NATURAL PRODUCTS ASSOCIATION

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March 24, 2022
Testimony of Kyle Turk
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Re: Senate Consumer Protections Committee Hearing for SB2613

The Natural Products Association (NPA) is the leading and largest trade association representing the natural products industry. We advocate for our members who supply, manufacture, and sell natural ingredients or finished products for consumers. In addition, NPA is the voice of responsible industry stakeholders before federal, state, and local governments. Founded in 1936, NPA represents approximately 750 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers, and distributors of natural products, including foods, dietary supplements, and health/beauty aids.

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 he was 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 don't always eat the way they should. Supplements are easy to add to our daily diets. This is often the first step many people take toward greater nutritional awareness and adopting 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 the role supplements can play 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:

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.

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Safety: The legislation maintains the U.S. Food and Drug Administration's (FDA) authority to safeguard the public against any unsafe product. *FDA has the power to immediately remove products from the market if the FDA believes that 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, October 15, 1994.

Structure/Function Claims: Under provisions outlined in DSHEA, dietary supplement marketers may include on product labels truthful and not-misleading claims that describe the role of a nutrient in supporting wellness. These claims are referred to as structure/function claims or nutritional support claims. Manufacturers must provide the FDA with proof for 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 has primary responsibility for claims in advertising, 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 has the authority to 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 drug products. FDA is responsible for exercising its enforcement authorities against any adulterated, misbranded, or misbranded dietary supplement product.

Targets Products that Contain Proven Natural Ingredients

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While we understand the legislation's intent, the committee must know that supplements are simply 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.

Additionally, some have incorrectly stated that the FDA does not review dietary supplements for safety before entering the market. 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 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 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 SAERs. In 2019, 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.

The Adverse Event Reporting System is a database that contains information on adverse events and product complaint reports submitted to FDA for foods, dietary supplements, and cosmetics. The database is designed to support FDA's safety surveillance program. Adverse Events can include minor to major medical events and complaints about off-taste or color of a product, defective packaging, and other non-medical issues.

Doctors, health care professionals, and even consumers may submit an adverse event with any dietary supplement. Thankfully, that overall number is relatively low compared to foods and pharmaceuticals. Still, we were explicitly interested in whether there were any cases involving eating disorders and weight-management or muscle-building supplements.

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

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

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.

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 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 some chocolate as a bit of a treat. Creatine, which is 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, would be prohibited from sale. Branch Chain Amino Acids and Essential Amino Acids, which also have an extensive history of safe use, would also be banned.

Thermogens are another natural ingredient targeted in this legislation. Like lipotropics, thermogenic are found in healthy foods and products we use every day, such as caffeine in a cup of coffee.

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 Rhode Island State Department of Health, obesity has reached epidemic proportions in Rhode Island. Sadly, 30.2% of Rhode Island adults are either overweight or obese, and obesity among children and adolescents has tripled. Currently, one-third of Rhode Island'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 S2613 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 that millions of Americans use every day to promote their health and wellness, Rhode Island should be looking to promote health behaviors and supporting health and wellness, not deterring it.

Unfortunately, S2613 discriminates against people fighting weight management issues, forcing them to a separate counter to evaluate various weight management products.

Punishment Does Not Fit the Crime

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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 $2,000, while under Rhode Island law, the fine for selling alcohol to a minor is $250. So is selling creatine really a more significant safety concern than selling alcohol?

Harmful to Rhode Island's Economy

There is a broader economic impact to consider. In Rhode Island, the natural products industry has an economic impact of nearly $52 million, providing almost 2,000 jobs and nearly $10 million in state taxes. Rhode Island'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. The bill fails to consider whether retailers have the physical space to segregate the products. Brick and mortar have been crippled over the last two years, and legislation like this one is just another nail in their coffins.

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 Rhode Islanders who value health and wellness, hurts responsible retailers, and drains Rhode Island's budget through lost sales taxes. Nobody wins. We support efforts to stop illegal drugs masquerading as natural products. Of course, no one wants any consumer 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 their enforcement authority against companies that attempt to sell these products. The federal government has vast enforcement powers and has 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 point suggesting weight-management and muscle-building dietary supplement use is correlated to eating disorders.

Thank you,

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