NYC Health

Testimony

of

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Assistant Commissioner, Bureau of Mental Health

New York City Department of Health and Mental Hygiene

before the

New York City Council Committee on Health

on

Body Image and Inclusivity

January 28, 2020

Committee Room, City Hall

New York, NY

Good morning Chair Levine and members of the committee. I am Dr. Myla Harrison, Assistant Commissioner of the Bureau of Mental Health at the New York City Department of Health and Mental Hygiene. I am joined by Dr. Chanelle A. Coble, a pediatrician affiliated with NYC Health and Hospitals at Bellevue and NYU Langone Hospitals. On behalf of Commissioner Barbot, thank you for the opportunity to testify on the issues of body image today.

The Health Department is committed to protecting and promoting the health of all New Yorkers and aims to ensure that New Yorkers have access to high quality mental health care, preventive and primary care, and nutritious food regardless of zip code.

No one should face discrimination in any form, especially biases and prejudice aimed at the way their body looks, and no one should experience societal pressure to change the way their body looks. All people regardless of their body type should be treated with respect and dignity.

While the Health Department does not collect data on rates of body image challenges and eating disorders among New Yorkers, we know from academic work that people who idealize thinness tend to be dissatisfied with their body image and tend to experience anxiety, depression, eating disturbances, and poor self-esteem. Women who are exposed to images of thin women experience not only decreased body image and satisfaction but also increased anxiety.

Because social media is nearly ubiquitous, we need to be attentive to the impact of social influencers on New Yorkers, including celebrities who make money based on the number of people who buy the products they promote online. 72% of Americans use at least one social media site, and for many, social media is part of their daily routine. Among teens, over 90% report being online daily and 70% report using social media multiple times per day. On social media, users may be exposed to images from social media influencers that idealize thinness and promote untested products that claim to bring weight loss and beauty. A study of users of one social media site found that those who endorsed a thin-appearing female body type tended to also engage in social comparison and express intentions to engage in extreme weight loss. Low self-esteem and depressive symptoms have been directly linked with social media users' internalization of thinness as the ideal body form.

Although academic literature on body image has primarily focused on straight, cisgender women, LGBTQ and gender non-conforming people also face pressure to conform to standards of beauty. Among young people, LGBTQ and gender non-conforming youth are twice as likely than their non-LGBTQ peers to be dissatisfied with their body image and four times more likely to report disordered eating behaviors.

Individuals with body dissatisfaction are at greater risk for disordered eating behaviors, such as skipping meals, eliminating certain foods, or engaging in extreme exercise to burn off calories. Research has demonstrated that idealizing bodies and engaging in social comparison on social media are behaviors that are linked to disordered eating. Disordered eating behavior represents one risk factor for eating disorders, however eating disorders are defined by extreme preoccupations with food and weight that interfere with functioning and can be life threatening. While eating disorders are caused by a complex interaction of genetic, biological, behavioral, psychological, and social factors, addressing social media influencers' promotion of untested,

unproven weight loss products may be one strategy that can ameliorate one of the factors that may be related to eating disorders.

The City of New York is working to educate New Yorkers about body image issues and promote inclusivity. The Department of Education provides health education in body image and body confidence for middle school and high school students during the HealthSmart Nutrition unit. At all grade levels, lesson plans include skills development around media literacy and analyzing information for reliability and informed decision making. At NYC Health and Hospitals, physicians screen patients for eating disorders as part of routine primary care, and outpatient treatment for eating disorders is available at certain H+H locations throughout the City. If a patient requires more intensive care such as an extended hospitalization or long-term outpatient care, they are referred to institutions that specialize in this care.

If you or a loved one are seeking help with an eating disorder, we encourage you to call NYC Well. NYC Well is a phone, text, and online chat service that operates 24/7, 365 days a year and is staffed with English, Spanish, Cantonese, and Mandarin speakers, with additional interpretation services available in more than 200 languages. It is a confidential service staffed with crisis counselors and peers with lived mental health experience. NYC Well counselors can refer callers to over 150 providers throughout New York City who offer counseling, treatment, or support for eating disorders.

We also encourage the Council to contact the New York State Department of Health for more information on publicly funded resources and services for people impacted by eating disorders. The State Department of Health funds three Comprehensive Care Centers for Eating Disorders, including the Metropolitan Comprehensive Care Center for Eating Disorders, which is a collaboration of New York-Presbyterian Hospital, Cohen Children's Medical Center, and the New York State Psychiatric Institute at Columbia University Medical Center. With Columbia University Department of Psychiatry serving as an entry point, this Comprehensive Care Center for Eating Disorders offers a comprehensive range of specialized clinical services at all levels of care to patients of all ages.

Regarding the legislation being heard today, Intro 1485, which would restrict the sale of senna- and saffron-based products in New York City, the Administration appreciates Council's concern in enacting protective measures for consumers. However, to date we have not received any complaints about these types of products and do not have the expertise to assess the nutritional effects of these products. We would like to investigate this issue and discuss further with Council the best way to address the potentially harmful effects of these products.

We remain committed to ensuring that all New Yorkers receive the mental health care they need. Thank you to the Council for your focus on these important topics.

I am happy to take your questions.

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NATIONAL EATING DISORDERS ASSOCIATION TESTIMONY BEFORE THE COMMMITTEE ON HEALTH IN SUPPORT OF INT. NO. 1485-2019

"A Local Law to Amend the Administrative Code of the City of New York, in Relation to Restricting the Sale of Senna- and Saffron-based Products"

Kerry Donohue, Public Policy Manager, National Eating Disorders Association

January 28, 2020

Good Morning. My name is Kerry Donohue and I am here today on behalf of the National Eating Disorders Association, to express our strong support for NYC Bill No.1485. Thank you to Chairperson Mark Levine and all members of the Committee on Health for the opportunity to speak today.

I currently serve as the Public Policy Manager at the National Eating Disorders Association, also known as NEDA. NEDA is the largest national organization supporting families and individuals affected by eating disorders, and is based right here in New York City. NEDA serves as a catalyst for prevention, cures and access to quality care. I am proud to be with you here today to speak about the importance of this legislation and its impact on the eating disorders community.

First, I would like to thank you, Councilmember Levine, for your sponsorship of this important initiative. We appreciate your leadership in working to protect minors and other individuals across the City by limiting access to senna- and saffron-based products. These products are often included in things like dietary supplements, and sold with claims of weight loss. They are often sold without evidence supporting their efficacy or safety, and pose a particularly concerning risk to those struggling with, or at risk for developing an eating disorder.

Eating disorders, such as anorexia nervosa, binge eating disorder, bulimia nervosa, and others, are serious, potentially life-threatening conditions. 30 million Americans will suffer from an eating disorder at some time in their life. In New York City, the number of people currently struggling with an

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eating disorder is estimated to be approximately 848,000[1]. Eating disorders have the second highest mortality rate of any mental illness, right behind the current opioid crisis. Eating disorders do not discriminate. They affect people of all genders, races, ages, and socioeconomic backgrounds.

Research shows that weight loss products such as "skinny teas", and other dietary supplements sold for weight loss, can be a catalyst for these *life threatening* illnesses. 35% of "normal dieters" progress to pathological dieting. Of those, 20-25% progress to partial or full-syndrome eating disorders[2]. These products, including those with senna- and saffron-, often give false claims about "miracle" weight loss, which can be very harmful to those struggling with eating disorders, causing some individuals to aim for *unreachable, and frankly,* ***dangerous*** *expectations*.

Recent research from the Harvard School of Public Health found that adolescent and young adult women who used over-the-counter diet pills or laxatives for weight control were six times more likely than peers who did not use these products to be diagnosed with an eating disorder within one to three years of beginning use of these products[3].

In addition, any product that encourages people to intentionally lose weight is directly perpetuating weight stigma—discrimination or stereotyping based on a person's body size. For people with eating disorders, discrimination, or the fear of discrimination if their weight increases as a necessary result of improved health and recovery, can be a matter of life and death. NEDA would also like to emphasize the potential of these and similar substances to contribute to poor body image in youth, which has been correlated to a number of problematic outcomes, including suicidality.

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[1] *Hudson JI, Hiripi E, Pope HG Jr, and Kessler RC. (2007). The prevalence and correlates of eating disorders in the National Comorbidity Survey Replication. Biological Psychiatry, 61(3):348-58. doi:10.1016/j.biopsych.2006.03.040.*
[2] *Shisslak, C.M.; Crago, M.; Estes, L.S. (1995). The spectrum of eating disturbances. International Journal of Eating Disorders 18(3): 209-219*
[3] *Levinson JA, Sarda V, Sonneville K, Calzo JP, Ambwani S, Austin SB. Diet pill and laxative use for weight control and subsequent incident eating disorder in U.S. young women (2001-2016). Am J Public Health 2020; 110(1): 109-111.*

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NEDA views this initiative as an important step toward the prevention of eating disorders in the City of New York. For these and other reasons, NEDA asks the Committee to support this important bill to protect residents of New York City from senna- and saffron-based products, and to take steps to keep these products out of the hands our youth.

Thank you for your time and consideration, and thank you again for the opportunity to speak today.

The National Eating Disorders Association (NEDA) is the largest nonprofit organization dedicated to supporting individuals and families affected by eating disorders. NEDA supports individuals and families affected by eating disorders, and serves as a catalyst for prevention, cures and access to quality care. Through our programs and services, NEDA raises awareness, builds communities of support and recovery, funds research and puts life-saving resources into the hands of those in need. For more information, visit www.nationaleatingdisorders.org.

Draft testimony of Renee Cafaro, US Editor of SLiNK magazine, body image influencer and former NY government staffer

"Detox" teas are some of the most dangerous diet scams as they are marketed as healthy and promoting overall wellness. Additives like Senna are laxatives that not only block the absorption of nutrients and cause GI problems, they perpetuate the harmful message of the weight loss industrial complex that one must drop pounds quickly in order to be healthy. Diet products and marketing have been proven to lower self-esteem and cause body dysmorphia leading to eating disorders in many young women. For decades, women have abused and misused laxatives and diuretics for fast water weight reduction, and we know that's wrong. If your kid's favorite influencer was telling them to fast and consume nothing but water and Ex-Lax, we would all clearly see how disordered and unhealthy that is. Kardashians and Real Housewives pushing these "teatox cleanses" with senna are just as unhealthy.
First of all many doctors have debunked the whole concept of "detox" as it is your liver that does this function naturally. Secondly, these do not provide any nutrients or benefits for overall wellness, just plain old tea ingredients and a natural laxative.

In my capacity as the editor of a body positive print magazine and body image influencer, have been on many panels and national media outlets discussing the perils of diet culture, in particular, the effects of diet scam products and the myth that weight is the only metric for health. I personally fell victim to OTC, non-FDA approved diet products that claimed to be "safe and all-natural."

<<<personal story of becoming a "fat anorexic", still on the BMI scale as obese but eating less than 500 calories a day and becoming dependent on OTC diet pills and diuretics. >>>>

This bill is a great step towards informing the public of the risks of these products and help loosen the grip diet culture has on our young New Yorkers. I would urge this committee to further delve into regulating other non-FDA approved diet products such as weight loss gummies and those with herbal stimulants. Furthermore, I urge Council to work with other committees and reach out to DCA to tackle this issue further with a PSA campaign on the dangers of diet products. Perhaps, efforts can be made with the MTA to stop putting up triggering ads from companies like Flat Tummy near schools.

