NATURAL PRODUCTS ASSOCIATION

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Testimony of Daniel Fabricant, Ph.D.
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Re: Maryland Economic Matters Committee RE HB 634

Founded in 1936, NPA is the nation's oldest and largest nonprofit organization dedicated to the natural products industry. NPA represents over 700 diverse member organizations and more than 10,000 retail, manufacturing, wholesale, and distribution locations, united in providing consumers access to safe products to maintain and improve their health.

As the former Director of the FDA's Division of Dietary Supplement Programs during the Obama Administration and now an industry executive, I write to you with grave concerns regarding A3512/S2387. I would be remised if I didn't mention that my tenure at the FDA is considered one of the most proactive enforcement periods in the FDA's modern history.

As you know, HB 634 would prohibit the sale of dietary supplements marketed for weight loss to people under 18 while restricting access to these safe, popular, and well-researched products to consumers over 18. The legislation fails to list specific ingredients or products of concern, nor is the sponsor capable of pointing to any dietary supplements that are the genesis of this legislation during testimony in the assigned committees. Instead, the legislation tasks the Department of Public Health to replicate the FDA's Center for Food Safety and Applied Nutrition role to determine which dietary supplement shall be prohibited for sale to consumers under 18 without a prescription. It is critical to note that the FDA, the chief regulator of dietary supplements, has not prohibited or restricted the sale of any dietary supplement to people under 18.

If this legislation became law, Maryland would be the first to ban a food product from a specific demographic. While this legislation has been duplicated in a handful of states, it is essential to note that legislative bodies and state executives recognized the faultiness of this legislation. In fact, Governors Gavin Newsom and Kathy Hochul vetoed the legislation because "dietary supplements… are not considered drugs and, therefore, this measure… to evaluate every individual weight loss and dietary supplement for safety, which is beyond the scope of the department's capabilities."

While we understand the legislation intends to reduce youth exposure to eating disorders, you and your conference must know that supplements are natural products found in food and nature. In addition, NPA members and other industry stakeholders invest significant human resources and capital to ensure their products are safe.

Unfortunately, many have mistakenly lumped over-the-counter diet pills as dietary supplements when they are regulated as over-the-counter drugs by the FDA, which differs from how the supplements are regulated.

Our industry has a strong reputation and brand loyalty with the millions of American consumers who use these products daily. Recent estimates suggest that at least 80% of Americans take at least one dietary supplement as a safe, effective, and affordable way to maintain good health and augment inadequate diets. While a healthy diet is a foundation for better health, even the most well-informed and well-intentioned consumers sometimes eat differently than they should. Supplements, which are easy to add to our daily diets, are often the first step many take toward greater nutritional awareness and healthy lifestyle choices.

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Whether taking a multivitamin, herbal product, or specialty supplement, people can live healthier lives by supplementing their diets.

FDA has a robust regulatory framework to understand what dietary supplements are being sold and who is selling them. Dietary supplements are regulated under several different laws, including the Nutrition Labeling and Education Act of 1990 (NLEA), the Dietary Supplement Health and Education Act of 1994

(DSHEA), the 1997 Food and Drug Administration Modernization Act (FDAMA), the Dietary Supplement and Non-Prescription Drug Consumer Protection Act, and the FDA Food Safety and Modernization Act of 2011 (FSMA). In 1994, Congress to an essential step in recognizing dietary supplements' role in promoting health with the passage of the DSHEA. DSHEA ensures access to safe products made to quality standards and emphasizes the importance of communicating the positive health benefits of supplements so consumers can make informed decisions about their health. In addition, this law that regulates dietary supplements requires companies to submit safety data and includes critical provisions:

Definition: DSHEA defines a dietary supplement as any product that contains one or more dietary ingredients, such as vitamins, minerals, herbs, or other botanicals, amino acids, or other ingredients used to supplement the diet. Dietary supplement ingredients may not be regulated as food additives or drugs.

Safety: The legislation maintains the U.S. Food and Drug Administration's (FDA) authority to safeguard the public against unsafe products. FDA has the power to immediately remove products from the market if the FDA believes that the product or ingredient represents a public health hazard. There are several instances of the FDA exercising this authority, most notably with ephedra.

