

Odds, Arcs, and Policy Change: A Step-by-Step Look at a Public Health Campaign Taking on the Dietary Supplements Industry

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What are the odds that an impeccably conducted study in a high-impact scientific journal showing compelling – even incontrovertible – evidence that a consumer product is harmful, perhaps deadly, will lead to swift policy change to protect consumers? Just about nil, you guess? You’d be right, but of course you could argue that’s a “straw” question because everyone knows that no single study’s results can ever be considered incontrovertible.

So what if I say a dozen studies show these same compelling findings? What would the odds be then? How about hundreds of studies, plus major federal government reports, along with countless U.S. Food and Drug Administration (FDA) warnings? Surely the public policy response will finally be swift and decisive? Sadly, no, the odds of all that evidence on its own catalyzing public policy still hovers somewhere barely above nil. Outrageous and perplexing to most of us

who consider ourselves scientists? Yes, but welcome to the world of dietary supplements.

Before I continue on supplements, I need to say a word about the unspoken assumption of many scientists that the evidence we generate has a direct and unmediated connection to

policy: Accrue enough evidence, and policy will change. But the path from evidence to policy change is better thought of as an arc – a policy translation arc – with three crucial steps: 1) accrue compelling evidence; 2) generate viable policy options; and 3) energize political will in support of one or more of those options.¹ Understanding this basic idea—that evidence plays an important role but is just one step in the public health policy translation arc—will help make the dietary supplements situation seem a lot less perplexing.

Now back to supplements: About half of American adults² and a third of children³ use dietary supplements, which include vitamins, minerals, and a dizzying array of herbal

¹ Mello MM, Studdert DM, Brennan TA. Obesity – The new frontier of public health law. *N. Engl. J. Med.* 2006;354(24):2601-2610.

² Bailey RL, Gahche JJ, Miller PE, Thomas PR, Dwyer JT. Why US adults use dietary

supplements. *JAMA Internal Medicine.* 2013;173(5):355-361.

³ Bailey RL, Gahche JJ, Thomas PR, Dwyer JT. Why US children use dietary supplements. *Pediatr. Res.* 2013;74(6):737-741

products. We've all seen them lining the shelves of pharmacies, groceries, health food stores, and even gym boutiques selling workout products. What many people do not know is that dietary supplements are not prescreened for safety or efficacy by the FDA. In 1994, Congress passed the disingenuously named Dietary Supplement Health and Education Act (DSHEA), which prohibits the FDA from prescreening dietary supplements before they enter the market.⁴ So how do we know if a supplement is effective or even that what's listed on the label is really what's in the box or bottle? We don't – it's as simple as that.

In the absence of FDA prescreening, many dietary supplements on the consumer market, especially those sold for weight loss and muscle building, have been found to be adulterated with prescription pharmaceuticals, banned substances, heavy metals, pesticides, and other dangerous chemicals.^{5,6,7,8,9} Weight-loss and muscle-building dietary supplements have been linked to stroke, testicular cancer, liver and

other organ damage, sometimes necessitating organ transplant or resulting in death.⁵ In fact, the rate of liver failure has risen 185% in the past decade,⁵ and 16% of serious drug-induced liver injury cases in the United States are attributed to dietary supplement use, the majority being those sold for weight loss and muscle building.¹⁰

A recent national study by the Centers for Disease Control and Prevention estimated that dietary supplements result in over 23,000 emergency department visits every year, and weight-loss supplements in particular account for over a quarter of these visits.¹¹ Which age group is hit hardest by the dangers of the weight-loss supplements? Young adults ages 20-34 years. And for young people ages 5-19 years, weight-loss supplements make up the largest single type sending them to the emergency department too. It's worth noting that these products are not medically recommended for healthy weight loss or strengthening for people of any age and especially not for adolescents. In 2016 the American Academy of Pediatrics

⁴ Pomeranz JL, Barbosa G, Killian C, Austin SB. The dangerous mix of adolescents and dietary supplements for weight loss and muscle building: Legal strategies for state action. *J. Public Health Manag. Pract.* 2015;21(5):496-503.

⁵ Park S, Viray M, Johnston D, Taylor E. Notes from the field: Acute hepatitis and liver failure following the use of a dietary supplement intended for weight loss or muscle building — May–October 2013. *Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention.* 2013;Oct. 11, 2013.

⁶ Park S, Viray M, Johnston D, Taylor E. Notes from the field: Acute hepatitis and liver failure following the use of a dietary supplement intended for weight loss or muscle building — May–October 2013. *Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention.* 2013;Oct. 11, 2013.

⁷ U.S. Food and Drug Administration. *Tainted products marketed as dietary supplements_CD*. 2017.

⁸ Cohen PA, Travis JC, Keizers PHJ, Deuster P, Venhuis BJ. Four experimental stimulants found in sports and weight loss supplements: 2-amino-6-methylheptane (octodrine), 1,4-dimethylamylamine (1,4-DMAA), 1,3-dimethylamylamine (1,3-DMAA) and 1,3-dimethylbutylamine (1,3-DMBA). *Clin. Toxicol.* 2017 (Epub ahead of print).

⁹ Brown AC. An overview of herb and dietary supplement efficacy, safety and government regulations in the United States with suggested improvements. Part 1 of 5 series. *Food Chemistry and Toxicology.* 2017;107(Pt A):449-471.

