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RE-REGULATING DIETARY SUPPLEMENTS

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In 1994, Congress introduced the Dietary Supplement Health and Education Act (DSHEA) to create a regulatory framework for the dietary supplement industry. Since the passage of DSHEA nearly thirty years ago, U.S. adults have steadily increased their annual consumption of dietary supplements. The once \$4 billion industry comprising approximately 4,000 products has swelled to a \$40 billion trade with anywhere from 50,000 to 80,000 dietary supplements available over-the-counter.

Despite the increased market size of dietary supplements, the Food and Drug Administration's (FDA) pre-market authority to regulate the introduction of dietary supplements into the stream of commerce has remained subdued. Under DSHEA, the FDA has limited authority to review dietary supplements before entering the market. Unlike pharmaceuticals, which must be shown to be safe and effective prior to approval and marketing, dietary supplements can be sold to consumers without such reassurances. Instead, the FDA's authority is generally limited to post-market enforcement under DSHEA. In fact, the FDA lacks the express authority to remove dietary supplements from the market unless it can establish that the products are unsafe, adulterated, mislabeled or misbranded.

Given the morbidity and mortality associated with adulterated dietary supplements and the challenges in addressing the latest fads before they cause harm, Congress must give the FDA the power it needs to be proactive. The FDA desperately needs the tools to regulate the dietary supplement industry and remove harmful dietary supplements from the market. We call on Congress to amend DSHEA to grant the FDA the express statutory authority to (1) regulate dietary supplements prior to entering the market; (2) require manufacturers to submit Supplement Labels to the FDA for pre-market review; (3) require that supplements undergo both pre-market composition testing and post-market randomized composition testing; (4) strengthen agency authority to remove adulterated dietary supplements from the market; and (5) establish an excise tax on dietary supplements.

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I. INTRODUCTION

On a box covered in pink emblems, Dr. Reade Slim Sense read: “Clinically proven fat burner for healthy and safe weight loss.”¹ Despite touting “100% natural, non-GMO ingredients,” Dr. Reade Slim Sense came under Food and Drug Administration (FDA) scrutiny in July 2022, when the agency issued a public notification warning consumers that it confirmed, through laboratory analysis, the dietary supplement in fact contained a drug ingredient linked to “psychiatric disturbances,” “impairments in attention or memory,” and at least one type of cancer.² The supplement stayed on the market, and by January 2023, the FDA had issued a warning letter to distributor Adam’s Secret about Dr. Reade and other supplements sold on the distributor’s website which contained drug ingredients.³ But even then, the FDA lacked power to immediately pull these hidden drugs from shelves. In its warning letter, the FDA told the distributor, “It is *your responsibility* to ensure that your firm complies with all requirements of federal law, including FDA regulations.”⁴

¹ *Public Notification: Dr. Reade Slim Sense contains hidden drug ingredient*, FOOD & DRUG ADMIN. (July 15, 2022), <https://www.fda.gov/drugs/medication-health-fraud/public-notification-dr-reade-slim-sense-contains-hidden-drug-ingredient>.

² *Id.*

³ *Warning Letter: HIS Enterprise Inc dba Adam’s Secret USA, LLC*, FOOD & DRUG ADMIN. (Jan. 10, 2023), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/his-enterprise-inc-dba-adams-secret-usa-llc-646494-01102023>.

⁴ *Id.*

Nearly fifty-eight percent of American adults report using dietary supplements, and the percentage of consumers increases with age.⁵ Since 1994, the once \$4 billion industry comprising approximately 4,000 unique products has swelled to a \$40 billion trade with anywhere from 50,000 to 80,000 dietary supplements available over-the-counter in drug stores, groceries, and gas stations.⁶ Often, supplements are touted as all-natural additions to support a healthy lifestyle. Seemingly harmless, vitamins, minerals, and herbs are marketed to provide essential nutrients, boost the immune system, prevent chronic diseases, treat illnesses, and even lower the risk of developing cancer.⁷ But in other cases, patients select products that could be detrimental to their health.⁸ Notably, the FDA and independent researchers have warned of many supplements sold under the guise of promoting weight loss and sexual enhancement that contain unapproved pharmaceutical ingredients, from laxatives to antidepressants to the male enhancement drug sildenafil [Viagra].⁹

Today's legal framework does not support a system in which the FDA, tasked with regulating dietary supplements, can assure their safety. The FDA is taking steps

⁵ Mishra Suruchi, et al., *Dietary Supplement Use Among Adults: United States, 2017-2018*, NCHS Data Brief, No. 399 NAT'L CTR. FOR HEALTH STAT. (2021).

⁶ *Statement from FDA Commissioner Scott Gottlieb, M.D., on The Agency's New Efforts to Strengthen Regulation of Dietary Supplements by Modernizing and Reforming FDA's Oversight*, FOOD & DRUG ADMIN. (Feb. 11, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>.

⁷ *Id.*

⁸ *See generally Dietary Supplements: What You Need to Know*, NAT'L INSTS. HEALTH OFF. DIETARY SUPPLEMENTS, <https://ods.od.nih.gov/factsheets/WYNTK-Consumer/> (last updated Sept. 3, 2020).