New Products/Ingredients: Before marketing a new dietary ingredient, a manufacturer must provide the FDA with adequate safety data before marketing. A "new dietary ingredient" is defined as a dietary ingredient that was first marketed after the enactment of DSHEA on October 15, 1994. The law requires manufacturers and distributors who wish to market dietary supplements that contain a new dietary ingredient to notify the FDA about these ingredients before interstate commerce. The notification must include information that is the basis on which the manufacturer or distributor has concluded that the dietary supplement containing a new dietary ingredient is expected to be safe under the conditions of use. The NDI provision is a 75-day pre-market system dealing with safety.

Structure/Function Claims: Under provisions outlined in DSHEA, dietary supplement marketers may include truthful and not-misleading claims on product labels that describe a nutrient's role in supporting wellness. These claims are referred to as structure/function claims or nutritional support claims. Manufacturers must provide the FDA with proof of these claims before marketing the supplement. Additionally, The Federal Trade Commission (FTC) and the FDA work together to regulate the marketing of dietary supplements. The FDA is primarily responsible for product labeling claims, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC is primarily responsible for advertising claims, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the internet is subject to regulation in the same fashion as promotions through any other media.

Labeling: A dietary supplement label must list the name and quantity of each active ingredient; identify the product as a dietary supplement; and, for herbal supplements, identify the part of the plant from which it is taken. Nutrition labeling must be present in a format appropriate to the product. The FDA inspects facilities to gather critical information. As part of this evaluation, labeling review is a required element, and labels lacking necessary information are described as misbranded and thus not compliant with the

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law. In addition, compliance and surveillance samples may be collected during inspections. Samples will generally consist of the label and any labeling available with the product at the time of purchase; this may include labeling and marketing information available on the product page for the website where the product is sold. Dietary supplements that carry a structure/function claim must submit to the Agency no later than 30 days after the marketing of the dietary supplement the following:

- The name and address of the manufacturer, packer, or distributor of the dietary supplement product;
- The text of the statement that is being made;
- The name of the dietary ingredient or supplement that is the subject of the statement;
- The name of the dietary supplement (including the brand name); and
- The signature of a responsible individual or the person who can certify the accuracy of the information presented must certify that the information contained in the notice is complete and accurate and that the notifying firm has substantiation that the statement is truthful and not misleading.

Good Manufacturing Practices (GMPs): Under DSHEA, supplements must comply with current good manufacturing practices. The FDA can issue special regulations on GMPs for dietary supplements. Dietary supplement GMPs are modeled after food GMPs. By law, companies must register all facilities that manufacture, process, package, or hold dietary supplements in the United States.

Office of Dietary Supplements: DSHEA's passage established an office within the National Institutes of Health to coordinate research on dietary supplements and disease prevention, develop a database of supplement research, and advise the Secretary of Health and Human Services on supplement regulation, safety, and health claims. FDA regulates both finished dietary supplement products and dietary ingredients. The NIH dietary supplement label database currently houses over 140,000 on-market and off-market dietary supplements providing the FDA with a picture of the dietary supplement market. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. The FDA enforces authorities against adulterated, misbranded, or misbranded dietary supplement products.

The Dietary Supplement and Non-Prescription Drug Consumer Protection Act legislation was first introduced in 2006, and I am proud of NPA's leadership role in the creation of this law. This critical piece of legislation amended the federal Food, Drug, and Cosmetic Act to require the reporting of adverse events for over-the-counter drugs and dietary supplements. The Adverse Event Reporting (AER) bill resulted from an extensive collaboration between a bipartisan group of lawmakers, including Senators Hatch, Harkin, Enzi, Kennedy, and Durbin. The legislation preempted the states most notably because it was important for the federal government to maintain authority over the interstate commerce of dietary supplements. In addition, the legislation increased responsibilities on the part of manufacturers, and the reporting has shown that the safety record of dietary supplements compares favorably to other health-related health products.

Additionally, the FDA created the adverse event reporting system (AERs) to collect and review adverse event reports on dietary supplements. The AERs provide an essential monitoring tool for identifying potential serious public health issues associated with using a particular product or type of product that needs to be investigated and critically evaluated. FDA's AER system is a multipronged approach that includes detecting adverse events, generating signals of possible health concerns, assessing those signals, and taking appropriate safety actions based on its assessment. An adverse event is an incident of illness or injury that may be associated with a product or ingredient. With further investigation, the association may

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or may not be confirmed. FDA receives reports from various sources, including consumers and health professionals.