In support of the Bill to ban the sale of skinny teas to minor

Hello,
I support the Bill that will ban the advertisement and sale of “skinny tea” to anyone under 18.

Thank you for protecting our youth.
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Amanda Katz
Written Testimony - NYC COUNCIL HEARING
Written: January 29, 2020

To the honorable Councilman Levine and members of the City Council Committee on Health:

Thank you for gathering today to consider banning the sales of skinny teas; a product promoting unhealthy behaviors generally leading to long term mental and physical health risks.

My name is Amanda Katz and I am a proud resident of New York, born and raised in Queens, currently residing in the Upper West Side of Manhattan. I'd like to begin my testimony with my history and the personal harm this product has caused my mental and physical health.

For six dark years, I suffered from anorexia nervosa. As you may already know, anorexia has the highest mortality rate amongst mental health disorders.

My body was small. My life was small.

An eating disorder is not about food. However, it is a vehicle of control for those of us who believe we are out of control.

It's no wonder diet culture profits (or rather, profited) off of people like me. We live in a society that not only puts a strong emphasis on appearance, but also screams "skinny is better" as if being a small size means one is healthy.

I would know. At my lowest weight of 88 pounds in my 5' 2" frame, I was the least healthy I've ever been.

Companies like those who've created Skinny teas, often known as "detox teas," are in the busy of feeding the literal hunger for the pursuit of perfection. If I was starving, I'd have a cup. If I felt full (how I should have felt), I'd have a cup. This cup provides endless empty promises. I write today to pour them out.

New Yorkers deserve a city that's at the forefront of reshaping standards, not our bodies into smaller sizes. New Yorkers deserve to leave their homes and go to any store, feeling secure in their consumer choices. New Yorkers deserve knowing the long term impact of dieting and furthermore, how products like detox teas are ultimately ineffective and unsustainable. New Yorkers deserve better.

I wish I could be at the hearing today but I am fortunately teaching right now. You see, I'm a group fitness coach. My role is challenge people through fitness so they can ultimately feel like their strongest selves. Another part of my job is to shift their perception on what fitness looks like. I must remind them: all bodies are good bodies. Because, they are.

To the Honorable Councilmembers present, you have a choice today. I do not believe in good conscience you would choose "skinny" as a measurement of health.

I hope you'll choose those of us who've survived.
I hope you'll choose those of us who are fighting.
I hope you'll choose New York.

Detox legislation

I'm a born and raised NYer. Unfortunately I took herballife and many other nonsense drugs in the 90's. I have permanent kidney damage. This legislation will prevent impressionable young bodies from damaging capitalists. These companies know their products are deleterious but market to minors nonetheless.

Best

Lauren Billings

Brooklyn, NY

The Dangerous Mix of Adolescents and Dietary Supplements for Weight Loss and Muscle Building: Legal Strategies for State Action

Jennifer L. Pomeranz, JD, MPH; Grant Barbosa, JD; Caroline Killian, PhD; S. Bryn Austin, ScD

Adolescents use dietary supplements marketed for weight loss or muscle building, but these are not recommended by physicians. These products are often ineffective, adulterated, mislabeled, or have unclear dosing recommendations, and consumers have suffered injury and death as a consequence. When Congress passed the Dietary Supplement Health and Education Act, it stripped the Food and Drug Administration of its premarket authority, rendering regulatory controls too weak to adequately protect consumers. State government intervention is thus warranted. This article reviews studies reporting on Americans' use of dietary supplements marketed for weight loss or muscle building, notes the particular dangers these products pose to the youth, and suggests that states can build on their historical enactment of regulatory controls for products with potential health consequences to protect the public and especially young people from unsafe and mislabeled dietary supplements.

KEY WORDS: adolescents, body modification, dietary supplements, law, policy, state government

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA), establishing a new regulatory framework for a class of products that previously straddled the line between food and drugs.[1] Dietary supplements are intended to supplement the diet and contain vitamins, minerals, herbs, botanicals, amino acids, concentrates, metabolites, constituents, or extracts.[2] The market for dietary supplements in the United States has grown to a $32 billion a year industry,[3] with more than half of adults reporting regular use.[4] The Food and Drug Administration (FDA) is the primary regulatory body authorized to oversee safety and labeling of these products, whereas the Federal Trade Commission (FTC) enforces laws that prohibit unfair or deceptive marketing both on the Internet, television, and radio and in print.

A substantial portion of supplements are marketed for weight loss or muscle building, and adolescents use these products. However, these products are not recommended by physicians, and most are not effective to accomplish the promised results. Rather, many of these products are adulterated, mislabeled, or have unclear dosing recommendations. The DSHEA created a reactionary, rather than preventive, framework, rendering the FDA's regulatory control too weak to adequately protect consumers.[3] In comparison, Health Canada assesses the safety, efficacy, and manufacturing quality of all such products before permitting their sale in Canada, and it additionally conducts postmarket monitoring.[5] Experts have repeatedly called for Congress to increase the FDA's authority over dietary supplements, and federal bills have been proposed to do address specific deficiencies.[3,6-8] Nonetheless, there is not a promising federal solution in sight and thus

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No human subjects were involved in this study so institutional review board approval was not needed.

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state intervention is warranted. State governments can build on their historical enactment of regulatory controls for products with potential health consequences (eg, tobacco, alcohol) to protect the public from unsafe and mislabeled dietary supplements.

This article reviews studies reporting on Americans' use of dietary supplements marketed for weight loss or muscle building and notes the particular dangers these products pose to the youth. In light of the lax federal regulatory environment, this article suggests that state governments should use their current authority to protect the public, and especially the youth, from these products. Specifically, state attorneys general (AGs) should use their consumer protection authority to address mislabeled products. State governments should conduct laboratory testing, generate safety warning and education materials, institute minimum purchase age limits, enact taxes, and ban particularly dangerous products. Finally, manufacturers, pharmacies, and other retail establishments should engage in self-regulation to protect their customers and especially adolescents.

Use and Safety of Dietary Supplements

Dietary supplements of all types are widely available in pharmacies, grocery stores, and specialty chains and on the Internet. Among US adults, nationally representative studies found 17.0% of adults used supplements for sports performance in the past year,[4] 20.6% of women and 9.7% of men have ever used weight loss supplements, with women aged 18 to 34 years having the highest rate of past year use at 16.7%.[9]

Adolescents also use products marketed for weight loss and muscle building. A 1999 national study of the youth aged 12 to 19 years found that in the past year, 8% of girls and 10% of boys reported using protein powders or shakes and 0.4% of girls and 4% of boys had used creatine.[10] In 2002, the US National Health Interview Survey found that 29.1% of adolescents and young adults aged 14 to 19 years had used any type of dietary supplement in the past 30 days, with 10.7% ever having used weight loss supplements and 4.7% ever having used creatine in their lifetimes.[11] A 2010 study of a representative sample of middle and high school students in Minnesota found that among boys, 34.7% used protein powders or shakes, 5.9% reported using steroids, and 10.5% used other muscle-enhancing substances, including dietary supplements, and among girls, 21.2% reported using protein powders, 4.6% used steroids, and 5.5% used other related substances.[12]

The use of supplements for weight loss and muscle building is associated with mental health vulnerabilities such as eating disorders and body dysmorphic disorder.[10,13] Adolescents and young adults with a history of depression and body dissatisfaction or preoccupation are at elevated risk of using this category of supplements beyond levels recommended by the manufacturer.[10,13,14] In addition, evidence suggests that among young people, regular use of muscle-building supplements represents a gateway to anabolic steroid use.[15]

Dietary supplements are not recommended by health care providers as a healthy or effective way to lose weight or build muscle.[9,16,17] Dietary supplements marketed for weight loss and muscle building are particularly problematic and associated with health risks due to the inclusion of substances that are legal but unsafe in the concentrations used in the product, adulteration with prescription pharmaceutical compounds or illegal substances such as steroids,[18] excessive dosing by consumers, and unintended interactions with prescription medications.[19-23] Weight loss and muscle-building supplements have been tied to significant adverse health effects, including gastrointestinal impairment, tachycardia, hypertension, myocardial infarction, stroke, and severe liver injury, sometimes requiring transplant or leading to death.[3,17,24] In the last decade, cases of products spiked with previously banned substances, such as thermogens, have been on the rise and the use of these products has resulted in serious injury, organ failure, and death.[25,26] In addition, dosing of relatively safe compounds at high levels, such as epigallocatechin gallate from green tea extracts, has led to these products exerting toxic effects even when used as directed by the label.[27] However, not all adverse events are reported to the FDA. There are several methods for consumers and health care providers to report adverse events, so the FDA is often slow to learn about a cluster of cases[3] or is not informed at all (eg, calls to poison control centers go uncommunicated to federal authorities).[28] Furthermore, consumers do not always associate health problems with dietary supplement use or notify their health care provider that they are using these products.[3,8,9,17]

Recent notable cases of widespread harm caused by dietary supplements of this class involved the popular product OxyELITE Pro (USPlabs LLC, Dallas, Texas) marketed for muscle building, which the FDA pulled from the market only after it caused serious injury to adult and adolescent consumers. By February 2014, the supplement was found to have caused 1 death and 97 cases of serious liver injury, requiring hospitalization and 3 liver transplants.[3,29] Following its summary report on OxyELITE Pro, the Centers for Disease Control and Prevention urged health care providers to screen for supplement use among patients who present with acute hepatitis and warned consumers to exercise heightened caution with dietary supplements in

the weight loss and muscle-building categories, recommending that any patients using these products should be closely supervised by a health care provider to monitor for adverse health effects.[29] Such monitoring could improve postuse safety but does little to prevent use, misuse, or adulterants in the supply chain.

Many consumers and health care professionals are unaware that the adulteration of dietary supplements is a widespread problem.[30] A nationally representative study of US adults found almost two-thirds of respondents who use dietary supplements believe that they are both safe and effective for weight loss.[31] In addition, half of both users and nonusers in this study believed that the government prescreens the products for safety and efficacy before they are released onto the market.[31] In another study of US Army soldiers, a group that regularly uses supplements for muscle building among other expected health benefits, 67% of soldiers were at least somewhat confident that dietary supplements work as advertised and 71% thought they are safe to consume.[32] Thus, efforts at the federal level to alert consumers that the integrity of these products has not been validated or verified by an outside authority are insufficient.

The formulations and dosing of compounds within dietary supplements have not been evaluated, and for many of these products, safe levels of use have yet to be determined.[33] Even if manufacturers declare the contents of their products accurately, the biological effects and safe ranges of use for dietary ingredients and supplement formulations are difficult to define even for experts. Because no standard daily value dosing information exists for many of these compounds, safe ranges of dietary ingredients present within dietary supplements are not well understood.