⁹ Jenna Tucker et al., *Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated With US Food and Drug Administration Warnings*, JAMA Network Open, 2018, at 5; *see also* FOOD & DRUG ADMIN., *Public Notification: CHU Dietary Supplement Product Contains Hidden Drug Ingredients* (2019), <https://www.fda.gov/drugs/medication-health-fraud/public-notification-chu-dietary-supplement-product-contains-hidden-drug-ingredients>.

to reign in the multi-billion-dollar industry, but under the Dietary Supplement Health and Education Act of 1994 (DSHEA) – the law granting the FDA authority to regulate dietary supplements – the FDA’s authority is practically limited to post-market review of supplement safety. In a game of whack-a-mole, the FDA primarily relies on voluntary consumer and provider reports of severe adverse effects of a particular dietary supplement to learn of the potentially detrimental effects of a dietary ingredient or the pharmaceutical adulteration of a supplement.¹⁰

By the FDA’s own admission, its post-market measures do not keep unsafe products out of consumers’ hands.¹¹ In its proposed FY2024 budget, the FDA suggested modernizing DSHEA “to provide for a transparent marketplace, help facilitate a risk-based regulation of dietary supplements, and clarify FDA’s authorities related to products marketed as ‘dietary supplements.’”¹² Specifically, in addition to “clarifying its authorities,” the FDA has proposed to “require all dietary supplements to be listed with the FDA.”¹³ The proposal is a step in the right direction but insufficient to reign in a largely unregulated industry. We call on Congress to amend DSHEA to grant the FDA the express statutory authority to regulate dietary supplements prior to entering the market by requiring manufacturers to submit

¹⁰ *Public CFSAN Adverse Event Reporting System (CAERS)*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers> (last visited Aug. 13, 2023).

¹¹ *Weight Loss, Male Enhancement and Other Products Sold Online or in Stores May be Dangerous*, FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/weight-loss-male-enhancement-and-other-products-sold-online-or-stores-may-be-dangerous> (last updated Dec. 8, 2021).

¹² *Summary of FY 2024 Legislative Proposals*, FOOD & DRUG ADMIN., <https://www.fda.gov/media/166049/download> (last visited Aug. 13, 2023).

¹³ *Id.*

Supplement Labels to the FDA for pre-market review; require that supplements undergo both pre-market composition testing and post-market randomized composition testing; provide the FDA the express authority to remove adulterated dietary supplements from the market; and establish an excise tax on dietary supplements.

II. BACKGROUND

In its opinion in *Nutrilab, Inc. v. Schweiker* in 1983, the Seventh Circuit drew a bright line between food and dietary supplements,¹⁴ supporting the FDA's stance that it had regulatory power over supplements. In *Nutrilab*, a manufacturer sued the FDA over a request to pull its starch blocker from shelves after the agency classified the weight loss supplement as a drug which would require agency approval prior to sale in the US.¹⁵ The starch blocker was extracted from raw kidney beans and sold in pill form. Purportedly, when taken with a meal, it disabled the alpha-amylase enzyme that digested starch, therefore preventing the body's metabolism of starch-derived calories.¹⁶ The Court rejected the plaintiff's argument that its derivation from kidney beans, a food, made starch blockers a food, too, finding that under the "common sense" definition, starch blockers could not be food because they were not used for their "taste, aroma, or nutritive value."¹⁷ Instead, the Court noted, "they are taken for their ability to block the digestion of food and aid in weight loss."¹⁸

¹⁴ *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 337 (7th Cir. 1983).

¹⁵ *Id.* at 335.

¹⁶ *Id.* at 335-36.

¹⁷ *Id.* at 337-38.

¹⁸ *Id.* at 338.

In 1994, Congress passed DSHEA, creating a new regulatory framework for dietary supplements and establishing standards for the dietary supplement industry.¹⁹ With DSHEA's passage, pills like starch blockers became dietary supplements, and the FDA's clear delineation suddenly became much murkier.²⁰ DSHEA defines a dietary supplement as any product, excluding food or drugs, that contains a "vitamin, mineral, herb, or amino acid" that is "intended to supplement the diet" and is "labeled as a dietary supplement."²¹ Under DSHEA, dietary supplement manufacturers and distributors are responsible for evaluating safety and effectiveness and labeling their products before marketing.²² Dietary supplements can be classified solely as foods, even if they make health-related claims, though the FDA has little oversight authority over those claims.²³

A manufacturer that makes a claim about the effects of the dietary supplement on a structure or function of the human body, a claim of a benefit related to classical nutrient deficiency disease, or a claim of general well-being in the labeling of a dietary supplement, must substantiate their claims and assert that their claim is "truthful and not misleading."²⁴ The requirement mirrors a ban against adulterated²⁵ or

¹⁹ DIETARY SUPPLEMENT HEALTH & EDUCATION ACT.

²⁰ PETER BARTON HUTT ET AL., FOOD & DRUG LAW 88-9 (4th ed. 2014).

²¹ DIETARY SUPPLEMENT HEALTH & EDUCATION ACT § 3.

²² *Id.* §8.