When a possible health problem signal is generated from the adverse event reporting system, the FDA assesses whether it is a health problem warranting regulatory action. The FDA can consider these signals by reviewing scientific literature, consulting with experts, reviewing clinical data, conducting laboratory tests, and/or commissioning studies. If FDA confirms that a public health problem exists, such as an

eating disorder, it can take a range of safety actions, such as issuing warnings to consumers and health professionals, issuing import alerts, requesting product recalls, or seizing products. In addition, adverse event reports received by a brand owner or manufacturer must be submitted to the FDA 15 business days after receiving the report.

The AERs are essential in determining a temporal relationship between a product and an eating disorder. The FDA uses this system to add warnings to products it regulates. It is critical to note that this AER system is identical to those used for drugs with a long history of identifying drugs that lead to or exacerbate eating disorders.

Additionally, many supporters of this legislation have cited studies that lack a significant testing protocol called Challenge-Dechallenge-Rechallenge (CDR). The goal of CDR is to determine whether there is a reasonable possibility that a product is etiologically related to the adverse event. Causality assessment includes, for example, temporal relationships through CDR, a medical testing protocol in which a product is administered, withdrawn, then re-administered while being monitored for adverse effects at each stage. CDR is used when statistical testing is inappropriate due to an idiosyncratic reaction by a specific individual, very common with eating disorders, or a lack of sufficient test subjects. The unit of analysis is the individual.

Thus, the hypothesis that supplements lead to or exacerbate eating disorders would then be picked up by AERs if it existed. Fortunately, through the FDA's AER system, FDA makes data for instances like this readily available. In addition, in 2019 and 2022, NPA filed a Freedom of Information Act (FOIA) inquiry into the FDA to explore any adverse events for any cases involving eating disorders and dietary supplements. Thankfully, according to the FDA, no data point connects eating disorders to dietary supplements.

Case reports regarding specific products are also absent from these discussions. It's unclear why these standard pharmacovigilance aspects are absent from the dialogue when they really should be at the heart of any science-based discussion on the assessment of causality. Furthermore, during testimony, those who had testified in support of the legislation failed to mention any dietary supplement or ingredient that is linked to developing an eating disorder. Instead, they referenced over-the-counter drugs regulated differently from dietary supplements, but their AER system standards are identical.

The FTC and the Food and Drug Administration (FDA) share jurisdiction over marketing dietary supplements, foods, drugs, devices, and other health-related products. The agencies coordinate their enforcement and regulatory efforts pursuant to a Memorandum of Understanding – often called the "FDA-FTC Liaison Agreement" – that governs the basic division of responsibilities between them. The FDA has primary responsibility for claims that appear in *labeling*, including the package, product inserts, and other promotional materials available at the point of sale. The FTC has primary responsibility for claims in all forms of *advertising*. Because of this shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible. Marketers should be aware that the FDA/FTC Liaison Agreement doesn't limit the FTC's jurisdiction or prohibit the agency from taking action against deceptive labeling claims or obtaining orders that address all forms of

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marketing, including claims that appear in labeling.

While both the FTC and the FDA require the marketing of dietary supplements and other health-related products to be truthful and accurate, there are some key differences in the agencies' legal frameworks and approaches that marketers should keep in mind.

Unlike FDA law, FTC law makes no bright-line distinctions between categories of health-related products

or claims. For example, provisions in the Dietary Supplement Health and Education Act of 1994 (DSHEA) regarding "structure/function" claims in labeling don't govern the FTC's assessment of those claims in advertising. As a result, the FTC follows the same basic steps when evaluating any health-related claim regardless of whether, under FDA law, the claim would be considered a health claim, a structure/function claim, or a drug claim. Similarly, the FTC's approach to advertising health-related products is the same regardless of whether, under FDA law, the product is considered a food, a supplement, or a drug.

To determine whether advertising complies with FTC law, it is first necessary to identify all claims the advertising materials communicate to reasonable consumers. Once the claims are identified, the FTC assesses the scientific evidence the company relies on to determine whether there is adequate support for those claims. The following sections describe this two-step process with examples illustrating how ad interpretation and substantiation principles apply in advertising for dietary supplements and other health-related products. Furthermore, the FTC views advertising claims from the standpoint of the intended audience.

The Federal Trade Commission regulates dietary supplement advertising as it does for all consumer products by enforcing truth-in-advertising laws. It applies the same standards across all forms of advertising, whether in print, online, social media, mail or any other form of advertising. Federal law requires any form of advertising of a product must be truthful, not misleading, and backed by scientific evidence.

