a health and wellness company specializing in nutrient-dense, plant-based meal replacement products designed to support optimal human performance and longevity. Its flagship offerings are formulated with over 90 essential nutrients—including vitamins, minerals, antioxidants, other botanicals, enzymes, and probiotics—to provide comprehensive nutritional support in a single serving. Committed to evidence-based formulations and high-quality, non-GMO ingredients, Living Fuel positions itself as a leader in functional nutrition, aiming to deliver measurable health benefits through its scientifically crafted superfood products. Claims for which Living Fuel International, Inc., seeks use on the labels and in the labeling of its products are identified in Exhibit 3.

The Health Ranger Store, Inc. established in 2012 by Mike Adams, is a U.S.-based online retailer specializing in organic, non-GMO, and lab-verified health products, including supplements, superfoods, and personal care items. All products undergo rigorous testing at CWC Labs, an ISO-accredited analytical laboratory, to ensure purity and potency, with certifications such as USDA Organic and Non-GMO Project Verified. Committed to transparency and sustainability, the company aims to provide consumers with clean, effective, and ethically sourced health solutions. Claims for which The Health Ranger Store, Inc. seeks use on the labels and in the labeling of its products are identified in Exhibit 3.

Sanacor International, Inc. and Evolution Nutraceuticals, Inc. dba Cardio Miracle is a Utah-based health supplement company founded in 2013 specializing in advanced nitric oxide and cardiovascular support formulations. Its flagship product combines key nutrients such as L-arginine, L-citrulline, vitamins D and K, and antioxidants to support endothelial function, circulation, and overall cardiovascular health. As a petitioner for health claims at the FDA, Cardio Miracle is committed to grounding its applications in emerging scientific evidence and advancing public access to nutraceuticals that align with optimal health outcomes. Claims for which Cardio Miracle seeks use on the labels and in the labeling of its products are identified in Exhibit 3.

Accordingly, each of the health claims noticed herein is sponsored by one or more of the commercial petitioners named above, as shown in Exhibit 3.

The Governing Statute for Health Claims Based on Authoritative Statements of Scientific Bodies of the U.S. Government with Official Responsibility for Public Health Protection or Research Directly Relating to Human Nutrition: 21 USC 343(r)(3)(C)

The Food and Drug Administration Modernization Act, codified at 21 USC 343(r)(3)(C), establishes an avenue for FDA to authorize market entry of certain health claims on food labels and in food labeling without satisfying the requirements of 21 USC 343(r)(B)[3].

The statute provides that "notwithstanding the provisions" of 343(r)(B) (i.e., the Significant Scientific Agreement, or SSA, standard), a claim of the type described in subparagraph (1)(B) (i.e., a nutrient-disease relationship claim or health claim) "which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B)" (i.e., under the SSA standard) "**shall be authorized and may be made with respect to a food[4] if**"

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[3] 21 USC 343(r)(3)(B)(i), which establishes the so-called Significant Scientific Agreement standard (SSA), reads in pertinent part:

> The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific principles and procedures), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 USC 343(r)(1)(B) referenced therein reads in pertinent part:

> **(1)** . . . if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—
>
> * * * *
>
> **(B)** characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

- [4] In "Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements (Proposed Rule), 64 FR 3250-3255 (Jan. 21, 1999), https://www.govinfo.gov/content/pkg/FR-1999-01-21/html/99-1365.htm#:~:text=Section%20304%20of%20FDAMA%20permits,nutrient%20levels%20identified%20in%20Sec., the FDA proposed a rule that dietary supplements, a subset of foods within the FDCA, bear health claims based on authoritative statements, thus harmonizing dietary supplement with general "food" regulation consistent with the contextual meaning of the FDCA, which defines dietary supplements as a subset of foods. See 21 USC 321 (ff) ("Except for purposes of paragraph (g) and Section 350f of this title, ***a dietary supplement shall be deemed a food*** within the meaning of this chapter") (emphasis added). FDA never rescinded that proposed rule. See also "Guidance for Industry: Notification of Health Claim and Nutrient Content Claim Based on Authoritative Statement of a Scientific Body" (June 1988), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-notification-health-claim-or-nutrient-content-claim-based-authoritative-statement#:~:text=Finally%2C%20FDA%20believes%20that%20there,r)(5)(D) (explaining that authoritative statements would be allowed on the labels and in the labeling of dietary supplements). The proposed rule and aforementioned reference in the Guidance were the operative at the agency (and used in the assessment of authoritative statement petitions for dietary supplements) until 2024. But in a March 28, 2024 guidance (and without resort to notice and comment rulemaking to reverse the proposed rule of January 21, 1999), FDA did a *volte face*, stating it would not allow health claims based on authoritative statements to be made for dietary supplements, only for conventional foods. See "Label Claims for Conventional Foods and Dietary Supplements" (March 28, 2024), https://www.fda.gov/food/nutrition-food-

these conditions are met: (1) the claim is one based on an authoritative statement of a scientific body of the U.S. government with official responsibility for public health protection or research directly relating to human nutrition, 21 USC 343(r)(C)(i), and (2) the person submitting the claim supplies the Secretary with (a) information to show via a concise description that the statement is one from an aforementioned scientific body of the U.S. Government and not an employee of that body acting in his individual capacity; (b) the exact wording of the claim; (c) a copy of the authoritative statement; and (d) a balanced representation of the scientific literature relating to the relationship between the nutrient and a disease or health-related condition to which the claim refers. 21 USC 343(r)(C)(ii). Additionally, the claim must be (d) one that enables consumers to understand the relative significance of the information within the context of a total daily diet.

For each claim sought, the statutorily required information is supplied hereinbelow.

Congress defined an "authoritative statement" as one "published" by a "scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition." 21 USC 343(r)(3)(C)(i). The statute gives as examples the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the National Academy of Sciences (NAS) or any of its subdivisions. The legislative history for the Act supplies additional examples, including: the National Cancer Institute and the National Heart, Lung, and Blood Institute. The FDA added to these the Surgeon General within the Department of Health and Human Services; the Food and Nutrition Service (FNS); the Food Safety and Inspection Service (FSIS); and the Agricultural Research Service within the Department of Agriculture (ARS).

Congress additionally required that the authoritative statement (e) be "currently in effect." 21 USC 343 (r)(3)(C)(i).