²³ Lewis A. Grossman, *Food, Drugs, and Droids: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1097, 1134 (2008); *Dietary Supplements: What Are They and How Are They Regulated?*, PEW CHARITABLE TRUSTS (Oct. 2017), https://www.pewtrusts.org/~/media/Assets/2017/10/HCP_Dietary_Supplements_What_Are_They_and_How_Are_They_Regulated_final.pdf.

²⁴ 21 U.S.C. § 343.

²⁵ 21 U.S.C. §§ 321(ff)(3)(B), 342(f)(1)(A)(ii), 342(f)(1)(C).

misbranded²⁶ dietary supplements. A dietary supplement is deemed adulterated if it contains a poisonous or deleterious substance that is injurious to health, poses an imminent hazard to public safety or health, or if the dietary supplement has been prepared, packed, or held under unsanitary conditions.²⁷ However, a dietary supplement may also be deemed adulterated if it omits any material ingredient.²⁸ The statute does not include the presence of drug ingredients in its definition of “adulteration.” Instead, the FDA often labels supplements that contain drug ingredients as an illegal sale of an unapproved drug product or a misbranded drug.²⁹

The definition of dietary supplement explicitly excludes any new drug or drug authorized for investigation that was not, prior to its approval as a drug, marketed as a dietary supplement or food.³⁰ Therefore, where a supplement contains an active pharmaceutical ingredient, it transforms into an unapproved drug subject to recall.³¹ A product is misbranded if it contains a drug, but fails to include “adequate directions for use,” which for prescription drug products can only be accomplished “safely at the

²⁶ 21 U.S.C. §§ 343(a), 343(s)(1)-(2), 352(f)(1), 353(b)(1)(A); *see, e.g., Warning Letter: Anabolic Laboratories Inc.*, FOOD & DRUG ADMIN. (Nov. 14, 2022), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/anabolic-laboratories-inc-636308-11142022>.

²⁷ 21 U.S.C. § 342.

²⁸ *Id.*

²⁹ U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-250, DIETARY SUPPLEMENTS: FDA SHOULD TAKE FURTHER ACTIONS TO IMPROVE OVERSIGHT AND CONSUMER UNDERSTANDING 20 (2009) [hereinafter GAO DIETARY SUPPLEMENTS REPORT].

³⁰ 21 U.S.C. § 321(ff)(3)(B). The Secretary has discretion to issue a regulation overriding this general rule. *Id.*

³¹ *See, e.g., Jongu 4308 Issues Voluntary Nationwide Recall of Hydro Pineapple Burn Due to the Presence of Undeclared Sibutramine*, FOOD & DRUG ADMIN. (Aug. 11, 2021), <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/jongu-4308-issues-voluntary-nationwide-recall-hydro-pineapple-burn-due-presence-undeclared>.

direction, and under the supervision, of a licensed practitioner.”³² Dietary supplements, additionally, are misbranded if they do not list all ingredients or are “false or misleading.”³³

Once a dietary supplement has been deemed adulterated or misbranded, DSHEA authorizes the FDA to take action against the manufacturer that introduced the supplements into the market.³⁴ Generally, the first step is to issue a “Warning Letter”³⁵ notifying the dietary supplement manufacturer that its product is adulterated or misbranded while urging a “voluntary recall.”³⁶ When the FDA requests a voluntary recall, the product remains available to consumers until the manufacturer complies. If the manufacturer complies with the request, the FDA publicizes the recall notice.³⁷

Even in the face of a voluntary recall, a bad actor could theoretically rebrand the same product or sell a subsequent, tainted batch.³⁸ If the dietary supplement has been extensively distributed or poses a serious health hazard, the FDA can also issue a public notice of the potential dangers of consuming the adulterated supplement.³⁹

³² 21 U.S.C. §§ 352(f)(1), 353(b)(1)(A); *see, e.g., Warning Letter: Anabolic Laboratories Inc.*, FOOD & DRUG ADMIN. (Nov. 14, 2022), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/anabolic-laboratories-inc-636308-11142022>.

³³ 21 U.S.C. §§ 343(a), (s)(1)-(2).

³⁴ *Dietary Supplements*, FOOD & DRUG ADMIN. (2022), <https://www.fda.gov/food/dietary-supplements>.

³⁵ Pieter A. Cohen, *The FDA and Adulterated Supplements—Dereliction of Duty*, JAMA NETWORK OPEN, Oct. 12, 2018, at 1.

³⁶ *Id.*

³⁷ *Id.*; *Recalls of Food & Dietary Supplements*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/recalls-outbreaks-emergencies/recalls-foods-dietary-supplements> (last updated Jan. 25, 2022). Interestingly, the Recall Notice is published under “Drug” recalls rather than “Food” recalls on the FDA’s website.

³⁸ *See* Pieter A. Cohen et al., *Recalls, Availability, and Content of Dietary Supplements Following FDA Warning Letters*, 328 JAMA 393, 394 (2022).

³⁹ *FDA 101: Dietary Supplements*, FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements> (last updated June 2, 2022).