The Federal Trade Commission's broad mandate is to prevent "unfair or deceptive acts or practices." That includes making sure the information marketers provide about the benefits and safety of dietary supplements is accurate so consumers can make informed decisions. Sections 5 and 12 of the FTC Act, along with the FTC's policy statements on deception and advertising substantiation, are the foundation of FTC truth-in-advertising law and can be distilled down to two common-sense principles:

1) Advertising must be truthful and not misleading; and

2) Before disseminating an ad, advertisers must have adequate substantiation for all objective product claims conveyed, expressly or by implication, to consumers acting reasonably.

A deceptive ad is one that contains a material misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances. The type of substantiation needed for a claim depends on many factors, including the product being marketed and the nature of the claim. As a general rule, however, claims about the health benefits or safety of foods, dietary supplements, drugs, and other health-related products require substantiation in the form of competent and reliable scientific evidence.

The term "advertising" refers not only to traditional TV, radio, print, and internet ads but also more broadly to the variety of marketing techniques and promotion methods that marketers engage in to increase consumer interest in, or demand for, their products. Thus, as used here, advertising includes statements or depictions on packaging and labeling; in promotional materials such as brochures or social booklets; on the internet and in other digital content; in social media and influencer marketing; in press

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releases, press interviews, or other media appearances; at trade shows, conferences, and seminars; and indirectly through healthcare practitioners or other intermediaries. Promotional product information distributed through any of these means must comply with the same truth-in-advertising principles that apply to traditional ads.

Marketers of dietary supplements and other health-related products ensure that anyone participating in marketing is familiar with basic FTC advertising principles. In addition, all who participate directly in marketing and promotion or who have the authority to control those practices have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support for those claims. Accordingly, the FTC has taken action not just against product marketers but also, in appropriate circumstances, against individual owners and corporate officers of the marketer, as well as ad agencies, distributors, retailers, catalog companies, infomercial producers, expert endorsers, and others engaged in deceptive marketing and promotion.

The consequences of deceiving consumers about a product's safety, efficacy, or other benefits can be substantial. The FTC can obtain an order that stops the deceptive claims and requires that future marketing be truthful and substantiated. In appropriate circumstances, the FTC also can mandate certain disclosures or require that a marketer engages in corrective advertising to cure any lingering deception in the marketplace. In particularly egregious instances, the FTC has asked a court to ban a company or individual from engaging in certain marketing activities. The FTC also can seek financial remedies, including, in some instances, consumer refunds or civil penalties.

In addition, I would ask you to focus on the legal infirmities of the legislation, including the following examples:

First, the legislation is preempted by federal law. In passing the Food, Drug, and Cosmetic Act ("FDCA"), Congress charged the FDA to "protect the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). In 1994, the FDCA was further amended with DSHEA. DSHEA established a new category of food products – dietary supplements – with unique, comprehensive safety, labeling, manufacturing, and other related standards. DSHEA was introduced to counteract unnecessarily stringent federal intervention in the manufacturing, selling, and labeling of dietary supplements. See, e.g., 103 CONG. REC. S17049 (daily ed. Nov. 23, 1993) (statement of Sen. Hatch). Since its passage, the FDA has recognized that "DSHEA's purpose [is] to broaden the scope of labeling claims that may be made for dietary supplements without subjecting them to regulation as drugs." 65 Fed. Reg. 1000-01, 2000 WL 4559, *1024. By requiring some consumers to have a prescription to purchase certain dietary supplements, the legislation treats supplements the same as drugs, contrary to federal law. The bill should be rejected as preempted.

Second, the legislation is vague and ambiguous as to what products it covers. Section G(2)(I) of the bill provides, in relevant part: "'An ingredient approved by the U.S. Food and Drug Administration for Weight Loss; a steroid; or creatine, green tea extract, raspberry ketone, garcinia cambogia, or green coffee bean extract"

Further, the Department of Public Health is not required to consult with the dietary supplement industry or consumers that have benefitted from supplement products. This section, read with the legislative history of the legislation, requires that dietary supplements containing creatine and other safe and well-studied ingredients be regulated and potentially subject to mandatory warnings that are inappropriate and a violation of the First Amendment. The First Amendment protects commercial speech. See, e.g., Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976). This protection has "great relevance" in "the fields of medicine and public health." Sorrell v. IMS Health Inc., 131 S. Ct.