In 21 USC 343(r)(3)(C), Congress required the Secretary--"notwithstanding the provisions" of 343(r)(B) (i.e., the Significant Scientific Agreement, or SSA, standard)--to authorize health claims if based on authoritative statements of scientific bodies of the United States Government with official responsibility for public health protection or research directly relating to human nutrition. In 21 USC 343(r)(3)(D), Congress restricted the Secretary's power

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labeling-and-critical-foods/label-claims-conventional-foods-and-dietary-supplements#:~:text=FDAMA%20does%20not%20include%20dietary,dietary%20supplements%20at%20this%20time. Because by FDA's own admission a "guidance" has no legally binding effect, the announcement does not preclude this submission or negate the prior proposed rule. Moreover, given the repeated reference to foods within the statutory definition of a dietary supplement in 21 USC 321(ff), the agency lacks statutory authority to construe the term "food" to exclude dietary supplements (and the dietary ingredients subsumed within that definition); that interpretation would be suboptimal and contrary to contextual meaning, thus violating *Loper-Bright Enterprises*. In the absence of statutory language and of clearly expressed congressional intention, FDA has no legal basis for excluding dietary supplements from authoritative statement claims. To prohibit dietary supplements from having access to such claims would be an act of content-based and speaker-based discrimination in violation of the First Amendment. Moreover, it would violate a major canon of statutory construction, which canon requires that if a statute is susceptible to two interpretations, one of which would render it unconstitutional and the other valid, the interpretation that upholds the statute's constitutionality must be adopted. See *Ashwander v. Tennessee Valley Authority,* 297 U.S. 288 (1936).

to limit this class of health claims to the post-authorization context following notice and comment rulemaking as to the claim and via regulation promulgated, or by district court order in an enforcement proceeding. In 21 USC 343(r)(3)(D), the statute reads:

> **(D)** A claim submitted under the requirements of clause (C) ***may be made until***—
> **(i)** such time as the Secretary issues a regulation under the standard in clause (B)(i)—
> **(I)** prohibiting or modifying the claim and the regulation has become effective, or
> **(II)** finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or
> **(ii)** a district court of the United States in an enforcement proceeding under subchapter III has determined that the requirements of clause (C) have not been met.

(Emphasis added).

In convoluted logic in its 1998 Guidance, the agency went beyond its statutory remit and read into subpart (C) for authoritative statement health claim authorization an SSA review requirement, despite the fact that Congress excluded that requirement from subpart (C) and limited it to the post health claim authorization context in subpart (D)—applicable therein only following agency rulemaking or a district Court's enforcement order. That power grab served the end of censorship, thus also construing the statute to effect a First Amendment violation.

In its 1998 Guidance FDA thus demanded what Congress disallowed; SSA review for health claim submissions based on authoritative government statements, effectively amending the statute by reinserting the very SSA review requirement into subpart (C) that Congress expressly excluded. That reinterpretation, to the extent it could ever pass muster under *Chevron,* plainly fails muster under *Loper Bright Enterprises* and the applicable canons of statutory construction. The agency interpretation not only contradicts the express exemption from SSA afforded authoritative statements in 21 USC 343 (r)(3)(C)(i), it also contradicts the intended meaning of the subsection as stated in the legislative history.

The Legislative History for 21 USC 343(r)(3)(C) Does Not Allow FDA to Impose the SSA Requirement on Health Claim Notices Based on Authoritative Statements

The legislative history concerning 21 USC 343(r)(3)(C) is contained in U.S. House Report 105-399 (Conf. Report) and U.S. Senate Report 105-43. H.R. Rep. No. 105-399, 105th Cong., 1st Sess. (1997); S. Rep. No. 105-43, 105th Cong., 1st Sess. (1997). In the House Report, the following explanation appears for the amendment to the Food Drug and Cosmetic Act governing health claims based on authoritative statements:

> ***(Sec. 303) allows a health or nutrient content claim not authorized by the Secretary*** if: (1) a U.S. governmental scientific body with public health protection or research responsibility directly relating to human nutrition or the National Academy of Sciences

has published an authoritative statement, currently in effect, about the relationship to which the health claim refers or that identifies the nutrient level to which the nutrient claim refers; (2) a person has notified the Secretary; (3) the claim and food are in compliance with certain requirements; and (4) the claim is stated in a way that is an accurate representation of the authoritative statement and in a way that it enables the public to understand the information and its significance. (Emphasis added).

The House Report thus makes clear that a health claim under 21 USC 343(r)(3)(C) is to be allowed ***without authorization from the Secretary*** if based on publications of other federal governmental scientific bodies with public health protection or research responsibility. There is in this history no statement that FDA is given authority to require SSA review or approval as a condition precedent to authorization of health claims based on authoritative statements. Nor is there any reference to an intention to give FDA authority to impose other requirements beyond those specified in the statute's text.

The Senate Report further elucidates the intended meaning. The Senate Report reads in pertinent part:

9. the legislation simplifies the approval process for indirect food contact substances and ***provides a more reasonable standard for some health claims.***

…. The legislation also provides for health claims for foods, with premarket notification, when the claims are based on authoritative recommendations by an authoritative scientific body of the U.S. Government such as the National Institutes of Health, the Centers for Disease Control and Prevention, or the National Academy of Sciences.

Title VI—Better Allocation of Resources Setting Priorities

Health Claims of Food Products

This legislation makes amendments to section 403(r) of the Federal Food, Drug, and Cosmetic Act to authorize truthful, nonmisleading health claims that are based on published authoritative statements of scientific bodies of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition.

* * * *

Under existing section 403(r)(3), health claims can be made for food only after FDA issues a regulation authorizing the specific claim. This same preclearance requirement applies to all health claims—from the novel claim, to the claim that would be supported by an authoritative statement of an official public health agency of the Federal Government. ***This procedure is inefficient and fails adequately to benefit from the deliberative processes in which authoritative scientific bodies engage in issuing statements on matters of public health.*** Important Federal public health organizations as part of their official responsibilities, routinely review the scientific evidence pertinent to diet and disease relationships, and publish statements developed through such reviews. ***The Surgeon General and National Academy of Sciences***

have published authoritative reports on such relationships. The National Cancer Institute has issued pamphlets recommending food choices to reduce the risk of cancer. The National Heart, Lung, and Blood Institute has issued a range of authoritative publications aimed at reaching the risk of hypertension and heart disease in the United States population.

The failure of the current system to give adequate weight to the statements of such authoritative bodies, coupled with the prohibitive economic burden that permits only the largest food companies and trade organizations to file a health claim petition to gain approval of a new health claim, has deprived the public of the full disease prevention benefits health claims were intended to provide.

This legislation maintains the rigorous scientific standard health claims must meet under existing law but streamlines the procedure for making health claims when the scientific basis for a claim has been developed by an authoritative scientific body outside FDA. This procedure targets regulatory resources more effectively, and promises to benefit public health substantially more than the current system.

The history of the folic acid and neural tube defects health claim dramatizes the critical need for this legislation. In 1992, the Centers for Disease Control and Prevention (CDC) issued the following recommendation to women of childbearing age, aimed at reducing the risk of pregnancies affected by neural tube defects:

> All women of childbearing age in the United States who are capable of Becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or [other neural tube defects].
>
> Centers for Disease Control, 41 Morbidity and Mortality Weekly Report (September 11, 1992).

The CDC estimated that this recommendation could reduce the number of cases of spina bifida and other neural tube defects in the United States by 50 percent.

Despite the significant scientific agreement among qualified experts concerning the evidence supporting the recommendation, manufacturers of foods containing folic acid were prohibited from making claims about the benefits of folic acid in reducing the risk of neural tube defects until FDA approved the claim through a notice and comment rulemaking procedure.