If a dietary supplement manufacturer declines to issue a voluntary recall, the FDA can issue mandatory recalls or product seizures of an adulterated supplement from the market,⁴⁰ but only if the agency can establish that the dietary supplement is harmful.⁴¹ Finally, the FDA can seize dietary supplements that are imported from international manufacturers⁴² or seek an injunction against manufacturers and distributors that violate the law.⁴³

Unlike pharmaceuticals, which must undergo clinical trials demonstrating their safety and effectiveness prior to FDA approval, dietary supplements are not required to demonstrate either.⁴⁴ DSHEA does not grant the FDA the authority to require pre-market approval for dietary supplements entering the market⁴⁵ or to conduct post-market research studies that would corroborate the safety or effectiveness of the dietary supplement.⁴⁶ In general, the FDA's authority is limited to post-market enforcement of DSHEA.⁴⁷

⁴⁰ Charles M. White, *Dietary Supplements Pose Real Dangers to Patients*, 54 ANNALS OF PHARMACOTHERAPY 815 (2020).

⁴¹ *Id.*

⁴² U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-250, DIETARY SUPPLEMENTS: FDA SHOULD TAKE FURTHER ACTIONS TO IMPROVE OVERSIGHT AND CONSUMER UNDERSTANDING 20 (2009) [hereinafter GAO DIETARY SUPPLEMENTS].

⁴³ *Id.*

⁴⁴ Roseann B. Termini, Vincent A. Sannuti, *A Look Back at the DSHEA - Over 25 Years Later: The Dangers of a Reactionary Approach to Dietary Supplement Regulation*, 22 QUINNIPIAC HEALTH L. J. 171, 181 (2019).

⁴⁵ George Kennett, *Time for Change: Stepping up the FDA's Regulation of Dietary Supplements to Promote Consumer Safety and Awareness*, 33 J. OF L. & HEALTH 48, 62 (2020).

⁴⁶ Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 1 AM. J. L. & MED. 175, 211-12 (2005).

⁴⁷ Ralph L. Quinones, et al., *The Regulation of Dietary Supplements Within the United States: Flawed Attempts at Mending a Defective Consumer Safety Mechanism*, 47 J. OF CONSUMER AFFS. 328, 334 (2013).

However, “new dietary ingredients” (NDIs) are subject to FDA review in the first seventy-five days of availability. Dietary supplements that contain NDIs—defined as ingredients introduced after October 15, 1994, the effective date of DSHEA—are deemed adulterated unless the dietary supplement contains only known dietary ingredients which have been present in the food supply, have a history of use, or have other evidence establishing that the dietary ingredient is expected to be safe.⁴⁸ Dietary supplement manufacturers introducing an NDI into the market must notify the FDA, within seventy-five days of introducing the supplement into interstate commerce, the basis on which the manufacturer relied to conclude the NDI was reasonably expected to be safe.⁴⁹ The dietary supplement containing the NDI is deemed adulterated if such pre-market notification is not submitted to the FDA.⁵⁰

What the FDA cannot do is require testing of a dietary supplement before marketing to confirm it contains only those ingredients which it advertises.⁵¹ Manufacturers must affirm that they comply with dietary supplement safety standards prior to selling their products.⁵² This dearth of regulatory authority creates an opportunity for bad actors to supply consumers with tainted supplements with limited recourse.

Many, including the FDA itself, have cast doubt on the effectiveness of current recall and public notice measures. Research shows consumers continue to buy

⁴⁸ 21 U.S.C. § 350b(a).

⁴⁹ *New Dietary Ingredients in Dietary Supplements – Background for Industry*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/new-dietary-ingredients-dietary-supplements-background-industry>(last updated Feb. 09, 2023).

⁵⁰ *Id.*

⁵¹ *FDA 101: Dietary Supplements*, *supra* note 39.

⁵² *Id.*

products after voluntary recalls are issued.⁵³ One study found that of thirty-one products the FDA tested that contained ephedrine or amphetamine analogues, almost a third of them were still on the market *six years* after the FDA issued warning letters.⁵⁴ By contrast, only three percent of the products were voluntarily recalled by manufacturers following the FDA's warning letter.⁵⁵ Another study examining twenty-seven dietary supplements recalled from 2009 through 2012 found that two-thirds were still available for purchase post-recall.⁵⁶ Some of those supplements contained both the pharmaceutical ingredient the FDA identified, *plus others*.⁵⁷ Yet another study examined the prevalence of one supplement, Pai You Guo, recalled in 2010 because it contained the pharmaceutical ingredients sibutramine and phenolphthalein.⁵⁸ In this case, Cohen and his colleagues again found that voluntary recalls were ineffective; of all respondents, almost half did not even *start* using Pai You Guo until after it was recalled, and over six in ten continued purchasing it after a recall.⁵⁹ The FDA has warned consumers that after testing seventy products sold on popular e-commerce platforms Amazon, eBay, and Walmart.com, most contained undeclared pharmaceutical ingredients, including fluoxetine [Prozac], an

⁵³ Cohen et al., *Recalls, Availability and Content of Dietary Supplements Following FDA Warning Letters*, *supra* note 38; Pieter A. Cohen et al., *Prohibited Stimulants in Dietary Supplements After Enforcement Action by the US Food and Drug Administration*, 178 JAMA INTERNAL MED. 1721, 1721 (2018).

