NATURAL PRODUCTS ASSOCIATION

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Testimony of Kyle Turk
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Re: New Jersey Assembly Health Committee Hearing on A 3512

Founded in 1936, the Natural Products Association (NPA) is the oldest and largest trade association representing the natural products industry representing over 700 diverse member organizations united in providing consumers with access to safe products that will maintain and improve their health. 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 to dietary supplements and ingredient manufacturers. NPA's GMP standards include all of the FDA's GMP requirements of 21 C.F.R. Part 111 and specific requirements that exceed Part 111 or reflect best industry practices.

NPA is led by Daniel Fabricant, Ph.D., the top enforcement official at the Food and Drug Administration's Division of Dietary Supplements during the Obama Administration. His time at the FDA is considered one of the most productive enforcement periods in the FDA's modern history. While there, his division averaged approximately 15 legal actions annually and more than 200 administrative actions per year. Protecting the American people was his job while at the FDA. He has brought that same mindset to the Natural Products Association.

The Regulatory Landscape for Dietary Supplements

According to a recent survey, 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 are easy to add to our daily diets. This is often the first step many take toward greater nutritional awareness and healthy lifestyle choices. Whether taking a multivitamin, herbal product, or specialty supplement, people can live healthier lives by supplementing their diets.

The passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994 represented a balanced and informed approach to protecting consumer health and access to dietary supplements. With DSHEA, Congress took an essential step in recognizing supplements' role in promoting health and preventing chronic illness. In addition, DSHEA ensures access to safe products made to quality standards. The law also emphasizes the importance of communicating the positive health benefits of supplements so consumers can make informed decisions about their health.

Additionally, DSHEA included critical provisions including:

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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.

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 has primary responsibility for claims on product labeling, 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.

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.

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 nearly 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

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drug products. The FDA enforces authorities against adulterated, misbranded, or misbranded dietary supplement products.

Adverse Event Reporting System and MedWatch

In 1993 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 adverse event reporting system for dietary supplements 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 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 an actual health problem warranting attention. 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, 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. The law requires that adverse event reports received by a brand owner or manufacturer must be submitted to the FDA no later than 15 business days after the report is received.

Targets Products that Contain Natural Ingredients

While we understand the legislation's intent, the committee must know that supplements are natural products found in food and nature. NPA members and other industry stakeholders invest significant human resources and capital to ensure their products are safe. These include good manufacturing processes, random product testing, adhering to appropriate marketing guidelines, and following every other rule and regulation that the FDA and the FTC have made for 25 years.

Many have mistakenly lumped over-the-counter diet pills, such as Alli, as dietary supplements when they are regulated as over-the-counter drugs by the FDA, which differs from how the FDA regulates dietary supplements. The Federal Food, Drug, and Cosmetic Act require manufacturers and distributors to notify the FDA about their ingredients. The notification must include information that is the basis on which the manufacturer or distributor has concluded the dietary supplement is expected to be safe under the conditions of use suggested in the labeling.

In 2011, dietary supplements were included in the Food Safety Modernization Act (FSMA). FSMA sought to strengthen the food safety system by giving FDA an updated mandate and new

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authorities to address food safety concerns. For example, a critical section of FSMA enhanced the FDA's authority to require all facilities that manufacture, process, pack, and store foods (including dietary supplements) to register with the FDA and directed the agency to increase the frequency of its inspections of domestic food facilities.

As we understand it, this legislation's premise suggested that there may be a prevalence of weight management and muscle-building supplements being used by teenagers and that their use led to eating disorders. Supporters of the bill have cited estimates for eating disorders and supplements. Thankfully, we do not have to estimate as the FDA makes this data readily available through AERs. In 2019 and 2022, NPA filed a Freedom of Information Act (FOIA) inquiry to the U.S. Food and Drug Administration to explore any adverse events for any cases involving eating disorders and weight-management or muscle-building products.

Thankfully, according to the FDA, no data point connects eating disorders to weight management or muscle-building products.

So as former regulators, and experts in this field who have professionally reviewed governmental data, we would say that unless there is new information we don't know about, there is no basis to suggest that those with eating disorders are associated with consuming muscle-building products.