Without appropriately accounting for the CDC recommendations, FDA promulgated a rule in January 1993, prohibiting claims concerning the relationship. In the wake of controversy concerning FDA's action, and despite the absence of any change in the scientific evidence, the Agency reversed course, proposing to authorize such claims in October, 1993. Final regulations authorizing the claim were promulgated in March 1996. Undoubtedly, many children suffered from preventable neural tube defects as a result of FDA delay in authorizing health claims based on the 1992 CDC recommendation.

The amendments this legislation makes to section 403(r)(3) of the Federal Food Drug and Cosmetic Act would prevent a recurrence of the kind of problem presented by the folic acid/neural tube defect claim. While the legislation makes no change to the existing standards governing the health claim approval process, it establishes an alternative procedure by which health claims supported by an authoritative statement of an appropriate scientific body of the U.S. government are authorized. Such claims could be made after premarket notification to FDA, without the delay that accompanies the rulemaking process. The legislation would require manufacturers intending to make such a health claim to submit a premarket notice to FDA concisely describing the claim and the authoritative statement relied upon.

The notice would be submitted at least 120 days before the first introduction of a food bearing the claim into interstate commerce.

Although the legislation would eliminate the requirement for FDA approval of such claims, it would continue to require foods to conform to the "disqualifying nutrient levels" established by FDA under section 403 (r)(3)(A)(ii) and require all health claims to be presented in a truthful, non-misleading manner in conformance with sections 403(a) and 201(n) of the Federal Food Drug and Cosmetic Act. For example, a food bearing a truthful health claim based on an authoritative statement would need to make a material dietary contribution of the substance to which the claim refers to meet the requirements of sections 403(a) and 201(n). The legislation specifically mandates that a health claim accurately represent the authoritative statement on which it is based, and be presented in a manner enabling the public to comprehend the significance of the claim in the context of a total diet.

The agency retains full authority to take enforcement action against a health claim that mischaracterizes the authoritative statement upon which it is based, or that is otherwise misleading. The 120 day premarket notice requirement would enable FDA to identify misleading claims and take action to prevent their use before products bearing such claims are introduced to the market. In response to notifications filed by dietary supplement manufacturers concerning claims made under section 403(r)(6) of the Act, a provision adopted as part of the Dietary Supplement Health and Education Act of 1994, FDA issues "courtesy letters" promptly alerting manufacturers when claims submitted in their notification present a risk of enforcement action. Such an approach is an efficient and effective means of deterring manufacturers from making violative claims.

Under this legislation, the agency retains the full range of enforcement powers it has possessed historically to remedy misleading claims, including the powers of product seizure, injunction, and criminal penalties. In addition, new section 403(r)(3)(D) assures that FDA retains full authority to regulate health claims based on the statements of authoritative bodies through rulemaking. ***Once FDA regulations governing health claims concerning a particular diet/disease relationship (e.g., calcium and osteoporosis) have become effective, no claim concerning that diet/disease relationship based on the statement of an authoritative scientific body could be made unless it is consistent with the FDA regulation. The legislation specifically provides that FDA may prohibit or modify such health claims through rulemaking. In any such proceeding, the standards and criteria for health claims prescribed in section***

403(r)(3) and implementing regulations, including the significant scientific agreement standard, would be fully applicable.

(Emphasis added).

The House Report makes clear that health claims based on authoritative statements of scientific bodies of the United States with official responsibility for public health protection or research are to be allowed into the market without SSA authorization from the Secretary (and, by delegation, the FDA Commissioner). The Senate Report reinforces that point, explaining that the amended health claim provision was designed to prevent the kind of FDA prohibition and delay attendant to FDA's decade long failure to authorize CDC's folic acid/neural tube defect claim on dietary supplement labels. That delay arose first from FDA's SSA denial of the claim and thereafter from FDA delay in authorizing the claim, during which Congress notes preventable neural tube defect births occurred ("The amendments this legislation makes to section 403(r)(3) of the Federal Food Drug and Cosmetic Act would prevent a recurrence of the kind of problem presented by the folic acid/neural tube defect claim"). **The creation of 21 USC(r)(3)(C) thus "eliminates the requirement for FDA approval of" health claims when based on authoritative statements of scientific bodies of the United States with official responsibility for public health protection or research**. It instead establishes an "alternative procedure" whereby accurate representations of authoritative statements published by other U.S. Government scientific bodies are authorized without need for satisfying FDA's SSA requirement: **"[I]t establishes an alternative procedure by which health claims supported by an authoritative statement of an appropriate scientific body of the U.S. government are authorized. Such claims could be made after premarket notification to FDA, without the delay that accompanies the rulemaking process."**

FDA's "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (June 1998)" Misinterprets and Violates 21 USC USC 343(r)(3)(C)

In its 1998 Guidance[5], FDA prescribed rules to guide the regulated class in filing notices of intended use of health claims based on authoritative statements of federal scientific bodies. The rules exceed the requirements of 21 USC 343(r)(3)(C) and defeat the purpose of the statute by commanding that SSA be satisfied as a condition precedent to health claim allowance.

[5] In its 1998 Guidance, FDA deemed the following to be scientific bodies of the United States with official responsibility for public health protection or research directly relate to human nutrition: the National Academy of Sciences (NAS) or any of its subdivisions; the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Surgeon General within the Department of Health and Human Services; the Food and Nutrition Service (FNS); the Food Safety and Inspection Service (FSIS); and the Agricultural Research Service within the Department of Agriculture (ARS). Although FDAMA "does not provide for health claims based on authoritative statements for dietary supplements," FDA nevertheless "intends to propose that health claims based on authoritative statements be permitted for dietary supplements."

Through the 1998 Guidance, FDA issues these specific instructions for the content of notices to the agency based on authoritative statements:

(1) FDA requires that the authoritative statement be published by NAS, NIH, CDC, the Surgeon General, FNS, FSIS, or ARS.

(2) FDA requires that the statement be "currently in effect."

(3) FDA requires that the statement "not include a statement of an employee of the scientific body made in the individual capacity of the employee."

(4) FDA requires that the statement "reflect a consensus within the identified scientific body if published by a subdivision of one of the Federal scientific bodies."

(5) FDA requires that the statement "be based on a deliberative review by the scientific body of the scientific evidence."

(6) FDA requires that the health claim based on the authoritative statement satisfy the SSA standard in 21 USC 343(r)(3)(B)(i).

(7) FDA requires that the health claim not be based on findings FDA characterizes as preliminary results.

(8) FDA requires that the health claim not be based on statements that FDA considers inconclusive research.

(9) FDA requires that the health claim not be based on statements intended to guide future research.

(10) FDA requires the notification to include the "exact words used in the claim."

(11) FDA requires the notification to include "a concise description of the basis upon which such person relied for determining that the requirements" for an authoritative statement "have been satisfied."

(12) FDA requires "a copy of the statement referred to . . . upon which such person relied in making the claim."

(13)FDA requires what it considers "a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers."