Federal Oversight

The FDA has authority over the safety and labeling of dietary supplements. Prior to the enactment of the DSHEA, dietary supplements were either regulated as food or drugs under the Food, Drug, and Cosmetic Act (FDCA). If a dietary supplement "was used primarily for its taste, aroma, or nutritive value," it was regulated as a food, whereas those that made therapeutic claims, that is, claims to treat or prevent disease or affect the structure or function of the body, were considered drugs for regulatory purposes.[1] As such, these latter supplements would have to meet rigorous drug safety and efficacy requirements, including premarket approval in most cases.[1] Many products that are the subject of this article would have been regulated as drugs prior to 1994.

The FDCA prohibits adulterated, unsafe, or mislabeled dietary supplements.[34] However, the DSHEA created a new regulatory framework that stripped most of the FDA's premarket authority over dietary supplements from the agency. In fact, Congress prohibits the FDA from prescreening dietary supplements for safety or efficacy before entrance into the market.[35] Thus, manufacturers are expected to self-assess the safety of their products and adhere to good manufacturing practices, but they are not required to disclose the basis of their assessment (called substantiation documents).[7] If the FDA questions a product's safety or the truthfulness of its label, it must conduct its own testing and collect epidemiologic data to prove that a product is unsafe and responsible for harm before taking regulatory action aimed at removing an ingredient or product from the market.[36] This reactionary system relies on the presence of injury or fatality before regulatory action can occur. The FDA is under resource constraints while facing an expanded set of obligations,[37] making it unfeasible for the agency to test all potentially adulterated, unsafe, or mislabeled products.[38]

The FDA is mainly relegated to issuing consumer warnings[39] and warning letters to dietary supplement manufacturers (in addition to occasional seizures and the initiation of criminal prosecutions).[40] It is unclear whether consumer warnings successfully reach the public or convey the health risks associated with the product's use or whether warning letters sent to manufacturers have any deterrent effect or lead to product reformulation or removal from the market. What is clear is that prohibited, adulterated, and unsafe products available on store shelves and Web sites are purchased and consumed by adolescents.[41] For example, the FDA warns that human chorionic gonadotropin weight loss products are illegal and that there are no human chorionic gonadotropin products approved for over-the-counter use.[42] However, these are available for sale on store shelves* and online.[43]

Increased federal regulation is in fact essential; however, since this is not imminent, state governments should increase their regulatory control over dietary supplements using core public health policy solutions. In addition, state AGs currently play a unique consumer protection role that could be expanded in this context.

Marketing and AG Action

The FTC Act prohibits unfair or deceptive marketing of dietary supplements. The FTC created an advertising guide for the dietary supplement industry to "ensure that consumers can get accurate information" so that they can make "informed decisions

*Found in Shaw's grocery store in Boston, Massachusetts.

about these products."[44] The agency has been active in bringing actions against companies that deceptively market "fad weight loss products," including dietary supplements.[45] States have a method to bolster these efforts through the authority of the state AGs.

All 50 states and the District of Columbia have consumer protection statutes that mirror the FTC Act's prohibition on unfair or deceptive acts or practices and are routinely enforced by state AGs. Attorneys general work independently and across states, as well as in concert with federal agencies, to address questionable marketing or labeling practices.[46] Unlike the FDA, AGs can require companies to turn over substantiation documents so that if they question a claim on a supplement's packaging, they do not have to conduct their own research before taking action.

State AGs have brought actions against dietary supplement manufacturers for making false claims related to cancer risk,[47,48], weight loss,[49] and cold remedies,[50] but this can be expanded to create a concerted action against supplement manufacturers that promise impossible body modification results. For example, the former Connecticut AG informed diet companies that their "claims of lasting weight loss must be supported by credible scientific data" if they are to do business in the state.[51] Thus, AGs can also use their bully pulpit and consumer education mission to alert consumers of dangerous products or warn companies that nefarious practices will not be tolerated.[51]

State Governments

State governments have the authority to enact laws to protect the health, safety, and general welfare of their population.[52] This authority is called the "police power," and every state delegates this power to its political subdivisions to varying degrees.[52] Pursuant to their police power, state and, to the extent permitted, local governments (collectively states) can regulate products and the retail environment through direct controls or through conditional licensing, which is when the government conditions the retailers' license to operate on its agreement to undertake or refrain from certain actions.[53] States should additionally not preempt, or trump, the ability of local governments to enact stricter restrictions to protect their communities.

State Laboratory Testing

All state health agencies have laboratories that are most commonly used to test for bioterrorism agents, foodborne illness, and influenza.[54] States could consider including a requirement to test questionable dietary supplements for adulteration. A small percentage of states share laboratory resources with each other, but if a new mandate was instituted, this might increase collaboration and minimize duplicative efforts.[54]

In 2005, the Acting Governor of New Jersey issued an executive order establishing the Governor's Task Force on Steroid Use and Prevention.[55] Among its dictates, the order directed the state department of health to develop and implement a program to randomly test dietary supplements available in New Jersey for steroid contamination.[56] This service is not in effect, and it is unclear whether it ever was enforced. However, such a program might detect adulterants quicker than the federal government and would be preventive. Local health departments have routinely been the first to detect harmful supplements in the marketplace due to local reporting efforts.[3] If this knowledge was coupled with testing capabilities, the response to adulterated supplements could be quicker. Such oversight might additionally encourage manufacturers to engage in stronger quality controls.[8]

Banning Products

In 2004, the FDA declared dietary supplements containing ephedrine alkaloids to be adulterated, and thus prohibited, because of the unreasonable risk of injury associated with their ordinary use.[57] Prior to FDA action, states regulated ephedrine alkaloids. In 1998, Minnesota began requiring a prescription for ephedrine-containing products marketed, advertised, or labeled for weight loss, muscle enhancement, or appetite control, among other purposes.[58] In 2003, Illinois became the first state to ban the sale of all ephedra-containing products,[59] and California and New York banned the sale of dietary supplements with ephedrine alkaloids.[60,61] Subsequent to the FDA regulation, these state laws remain in effect and enable the state to independently enforce the prohibition when illegal products are discovered on store shelves. When evidence increases about the dangers of new products, states can enact prohibitions on their sale prior to FDA action.

Safety Warning Labels and Education

The DSHEA requires dietary supplements to disclose ingredient and quantity information on the supplement panel, and if the label conveys a structure-function claim, it must include the following disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."[62] However, the disclaimer has been

found to be ineffective to convey the risks involved with consuming these products.[63]

The FDCA preempts states' ability to require different factual information on product labels than that required under the DSHEA, but it does not preempt state authority to require a factual "warning concerning the safety of the food or component of the food."[64] States can require warning signs in the form of wall posters and signs at the checkout, or additions to product labels such as shelf-tags or warning stickers on the product package.[65] For example, in 2002, California required that dietary supplements with ephedrine alkaloids or steroid hormone precursors to include warnings on the products' label that they are not intended for use by individuals who are younger than 18 years, pregnant, or nursing and suggested that users consult a physician if they have a family history of many common health problems.[66] The law also required a warning for users not to exceed the recommended dose due to the risk of serious harms.[66] Such warnings may be warranted for the entire class of weight loss and muscle-building products.

Because states are not preempted from requiring safety warnings, they may consider requiring retail establishments to place a sign at the point of sale, stating, for example, that supplements are not required to be tested or evaluated for safety by the FDA, or specific safety alerts on products linked to injury with overuse, for example, noting that excessive consumption of epigallocatechin gallate from green tea is linked to liver failure. Future research should be conducted to evaluate whether the warnings effectively convey product risks and do not encourage use by adolescents looking to engage in risky behavior.

States may also consider expanding this effort to create broader educational campaigns to warn their citizens, and especially parents, of the safety issues associated with this class of dietary supplements. If funding is available, states could consider incorporating this information into public service announcements or create targeted educational presentations at high schools or directed at the parents of adolescents. Evaluation of such programs would be necessary.

Age Limits

In the United States, it is a common practice to permit the sale of dangerous products to adults with appropriate warnings (eg, tobacco, alcohol) but simultaneously restricting the minimum age to legally purchase them. Given that there are not strict safety, quality, or efficacy controls for supplements marketed for weight loss and muscle building, these products are inherently risky and not medically indicated. The youth may be unable to weigh the harms associated with using these products, may be prone to taking more than the recommended dose, and may be at greater risk for injury by an adulterated product due to their developing bodies. As such, states can protect the youth by instituting age restrictions.

The FDA approved the over-the-counter diet drug Alli (orlistat), which has undergone safety testing, for adults 18 years or older.[67] In 2003, Florida enacted a law prohibiting the sale of dietary supplements for weight loss that contain ephedrine alkaloids to persons younger than 18 years.[68] California and Rhode Island have statutes prohibiting manufacturers, retailers, or other persons from selling or otherwise giving minors younger than 18 years dietary supplements containing ephedrine alkaloids or 1 of 6 types of anabolic steroids.[69,70] As is the case with ephedrine alkaloids, federal law prohibits dietary supplements from containing anabolic steroids.[30,71] Nevertheless, products exist in the market that are adulterated with the steroids, unbeknownst to retailers or consumers.[72] Age restrictions provide the state with an additional method of enforcement. States should consider instituting a minimum age to purchase all dietary supplements marketed for weight control and muscle building.

Taxation

Taxation is a core public health strategy to increase the price of products in order to deter consumption and raise revenue. Taxation of tobacco and alcohol is associated with large reductions in youth consumption.[73,74] The revenue generated from a tax on supplements marketed for weight and muscle building could fund the other regulatory efforts discussed earlier. Additional research into the economic implications of such a tax is warranted to determine whether a small tax could generate enough revenue to implement other controls or whether a larger tax would discourage consumption or just ultimately be regressive for low-income persistent users.

Industry Self-regulation

Pharmacies and other trusted retailers should be informed about the products they choose to display on their store shelves and the inherent risks involved with dietary supplements claiming to promote weight loss or build muscle. Retailers can consider self-regulating similar to the much applauded announcement by CVS Caremark that it would discontinue selling tobacco products in its pharmacies.[75] Dietary supplements are not recommended by physicians for weight loss or

muscle building, and the potential for adulteration makes it unclear whether retailers are selling previously banned dietary ingredients to their customers.[18] Thus, retailers can protect their customers by pulling this class of products from store shelves. At a minimum, retailers should act to protect the youth by agreeing to stop selling this class of products to minors.

Manufacturers who want their products recognized as safe and of the highest quality can participate in the voluntary US Pharmacopeia (USP) verification service.[76] The federal government officially recognizes USP standards in the FDCA.[34] Manufacturers who submit to a full good manufacturing practice audit and quality testing of their products at USP laboratories can carry a USP verification mark that certifies that the product has met USP requirements. Retailers and manufacturers can educate consumers that this is a true mark of quality, and retailers can agree to carry only those products with a USP seal.

Conclusion

The lax federal regulatory scheme for dietary supplements leaves extreme gaps in federal oversight that should be filled by state governments. States should use core public health policy strategies to protect consumers and especially young people from ineffective, mislabeled, and potentially dangerous products marketed for weight control and muscle building. In light of the increasing cases of injury caused by these products, it is not wise to wait for unexpected federal change. State governments have a responsibility to protect adolescents and should act imminently. In addition, states should be more vocal about the fact that dietary supplements are not regulated in the manner expected by the American population. Parents, especially, need this information to protect their children.