⁵⁴ Cohen et al., *Recalls, Availability and Content of Dietary Supplements Following FDA Warning Letters*, *supra* note 38.

⁵⁵ *Id.*

⁵⁶ Pieter A. Cohen et al., *Presence of Banned Drugs in Dietary Supplements Following FDA Recalls*, 312 JAMA 1691, 1691 (2014).

⁵⁷ *Id.*

⁵⁸ Pieter A. Cohen et al., *Use of a Pharmaceutically Adulterated Dietary Supplement, Pai You Guo, Among Brazilian-Born Women in the United States*, 27 J. GENERAL INTERNAL MED. 51, 51 (2014).

⁵⁹ *Id.* at 53.

antidepressant.⁶⁰ The Dr. Reade supplement that touted its “100% natural” ingredients and scientific formulation contained lorcaserin [Belviq], a weight-loss drug the manufacturer had voluntarily pulled from U.S. markets at the FDA’s request after testing showed negative psychiatric and memory effects.⁶¹ Without additional testing, consumers have no way of determining whether subsequent batches of the Dr. Reade weight loss supplement, or any other supplement, still contain banned ingredients.

The FDA admits that this post-market whack-a-mole is not particularly effective at stopping adulterated supplements from landing in consumers’ hands. In a consumer update on its website, the FDA states, “It is clear from the results of our decade of testing that retailers and distributors, including online marketplaces, do not effectively prevent these types of potentially harmful products from being sold to consumers.”⁶² Given that FDA’s reactive measures are ineffective, Congress must give the FDA the power it needs to act proactively.

III. THE NEED FOR LEGISLATIVE REFORM

The FDA’s lack of pre-market authority over dietary supplements has resulted in the introduction of harmful products into the stream of commerce.⁶³ Nationwide, over 23,000 emergency department visits per year are attributable to the use of

⁶⁰ *Weight Loss, Male Enhancement and Other Products Sold Online or in Stores May be Dangerous*, *supra* note 11.

⁶¹ *Public Notification: Dr. Reade Slim Sense contains hidden drug ingredient*, *supra* note 1.

⁶² *Tainted Sexual Enhancement Products*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/medication-health-fraud/tainted-sexual-enhancement-products> (last updated Nov. 21, 2022).

⁶³ Amy Hudson, et al., *A Review of the Toxicity of Compounds Found in Herbal Dietary Supplements*, 84 PLANTA MED. 613, 615 (2018).

dietary supplements.⁶⁴ Of those emergency department visits, 65.9% involved the consumption of herbal or complementary nutritional products.⁶⁵ Herbal and dietary supplements now account for 20% of hepatotoxicity cases in the United States, with incidence on the rise.⁶⁶ The greatest concern, however, is attributed to weight loss and energy supplements, which represented 71.8% of all supplement-related adverse events.⁶⁷

One of the most infamous dietary supplements to be removed from the market was DMAA (1,3-dimethylamylamine), an amphetamine derivative marketed for increased sports performance and weight loss.⁶⁸ In 2012, the FDA began issuing warning letters to several manufacturers of DMAA-containing products to cease manufacturing and sale after receiving over one-hundred reports of illnesses, including six deaths.⁶⁹ One of those manufacturers, USPlabs, sold the popular workout and weight loss supplements, Jack3d and OxyELITEPro.

Between February 2012 and February 2014, the FDA received 114 reports of adverse events involving the consumption of OxyELITEPro.⁷⁰ Out of the 114 adverse

⁶⁴ Andrew I. Geller, et al., *Emergency Department Visits for Adverse Events Related to Dietary Supplements* 373 NEW ENG. J. OF MED. 1531, 1533 (2015).

⁶⁵ *Id.* at 1535.

⁶⁶ Victor J. Navarro, et al., *Liver Injury from Liver and Herbal and Dietary Supplements* 65 AM. ASS'N. FOR THE STUDY OF LIVER DISEASES 363, 365 (2017).

⁶⁷ Geller, *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, *supra* note 64, at 1536.

⁶⁸ *DMAA in Products Marketed as Dietary Supplements*, FOOD & DRUG ADMIN. (Aug. 2018), <https://www.fda.gov/food/dietary-supplement-products-ingredients/dmaa-products-marketed-dietary-supplements>.

⁶⁹ Harris R. Liberman, et al., *Surveillance of the Armed Forces as a Sentinel System for Detecting Adverse Effects of Dietary Supplements in the General Population*, 21 PUB. HEALTH NUTRITION 882, 883 (2017).