(14)FDA requires that the balanced representation of the scientific literature include a "bibliography of the scientific literature on the topic of the claim" and a "brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement."

(15)FDA requires that the health claim be "stated in a manner so that the claim is an accurate representation of the authoritative statement referred to . . . so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet."

(16)FDA requires that the food for which a claim is made not exceed the disqualifying amounts of nutrients that may increase the risk of a disease or health-related condition in the general population.

(17)FDA requires that a claim based on an authoritative statement not be false or misleading in any particular.

Each of the 1998 Guidance requirements in bold in (4) – (9) above are not present in the statute and contradict its plain and intended meaning.

In this submission, the parties submit evidence of compliance with the requirements of 21 USC 343(r)(3)(C) and not with those gratuitously demanded by FDA that contradict the requirements of the statute and exceed its requirements. Consequently, the parties provide all information called for in (1) – (3) and (10) – (17) above. In the aftermath of *Loper Bright Enterprises*, FDA's demand for information called for in (4) – (9) above is not a permissible construction of the statute.

The Impact of Loper Bright Enterprises on FDA's 1998 Guidance Requiring SSA Preclearance and Satisfaction of Conditions Beyond Those Specified in the Statute

Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 144 S.Ct. 2244 (2024), FDA is denied the interpretive latitude it had under *Chevron USA v. Natural Res. Def. Council,* 467 U.S. 837 (1984). FDA imposition of the requirements listed in (4) – (9) above exceed those specified in the statute. Its insistence on SSA preclearance directly contradicts the statute. In those respects FDA contradicts the plain and intended meaning of the statute. Consequently, FDA must in this proceeding revoke those requirements and reinterpret the statute to comport with its plain and intended meaning. Doing so requires that it limit its requirements to those listed in (1) – (3) above and to (10) – (17) above and that it drop as a condition precedent to health claim authorization under 21 USC 343(r)(3)(C) its demand for satisfaction of SSA, thereby directly contradicting the statutory language.

In the *Loper Bright Enterprises*, the Supreme Court overruled *Chevron USA v. Natural Res. Def. Council,* 467 U.S. 837 (1984), and with it the doctrine of judicial deference to administrative agency interpretation of statutory law. Under Chevron,

> [C]ourts used a two-step framework to interpret statutes administered by federal agencies. After determining that a case satisfies various proconditions . . . for *Chevron* to apply, a reviewing court must first assess "whether Congress has directly spoken to the precise question at issue." *Id.* At 842. If, and only if, congressional intent is "clear," that is the end of the inquiry. *Ibid.* But if the court determines that "the statute is silent or ambiguous with respect to the specific issue" at hand, the court must, at *Chevron's* second step, defer to the agency interpretation if it "is based on a permissible construction of the statute." *Id. At 843.*
>
> 144 S.Ct. at 2254.

In overruling *Chevron*, the Supreme Court explained that under the Administrative Procedure Act, 5 USC 706, "agency interpretations of statutes—like agency interpretations of the Constitution—are *not* entitled to deference." Rather, it "remains the responsibility of the court to decide whether the law means what the agency says." 144 S.Ct. at 2261. The Court now requires "the best reading" of a statute, not merely an agency's plausible reading, reasoning: "It . . . makes no sense to speak of a 'permissible' interpretation," *Id.* at 2268, rather, "[i]n the business of statutory interpretation, if it is not the best, it is not permissible." *Id.* Moreover, it is no longer enough for an agency to proclaim itself expert in an area of regulation as a justification for usurping the role of the Courts in determining the meaning of the law. The "tool kit" the Courts use where the statutory language is silent or ambiguous on a point is one of discerning plain meaning by reference to context guided by the canons of statutory construction. Ambiguities are to be resolved consistent with intended meaning, discernible from the statute as a whole and from the legislative intent expressed in the House and Senate Committee reports, and commentary on the floor of Congress by bill sponsors.

Any Action by FDA to Compel the Health Claims Here in Issue to Undergo SSA Review, or to Deny Them, Necessarily Creates an As-Applied First Amendment Challenge Against FDA's Content-Based and Speaker-Based Order

Under the 1998 Guidance, FDA states its intention to review every proposed health claim noticed pursuant to 21 USC 343(r)(3)(C) under the SSA standard in 21 USC 343(r)(3)(B)(i). In this instance health claims are based on authoritative statements of scientific bodies of the U.S. government with official responsibility for public health protection or research directly relating to human nutrition. In other words, the Government itself is the source of the information represented in the health claims. Those authoritative statements this Government makes directly to the public. The health claims directly represent the very statements made by the Government and do so in context with the precise substances at the precise dose levels identified by the Government as having disease risk reduction effects. Consequently, if FDA either burdens or prohibits any of the health claims here in issue it engages in content-based and speaker-based discrimination, inviting an as-applied challenge. Content-based and speaker-based speech burdens and bans are presumptively unconstitutional under the First Amendment. See, e.g.,

Sorrell v. IMS Health Inc., 564 U.S. 552, 571 (2011) (citing *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992). The speech in issue is non-commercial and scientific, indeed substantively the government's own, entitled to strict scrutiny protection. See generally *Miller v. California*, 413 U.S. 15, 34 (1973) (explaining that the "First Amendment protects works" which have "scientific value"); *Roth v. United States*, 354 U.S. 476, 484 (1957) (quoting letter of Continental Congress citing scientific advancement as a reason for protecting freedom of the press). The mere fact that the scientific speech lifted from government publications and placed on the very products identified in those publications enters commerce when on labels and in labeling does not diminish the intrinsic fact that the substance of the statements is non-commercial and scientific and thus entitled to full First Amendment protection. Even so, if the content were assessed under intermediate scrutiny afforded commercial speech, it would still result in the same outcome, an unconstitutional act of suppression because the means chosen do not effectuate the alleged ends of protecting consumers from deception. Indeed, the speech is substantively the very speech the government itself communicates to the public.

In the first instance, FDA cannot logically or reasonably contend that speech vetted by its sister agencies and presented to the public is either inherently or potentially misleading. In the grand scheme of things, FDA is not the ultimate or penultimate truth cipher among scientific bodies of the U.S. government with official responsibility for public health protection or research directly relating to human nutrition, but is, instead, co-equal with its sisters. At best, FDA must contend that the speech somehow is transmogrified when it leaps from an authoritative statement published by a government agency to the label or labeling of a product containing the very ingredients identified as health enhancing by that agency. That idea, once argued by the Department of Justice to the U.S. Court of Appeals in *Pearson v. Shalala*, stretches logic beyond the breaking point and neuters the First Amendment by causing it to have only situational meaning, positions rejected by our Court of Appeals.