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Original article

Taking Stock of Dietary Supplements' Harmful Effects on Children, Adolescents, and Young Adults

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A B S T R A C T

Purpose: The aim of the study was to evaluate the relationship between supplement categories and adverse events in children, adolescents, and young adults.
Methods: This is a retrospective observational study using adverse event reports between January 2004 and April 2015 in the U.S. Food and Drug Administration Adverse Event Reporting System on food and dietary supplements database. We quantified the relative risks for severe medical events of dietary supplements sold for various functions relative to vitamins among individuals aged between 0 and 25 years. Severe medical events include death, disability, life-threatening events, hospitalization, emergency room visit, and/or required intervention to prevent permanent disability.
Results: There were 977 single-supplement–related adverse event reports affecting individuals aged between 0 and 25 years over 11 years (50.6% female; age: mean = 16.5 years, standard deviation = 7.5 years). Supplements sold for muscle building (risk ratio [RR] = 2.7; 95% confidence interval [CI] = 1.9–4.0), energy (RR = 2.6; 95% CI = 1.9–3.6), and weight loss (RR = 2.6; 95% CI = 1.9–3.4) were associated with almost three times the risk for severe medical events compared with vitamins.
Conclusions: Consumption of dietary supplements sold for weight loss, muscle building, and energy involved increased risks for severe medical events compared with vitamins. Proactive enforcement of regulations is needed to reduce access and consumption among children, adolescents, and young adults.

IMPLICATIONS AND CONTRIBUTION

Using Food and Drug Administration adverse event data, this study documents that dietary supplements sold for weight loss, muscle building, and energy are associated with almost three times the risk for severe medical events relative to vitamins in youth. Health care providers should counsel patients against using these supplements.

The dietary supplement market is projected to generate approximately $57 billion in revenue by 2024 in the U.S. [1]. Dietary supplements are consumed by 52% of the U.S. population [2], including 9% of infants aged younger than 1 year [3]. There is little regulation of the safety of these products; however, as a result of the Dietary Supplement Health and Education Act (DSHEA) passed by the U.S. Congress in 1994. DSHEA prohibits the Food and Drug Administration (FDA) from prescreening supplements for safety or efficacy and instead forces the agency to rely on an honor system in which manufacturers are expected by the government to ensure the safety of their products before launching them on the market [4]. This honor system, however, has been insufficient in mitigating the risks of dietary supplements to consumers.

Conflicts of interest: The authors have no conflict of interests to disclose.

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The FDA has issued numerous warnings on the safety of supplements sold for weight loss, muscle building, sexual function, and energy, and on the toxic ingredients found in these supplements [5,6]. Many dietary supplements in these categories have been found to have misleading labels and to have been adulterated with dangerous ingredients, including undeclared prescription pharmaceuticals, steroids, kava, and germander, which can lead to liver damage and other health harms [7–11]. These and other adulterated ingredients have led to severe adverse events including deaths [5]. Specifically, supplements sold for weight loss have been associated with adverse events such as chronic diarrhea, constipation, dehydration, hypokalemia, metabolic acidosis, cardiac arrhythmia, hemorrhagic and ischemic stroke, and hepatic and renal failure [12–15]; supplements sold for muscle building have been associated with testicular cancer [16]; supplements sold for sexual function have been associated with changes in blood pressure, hypomania, insomnia, anxiety, irritability, nausea, headaches, loss of consciousness, and seizures [17,18]. Energy drinks is a particularly worrisome category among youths because they are frequently consumed by youths and have been found to affect cardiac and neurological systems [19]. The U.S. Centers for Disease Control and Prevention (CDC) estimated that 23,000 emergency room (ER) visits in the U.S. each year are attributed to dietary supplement use [20]. Not surprisingly, health care providers do not recommend using dietary supplements as a healthy or effective way to lose weight or build muscle [21,22].

Despite documented risks and warnings, the supplement industry continues to sell unsafe products tainted with undeclared, toxic ingredients to youth without restriction [23]. It is likely that dietary supplement users, particularly children, adolescents, and young adults, have little awareness of the health risks associated with dietary supplement consumption. A survey with a nationally representative sample of adults in 2005–2006 found that 50% of users and nonusers both mistakenly perceive that dietary supplements are approved for its safety and efficacy before marketed, and about two thirds of the respondents believed that manufacturers were mandated to declare side effects on the labels [24]. The use of dietary supplements sold for muscle building and weight loss have been prevalent among adolescents and young adults. In the 2002 U.S. National Health Interview Survey, 29.1% of adolescents aged between 14 and 19 years reported having used any type of dietary supplement in the past 30 days [25]. A national study conducted in 1999 found that 8%–10% of youths aged between 12 and 19 years had consumed protein powders or shakes in the past year [26]. In 2010, another study of a representative sample of middle and high school students in Minnesota, 34.7% of the boys and 21.2% of the girls in the study, reported having used protein shakes or powders [27]. A population-based telephone survey found that in adults, the estimated prevalence of lifetime weight loss product use is 20.6% in women and 9.7% in men, and the usage is found to be most common among women aged 18–34 years, with an estimated prevalence of 16.7% [7].

Although the dangers of dietary supplements and the prevalence of using dietary supplements in adolescents and young adults have been established, little is known about the consequences of consuming dietary supplements among individuals aged 0–25 years. The aim of the present study was to evaluate the relationship between supplement categories and adverse events in children, adolescents, and young adults, in three age groups: 0–11 years, 12–17 years, and 18–25 years. We evaluated the risks for severe medical outcomes for the weight loss, colon cleanse, muscle building, sexual function, energy, others relative to vitamins, which is most commonly consumed by individuals of all ages [2,28].

Methods

Data/sample

Our retrospective case series study was conducted using data from the U.S. FDA Adverse Event Reporting System (FAERS) on food and dietary supplements. FAERS database [29,30], which consists of both voluntary and mandatory adverse event reports dated from January 2004 through April 2015, is intended for the safety surveillance of products on the market. Voluntary reports were submitted by consumers or healthcare professionals, whereas mandatory reports were submitted by manufacturers, packers, or distributors. Manufacturers are required to report to the FDA when they receive adverse event report regarding their product(s) from healthcare professionals or consumers [30]. Each report contains information on the product (i.e., company and product name) and the adverse events (clinical outcomes and symptoms) experienced by the person affected. Among the 40,086 adverse event reports involving people of all ages in the database, we included in the present study 1,392 nonduplicative adverse event reports that involved dietary supplements among individuals aged 0–25 years. We considered a report to be nonduplicative for each observation that has a unique report number. However, it is possible for duplicates to remain if the same adverse events have been reported independently by the company, the consumer, and a healthcare provider. Each report contains at least one supplement and one or more clinical outcomes. Among 1,392 adverse event reports, 334 multiple-supplement–related reports, 22 reports with missing data on gender, and 59 reports with missing data on primary category of dietary supplements were excluded from the analysis, resulting in a final analytic sample of 977 adverse event reports.

Exposure categorization

We performed a systematic Web searching to categorize dietary supplements listed in the FAERS database. Based on the company and product names for each supplement in FAERS, we obtained the information on the claims about the product from multiple sources with priority given to the company's Web site and then amazon.com. When information was unclear or unavailable on the company Web site and amazon.com, we extracted information from Web sites yielded by Google searches of the company and the supplement product name. In cases where claims about a product included a single function, we categorize based on the category under which the supplement had been listed on the company Web site or amazon.com. When the supplements were advertised with multiple claims, we assigned primary category based on the most salient function in claims printed on the supplement packaging. Using this protocol, three trained research associates (Y.K., J.S., and a third associate) assigned the supplements in the 40,086 adverse event reports into one of the six categories: weight loss, colon cleanse, muscle building, sexual function, vitamin, or other. The first author (F.O.) performed systematic checks throughout the categorization process to ensure accuracies. Subsequent to the initial

categorization, F.O. then repeated the categorization process to add energy as a seventh category.

Clinical outcome categorization

In each adverse event report in FAERS, up to seven clinical events were included. We grouped the clinical outcomes into severe and nonsevere medical outcomes. Severe medical outcomes were defined as the event of death, disability, life-threatening events, hospitalization, ER visit, and/or required intervention to prevent permanent disability. Nonsevere medical outcomes were identified when described in the database as nonserious (e.g., nonserious injuries/illness, visited a health care provider) or in a way that was nebulous (e.g., congenital abnormality, other serious, serious injuries/illness). Examples of symptoms that fell under the subcategory of nonserious injuries/illness include abdominal pain, back pain, chills, and so on. Symptoms, such as abasia, anxiety, and blood pressure increase, fell under the subcategory of other serious injuries/illness.

Statistical analysis

In the first set of analyses (N = 977), we focused on adverse event reports that include a single supplement to isolate the association for each supplement category with the medical outcome. We first investigated our sample characteristics by performing chi-square tests on the proportions of gender, severe medical outcome on aggregate, and by outcome type across age groups (0–11, 12–17, and 18–25 years). We then examined the distribution of supplement categories by gender and age groups and also by types of severe medical outcomes (disability, death, life-threatening events, hospitalizations, ER visits, and required intervention to prevent permanent disability). We conducted multivariable Poisson regression with robust standard error variance to ascertain the risk of severe medical outcomes in six dietary supplement categories with vitamin as the reference group, adjusting for gender and age in continuous years. We repeated the analyses by stratifying age groups (0–11, 12–17, and 18–25 years). Finally, for supplemental analyses, we added back into the database the 334 adverse event reports that included more than one supplement and again excluded those with missing data on gender or primary category (N = 121); we then repeated the set of analyses described previously with the 1,271 adverse reports that involve one or more supplements. We report our results in the supplemental materials.

Results

Among the 977 single-supplement–related adverse event reports included in the analyses, results of chi-square tests suggested no statistical differences in proportions of gender across the three age groups ($\chi^2 = 1.3$, $p = .5$), but statistically different proportions of hospitalization ($\chi^2 = 15.6$, $p < .01$), and severe medical outcome(s) ($\chi^2 = 28.5$, $p < .01$) across age groups (Table 1). Among 977 adverse event reports, 166 reports involved hospitalization, 39 reports involved life-threatening events, and 22 reports involved death. Figure 1 illustrates the distribution of the supplement categories across gender and age groups. Frequency of adverse events appeared to be highest in the age group 18–25 years and lowest in the age group 12–17 years, for both women and men. Among those aged 18–25 years, the frequency of adverse events seemed to be the highest for weight-loss supplements in both women and men. Within the 18–25 years group, adverse events associated with supplements sold for muscle building, cleanse, sexual function, and energy seem to be more commonly reported among men compared with women (Figure 2).