¹⁰ Navarro VJ, Barnhart H, Bonkovsky HL, et al. Liver injury from herbals and dietary supplements in the U.S. Drug-Induced Liver Injury Network *Hepatology.* 2014;60:1399–1408.

¹¹ Geller AI, Shehab N, Weidle NJ, et al. Emergency department visits for adverse events related to dietary supplements. *N. Engl. J. Med.* 2015;373(16):1531-1540.

came out with two reports saying as much.^{12,13}

With the industry virtually unfettered by regulatory controls,⁴ what's to stop retailers and manufacturers from hawking their snake oil to any anxious teen struggling with body image in the face of incessant societal pressure to lose weight or get ripped? Nothing. Instead, the industry continues to grow at an astronomical pace. Today there are more than 50,000 dietary supplement products on the US market,⁹ which is now estimated to generate \$37 billion in annual revenue.¹⁴ All the while, important evidence from researchers continues to mount. Harvard Medical School's Dr. Pieter Cohen, MD, widely considered among the nation's premier medical scholars on all that is wrong with supplements in terms of health and safety, just came out with yet another chilling laboratory study revealing the dangerous and illegal – yet undisclosed – stimulant ingredients in weight-loss and sports supplements found on many store shelves today.⁸

To be sure, there have been loud and forceful calls from the public health community for the FDA to act, and the FDA has most certainly heard our calls. In fact, earlier this fall the FDA sponsored a hearing on supplements, inviting public comment on these products.¹⁵ But here's the rub: The FDA *can't* act — or at least not in the ways

that we would want to adequately protect consumers. The reason goes back nearly a quarter century to DSHEA, which, with a great deal of industry lobbying behind it, explicitly forbids the FDA from taking the types of proactive steps with dietary supplements to protect consumers that the agency does with prescription and over-the-counter drugs.

So what's a conscientious public health professional to do? A few years ago, I asked this question of leading public health law scholar Jennifer Pomeranz, JD, MPH, who is both a Harvard Chan School alum and author of *Food Law for Public Health*.¹⁶ This was her answer (more or less): Roll up your policy advocate sleeves, and get to work on translating all that good evidence into sound consumer protection policy options for state and municipal governments. It was clear we had Step #1 of the policy translation arc – compelling evidence—well covered, so next we needed to move on to Step #2 to generate viable policy options for local governments to act on.

Pomeranz led a legal research project we worked on together detailing a number of viable and feasible options for government action by cities and states.⁴ And then my training program – the Strategic Training Initiative for the Prevention of Eating Disorders (STRIPED), based at the Harvard Chan School and Boston Children's Hospital,

¹² Golden NH, Schneider M, Wood C, American Academy of Pediatrics. Preventing obesity and eating disorders in adolescents. *Pediatrics*. 2016;138(3):e1-e10.

¹³ LaBotz M, Griesemer BA, Council on Sports Medicine and Fitness, American Academy of Pediatrics. Use of performance-enhancing substances. *Pediatrics*. 2016;138(1):e20161300.

¹⁴ Anonymous. NBJ's Supplement Business Report 2015. *Nutrition Business Journal* 2015.

¹⁵ FDA to hold public meeting to discuss the development of pre-DSHEA dietary ingredients (press release). 2017. URL: <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm569167.htm>; Date Accessed: Nov. 16, 2017.

¹⁶ Pomeranz JL. *Food Law for Public Health*. New York: Oxford University Press; 2016.

pulled together a dedicated group of public health students from the Harvard Chan School, experts, and community leaders to sit down with Massachusetts Rep. Kay Khan. Together, we deliberated on the policy options Pomeranz and colleagues proposed to see what could work in our state.

A former psychiatric nurse and longtime champion in the Massachusetts State House for children and mental health, Rep. Khan, along with 20 other co-sponsors, introduced the first piece of legislation in the country designed to ban the sale of weight-loss and muscle-building supplements to minors in the state. Massachusetts House Bill No. 1195 (H.1195), “An Act Protecting Children From Harmful Diet Pills and Muscle-Building Supplements,” is now winding its way through the State House in the current legislative session. With some of the same successful strategies used to protect teens from tobacco, H.1195 would ban the sale of dietary supplements for weight loss and muscle building to minors in the state, move the products behind the counter, and mandate warning signs in stores.

Next, onto Step #3 of the arc: Energize political will. To raise the level of awareness and righteous opprobrium about the issue, STRIPED created the Out of Kids’ Hands Campaign to organize physicians, nutritionists, mental health professionals, and other clinicians along with coaches, parents, and young people who’ve been hurt by these products to urge their state legislators to support H.1195. The campaign offers training and talking points developed by Harvard Chan School students and others for communicating effectively with legislators and also for giving testimony at a legislative hearing. This fall Harvard Chan School students working with STRIPED helped

organize a well-attended educational briefing on the issue at the Massachusetts State House for lawmakers and their staff and also testified at the public hearing on the bill before the legislature’s Joint Committee on Public Health. Altogether we turned out 11 experts and community members to testify at the hearing in support of the bill and nearly three times that many to provide written testimony to the committee.

What’s next for H.1195? We don’t know if the committee will decide to move the bill forward for consideration by the full legislature or to table it for a future session. But we do know we’ve done right by the policy translation arc: The evidence base is rock solid, viable legal options for states and cities are identified and a new bill is in the state legislature, and a strategically targeted advocacy campaign is in place to catalyze community and policymaker support for policy action. With that, I’d say the odds finally just might be in our favor.

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