In any event, the speech here in issue concerns a precise category disfavored by this agency, speech concerning the association between nutrients and disease (more particularly, concerning the effect of nutrients on reducing the risk of disease). "Government regulation of speech is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed." *Reed v. Town of Gilbert, Ariz.*, 576 U.S. 155, 159 (2015). The regulations here in issue are thus content-based. Moreover, because the FDA acts only against regulatees who wish to communicate health claims based on authoritative statements on the label and in the labeling of food products in the market, the regulations are speaker-based. Laws designed or intended to suppress or restrict the expression of specific speakers because of the content of their expression violate the First Amendment. See *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 658 (1994) (explaining that strict scrutiny applies to regulations reflecting "aversion" to what "disfavored speakers" have to say); *United States v. Playboy Ent. Grp.*, 529 U.S. 803, 812 (2000). As such, FDA's content and speaker-based restrictions cannot survive constitutional muster unless they satisfy the heightened burden of strict scrutiny, which is the government's burden to prove.

Under strict scrutiny, FDA must show that its regulations are narrowly tailored to serve a compelling state interest, such that the means directly further the ends and there are no less speech restrictive alternatives to achieve its ends. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566

(2011); *Reed v. Town of Gilbert, Ariz.*, 576 U.S. 155, 163 (2015). Here, the FDA's interest is presumably one of ensuring that health claims based on authoritative statements of government agencies are accurate reflections of those statements and apply to the dietary ingredients in issue. Achievement of that interest does not require SSA satisfaction or FDA review of the "sufficiency" of its sister agencies' evidentiary evaluations and considerations. Yet, here, FDA presumes its subjective desires for more evidence than sufficient to establish the claim truthful, justifies claim suppression rather than allowance of the claim into the market. FDA's means are not narrowly tailored because they do not focus on the accuracy of what is republished by the parties, but in insisting that its own standard of review (SSA or, as it has interpreted it, conclusive proof) is satisfied. Yet truth can be conveyed about even scientifically inconclusive claims, as the United States Court of Appeals for the D.C. Circuit explained to this agency in *Pearson v. Shalala*, 164 F.3d 650 (1999), reh'g den., 172 F.3d 72 (1999).

Consequently, an accurate reflection of an authoritative statement of another federal agency can under the terms of the 1998 Guidance be suppressed by FDA from appearing on labels and labeling if FDA concludes subjectively that for one reason or another the evidence acceptable to its sister is unacceptable to it. Indeed, FDA demands not only SSA satisfaction (proof to a near conclusive degree, a literal impossibility in science) but also proof of a consensus within the identified scientific body; proof of a deliberative review by the scientific body of the scientific evidence; proof that the health claim is not based on findings FDA considers preliminary; proof that the health claim is not based on findings FDA considers inconclusive; or proof that the health claim is not based on statements FDA considers intended to guide future research. As the United States Court of Appeals for the D.C. Circuit made clear in *Pearson v. Shalala*, 164 F.3d 650 (1999), reh'g den., 172 F.3d 72 (1999), FDA has a First Amendment duty to avoid suppressing health claims backed by scientific evidence that harbor only a potential to mislead based solely on its view that supportive science is not enough, even if it deems the evidence supporting the claim inconclusive or preliminary. Its proper resort under *Pearson* is to allow the claim to be made and state its reservations as to conclusiveness in a reasonable, succinct, unbiased, claim qualification. It must allow the claim into the market relying on the less speech restrictive alternative of claim qualification, if it is to survive constitutional review.

But even were strict scrutiny not applied, and this content- and speaker-based restriction on scientific speech deemed wholly commercial in nature, the regulations would still fail under the applicable test. Under a commercial speech inquiry, FDA bears the burden of justifying its content-based prior restraints as consistent with the First Amendment (*Thompson v. Western States Medical Center*, 535 U.S. 357, 373 (2002)). To sustain its burden, FDA must show that the regulation directly advances a substantial governmental interest and that the measure is drawn to achieve that interest (see *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 571-572 (2011), citing: *State Univ. of New York v. Fox,* 492 U.S. 469, 480-481 (1989), and *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980)). There must be a reasonable "fit between" the means chosen and the ends. FDA is required to show that the harms it recites are real and that the means it has chosen will advance its ends to a material degree (*Edenfield v. Fane*, 507 U.S. 761, 762 (1993), quoting: "A governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree"). Here, FDA's harms are entirely

speculative; there is no basis to presume that the authoritative statements of FDA's sister scientific bodies already published to the public, when published as health claims on the label or in labeling of food, are inherently misleading. Moreover, suppressing that information, appearing as it does in publications of the government itself, is certainly a very indirect way of advancing the FDA's interest, one whose fit between means and ends are not reasonably calculated to achieve the ends of avoiding misleadingness.

Accordingly, even if FDA presumes its 1998 Guidance valid in all respects, or otherwise insists upon the provisions within it that conflict with the statute or impose requirements not specified in the statute, suppression of the health claims presented here will necessarily violate its enabling act and the First Amendment.

THE HEALTH CLAIMS NOTICED FOR AGENCY AUTHORIZATION PURSUANT TO 21 USC 343(r)(3)(C)

In compliance with 21 USC 343(r)(3)(C), ANH, Living Fuel, Health Ranger Store and Sanacor International and Evolution Nutraceuticals dba Cardio Miracle hereby submit the following responsive information requisite to FDA authorization of the foregoing health claims based on authoritative statements published by the National Institutes for Health and the Centers for Disease Control and Prevention.

Based on 21 USC 343(r)(3)(C) and relevant FDA regulations (21 CFR 101.70 and 101.14), the 118 health claims presented in Exhibit 1 are presented for FDA authorization based on corresponding, numbered authoritative statements shown in Exhibit 2. The federal scientific body (e.g., NIH, CDC) that issued each authoritative statement has been identified (Exhibit 2), and each statement and corresponding, numbered, proposed nutrient-disease claim explicitly describes the relationship between the nutrient or substance and a disease or health-related condition (21 CFR101.14(a)(1)). Each authoritative statement given in Exhibit 2 was found to be published on the specified federal agency website (shown in Exhibit 2) on the date of submission of this petition.

An internal review by the petitioners of the agency's publications revealed that as of the date of this submission the relevant government health agencies had not revoked or otherwise modified or delimited any of the foregoing authoritative statements. Additionally, none appear to have been superseded by newer findings (21 CFR 101.14(c)(2)(iv)). We therefore conclude that they are currently in effect.

The authoritative statements are published by and are presented to the public as statements of the NIH or the CDC, U.S. federal scientific bodies with public health protection or research responsibilities directly relating to human nutrition. These are not statements of employees or other representatives of the government scientific bodies made in their individual capacity.

To determine that the requirements for an authoritative statement have been satisfied, the parties hereto conducted detailed searches of the official websites of agencies under the

Department of Health and Human Services, and in particular the NIH and CDC. The largest repositories of information pertaining to nutrient-disease relationships were found on the websites of the Office of Dietary Supplements (ODS) (https://ods.od.nih.gov/factsheets/list-all/) and the National Center for Complementary and Integrative Health (NCCIH) (https://www.nccih.nih.gov/), both being offices of the NIH.