⁷⁰ Karl C. Klontz, et al., *The Role of Adverse Event Reporting in the FDA Response to a Multistate Outbreak of Liver Disease Associated with a Dietary Supplement*, 130 SAGE 526, 529 (2015).

event reports received, 48% of OxyELITEPro consumers described signs and symptoms of liver damage.⁷¹ Of those, 60% were hospitalized and three underwent liver transplantation.⁷² The FDA issued warning letters to USPlabs, urging them to initiate a voluntary recall of their products.⁷³ In response to those warning letters, USPlabs replaced DMAA with aegeline, an NDI with a similar composition to DMAA, without notifying the FDA as required by law.⁷⁴ USPlabs introduced the aegeline-containing OxyELITEPro into the market and continued sell OxyELITEPro until USPlabs voluntarily removed it from the market in November 2013.⁷⁵

The high volume and severity of reports led to a multi-agency investigation spearheaded by the FDA and the Department of Justice (DOJ). In 2020, a federal court in Texas sentenced two former USPlabs executives to prison and ordered USPlabs to pay 4.7 million dollars in criminal forfeiture.⁷⁶ The two former USPlabs executives were found guilty of conspiracy to introduce misbranded food into interstate commerce after they imported substances into the United States from China with false and misleading labeling to avoid law enforcement and regulatory attention.⁷⁷

⁷¹ *Id.*

⁷² *Id.*

⁷³ Natasha Singer, Peter Lattman, *F.D.A. Sends Warning Letters to 10 Marketers of 'Workout Boosters'*, NEW YORK TIMES (April 27, 2012), <https://www.nytimes.com/2012/04/28/health/fda-sends-warning-letters-to-10-marketers-of-workout-boosters.html>.

⁷⁴ Klontz et al., *The Role of Adverse Event Reporting in the FDA Response to a Multistate Outbreak of Liver Disease Associated with a Dietary Supplement*, *supra* note 70 at 527.

⁷⁵ *Id.*

⁷⁶ News Release, U.S. DEP'T OF JUST., Two Individuals and Two Companies Sentenced in Scheme to Fraudulently Sell Popular Dietary Supplements (Oct. 15, 2020), <https://www.justice.gov/opa/pr/two-individuals-and-two-companies-sentenced-scheme-fraudulently-sell-popular-dietary>.

⁷⁷ *Id.*

Despite well-documented reports of harmful dietary supplements sold on US markets, Congress has been reluctant to introduce new legislation granting the FDA pre-market authority to ensure the safety of dietary supplements before they enter the market.⁷⁸ Antiquated legislation and congressional inaction have resulted in numerous calls for legislative reform by scholars, healthcare professionals, and industry officials.⁷⁹ Unsurprisingly, the dietary supplement industry argues that tighter control over the industry would frustrate innovation, delay the introduction of dietary supplements into the stream of commerce, and increase the cost to consumers.⁸⁰ Even if proven to be true, such claims should not outweigh the public's interest in ensuring dietary supplements on the market are safe.

IV. PROPOSAL

To achieve the FDA's goal of ensuring the safety of dietary supplements on the market, we call on Congress to grant the FDA the express statutory authority to regulate dietary supplements prior to entering the market. Specifically, the FDA should be able to require manufacturers to submit Supplement Labels to the FDA for pre-market review—this must include pre-market composition testing followed by post-market randomized composition testing performed by an authorized laboratory. The FDA must also be given express authority to swiftly remove adulterated dietary supplements from the market and to establish an excise tax on dietary supplements.

⁷⁸ Press Release, AM. MED. ASS'N, *AMA Policy Calls for Increased Regulation of Dietary Supplements* (Nov. 18, 2020), <https://www.ama-assn.org/press-center/press-releases/ama-policy-calls-increased-regulation-dietary-supplements>.

⁷⁹ *Id.*

⁸⁰ *Dietary Supplement Industry Argues 2016 Guidance Contrary to DSHEA*, NAT. PROD. INSIDER (Dec. 4, 2016), <https://www.naturalproductsinsider.com/regulatory/dietary-supplement-industry-argues-2016-guidance-contrary-dshea>.

Undoubtedly, this proposal will require resources and political will to implement. Nonetheless, public need and desire for greater oversight appears to be mounting⁸¹ as the FDA struggles to keep consumers safe from harmful dietary ingredients and adulterated products. In March 2023, the FDA launched a new Dietary Supplement Ingredient Directory, where it posts ingredients commonly found in dietary supplements that the FDA has previously warned consumers about, including links to those warnings.⁸² Moreover, the industry's seemingly exponential growth and real risk of harm provide sufficient justification for implementing greater controls. Despite the breadth of this proposal, it is necessary and overdue to promote safety within the dietary supplement industry.

A. Grant the FDA express regulatory pre-market authority

Under DSHEA, the FDA has limited power to regulate dietary supplements pre-market. DSHEA does not grant the FDA express authority to regulate the dietary supplement industry, which has hindered the FDA's ability to promulgate new rules.⁸³ In its current form, DSHEA restricts the FDA's power to regulate dietary supplements on the market unless the FDA can establish that they are unsafe, adulterated, mislabeled, or misbranded.⁸⁴ Specifically, the FDA needs express

⁸¹ *Stronger Federal Oversight of Dietary Supplements Will Protect Consumers From Unsafe Products*, PEW TRUSTS (Jan. 26, 2023), <https://www.pewtrusts.org/en/research-and-analysis/articles/2023/01/26/stronger-federal-oversight-of-dietary-supplements-will-protect-consumers-from-unsafe-products>.

⁸² *FDA Launches New Directory of Ingredients Used in Products Marketed as Dietary Supplements*, FOOD & DRUG ADMIN. (March 26, 2023), <https://www.fda.gov/food/cfsan-constituent-updates/fda-launches-new-directory-ingredients-used-products-marketed-dietary-supplements>.