Based on results from Poisson regression models including adverse event reports involving a single supplement, relative to vitamins, supplements sold for muscle building (risk ratio [RR] = 2.7; 95% confidence interval [CI] = 1.9–4.0), energy (RR = 2.6; 95% CI = 1.9–3.6), and weight loss (RR = 2.6; 95% CI = 1.9–3.4) were associated with almost three times the risk for severe medical events compared with vitamins, after adjusting for age and gender (Table 2). Supplements sold with sexual function claims (RR = 2.4; 95% CI = 1.3–4.3), colon cleanse

Table 1
Sample characteristics of FDA adverse event reports filed 2004–2015 for individuals aged 0–25 years that involved only one supplement by age group (N = 977 reports)[a]

	Full sample, n (%) (N = 977)	Age 0–11 y, n (%) (N = 256)	Age 12–17 y, n (%) (N = 143)	Age 18–25 y, n (%) (N = 578)	Chi-square test[b]
Female	494 (50.6)	130 (50.8)	66 (46.2)	298 (51.6)	$\chi^2 = 1.3$ $p = .5$
Severe[c]	344 (35.2)	56 (21.9)	51 (35.7)	237 (41.0)	$\chi^2 = 28.5$ $p < .01$
Disability	22 (2.3)	4 (1.6)	0 (.0)	18 (3.1)	$\chi^2 = 5.8$ $p = .06$
Death	22 (2.3)	5 (1.9)	2 (1.4)	15 (2.6)	$\chi^2 = .9$ $p = .6$
Life-threatening events	39 (4.0)	7 (2.7)	9 (6.3)	23 (4.0)	$\chi^2 = 3.0$ $p = .2$
Hospitalization	166 (17.0)	25 (9.8)	21 (15.7)	120 (21.8)	$\chi^2 = 15.6$ $p < .01$
Emergency room visit	74 (7.6)	14 (5.5)	17 (11.9)	43 (7.4)	$\chi^2 = 5.4$ $p = .07$
Required intervention to prevent disability	39 (4.0)	4 (1.6)	3 (2.1)	32 (5.5)	$\chi^2 = 8.9$ $p = .01$

[a] Among 1,392 adverse event reports, 334 multiple-supplement–related reports, 22 reports with missing data in gender, and 59 reports with missing data in primary category were excluded from the analysis.
[b] Chi-square test of difference in proportions across age groups.
[c] A clinical outcome is classified as "severe," if adverse event report documented any of the six criteria: death, disability, life-threatening events, hospitalization, emergency room visit, required intervention to prevent permanent disability.

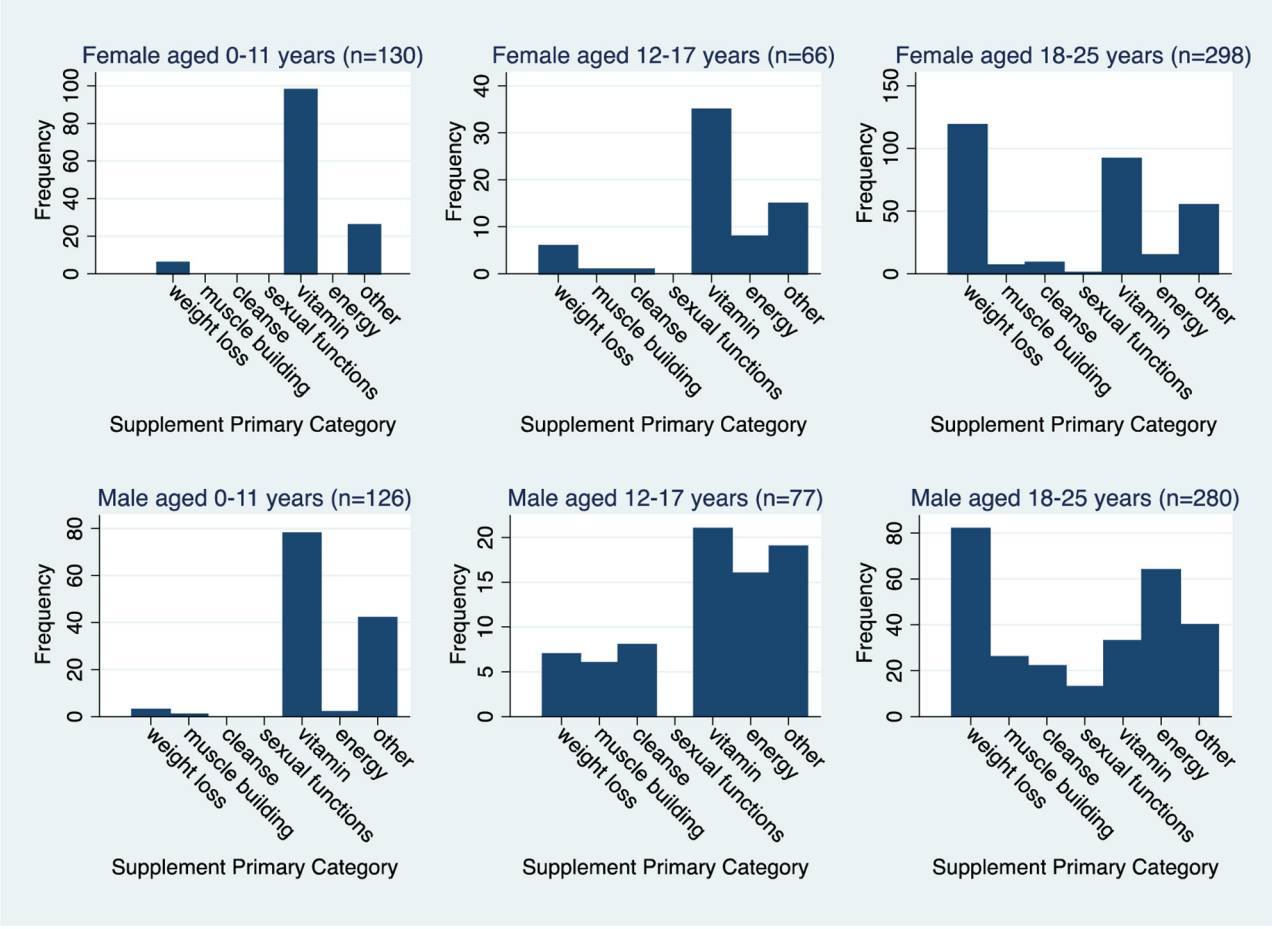

Figure 1. Distribution of supplement categories in FDA adverse event reports filed 2004–2015 for individuals aged 0–25 years that involved only one supplement (N = 977 reports): by gender and age group.

(RR = 1.7; 95% CI = 1.0–2.8), and others (RR = 1.5; 95% CI = 1.1–2.1) were respectively associated with two times the risk for severe medical outcomes compared with vitamins.

Stratified regression models suggest that the pattern of relationships between supplement categories and risks for severe medical outcomes may differ by age groups; however, direct tests of interactions between age group and supplement category were not feasible due to thin cells (Table 3). Among individuals aged 0–11 years, supplements sold for weight loss (RR = 3.1, 95% CI = 1.6–6.0) and other functions (RR = 1.9; 95% CI = 1.1–3.0) were associated with two to three times greater risk for severe medical outcomes compared with vitamins. In the age group 12–17 years, supplements sold for weight loss (RR = 3.2, 95% CI = 1.7–6.0), muscle building (RR = 2.6; 95% CI = 1.1–6.1), and energy (RR = 2.7; 95% CI = 1.4–5.0) were associated with two to three times the risk for severe medical outcomes compared with vitamins. Among those aged 18–25 years, male gender was associated with 1.3 times the risk for severe medical outcomes compared with female gender (RR = 1.3, 95% CI = 1.0–1.6). Within this oldest age group, supplements sold for weight loss (RR = 2.2, 95% CI = 1.5–3.2), muscle building (RR = 2.2; 95% CI = 1.4–3.5), sexual function (RR = 2.0; 95% CI = 1.0–3.7), and energy (RR = 2.2; 95% CI = 1.5–3.3) were associated with two times the risk for severe medical outcomes compared with vitamins. The results from the analyses including reports that involved one or more supplements (N = 1,271) are presented in Tables S1–S3 and Figures S1 and S2. The findings were similar to those reported above for analyses of adverse event reports involving only a single supplement.

Discussion

Over the course of 11 years, 1,392 adverse events were reported to the FDA among individuals aged between 0 and 25 years as a result of consuming one or more dietary supplements. In our study, approximately 40% of the 977 single-supplement–related adverse events involved severe medical outcomes, including death and hospitalization; supplements sold for weight loss, muscle building, and energy were associated with almost three times the risk for severe medical outcomes compared with vitamins; and supplements sold for sexual function and colon cleanse were associated with approximately two times the risks for severe medical outcomes compared with vitamins. It is important to keep in mind that vitamins, although used as a reference group in this study, were also linked with adverse events that merited reporting to the FDA.

Findings from our study were consistent with a recent study conducted by the CDC, where supplements in the vitamins and

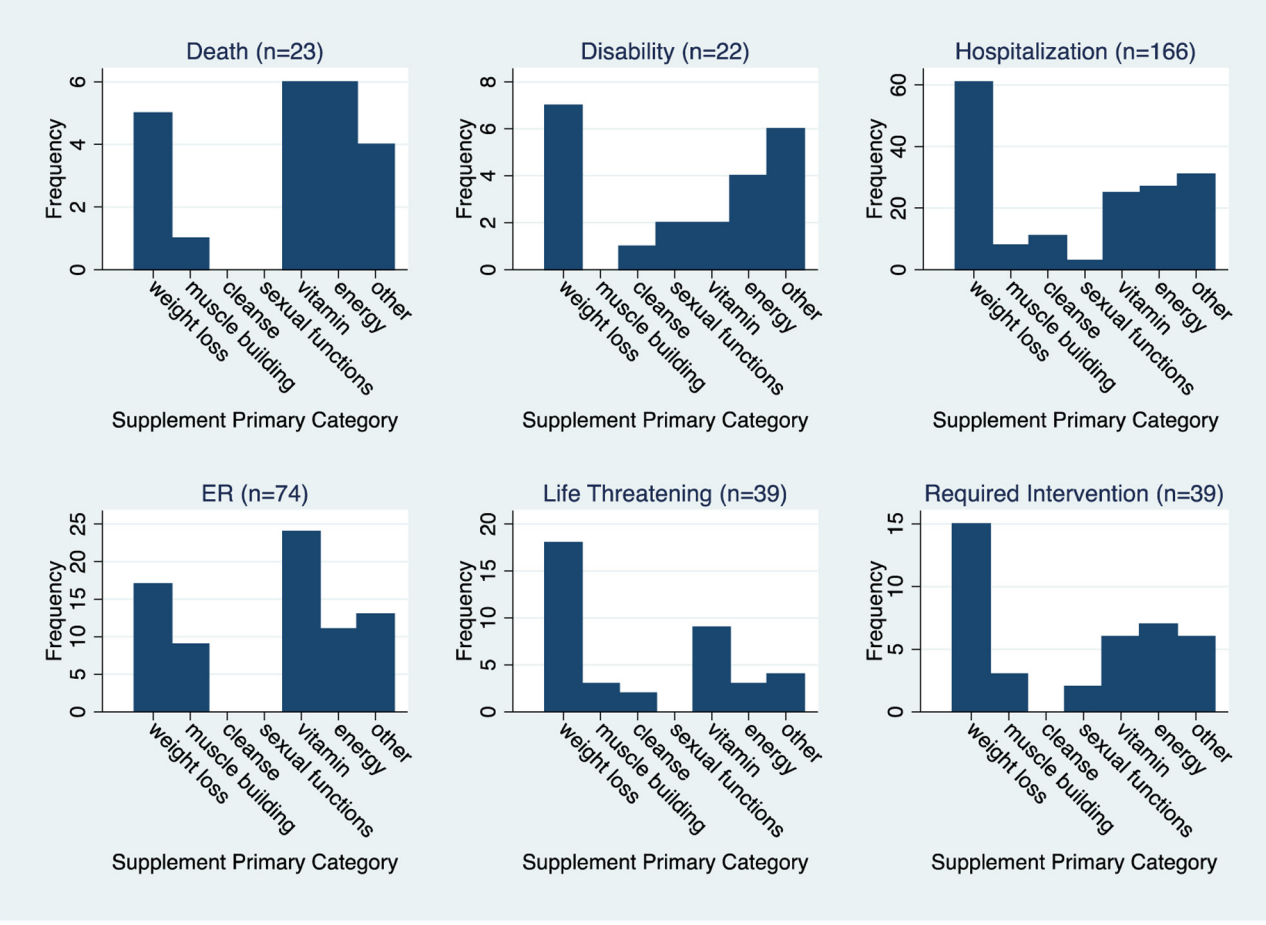

Figure 2. Distribution of supplement categories across medical outcomes in FDA adverse event reports filed 2004–2015 for individuals aged 0–25 years that involved only one supplement (n = 977 reports).