The proposed claims (Exhibit 1) based on corresponding, numbered, authoritative statements (Exhibit 2) have been conscientiously summarized to capture their intended meaning and to ensure they are readily understood by the average U.S. consumer on labels and in labeling. Furthermore, in the case of each authoritative statement, the science referenced by the authority has been reviewed and the dosing reported in Exhibit 3. This same exhibit lists the brand names of dietary supplements relevant to each corporate petitioner that contain dietary ingredients that are within the same dose range referenced in the corresponding, numbered authoritative statement.

All proposed health claims (as shown in the header of Exhibit 1) pertain to ingredients present in conventional (including 'functional') foods, medical foods and dietary supplements in amounts that the meet the minimum dose ranges specified in Exhibit 2. 21 USC 342(a)(1) ensures that inclusion amounts must not exceed those that may render a food product injurious to health causing it to be considered adulterated.

The numbered, proposed health claims (Exhibit 1) have been worded to provide an accurate representation of the authoritative statement, with reference to the place of publication of the authoritative statement, and, where relevant, qualification to ensure that the public understands the relative significance of the claim within the context of a total daily diet.

The foods for which these claims are made, namely conventional foods, medical foods, and dietary supplements (see Exhibit 1), does not exceed the disqualifying amounts of nutrients that may increase the risk of a disease or a health-related condition in the general population.

Even if FDA Refuses to Grant FDAMA Claims, It Must Allow the Claims under the First Amendment

The speech here in issue are claims directly based on authoritative statements communicated by federal government health agencies to the public concerning the very dietary ingredients in the very dose amounts offered by the petitioners. The claims mirror the substantive meaning of the authoritative statements. They are akin to lifting the content from the government publications and placing that content on a label and in labeling. This is essentially a republication of the government's own speech.

Under the First Amendment, the government is barred from exercising control over private editorial discretion such that it compels speech or denies the right to communicate the speech because of an aversion to the speaker or to the content. The First Amendment prohibits the government from using censorship to "tilt" public debate "in a preferred direction." *Moodey v. Net Choice LLC,* 603 U.S. 603 U.S. 707 (2024), citing *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 578-579 (2011). Government may not use prior restraint to deny publication of information

the government itself has acquired. See, e.g., *New York Times Co. v. Sullivan,*403 U.S. 713 (1971). The First Amendment's prohibition on prior restraints is all the more serious when the federal government presumes to forbid a private party from publishing the very content the government itself has already made public. There could be no more direct example of speaker and content-based censorship, which reaches the court with a strong presumption against its constitutionality.

In this instance, the government is equitably barred from arguing that its own publication of scientific information concerning nutrient-disease risk relationships is either false or misleading. Moreover, it lacks any legal or factual foundation to argue that the information when substantively condensed to a label claim by the petitioners is somehow transmogrified into falsehood. Rather, once released into the public domain by the agencies themselves the information is fair game for republication whether by the press or by the seller of a product containing the very dietary ingredient concerned in the very quantitative amounts tied to a reduction in disease risk.

For those reasons, FDA lacks constitutional authority to prevent the claims sought here. While it may not approve them, it cannot disallow them, and must make clear that the petitioners who seek to use them are free to do so by command of the First Amendment.

Executive Orders and Executive Memoranda Compel Allowance of the Claims

Action on this petition is warranted in fulfillment of the President's Memorandum, "Directing Repeal of Unlawful Regulations" (April 9, 2025); the President's Executive Order, "Unleashing Prosperity through Deregulation" (January 31, 2025); and the President's Executive Order, "Establishing the President's Make America Healthy Again Commission" (February 13, 2025).

Under the Memorandum of April 9, the President called on the heads of the executive departments and agencies to determine the lawfulness of the agency's regulations under recent Supreme Court precedent, including *Loper Bright Enterprises* and *West Virginia v. EPA*, 597 U.S. 657 (2022), among others. Those cases relied upon here compel FDA to revisit the regulations here in issue to ensure that its interpretation of its enabling statute and the limitations on its power under the First Amendment are aligned so that health information, such as that sought to reach the public at the point of sale here, is not suppressed.

Under the Executive Order of January 31, the regulatory prior restraints at issue here must be brought down to ensure that health information published by the government is transparently communicated to the public at the point of sale, enabling the public to make better informed food and dietary supplement choices, redounding to the health benefit of consumers and a reduction in the incidence of chronic disease and dependency on public resources for health care.

Under the Executive Order of February 13, the President established the MAHA Commission with one particular objective being the establishment of "transparency," allowing vital health information to reach the public, including the aim of ensuring that "all federally

funded health research should empower Americans through transparency and open-source data, and should avoid or eliminate conflicts of interest that skew outcomes and perpetuate distrust."

This petition advances that presidential memorandum and those presidential orders by ending FDA prior restraint that deprives the public at the point of sale of truthful, non-misleading nutrient-disease risk reduction information indispensable to better health outcomes.

Conclusion

For the foregoing reasons, ANH and Living Fuel International, Inc., Health Ranger Store, Inc., and Sanacor International, Inc. and Evolution Nutraceuticals, Inc. dba Cardio Miracle, by counsel, respectfully request that FDA authorize each of 118 nutrient-disease health claims presented herein or allow each claim to be made on the respective label and in the respective labeling of the foods or dietary supplements identified herein by the company sponsors listed herein.

Respectfully submitted,

ALLIANCE FOR NATURAL HEALTH USA;

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Dated: September 2, 2025

Note: Only Exhibit 1 is shown in the Media Pack. The full filing is available on request; please email office@anh-usa.org with subject 'Request for Full ANH FDAMA Filing 2025'. It will also be available publicly in due course via the FDA website.

EXHIBIT 1

Numbered, proposed nutrient/disease claims

Health Claim No	Substance(s)	Proposed Claims (applicable to adults, unless otherwise stated). Relevant foods: conventional/functional foods, dietary supplements, and medical foods. For minimum dosages see Exhibit 2.
1	Vitamin A and Carotenoids	Vitamin A reduces the risk of respiratory diseases/pneumonia.
2	Vitamin A and Carotenoids	Vitamin A may reduce the risk of premature death.
3	Vitamin A and Carotenoids	Natural vitamin A and /or carotenoids in food form may reduce the risk of certain cancers.
4	Vitamin A and Carotenoids	Dietary supplements containing carotenoids, including beta-carotene, or lutein and zeaxanthin, combined with vitamins C and E, zinc and copper, may reduce the rate of vision loss in people with age-related macular degeneration (AMD).
5	Vitamin A and Carotenoids	Vitamin A may reduce the risk of infections, such as measles and diarrhea.
6	Vitamin A and Carotenoids	Vitamin A may reduce the risk of anemia.
7	Vitamin A and Carotenoids	Vitamin A may reduce the risk of xeropthalmia.
8	Boron	Boron may reduce inflammation in the body.