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2653, 2664 (2011). Any regulation limiting such speech can be upheld only if (1) "the asserted governmental interest is substantial"; (2) "the regulation directly advances the governmental interest asserted"; and (3) "it is not more extensive than is necessary to serve that interest." Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 566 (1980); see also Sorrell, 131 S. Ct. at 2659 ("Speech in aid of pharmaceutical marketing ... is a form of expression protected by the . . . First Amendment" and striking down a statute that burdened such speech). Any restriction on commercial speech must be no broader than reasonably necessary to prevent deception. See, e.g., FTC v. Brown &

Williamson Tobacco Corp., 778 F.2d 35, 43 (D.C. Cir. 1985). The lack of "significant scientific agreement" about health claims made by dietary supplement manufacturers does not allow the government to ban that speech as false or misleading. The FTC cannot ban speech unless that speech lacks credible evidence. Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999). The speech compelled by the legislation violates the First Amendment.

NPA has taken a leadership role in promoting quality standards and has developed proactive certification programs. For example, NPA was the first organization to offer a third-party good manufacturing practices (GMP) certification program for dietary supplement and ingredient manufacturers. This certification is not only a requirement for NPA members but meets and exceeds the FDA's requirements of 21 C.F.R. Part 111. NPA is also responsible for the TruLabel Program, a dietary supplement registration and random-testing program adopted by NPA in 1990 and made a requirement for membership in 1995. This internal oversight program was designed to create a high level of confidence among retailers and consumers that products sold in the marketplace are accurately labeled, establish an ongoing self-regulatory process within the industry, demonstrate industry maturity to legislators, and provide a comprehensive industry product database. The TruLabel consists of a computerized database containing information from the label contents of dietary supplement products. Products are periodically selected for laboratory analysis to confirm the label. Selection for random product testing may occur through several mechanisms, including:

- Selection of categories
- Selection of sellers
- Selection based on complaints.

The commercial laboratories used for TruLabel testing are selected based on their integrity, experience, and reputation for the required analysis. NPA also partners with the globally recognized testing program *Informed-Choice* to help supplement manufacturers in the United States minimize the risk of contamination. This extensive testing program gives athletes the added confidence to know that the products they use to train and compete contain only the ingredients listed on the label.

In conjunction with the NPA is the Natural Products Foundation (NPF) which was organized exclusively to stimulate and support research, education, and knowledge regarding dietary supplements, nutritional foods, and related products, with the overall objective of advancing the knowledge of the public and thereby, improving public health. NPF is home to the Truth in Advertising Program, which ensures consumers receive accurate information about legally marketed dietary supplements to make an informed decision in promoting and maintaining their health. Additionally, the Truth in Advertising Program regularly meets with the FTC and FDA to present documentation highlighting advertisers responsible for making potentially non-compliant claims on behalf of dietary supplements. The Truth in Advertising Legal Advisory Council will review claims across all mediums as part of the program and send warning letters to noncompliant firms. Since 2010, the program has sent hundreds of warning letters to companies with illegal claims in their advertising. Every year, we find the advertisers increasingly receptive and open to our message of reform. Daily changes improve the industry's larger picture and protect consumers

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from false or misleading information. Nearly 80% of warning letter recipients have acknowledged the problems highlighted by the NPF investigation and worked to revise their promotional content and advertising practices. In the program's first four years, Truth in Advertising oversaw 600 advertising case reviews.

The truth is, prohibiting and restricting the sale of safe, effective, and well-researched dietary supplements will do more to undermine public health. One must also consider that this would be the first time in America's history to ban a food product for use by a specific category of people. As written, the

bill would ban ingredients found in commonly found foods. For example, lipotropic may sound unnatural to some, but it is found in the healthy and recommended foods we want our children to eat. This includes lean cuts of beef, chicken, turkey, bison, dairy, eggs, milk, and even chocolate. Creatine, found in red meat, has a long history of safe use and is the most researched dietary supplement, with more than 1,612 clinical trials, which would be prohibited from sale. Other essential nutrients include branch chain amino acids, Arginine, Citrulline, Glutathione, Carnitine, Iron, Magnesium, Zinc, Theanine, Taurine, Lysine, Beta-Alanine, and Glutamine, which all have an extensive history of safe use, would be banned.

We implore you to recommend opposition to HB 634 in the bill's current form on behalf of the entire dietary supplement industry. Since there is no link between the use of dietary supplements and eating disorders, NPA would support an amendment to the legislation, which would remove dietary supplements from the equation while addressing over-the-counter drugs. Sadly, in its current form, this legislation will prevent consumers from taking their health into their hands and restrict their ability to supplement their potentially nutrient-deficient diets, a fundamental lesson we learned during COVID-19.

Thank you,

Daniel Fabricant, Ph.D.
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