

Department of Medicine

Pieter Cohen, M.D.

Associate Professor of Medicine

Email: pcohen@cha.harvard.edu

Phone: 617-665-1016

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Re: Bills S16A & A431A: An Act protecting children from harmful diet pills and muscle-building supplements

Dear Honorable Members of the New York State Legislature,

I am a practicing internist and associate professor of medicine at Harvard Medical School. In my primary care practice, I routinely recommend dietary supplements to my patients to prevent and treat a wide variety of conditions. I strongly believe that all American consumers deserve, and expect, unfettered access to safe and accurately labeled supplements. Access to accurately labeled safe supplements is also essential for physicians in order to provide evidence-based high-quality medical care.

Not all supplements, however, are accurately labeled or demonstrably safe. Witnessing the adverse health effects of weight loss supplements among my own patients (Cohen 2012) has led me to study the safety of dietary supplements.

Despite my frequent advice to my patients to use dietary supplements in my practice, I do not recommend sports or weight loss supplements. Sports and weight loss supplements are two categories of supplements that are at higher risk of including misleading claims and containing banned and prohibited drugs compared to other categories of supplements.

Marketing dietary supplements as if they will lead to safe weight loss is misleading. I am not aware of evidence from any high-quality clinical trial that any of the hundreds of weight loss dietary supplements currently on the market can safely lead to long-term weight loss. Due to the current federal law, this lack of evidence does not prevent dietary supplement manufacturers from marketing their supplements as if they are effective and safe weight loss products (DSHEA 1994; Cohen 2016b). The labeling of supplements as weight loss aides, while permitted under federal law, does a great disservice to consumers seeking healthy approaches to losing weight.

In addition to misleading claims, the evidence suggests that sports and weight loss supplements pose particular health risks to consumers. Investigators from the Centers for Disease Control and Prevention (CDC) estimate that adverse events from supplements lead to more than 23,000

emergency department visits each year in the United States (Geller 2015). One of the categories of supplements that are most likely to lead to these emergency department visits are weight loss supplements (Geller 2015). In addition to the CDC's study, additional evidence links sports and weight loss products to harm: epidemiologists have linked 69 cases of hepatitis to a single brand of weight loss/sports supplement: 32 patients required hospitalization, 3 patients required liver transplants, and 2 died (Chatham-Stephens 2017; Hawaii News Now 2017).

There are many reasons that sports and weight loss supplements may pose risk to consumers. These products can be introduced into the marketplace by manufacturers without review or approval by the FDA (DSHEA 1994). Some sports and weight loss products have been found to contain prescription-strength levels of potent botanical stimulants (e.g., yohimbine and higenamine) (Cohen 2016a; Cohen 2019). These botanical stimulants are often also combined with high dosages of caffeine (Cohen 2013). Botanical stimulants are not benign: they may stress the heart, increase blood pressure and cause panic attacks (Cohen 2016a; Cohen 2019).

In addition to the risks posed from botanical stimulants combined with caffeine, the FDA have found hundreds of brands of sports and weight loss supplements to contain banned, experimental or prohibited drugs (Tucker 2018). These unapproved, experimental drugs found in these supplements include compounds similar to ephedrine, amphetamine and methamphetamine (Cohen 2017, Cohen 2015, Cohen 2014). In addition to these stimulants, the FDA has identified the drug DMAA, or dimethylamylamine, in hundreds of dietary supplements (Archer 2015). DMAA was widely available as an ingredient in sports and weight loss supplements for years before the FDA notified consumers that it may lead to serious cardiovascular disease including heart attacks (FDA 2013). The risks of supplements with high dosages of mixtures of stimulants include life threatening heart disease and stroke (Venhuis 2014, Archer 2015, Cohen 2015).

The FDA has attempted to remove DMAA and many other experimental stimulants from dietary supplements, but, to date, their enforcement actions have been unsuccessful. Despite what some industry lobbyists claim, there are several challenges that the FDA confronts in trying to remove dangerous supplements from the marketplace. The agency has no list of products available for sale and no effective system for detecting harm from the products that are available (Cohen 2014c). Furthermore, once the FDA identifies dangerous products, the agency often lacks the resources and tools to remove the products from commerce. For example, after the FDA recalled products containing active drugs, we were able to purchase dozens of the "recalled" supplements years after the FDA recall (Cohen 2014b). Our team found that two-thirds of the "recalled" supplements on sale were still adulterated with drugs (Cohen 2014b). In another study, we found that consumers purchased a weight loss supplement from local stores both before and after a FDA recall of the product (Cohen 2012). In addition to recalling individual products that pose health risks, the FDA has attempted to eliminate specific ingredients that pose health risks, such as the stimulant DMAA (FDA 2013). Unfortunately, these attempts have also often failed, and dozens of dietary supplements continue to openly list DMAA and other banned compounds as ingredients on their labels (Department of Defense 2017, Eichner 2016). Earlier this year, we published our latest study in which weight loss and sports supplements were found to contain 9 different prohibited ingredients in combinations never tested in humans (Cohen 2021).

Given the current federal regulatory framework, the FDA cannot guarantee consumers that sports and weight loss supplements sold as dietary supplements are effective and safe. Many experts believe that the best solution will be to address this at a state-by-state level until the current federal law can be reformed (Starr 2016). I strongly encourage you to consider how the New York legislature can create a safer environment for youths and teens in New York who may be tempted to consume potentially dangerous sports and weight loss dietary supplements.

Sincerely,



Pieter Cohen, MD
Associate Professor of Medicine, Harvard Medical School
Internist, Cambridge Health Alliance

Citations

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