9	Boron	Boron may reduce the risk of osteoarthritis.
10	Boron	Boron may reduce the risk of certain cancers.
11	Boron	Boron may increase bone strength.
12	Vitamin B1/Thiamin	Thiamin may reduce the risk of memory loss, muscle weakness and heart problems.
13	Vitamin B2/Riboflavin	Riboflavin may reduce the risk of migraine headaches.
14	Vitamin B2/Riboflavin	Riboflavin may reduce the risk of skin disorders, […], cataracts, sores at the corners of the mouth, sore throat, liver disorders, and reproductive and nervous system disorders.
15	Vitamin B2/Riboflavin	Riboflavin may reduce the risk of anemia.
16	Niacin	Nicotinic acid (at doses of 1600 mg or more daily) may lower LDL ('bad') cholesterol and triglycerides, and raise HDL ('good') cholesterol.
17	Vitamin B12/Cobalamin	Vitamin B12, vitamin B6 and folate may reduce the risk of heart attack or stroke in people with sub-normal blood levels of homocysteine.
18	Vitamin B12/Cobalamin	Vitamin B12 may reduce the risk of megaloblastic anemia.
19	Vitamin B12/Cobalamin	Vitamin B12 may reduce the risk of pernicious anemia.
20	Vitamin B12/Cobalamin	Vitamin B12 may reduce the risk of certain neurological problems.
21	Chromium	Chromium may reduce the risk of impaired glucose tolerance.
22	Chromium	Chromium may reduce the risk of type 2 diabetes.

23	Chromium	Chromium may reduce the risk of insulin resistance.
24	Chromium	Chromium may reduce the risk of metabolic syndrome.
25	Vitamin B6	Folate (500-5000 mcg DFE/d), vitamin B12 (1000-5000 mcg DFE/d) and vitamin B6 (20-25 mg DFE/d) may lower the risk of cardiovascular disease.
26	Vitamin B6	Vitamin B6 may reduce the risk of abnormal brain development in the fetuses of pregnant women.
27	Vitamin B6	Vitamin B6 supplementation may reduce the risk of vitamin B6 deficiency, the symptoms of which include: anemia, itchy rashes, scaly skin on the lips, cracks at the corners of the mouth, swollen tongue, depression, confusion, or a weak immune system. In infants, vitamin B6 deficiency may include irritability, extreme sensitivity in hearing, or seizures.
28	Vitamin B9/Folate	Food forms of folate may decrease the risk of several forms of cancer. Folic acid (pteroylmonoglutamic acid) taken at the recommended amounts (400 mcg DFE/day for children of 14 years and older and adults, except pregnant women, who should take 600 mcg DFE/day and lactating women, who should take 500 mcg DFE/day) may help reduce the risk of certain forms of cancer.
29	Vitamin B9/Folate	Folate supplements in the methylated form (5-methyltetrahydrofolate, or 5-MTHF) may reduce the risk of depression.
30	Vitamin B9/Folate	Vitamin B12 and folate supplementation may reduce the risk of megaloblastic anemia.
31	Vitamin B9/Folate	Adequate folate intake (600 mcg DFE/day) before conception and in the earliest days and weeks of pregnancy may reduce the risk of abnormal fetal brain and spine development.
32	Calcium	Calcium supplements may reduce the risk of preeclampsia in pregnant women who consume too little calcium in their normal diet.
33	Calcium	For those with low calcium status, increasing calcium intake may reduce the risk of metabolic syndrome.
34	Calcium	Normalizing calcium status may reduce the risk of osteomalacia.

35	Choline	Choline may reduce the risk of non-alcoholic fatty liver disease (NAFLD).
36	Copper	If your copper status is low, copper supplementation may reduce the risk of skin discoloration patches (*pityriasis alba*).
37	Copper	If your copper status is low, copper supplementation may reduce the risk of high blood cholesterol.
38	Copper	If your copper status is low, copper supplementation may reduce the risk of loss of balance and coordination.
39	Copper	If your copper status is low, copper supplementation may reduce your risk of infection.
40	Copper	If your copper status is low, copper supplementation may reduce your risk of connective tissue disorders affecting the ligaments and skin.
41	Copper	If your copper status is low, copper supplementation may reduce your risk of weak and brittle bones.
42	Vitamin C	Vitamin C helps the body make collagen needed for wound healing.
43	Vitamin C	Vitamin C helps support the proper function of the immune system needed to protect the body from infections.
44	Vitamin C	Vitamin C, in combination with vitamin E, lutein, zeaxanthin, zinc, copper, may help reduce the risk of age-related macular degeneration (AMD).
45	Vitamin D	Vitamin D reduces the risk of rickets in children.
46	Vitamin D	Vitamin D reduces the risk of osteomalacia (in adults).
47	Vitamin D	Vitamin D may reduce the risk of weak, painful muscles.
48	Vitamin D	Vitamin D may reduce the risk of loss of balance and falls in the elderly.

49	Vitamin D	Vitamin D supplementation may reduce the risk of infection by pathogenic bacteria and viruses.
50	Vitamin D	Vitamin D may reduce the risk of high blood pressure (hypertension).
51	Vitamin D	Vitamin D may reduce the risk of high blood cholesterol levels.
52	Vitamin D	Vitamin D may reduce the risk of developing multiple sclerosis (MS).
53	Vitamin E	Vitamin E may reduce the risk of infections.
54	Vitamin E	Vitamin E reduces the risk of cell adhesion and platelet aggregation, thereby reducing the risk of atherosclerosis.
55	Vitamin E	Vitamin E can prevent loss of body control, muscle weakness and numbness in the arms and legs, and vision problems caused by vitamin E deficiency.
56	Iodine	Adequate iodine during pregnancy reduces the risk of abnormal bone and brain development in fetuses.
57	Iodine	Iodine intake by pregnant women reduces the risk of stunted growth, intellectual disabilities and delayed sexual development of fetuses.
58	Iodine	Iodine intake in mildly iodine deficient children may reduce the risk of reasoning disabilities and abnormal cognitive function.
59	Iron	Iron intake during pregnancy may reduce the risk of abnormal fetal growth and development.
60	Iron	Iron intake by pregnant women may reduce the risk of low fetal birth weight or premature fetal birth.
61	Vitamin K	Vitamin K1 supplementation reduces the risk of excessive bruising or bleeding
62	Vitamin K	Vitamin K2 may reduce the risk of osteoporosis.

63	Magnesium	Magnesium may help reduce the risk of type 2 diabetes.
64	Magnesium	Magnesium may help reduce the risk of insulin resistance.
65	Magnesium	Magnesium may reduce the risk of bone fractures.
66	Magnesium	Magnesium may reduce the risk of osteoporosis.
67	Magnesium	Magnesium may reduce the risk of bone mineral density loss in post-menopausal women.
68	Magnesium	Magnesium may reduce the risk of migraine headaches.
69	Magnesium	Magnesium may help reduce the risk of heart arrythmia.
70	Magnesium	Magnesium may reduce the risk of cardiovascular disease.
71	Manganese	Manganese may reduce the risk of osteoporosis.
72	Manganese	Manganese may reduce the risk of blood clots.
73	Molybdenum	Molybdenum may reduce the risk of toxicity posed by drugs and toxic substances in the body.
74	Multivitamin/mineral Supplements	The combination of vitamin C (500 mg/day), Vitamin E (400 IU/day), zinc (80 mg/day), Copper (2 mg a day), lutein (10 mg/day) and zeaxanthin (2 mg/day) may reduce the risk of age-related macular degeneration (AMD).
75	Potassium	Potassium may reduce the risk of high blood pressure (hypertension), coronary heart disease and stroke.
76	Potassium	Increasing the daily intake of potassium while keeping sodium intake within the range of 4 to 6 grams daily may reduce the risk of hypertension and stroke.