other categories were most commonly involved in ER visits in the U.S. among young children, and supplements sold for weight loss and energy purposes were most commonly involved in adverse events among adolescents and young adults [23]. Our findings support the American Academy of Pediatrics' recommendation that dietary supplements are dangerous and should not be used for weight loss and muscle building purposes [21,22,31]. Emergence of increased risk for severe medical outcomes due to supplements sold for muscle building and energy in adolescence suggests opportunities for age-specific intervention to reduce consumption of these products by age 11 years. For example, one simulation study found that taxation of weight loss supplements may reduce consumption of weight loss supplements among individuals aged between 12 and 17 years [32]. Replication of this simulation study for other supplement categories, such as muscle building and sexual function, are needed to determine the potential effect of taxation on dietary supplements. Finally, child-proof medication caps may reduce the access to harmful dietary supplements among young children [33,34]. Moving forward, research on policy effectiveness related to dietary supplements are needed to reduce consumption of dietary supplements that are harmful to health.

The present study has four key limitations. First, both the case series design and under-reporting may have led to selection bias because only reported cases were available for analysis. It is possible that the reports in the analyses include more severe cases because individuals are less likely to report more minor adverse events and may not be able to recognize supplements as the cause of symptoms experienced. Moreover, clinicians do not report all

Table 2
Adjusted risk ratios (RR) and 95% confidence intervals (CIs) for severe medical event[a] in FDA adverse event reports filed 2004–2015 for individuals aged 0–25 y that involved only one supplement (N = 977 reports)[b]

	RR (95% CI)[c]
Dietary supplement categories (Ref: vitamins)	
Weight loss	2.6*** (1.9–3.4)
Muscle building	2.7*** (1.9–4.0)
Cleanse	1.7** (1.0–2.8)
Sexual function	2.4*** (1.3–4.3)
Energy	2.6*** (1.9–3.6)
Others	1.5*** (1.1–2.1)
Other covariates	
Male	1.1 (.9–1.3)
Ref: female	
Age of event (y)	1.0 (1.0–1.0)
Constant	.2*** (.1–.2)

*$p < .05$; **$p < .01$; ***$p < .00$.
[a] Death, disability, hospitalization, ER visit, intervention required to prevent permanent damage, or life-threatening events.
[b] Because gender was missing in 59 reports and primary category was missing in 22 reports, only 977 of 1,058 reported were included in the analysis.
[c] Adjusted for gender and age (continuous, years).

Table 3
Age stratified, adjusted risk ratios (RR), and 95% confidence intervals (CIs) for severe medical event[a] in FDA adverse event reports filed 2004–2015 for individuals aged 0–25 y that involved only one supplement (N = 977 reports)[b]

Number of observations	Age 0–11 y N = 256 RR (95% CI[c,d])	Age 12–17 y N = 143 RR (95% CI[c,d])	Age 18–25 y N = 578 RR (95% CI[c,d])
Dietary supplement categories (ref: vitamins)			
Weight loss	3.1*** (1.6–6.0)	3.2*** (1.7–6.0)	2.2*** (1.5–3.2)
Muscle building	7.5*** (4.7–12.0)	2.6* (1.1–6.1)	2.2*** (1.4–3.5)
Cleanse		1.0 (.3–3.9)	1.6 (.9–2.8)
Sexual function			2.0* (1.0–3.7)
Energy	.0*** (.0–.0)	2.7*** (1.4–5.0)	2.2*** (1.5–3.3)
Others	1.9* (1.1–3.0)	1.4 (.7–2.8)	1.4 (.9–2.2)
Other covariates			
Male	.7* (.4–1.1)	1.0 (.7–1.6)	1.3** (1.0–1.6)
Ref: female			
Constant	.2*** (.1–.3)	.2*** (.1–.4)	.2*** (.1–.3)

*$p < .05$; **$p < .01$; ***$p < .00$.
[a] Death, disability, hospitalization, ER visit, intervention required to prevent permanent damage, or life-threatening events.
[b] Because gender was missing in 59 reports and primary category was missing in 22 reports, only 977 of 1,058 reported were included in the analysis.
[c] Adjusted for gender.
[d] Empty cells are due to lack of observations in the respective combination of age groups and supplement category reported.

adverse events to FDA [35]. Our findings may represent only the tip of the iceberg regarding the adverse events associated with dietary supplements. Second, the categorization of supplements consumed are often not mutually exclusive, and multiple claims appear on the packaging for many products. Given this challenge, our categorization protocol assigned primary category based on the most salient or dominant claim on the marketing materials or packaging when multiple functions were claimed. Third, several hundred adverse event reports involved consumption of multiple supplements. The present study adopted a conservative approach by focusing our primary analyses on adverse event reports that involved one supplement only, then reporting supplemental analyses that included adverse event reports involving one or more supplements. Fourth, the FAERS database includes only adverse event reports attributed to supplement use but does not provide information on the number of people exposed to supplements who did not experience an adverse event reported to the FDS. However, given that vitamins are the most commonly consumed supplements among individuals of all ages [2,28], the strikingly high frequency of adverse events due to weight loss, muscle building, cleanse, sexual function, and energy supplements relative to vitamins despite the much higher exposure to vitamins in the population is cause for alarm and is a strong indicator of the dangers posed by the other categories of supplements. Future research to document the prevalence use of each category of supplement included in our study and across age and gender groups from representative U.S. samples will be essential to more precisely quantify the risk of these products. In addition, further data on prevalence of use and risk will be crucial to efforts to evaluate the effectiveness of harm reduction strategies at the population level.

The FDA's repeated warnings on the potential harm of dietary supplements are necessary but not sufficient to keep children, adolescents, and young adults safe. Many individuals remain uninformed about the potential harm of dietary supplements due to misinformation on the package [4,36]. The DSHEA, which prevents the FDA from robustly regulating the dietary supplements market, should be revised or repealed. The reliance of an honor system expecting manufacturers to ensure the safety of their products before launching them on the market has been utterly insufficient and ineffective in protecting the consumers from these preventable adverse events. As the dietary supplement industry continues to grow [1], efforts aiming at reducing access and consumption, implementing proactive enforcement of regulations, and providing clear warning at the point of purchase are paramount in preventing severe medical outcomes among children, adolescents, and young adults and consumers in general.

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Supplementary Data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jadohealth.2019.03.005.

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Invited Commentary | Public Health

The FDA and Adulterated Supplements—Dereliction of Duty

Pieter A. Cohen, MD

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The US Food and Drug Administration (FDA) plays an essential role in ensuring the safety of vitamins, minerals, botanicals, probiotics, amino acids, and glandular extracts sold as dietary supplements in the United States. While the FDA does not assess the safety of supplements prior to market, the agency is tasked with identifying and removing adulterated and hazardous supplements from the marketplace.

Adulteration of dietary supplements typically involves 1 of 2 patterns: economic adulteration, in which a less expensive ingredient is used in place of a more expensive ingredient listed on the label, or pharmaceutical adulteration, in which an active drug is included in a purportedly botanical supplement, for example, sildenafil in a "natural" sexual enhancement supplement. The FDA maintains a public database listing the brands of supplements it has identified as adulterated with drugs and the actions, if any, it has taken to remove the product from commerce.

An analysis of the FDA database of pharmaceutically adulterated supplements is the focus of a new study by Tucker and colleagues.[1] The authors found that between 2007 and 2016 the FDA identified 746 brands of supplements adulterated with pharmaceutical agents. The adulterants included prescription medications such as sildenafil and fluoxetine, withdrawn medications including sibutramine and phenolphthalein, and unapproved drugs including dapoxetine and designer steroids. Twenty percent of the adulterated supplements contained 2 or more undeclared drugs, for example, weight loss supplements containing both an anorectic and a laxative. Most supplements adulterated with drugs were marketed as weight loss, sexual enhancement, or sports supplements—the same categories that epidemiologists have found to be responsible for a disproportionate number of the estimated 23 000 emergency department visits attributed to dietary supplements each year in the United States.[2]

Given the potential public health risks of inadvertently ingesting unknown quantities of pharmaceutical drugs, once an adulterated supplement has been identified by the FDA, the agency frequently requests that the responsible firm voluntarily recall the product and, if the firm agrees, the agency publicizes the recall through email alerts and postings on its website. However, the effectiveness of voluntary recalls for supplements has been questioned.[3,4] In one study, investigators found that many supplements previously subject to recalls remained on sale and were still adulterated with pharmaceutical drugs, sometimes years after the initial recall.[3] In another study, consumers of a supplement subject to a voluntary recall were not aware of the recall and continued to purchase the product following the recall.[4]

Despite their limited effectiveness, voluntary recalls are the most common approach used by the FDA to remove adulterated supplements from commerce. In the current study, the agency discovered 746 distinct supplements to be adulterated but announced voluntary recalls for only 360. Only 360 of 746 (48%) were recalled, leaving the majority of adulterated supplements, more than 350 products, available for sale.

The database does not provide information as to why the FDA fulfilled its responsibilities less than half of the time, but it is possible that some firms might have refused to voluntarily recall their products. Warning letters may be used to nudge firms to recall supplements. In the current study, however, more than 140 firms were involved, but the FDA issued only 7 warning letters. The agency has other enforcement tools at its disposal when a firm does not agree to a voluntary recall, including mandating a recall (authority available since 2011 under the FDA Food Safety Modernization Act) or

making a referral to the Department of Justice. Tucker and colleagues[1] found that the agency seldom uses these enforcement tools: the FDA reported no mandatory recalls and only 1 Department of Justice investigation in response to the 746 brands of adulterated supplements.