It's important to note that FOIAs are free to file and can be submitted by anyone.

Challenge-Dechallenge-Rechallenge

The AERs are a precious tool in determining a temporal relationship between a product and an eating disorder. The FDA uses this system in conjunction with the Medwatch system to add warnings to products it regulates 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, the assessment of temporal relationships through CDR, which is 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 directly lead to eating disorders would then be picked up by AERs or Medwatch if it existed.

A Solution in Search of a Problem Undermines Public Health

The truth is, prohibiting the sale of healthy, safe, and legal products to minors will do nothing to promote public health and will do more to undermine it.

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One must also consider that this would be the first time in America's history banning 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, lipotropics may sound unnatural to some, but it is located 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 some chocolate as a treat. 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 currently being conducted, which would be prohibited from sale. Branch Chain Amino Acids and Essential Amino Acids, which also have an extensive history of safe use, would be banned.

Public Health and Natural Products

Obesity is a complex, multifactorial health issue that requires a comprehensive approach. Unfortunately, it is the second leading preventable cause of death in the United States and is associated with many comorbid conditions. According to the New Jersey State Department of Health, obesity has reached epidemic proportions in New Jersey. Sadly, 31.8% of New Jersey adults are overweight or obese, and obesity among children and adolescents has tripled. Currently, 24.7% of New Jersey's children are obese or overweight.

Individuals frequently struggle with the health and physical consequences and the professional and social consequences. Discrimination against obese individuals happens in schools, workplaces, and more. Sadly, if A 3512 passes, overweight and obese individuals will face this same discrimination in their local health food stores because dietary supplements that support weight management will now be more challenging to access. Instead of attacking safe products millions of Americans use daily to promote their health and wellness, New Jersey should be looking to promote healthy behaviors and support health and wellness, not deterring it.

Punishment Does Not Fit the Crime

The legislation before the committee today would mandate penalties for selling dietary supplements more severe than if that same retailer were to sell alcohol or tobacco to a child. Under this bill, the penalty for selling nutritional supplements would be $750, while under New Jersey law, the fine for selling alcohol to a minor is $250. So, is selling creatine a more significant safety concern than selling alcohol?

Harm New Jersey's Economy

There is a broader economic impact to consider. In New Jersey, the natural products industry is a $5 billion industry supporting over 45,000 jobs. New Jersey's economic engine, main street, includes retailers who supply their communities with nutritional products. As we have seen, Main Street has been crushed by the COVID-19
pandemic. A 3512 would prohibit customers' direct access to weight management products and limit direct access to only supervisory personnel. However, the bill fails to consider whether retailers have the physical space to segregate the products, which is mainly a problem for mom-and-pop health food stores. Additionally, the requirement that only supervisory personnel can sell products will increase costs for mom-and-pop retailers who wish to sell these products.

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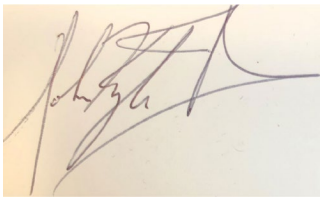
Unfortunately, this legislation will undoubtedly impact and won't be favorable for jobs and growth, hitting brick-and-mortar stores the hardest.

Conclusion

The proposal under consideration today would place onerous restrictions, most notably on small businesses such as your local pharmacy, convenience, or health food store, by prohibiting the sale of popular products. Restricting access to them is unfair to those who value health and wellness and hurts responsible retailers. Nobody wins. We support efforts to stop illegal drugs masquerading as natural products. Of course, no one wants consumers to use unlawful products like Selective Androgen Receptor Modulators (SARMs) or Selective Estrogen Receptor Modulators (SERMs). Still, they are already illegal by law, and the FDA uses its enforcement authority against companies that attempt to sell these products. The federal government has vast enforcement powers and a long track record of punishing criminals who break the law. We support vigorous enforcement of the law to protect consumers. Still, the FDA, the chief regulator of dietary supplements, found no data suggesting weight-management and muscle-building dietary supplement use is correlated to eating disorders.

Thank you,



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