⁸³ *FDA 101: Dietary Supplements*, *supra* note 39.

⁸⁴ Ilisa B. Bernstein, Karin L. Bolte, *Is My Patient Taking an Unsafe Dietary Supplement?*, 24 AM. MED. ASS'N J. ETHICS 390, 392 (2022).

authority to oversee and impose regulatory controls over the manufacturing, labeling, and distribution of dietary supplements prior to entering the market. Without express statutory authority, rules promulgated by the FDA are especially vulnerable to change with turnover in the prevailing political party during each political cycle.⁸⁵

Congress should also consider amending the FDCA provision on “new dietary ingredients”⁸⁶ to apply to all dietary supplements, not just those marketed after October 1994. Doing so will explicitly deem dietary supplements adulterated if they contain any dietary ingredients not “present in the food supply”⁸⁷—a distinction which clearly and unequivocally would put drug-laced supplements into the “adulterated” category. This amendment would place all dietary supplements squarely within the purview of FDA review at least seventy-five days prior to their entering the market.

B. Require preapproval of the Supplement Facts label

This Article proposes that Congress grant the FDA pre-market authority to review Supplement Facts labels. The FDA currently requires all dietary supplements to bear a label of its ingredients titled “Supplement Facts.”⁸⁸ In addition to dietary ingredients, “other ingredients”—“such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders”—must be listed below the label.⁸⁹ This statutory amendment would not only provide the FDA authority to review ingredient

⁸⁵ See Hank Schultz, *Supplement Groups Unite to Make Case Against Maryland ‘Diet Pills’ Bill*, NAT. PROD. INSIDER (Mar. 06, 2023), <https://www.naturalproductsinsider.com/regulatory/supplement-groups-unite-make-case-against-maryland-diet-pills-bill>.

⁸⁶ 21 U.S.C. § 350b.

⁸⁷ 21 U.S.C. § 350b(a)(1).

⁸⁸ 21 C.F.R. § 101.36 (2016).

⁸⁹ 21 C.F.R. § 101.4(g) (2016).

labels prior to their marketing, but it would also provide the FDA an avenue to catalogue all dietary supplements currently sold in the U.S.—a major gap in the FDA’s enforcement over the industry today, and one that the agency seems keen on closing, as evidenced by its FY 2024 budget proposal.⁹⁰

Both the Dietary Supplement Listing Act of 2022 and the dietary supplement-related provision of the FDA Safety and Landmark Advancements (FDASLA) Act of 2022, introduced in the Senate as part of the PDUFA reauthorization package, embraced a similar proposal.⁹¹ Generally, the policies would have required manufacturers to register their supplements with the FDA while disclosing the supplement’s name, ingredients, and health claims prior to marketing a product.⁹² With this information, the FDA could create a compendium of approved dietary supplements, akin to the Orange Book for approved drug products, to help consumers and industry officials identify safe dietary supplements and therapeutic doses. FDASLA would have also prohibited selling a product that does not meet the definition of a dietary supplement under 21 U.S.C. § 321.⁹³ Though PDUFA VII passed “clean”—without any policy amendments or riders⁹⁴—the mere consideration of two bills aimed at bolstering supplement regulation suggests that the requisite political will for greater industry oversight exists.

⁹⁰ *Summary of FY 2024 Legislative Proposals*, *supra* note 12.

⁹¹ FDASLA of 2022, S. 4348, 117th Cong. (2022).

⁹² Pieter A. Cohen et al., *Institutionalizing Misinformation—The Dietary Supplement Listing Act of 2022*, 387 NEW ENG. J. MED. 3, 3 (2022).

⁹³ FDASLA of 2022, S. 4348, 117th Cong. (2022).

⁹⁴ *Congress Set for Busy Lame Duck Session; To Take Up Expansive Set of Issues, Including Defense, Healthcare, Tax, and More*, JD SUPRA (Nov. 15, 2022), <https://www.jdsupra.com/legalnews/congress-set-for-busy-lame-duck-session-2661322/>.

C. Pre- and post-market composition testing requirements

Although dietary supplements are not considered pharmaceuticals, they more closely resemble drug products than food, which can trick consumers into believing supplements are regulated as tightly as drugs. However, unlike pharmaceuticals, dietary supplements do not undergo any composition testing.⁹⁵ As of mid-August 2023, the FDA had already issued twenty-four public notifications, warning consumers that several dietary supplements were tainted with undeclared drugs, including sildenafil [Viagra], tadalafil [Cialis], and sibutramine [Meridia].⁹⁶

It is unlikely that a more stringent labeling requirement would be sufficient to stop manufacturers from sneaking drug ingredients into dietary supplements—but requiring that the manufacturer submit evidence of supplement ingredients might. Thus, the FDA should require that manufacturers prove the composition of a supplement matches the ingredients listed on the Supplement Label, such that their products are safe for human consumption. Accordingly, we propose that Congress provide the FDA the authority to require manufacturers to submit their dietary supplements to composition testing—which would be conducted by an independent FDA-approved laboratory.