This new evidence is consistent with prior research that has highlighted major deficiencies in the FDA's regulation of supplements. In a similar study published in 2013, Harel and colleagues[5] found that the FDA identified 332 brands of supplements adulterated with pharmaceutical agents during the 9-year period from 2004 to 2012 but only 222 brands (67%) were recalled.[5] In another investigation from 2013, the FDA's analytical chemists uncovered a mixture of synthetic compounds, including an amphetamine analog, β-methylphenylethylamine (BMPEA), in weight loss and sports supplements.[6] The FDA did not inform consumers or issue warning letters. An independent study describing the FDA's inaction was published 2 years later,[7] and only then did the FDA begin to take steps to remove the supplements containing BMPEA from the market.

This pattern is currently repeating itself—the FDA has not warned consumers about additional stimulants discovered in weight loss and sports supplements. My colleagues and I informed the FDA in early 2017 that we had identified 2 experimental stimulants, 1,4-dimethylamylamine and octodrine, in dietary supplements.[8] One stimulant has never been approved by the FDA for use in humans, and the other was approved for use by inhalation in the 1940s but has since been removed from the US market. Neither stimulant has ever been FDA approved for oral consumption. Our research has since been confirmed by FDA-funded investigators,[9] yet as of September 2018 the FDA has not taken any regulatory action to remove these synthetic stimulants from commerce or warn consumers about the novel adulterants.

To counter the perception of regulatory inertia, FDA officials have emphasized their work to eliminate the stimulant 1,3-dimethylamylamine (1,3-DMAA) from supplements. The sympathomimetic 1,3-DMAA was originally introduced by Eli Lilly & Co in the 1940s as a nasal decongestant to compete with amphetamine marketed by Smith, Kline and French.[10] By the 1970s, 1,3-DMAA had been withdrawn from the US markets, but it reappeared in the 2000s as a replacement for ephedra in sports and weight loss supplements; by 2012 the stimulant was available in more than 200 brands of supplements.[10] The World Anti-Doping Agency banned the stimulant in sport in 2009. In 2011, Health Canada banned 1,3-DMAA from supplements and the US Department of Defense removed 1,3-DMAA supplements from military bases due to safety concerns. The stimulant received prominent media attention as potentially contributing to strokes and deaths of US troops. Only in 2012 did the FDA finally begin to use its full enforcement powers, including warning letters, product seizures, and mandatory recalls, to remove the stimulant from supplements.

More than FDA action will be required to ensure that all adulterated supplements are effectively and swiftly removed from the market. Congress would need to reform the Dietary Supplement Health and Education Act of 1994. One practical change would be to require firms to register supplements with the FDA prior to sale and Congress could provide the FDA with more effective enforcement tools such as immediately revoking a product's registration if a supplement is found to be adulterated with pharmaceutical drugs. In the meantime, the process that the FDA is required to follow to remove supplements from the marketplace will remain cumbersome and time-consuming; nevertheless, the agency's failure to aggressively use all available tools to remove pharmaceutically adulterated supplements from commerce leaves consumers' health at risk.

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Conflict of Interest Disclosures: Dr Cohen was the subject of a civil suit brought by Hi-Tech Pharmaceuticals, a supplement company, regarding β-methylphenethylamine (BMPEA); jury found in Dr Cohen's favor. Dr Cohen has collaborated in research with NSF International and received research support from Consumers Union.

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Diet Pill and Laxative Use for Weight Control and Subsequent Incident Eating Disorder in US Young Women: 2001–2016

Jordan A. Levinson, BA, Vishnudas Sarda, MBBS, MPH, Kendrin Sonneville, RD, ScD, Jerel P. Calzo, PhD, MPH, Suman Ambwani, PhD, and S. Bryn Austin, ScD

Objectives. To investigate the prospective association of diet pill and laxative use for weight control with subsequent first eating disorder diagnosis in young women.

Methods. We used longitudinal data from 10 058 US women spanning 2001 through 2016. We used multivariable logistic regression models, adjusting for age, race/ethnicity, and overweight status to estimate the association between weight-control behaviors and subsequent eating disorder diagnosis.

Results. Among those who had not previously received an eating disorder diagnosis, women who reported diet pill (adjusted odds ratio [AOR] = 5.6; 95% confidence interval [CI] = 3.0, 10.5) or laxative (AOR = 6.0; 95% CI = 4.2, 8.7) use for weight control had higher odds of receiving a subsequent first eating disorder diagnosis within 1 to 3 years than those who did not report using these products.

Conclusions. Use of diet pills or laxatives for weight loss can be dangerous and may be a warning sign that warrants counseling and evaluation for the presence of or risk of developing an eating disorder.

Public Health Implications. Policymakers and public health professionals should develop and evaluate policy initiatives to reduce or prohibit access to diet pills and laxatives abused for weight control. (*Am J Public Health.* 2020;110:109–111. doi: 10.2105/AJPH.2019.305390)

Research shows that unhealthy weight-control behaviors, including use of diet pills and laxatives for weight control, can put individuals at risk for the development of eating disorders.[1] Use of over-the-counter diet pills or laxatives is not recommended by health care providers as a healthy way to manage weight and can have severe health consequences.[2] Despite these risks, use of these products for weight control persists in people of all genders, ages, races/ethnicities, and socioeconomic statuses.[3,4] An estimated 15%[3] of adults report lifetime use of diet pills for weight control. Lifetime use of laxatives for weight control among adults is estimated at 5%[5] and from 15%[5] to 62% in those with eating disorders.[2]

Although use of diet pills and laxatives for weight control is common in people with eating disorders,[2,6] the prospective association of use of these products and subsequent diagnosis with an eating disorder is not known. Use of these products could indicate an incipient eating disorder or the presence of a full, yet undiagnosed eating disorder. Alternatively, a causal relationship may exist, as using diet pills and laxatives for weight control could serve as a "gateway" behavior to escalating weight-control practices,[7] dysregulate normal digestive functioning leading to more disordered eating,[8] and exacerbate emotion dysregulation through dependence on unhealthy and ineffective coping (i.e., diet pill and laxative use).[9]

We examined whether use of these products for weight control predicts subsequent clinical diagnosis with an eating disorder among young women who have not previously received an eating disorder diagnosis. We hypothesized that those who reported past-year use of diet pills or laxatives for weight control would be more likely than would those who did not to receive a first diagnosis of an eating disorder on the next wave of data collection (1–3 years later).

METHODS

We examined diet pill use, laxative use for weight control, and eating disorder diagnosis using longitudinal data from young women in the US-based Growing Up Today Study (GUTS), which enrolled children, aged 9 to 15 years in 2 stages: GUTS1 baseline in 1996 (n = 16 882) and GUTS2 baseline in 2004 (n = 10 442). Our analysis included GUTS1 and GUTS2 participants who provided data both on past-year use of these products and eating disorder diagnosis from 2001 to 2016. Participants were asked about their use of diet pills (In the past year, did you use diet pills to lose weight or to keep from gaining weight?) and laxatives (In the past year, did you take laxatives to lose weight or keep from gaining

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weight?) for weight control (coded as binary: "yes" if any past-year use; "no" if no past-year use). Surveys were administered annually or sometimes biennially.

We assessed eating disorder diagnosis on 10 waves. Four waves of surveys assessed diet pill use and 10 waves assessed laxative use. To assess eating disorder diagnosis, participants were asked if a doctor, nurse, or other health care provider had ever told them they had an eating disorder, such as anorexia nervosa or bulimia nervosa (coded as binary: yes/no). We excluded respondents if they reported being told they had an eating disorder before or on the same wave that they first reported diet pill or laxative use, and we also excluded them from subsequent analysis once they reported being told they have an eating disorder.

We conducted multivariable logistic regression modeling with 7564 responses from 6977 participants for diet pill use and 40 305 responses from 10 058 participants for laxative use to estimate the prospective association of past-year diet pill or laxative use for weight control with subsequent first report of an eating disorder diagnosis by a health care provider in the next wave of data collection, which could occur 1 to 3 years after the wave reporting product use. We did not consider first report of eating disorder diagnosis that occurred more than 1 consecutive wave from reported diet pill or laxative use as associated with product use. Models controlled for age, race/ethnicity, and overweight status at the time of response to the eating disorder diagnosis item, and generalized estimating equations accounted for repeated measures and sibling clusters. We conducted the statistical analyses using SAS version 9.2 (SAS Institute, Cary, NC).

RESULTS

We conducted analyses with data from 10 058 women, ranging from 14 to 36 years old, over the observation period from 2001 to 2016. Among 7564 responses included in diet pill analyses, 1.8% of these reporting diet pill use in the past year, compared with 1.0% of those not reporting diet pill use in the past year, subsequently reported a first eating disorder diagnosis from a health care provider in the next wave of data collection. Those who used diet pills had more than 5 times higher adjusted odds (adjusted odds ratio [AOR] = 5.6; 95% confidence interval [CI] = 3.0, 10.5) of receiving an eating disorder diagnosis from a health care provider within 1 to 3 years than those who did not. Among 40 305 responses included in the laxative use analyses, 4.2% of those reporting laxative use for weight control in the past year, compared with 0.8% of those not reporting past-year laxative use for weight control, subsequently reported an eating disorder diagnosis from a health care provider in the next survey wave of data collection. The appendix contains more information (available as a supplement to the online version of this article at http://www.ajph.org). Those who reported laxative use for weight control had 6 times higher adjusted odds (AOR = 6.0; 95% CI = 4.2, 8.7) of receiving an eating disorder diagnosis from a health care provider within 1 to 3 years than those who did not (Table 1).

DISCUSSION

Use of diet pills and laxatives for weight management can have deleterious effects.[2] In addition to the known risks associated with use of these products for weight control, we found that use of these products can precede first eating disorder diagnosis. Although the prospective association between unhealthy weight-control behaviors and eating disorder symptoms has been previously documented,[1,2] to our knowledge, this study is the first to estimate the prospective association of use of diet pills or laxatives for weight control and subsequent first diagnosis with an eating disorder. It is plausible that use of these products may increase the likelihood of eating disorder onset by contributing to behavioral dysregulation of eating,[7] physiological dysregulation of digestion,[8] or psychological dysregulation.[9]

Our study has several limitations. Many people with eating disorders are never diagnosed by a health care provider, leading to many missed cases of eating disorders. Relatedly, we controlled for race/ethnicity and overweight status because of well-documented diagnostic bias leading to underdetection of eating disorders in people of color and those at higher weights,[10] but residual confounding may still have affected our results. Future research should investigate possible pathways through which diet pill and laxative use might potentiate vulnerability to eating disorders. In addition, family members, clinicians, coaches, and others who work with young people should be aware that any use of diet pills or laxatives for weight control can be dangerous.[2] Repeated use of these products is a warning sign that warrants counseling and evaluation for the presence or risk of developing an eating disorder.