77	Potassium	Potassium supplementation may reduce the risk of kidney stones.
78	Potassium	Potassium supplementation may reduce the risk of osteoporosis.
79	Zinc	Zinc may reduce the risk of pathogenic bacteria and viruses.
80	Zinc	Zinc may reduce the length of wound healing.
81	Zinc	Zinc may reduce the duration of the common cold.
82	Zinc	Zinc may reduce the risk of pneumonia.
83	Zinc	Zinc may reduce the risk of type 2 diabetes.
84	Zinc	Zinc may reduce the risk of hypercholesterolemia.
85	Zinc	Zinc may reduce the frequency of infections.
86	Vitamin B5/Pantothenic acid	Pantothenic acid may reduce the risk of hyperlipidemia (abnormally high levels of lipids [fats] such as cholesterol or triglycerides in the blood).
87	Selenium	Selenium may reduce the risk of oxidative damage from infections.
88	Selenium	Selenium may reduce the risk of hypothyroidism (low thyroid activity).
89	Selenium	Selenium may reduce the risk of cognitive decline.
90	Selenium	Selenium may reduce the risk of Keshan Disease.

91	Selenium	Selenium may reduce the risk of cardiovascular disease by reducing inflammation, platelet aggregation, and lipid oxidation.
92	Asian ginseng (*Panax ginseng*)	Asian ginseng may help reduce the risk of excessive blood cholesterol levels.
93	Asian ginseng (*Panax ginseng*)	Asian ginseng may reduce the risk of chronic inflammation in the body.
94	Asian ginseng (*Panax ginseng*)	Asian ginseng may reduce the risk of erectile dysfunction (ED).
95	Ashwagandha (*Withania somnifera*)	Ashwagandha may reduce insomnia.
96	Astragalus (*Astragalus membranaceus)*	Astragalus may reduce the risk of lower respiratory infections.
97	Bromelain (from pineapple. *Ananas comosus*)	Preliminary research suggests that bromelain may reduce the risk of sinus congestion.
98	Chamomile (*Matricaria recutita, Chamomilla recutita*)	Chamomile may reduce the risk of mild depression.
99	Chamomile (*Matricaria recutita, Chamomilla recutita*)	Chamomile may reduce the risk of diarrhea in children and colic in infants.
100	Cranberry (*Vaccinium macrocarpon*)	Cranberry extracts may reduce the risk of repeat urinary tract infections (UTIs) in women.
101	Elderberry (*Sambucus nigra*)	Elderberry may reduce the risk of colds, flu, and other upper respiratory infections.
102	Flaxseed (*Linum usitatissimum*)	Flaxseed oil supplements containing alpha-linolenic acid (ALA) may help reduce the risk of insulin resistance.
103	Garlic (*Allium sativum*)	Garlic supplements may reduce total and LDL ('bad') cholesterol in people with high cholesterol levels.
104	Ginger (*Zingiber officinale*)	Ginger may reduce the risk of nausea and vomiting associated with pregnancy.
105	Ginkgo (*Ginkgo biloba*)	Ginkgo Biloba may help reduce the risk of dementia.

106	Grape (*Vitis* spp.)	Grape-derived antioxidants may reduce the risk of heart disease.
107	Grape (*Vitis* spp.)	Proanthocyanidin-rich grape seed extracts may reduce the risk of chronic venous insufficiency (CVI).
108	Green Coffee (*Coffea* spp.) Bean	Green coffee bean extracts may lower blood sugar levels.
109	Green Tea (*Camellia sinensis*)	Green tea may lower total and LDL ('bad') cholesterol.
110	Lavender (*Lavandula angustifolia*)	Lavender (*Lavandula angustifolia*) oil taken orally may reduce sexual dysfunction in menopausal and post-menopausal women.
111	Peppermint (*Mentha × piperita*)	Peppermint (*Mentha × piperita*) leaves (or oil) may help reduce the risk of irritable bowel syndrome (IBS).
112	Turmeric (*Curcuma longa*)	Turmeric (*Curcuma longa*) extracts may reduce the risk of osteoarthritis.
113	Omega-3 fatty acids	Omega-3 fatty acids rich in EPA and DHA may reduce inflammation.
114	Omega-3 fatty acids	Omega-3 fatty acids may reduce the risk of cancer.
115	Fiber	Fiber may help lower blood glucose and insulin levels after eating carbohydrates.
116	Fiber	Fiber may lower fasting blood glucose levels.
117	Fiber	Fiber may reduce the risk of high blood pressure (hypertension)
118	Fiber	Fiber may reduce the risk of chronic constipation.

ABOUT THE ALLIANCE FOR NATURAL HEALTH

The **Alliance for Natural Health USA (ANH-USA)** is a leading nonprofit dedicated to defending the right of all Americans to access natural, sustainable, and regenerative approaches to health—supporting people, communities, and the planet. Working closely with its sister organizations, **ANH International** and **ANH Europe**, ANH represents the largest coordinated voice worldwide advocating for safe, effective, and innovative natural health options.

Founded in 1992 as the **American Preventive Medical Association** in response to FDA raids on integrative physicians, the organization evolved into the **American Association for Health Freedom** in 2002, and in 2009 became the Alliance for Natural Health USA. Over three decades, ANH has built a record of legal and policy leadership, including six successful constitutional challenges against the FDA led by constitutional attorney **Jonathan W. Emord, J.D.**, who now serves as ANH-USA's General Counsel.

Under the scientific and strategic leadership of **Robert Verkerk, Ph.D.**, ANH champions health systems that prioritize **empowered self-care, prevention, and upstream regenerative solutions**—in contrast to drug-centric models that are proving unsustainable against the rising burden of chronic, preventable disease, autoimmune disorders, and aging populations.

ANH-USA uniquely unites **consumers, practitioners, and the natural health community** to speak with a single, independent, and non-partisan voice on Capitol Hill. With a grassroots network of more than **500,000 active supporters**, ANH has the ability to mobilize constituents across the nation to influence Congress and federal agencies. Unlike manufacturer trade groups, ANH remains free from vested or conflicted interests, allowing it to work in coalition with nonprofits, professional associations, and ethical companies on shared priorities while retaining full independence.

ANH-USA works in close alignment with **ANH International**, founded in 2002 by Dr. Verkerk, which continues to lead efforts to protect access to natural health across Europe and worldwide. In April 2023, Dr. Verkerk was appointed Executive and Scientific Director of ANH-USA, and now provides overall leadership of ANH's three regional offices.

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