Our proposal would grant the FDA the authority to require dietary supplement manufacturers to submit to pre-market composition testing and post-market randomized composition testing. This new regulatory authority will be more effective

⁹⁵ *Questions and Answers*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements> (last updated Oct. 26, 2022).

⁹⁶ Health Fraud Product Database, FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/health-fraud-scams/health-fraud-product-database> (last updated May 11, 2023).

at deterring manufacturers from introducing hidden ingredients into their dietary supplements after their product has undergone pre-market composition testing and entered the market.

D. Express authority to remove harmful or adulterated dietary supplements

As discussed in Section II, the FDA lacks the authority to remove harmful or adulterated substances from the market unless the FDA can establish that the supplement is harmful or adulterated. DSHEA places the burden of proof on the FDA to show that a dietary supplement presents a significant or unreasonable risk of illness or injury before the FDA can prohibit the sale of a supplement.⁹⁷ DSHEA's voluntary-recall-first approach allows adulterated dietary supplements to remain available to consumers for extended periods of time, as depicted by the history of OxyELITEPro sales in the United States.

Instead, we would allow the FDA to bypass the voluntary recall step and mandate a product's removal from the market when the FDA's investigation finds that a dietary supplement contains prohibited or hidden dietary ingredients, is unsafe or ineffective, misbranded, or mislabeled. This proposal shifts the burden to the manufacturer to affirmatively prove their product is safe before it can be reintroduced into the market. By shifting the onus to dietary supplement manufacturers, the FDA can conserve limited financial and human resources. While the harms associated with non-pharmaceutical dietary ingredients might garner

⁹⁷ Rahi Azizi, "Supplementing" the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority Over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act, 98 CAL. L. REV. 439, 441 (2010).

significant debate and require extensive research, the presence of a pharmaceutical or banned ingredient in a dietary supplement—a category of food—and the potential harm caused by its presence is relatively clear. The FDA is tasked with ensuring the safety of food and drugs consumed in the United States; the agency needs stronger authority to assure consumers that their dietary supplements are not tainted with drugs.

E. Establish an excise tax

To help fund augmented FDA oversight of dietary supplements, Congress should consider establishing an excise tax on supplement manufacturers and distributors. Congress might consider modeling the excise tax after the Airport & Airway Trust Fund Act of 1970, which established the Airport and Airway Trust Fund (AATF) as the primary source of funding for the Federal Aviation Administration (FAA).⁹⁸ To replenish the trust fund, the Airport & Airway Trust Fund Act levies an excise tax on users of the National Airspace System.⁹⁹ The revenue collected from the excise tax is deposited into the AATF.¹⁰⁰

Similar to the Airport & Airway Trust Fund Act, we propose that Congress establish a trust fund and levy an excise tax on dietary supplement manufacturers and distributors. The proposed trust fund, the Dietary Supplement Trust Fund (DSTF), could act as the FDA's primary source of revenue for the regulation of dietary

⁹⁸ *Airport & Airway Trust Fund Act of 1970*, U.S. DEP'T OF TRANSP., <https://www.faa.gov/about/budget/aatf>.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

supplements and would generate most of the funds necessary to finance the FDA's operational costs of increased federal oversight over the dietary supplement industry.

Dietary supplement manufacturers may attempt to pass those costs on to consumers via higher prices for dietary supplements. Certain products with legitimate medical uses—such as prenatal vitamins or calcium/vitamin D supplements for osteoporosis—would be specifically exempted from tax-related price increases, especially when prescribed by a physician.

V. CONCLUSION

The dietary supplement industry has grown exponentially since the passage of DSHEA nearly thirty years ago. The boom of dietary supplements has left the FDA nearly powerless to regulate the industry, to the extent that the FDA has publicly acknowledged a need for greater authority. As this Article demonstrates, the FDA's current regulatory structure is insufficient to protect consumers from adulterated dietary supplements.

State legislators, too, are taking notice of the unwieldy nature of the dietary supplement industry. In New York, for example, Assemblywoman Nily Rozic and Senator Shelby Mayer sponsored Assembly and Senate bills, respectively, that would restrict the sale of dietary supplements labeled as weight-loss or muscle-building products to minors.¹⁰¹

¹⁰¹ S.Res. S5823C, 2023 Leg., Reg. Sess. (N.Y. 2023), <https://www.nysenate.gov/legislation/bills/2023/S5823>; Assemb. B. A5610A, 2023 Leg., Reg. Sess. (N.Y. 2023) <https://www.nysenate.gov/legislation/bills/2023/a5610/amendment/a>.

The FDA desperately needs the tools to regulate the dietary supplement industry, remove harmful or ineffective dietary supplements from the market, impose pre- and post-market requirements, and enhance labeling requirements. We suggest Congressional reforms to grant the FDA express authority to regulate dietary supplements and hold dietary supplement manufacturers accountable for adulterated, misbranded, or mislabeled dietary supplements. Our proposal offers Congress a blueprint for preventing the introduction of adulterated and mislabeled dietary supplements into the market. The important question now is one for consumers: is the public is willing to sacrifice unlimited access to dietary supplements in exchange for greater assurances of safety?