TABLE 1—Prospective Adjusted Odds Ratios (AORs) and 95% Confidence Intervals (95% CIs) of Adolescent and Young Adult Women Receiving a New Eating Disorder Diagnosis From a Health Care Provider 1–3 Years After Reporting Diet Pill or Laxative Use for Weight Control: Growing Up Today Study Cohort, United States, 2001–2016

Incident Eating Disorder Diagnosis	Total Responses[a]	Responses Reporting Eating Disorder Diagnosis,[a] No. (%)	AOR[b] (95% CI)
Diet pill model			
Diet pill use, no[c]	6 469	63 (1.0)	1 (Ref)
Diet pill use, yes[c]	1 095	20 (1.8)	5.58 (2.97, 10.49)
Laxative model			
Laxative use, no[d]	39 289	293 (0.8)	1 (Ref)
Laxative use, yes[d]	1 016	43 (4.2)	6.03 (4.18, 8.69)

Note. Study size was n = 10 058 participants.

[a]Repeated measures responses from participants in prospective cohort over multiple survey waves.

[b]Multivariable models control for age, race/ethnicity, and overweight status. Models estimate odds of new eating disorder diagnosis associated with report of diet pill or laxative use for weight control on previous survey wave.

[c]Data on diet pill use collected in 4 waves of the survey.

[d]Data on laxative use collected in 10 waves of the survey.

PUBLIC HEALTH IMPLICATIONS

Results of this study suggest that use of diet pills and laxatives for weight control is predictive of later diagnosis of an eating disorder. Given the myriad health risks of these products well documented in the literature,[2] combined with our evidence that their use may be prospectively associated with eating disorder diagnosis, public health professionals, policymakers, and community advocates should pursue remedies to reduce access to and use of these products, such as a tax[11] on these products as well as legislation to ban the sale of diet pills to minors.[12] AJPH

CONTRIBUTORS

J. A. Levinson prepared the article. V. Sarda performed analyses. K. Sonneville, J. P. Calzo, and S. Ambwani conceptualized the study and prepared the article. S. B. Austin conceptualized the study, created the database, performed analyses, and prepared the article. All authors interpreted results.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

HUMAN PARTICIPANT PROTECTION

This study was approved by the Brigham and Women's Hospital human subjects committee.

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TESTIMONY
Submitted to the New York City Council Committee on Health in support of
Int. No. 1485, Sponsored by Councilor Mark Levine,
A Local Law to amend the administrative code of the city of New York, in relation to restricting the sale of senna- and saffron-based products

Submitted by S. Bryn Austin, ScD
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Director, Strategic Training Initiative for the Prevention of Eating Disorders

Jan. 27, 2020

Dear Esteemed Members of the New York City Council Committee on Health:

I am Professor of Pediatrics at Harvard Medical School and Professor in Social and Behavioral Sciences at the Harvard T.H. Chan School of Public Health. I am also the Director of the Strategic Training Initiative for the Prevention of Eating Disorders based at the Harvard T.H. Chan School of Public Health and Boston Children's Hospital. I would like to share research supporting NYC bill 1485, "A Local Law to amend the administrative code of the city of New York, in relation to restricting the sale of senna- and saffron-based products," filed by Councilor Mark Levine, and to strongly urge you to vote in favor of this important bill.

Senna is an herbal laxative, and saffron is an herbal stimulant that often are used in dietary supplements sold to consumers with claims of weight loss. Laxatives sold as over-the-counter drugs also often contain senna. Although most consumers believe that the fact that senna and saffron are herbs makes them a safe and effective way to manage weight, this misconception could not be further from the truth. Weight-loss supplements and over-the-counter laxatives containing senna, saffron, and other harmful ingredients have been linked with a wide range of serious health consequences, including: chronic diarrhea, constipation, and bowel dysfunction, dehydration, hypokalemia, metabolic

acidosis, and other electrolyte imbalances, cardiac arrhythmia, hemorrhagic and ischemic stroke, hepatic and renal failure, and death.(Steffen et al. 2007; Roerig et al. 2003; Blanck et al. 2007; Schneider 2003; Copeland 1994; Tozzi et al. 2006; Vanderperren et al. 2005) In addition, in a study conducted by my Harvard-based research team with data from over 10,000 adolescent and young adult women followed over a 15-year period found that those who used over-the-counter diet pills or laxatives for weight control were six times more likely than peers who did not use these products to be diagnosed with an eating disorder within one to three years of beginning use of these products.(Levinson et al. 2020) Eating disorders have among the highest mortality rate of any psychiatric disorder. (Arcelus et al. 2011)

Weight-loss dietary supplements, many of which contain senna or saffron extract, make up over $2 billion of the overall $40 billion a year U.S. market in dietary supplements. (Nutrition Business Journal 2018) We have all seen these products, which are commonly used by adults and children, in pharmacies, grocery stores, health food stores, and other retailers. What many people do not know is that dietary supplements are not prescreened for safety or efficacy by the U.S. Food and Drug Administration (FDA) before they enter the market. In 1994, Congress passed the Dietary Supplement Health and Education Act, which prohibits the FDA from prescreening dietary supplements before they enter the market. Instead, manufacturers are expected to adhere to the honor system and self-assess the safety of their own products.(Pomeranz et al. 2015)

In the absence of FDA prescreening, many dietary supplements on the consumer market, especially those sold for weight loss, have been found to be adulterated with prescription pharmaceuticals, banned substances, heavy metals, pesticides, and other dangerous chemicals.(Cohen 2014; Park et al. 2013; FDA 2017) A study led by the FDA tested a small selection of the tens of thousands of dietary supplements on the market and found hundreds of those sold for weight loss to be contaminated with pharmaceutical drugs and banned chemicals, which often are associated with serious health consequences.(FDA 2017)

Weight-loss dietary supplements have been linked with stroke, liver and other organ damage, sometimes necessitating organ transplant or resulting in death.(Cohen 2014) In fact, the rate of liver failure has risen 185% in the past decade,(Cohen 2014) and 16% of serious drug-induced liver injury cases in the United States are attributed to dietary supplement use, a high proportion of those being those sold for weight loss.(Navarro et al. 2014) The FDA relies on the report of serious adverse incidents such as injury or fatality to find out after the fact when dietary supplements have caused harm to consumers.(Pomeranz et al. 2015) Since consumers do not always associate health problems with dietary supplements and commonly believe that herbal ingredients such as senna or saffron are safe, they often do not reveal to their healthcare providers that they are using these products. As a result, the true number of adverse incidents due to dietary supplements sold for weight loss and over-the-counter laxatives containing senna is likely far higher than the number reported to the FDA.

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.(Geller et al. 2015) 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. Another recent study, this one of reports to poison control centers nationwide, documented nearly 275,000 reports related to dietary supplement use from the period from 2000 to 2012; the study also found that reports of supplements to poison control centers increased 50% between the years of 2005 to 2012.(Rao et al. 2017) Finally, a study published last year in *Journal of Adolescent Health*, a leading international journal in adolescent medicine, conducted by my Harvard-based research team using the FDA's Adverse Event Reporting System database, we found that youth using weight-loss supplements were nearly three times more likely than those using ordinary vitamins to experience severe medical harm, including hospitalization, disability, and even death.(Or et al. 2019)

In 2012, 17-year-old Christopher Herrera was hospitalized in Texas with severe liver damage after using a concentrated green tea extract – a known liver toxin – purchased at a nutrition store to lose weight. Doctors recalled that when he arrived, his chest, face, and eyes were "almost highlighter yellow" and the damage was so severe that Christopher was put on the waiting list for a liver transplant. Although young Christopher survived this near-fatal poisoning by a weight-loss supplement, he can no longer spend much time outdoors or exert himself through sports or exercise.(O'Connor 2013) The following year, the Hawaii Department of Health, U.S. Centers for Disease Control and Prevention (CDC), and FDA conducted a public health investigation when a number of otherwise healthy patients reported severe acute hepatitis and liver failure. The investigation identified 29 cases of hepatitis and found that 24 (83%) of these patients reported using OxyELITE Pro, a dietary supplement marketed for weight loss and muscle building, during the previous two months.(Park et al. 2013)

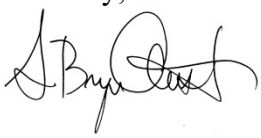
And finally, just a few weeks ago, the tragic story of 23-year-old Emily Goss of Amarillo, Texas, made headlines across the nation. She had been taking weight-loss supplements for several months leading up to Christmas of 2019, probably, like most people who use these products, assuming they were a safe way to shed a few pounds. Instead, she ended up with acute liver failure within just months of starting to use the supplement and had to undergo a liver transplant late last year. While doctors were able to prevent her death, the previously healthy young woman now faces of lifetime medications and medical management to keep their body from rejecting the new organ.(Castro 2020) These are just three of the many examples of serious health consequences linked with weight-loss supplements.(Cohen 2014; Park et al. 2013; FDA 2017)

Weight-loss dietary supplements and over-the-counter laxatives are not recommended by reputable physicians for healthy weight management. In fact, in 2016, the American

Academy of Pediatrics issued a report strongly cautioning against their use by teens.(Golden et al. 2016) Despite these warnings, we have an industry rife with unscrupulous manufacturers that have repeatedly failed to meet their legal obligation to ensure the safety of their products before they are placed on the consumer market. Knowing what we know today about the repeated violations of trust on the part of these manufacturers, how can we continue to let them and the retailers who profit from their products play Russian roulette with the children of New York City?

It is clear that action must be taken to protect New York City youth and other vulnerable consumers. In 2015, the New York State Attorney General, along with 13 other state attorneys general, signed a letter urging the U.S. Congress to increase regulation of and investigation into the dietary supplements industry.(NBC New York 2015) Now five years later, this issue is as urgent as it was then and needs your serious attention. City governments have the right and responsibility to act.(Pomeranz et al. 2015) NYC bill 1485 gives New York City lawmakers the opportunity to take action to protect children and other vulnerable consumers in the municipality from these harmful products. This bill would ban sale of products containing senna or saffron, many that are sold with deceptive promises of healthy weight loss, to minors younger than 18 years old. We must act now to put limits on the sale of these dangerous products to protect the children of New York City. I urge you to vote in support of NYC bill 1485. Thank you for your leadership on this important issue.

Sincerely,



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Citations

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Appearance Card | _____

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: 01/28/2020

(PLEASE PRINT)

Name: Myka Harrison

Address: 42-09 28th Street, LIC, NY 11101

I represent: DOHMH

Address: same

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card | _____

I intend to appear and speak on Int. No. 1485 Res. No. _____

☑ in favor ☐ in opposition

Date: 1/28/20

(PLEASE PRINT)

Name: Kerry Donohue

Address: 1500 Broadway, New York, NY

I represent: National Eating Disorders Assn

Address: _____

Please complete this card and return to the Sergeant-at-Arms

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THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. 485 Res. No. _____

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Steven Ettannani

Address: 42 Broadway, 8th FL NY, NY

I represent: NYC Department of Consumer Affairs

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☐ in favor ☐ in opposition

Date: Jan 28, 2020

(PLEASE PRINT)

Name: Dr. Chanelle Cobla

Address: _____

I represent: NYC Health + Hospitals

Address: _____

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. _____

☑ in favor ☐ in opposition

Date: 1/28/20

(PLEASE PRINT)

Name: Emme

Address: 270 Harrington Ave

I represent: Closter, NJ 07624

Address: _____

Please complete this card and return to the Sergeant-at-Arms