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Re-Regulating Dietary Supplements

Jessie L. Bekker,^{*} Alex Flores,^{**} & Michael S. Sinha^{***}

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, US 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 proven 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 requires tools to regulate the dietary supplement industry and remove harmful dietary

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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.

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 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 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 the 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

Nearly 58% 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

¹ *Pub. 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-reading-slim-sense-contains-hidden-drug-ingredient>.

² *Id.*

³ *See Warning Letter: HIS Enter. 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.* (emphasis added).

⁵ *See MISHRA SURUCHI ET AL., DIETARY SUPPLEMENT USE AMONG ADULTS: UNITED STATES, 2017-2018 399* (2021), <https://www.cdc.gov/nchs/products/databriefs/db399.htm#print>.

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, warnings from the FDA and independent researchers state that many supplements, sold under the guise of promoting weight loss and sexual enhancement, 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 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

⁶ See *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 See *id.*

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

⁹ See Jenna Tucker et al., *Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated With US Food and Drug Administration Warnings*, JAMA NETWORK, Oct. 12, 2018, at 4-5; see also *Public Notification: CHU Dietary Supplement Product Contains Hidden Drug Ingredients*, FOOD & DRUG ADMIN. (Oct. 9, 2019), <https://www.fda.gov/drugs/medication-health-fraud/public-notification-chu-dietary-supplement-product-contains-hidden-drug-ingredients>.

¹⁰ See *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 Sept. 8, 2023).

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 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 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 *Nutrilab, Inc. v. Schweiker*, issued 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,

¹¹ See *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 Legis. Proposals*, FOOD & DRUG ADMIN., <https://www.fda.gov/media/166049/download> (last visited Aug. 25, 2023).

¹³ *Id.*

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

¹⁵ See *id.* at 335.

¹⁶ See *id.* at 335-36.

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

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 its claims and assert that its claims are “truthful and not misleading.”²⁴ The requirement mirrors a ban against adulterated or misbranded dietary supplements.²⁵ 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

¹⁷ *Id.* at 337-38.

¹⁸ *Id.* at 338.

¹⁹ See Dietary Supplement Health & Educ. Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.).

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

²¹ See Dietary Supplement Health & Education Act, Pub. L. No. 103-417, Sec. 3, 108 Stat. 4327 (1994) (codified as § 21 U.S.C. § 321(ff)).

²² See Dietary Supplement Health & Education Act, Pub. L. No. 103-417, Sec. 8, 108 Stat. 4331, (1994) (codified as § 21 U.S.C. § 350(b)).

²³ See Lewis A. Grossman, *Food, Drugs, and Droids: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 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(6)(B).

²⁵ 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>.

held under unsanitary conditions.²⁶ However, a dietary supplement may also be deemed adulterated if it omits any material ingredient.²⁷ 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.²⁸

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.²⁹ Therefore, where a supplement contains an active pharmaceutical ingredient, it is transformed into an unapproved drug and subject to recall.³⁰ 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 direction, and under the supervision, of a licensed practitioner.”³¹ Dietary supplements, additionally, are misbranded if they do not list all ingredients or are “false or misleading.”³²

Once the FDA deems a dietary supplement adulterated or misbranded, DSHEA authorizes the FDA to take action against the manufacturer that introduced the supplements into the market.³³ Generally, the FDA’s first step is to issue a “Warning Letter” notifying the dietary supplement manufacturer that its product is adulterated or misbranded while urging a “voluntary recall.”³⁴ When the FDA requests a voluntary recall, the product remains available to

²⁶ See 21 U.S.C. §§ 342(a)(1)-(4), (C).

²⁷ See *id.* at § 342(b)(1).

²⁸ See U.S. GOV’T ACCOUNTABILITY OFF., GAO-09-250, *DIETARY SUPPLEMENTS: FDA SHOULD TAKE FURTHER ACTIONS TO IMPROVE OVERSIGHT AND CONSUMER UNDERSTANDING* 55 (2009).

²⁹ See 21 U.S.C. § 321(ff)(3)(B)(ii) (The Secretary has discretion to issue a regulation overriding this general rule).

³⁰ See, e.g., *Jongu 4308 Issues Voluntary Nationwide Recall of Hydro Pineapple Burn Due to the Presence of Undeclared Sibutramine*, U.S. 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>.

³¹ 21 U.S.C. § 352(f)(1); *Warning Letter: Anabolic Lab ’ys Inc.*, U.S. FOOD & DRUG ADMIN. (Nov. 14, 2022), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/anabolic-laboratories-inc-636308-11142022>.

³² 21 U.S.C. § 352(a), (s)(1)-(s)(2)(A)(i).

³³ See *Dietary Supplements*, U.S. Food & Drug Admin. (2023), <https://www.fda.gov/food/dietary-supplements>.

³⁴ Pieter A. Cohen, *The FDA and Adulterated Supplements—Dereliction of Duty*, JAMA NETWORK OPEN, Oct. 12, 2018, at 1.

consumers until the manufacturer complies. If the manufacturer complies with the request, the FDA publicizes the recall notice.³⁵

Even in the face of a voluntary recall, a bad actor could theoretically rebrand the same product or sell a subsequent, tainted batch.³⁶ 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.³⁷ 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, but only if the agency can establish that the dietary supplement is harmful.³⁸ Finally, the FDA can seize dietary supplements that are imported from international manufacturers or seek an injunction against manufacturers and distributors that violate the law.³⁹

Unlike pharmaceuticals, which must undergo clinical trials demonstrating their safety and effectiveness prior to FDA approval, dietary supplements are not required to demonstrate either.⁴⁰ DSHEA does not grant the FDA the authority to require pre-market approval for dietary supplements entering the market or to conduct post-market research studies that would corroborate the safety or effectiveness of the dietary supplement.⁴¹ In general, the FDA's authority is limited to post-market enforcement of DSHEA.⁴²

³⁵ *Id.*; Interestingly, the Recall Notice is published under “Drug” recalls rather than “Food” recalls on the FDA’s website. See *Recalls of Foods and Dietary Supplements*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/recalls-outbreaks-emergencies/recalls-foods-dietary-supplements> (last updated Jan. 25, 2022).

³⁶ See Pieter A. Cohen et al., *Recalls, Availability, and Content of Dietary Supplements Following FDA Warning Letters*, 328 JAMA NETWORK 393, 394 (2022).

³⁷ See *id.*

³⁸ See Charles M. White, *Dietary Supplements Pose Real Dangers to Patients*, 54 ANNALS OF PHARMACOTHERAPY 815, 815-17 (2020).

³⁹ See U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 28, at 55.

⁴⁰ See 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 Regul.*, 22 QUINNIPIAC HEALTH L. J. 171, 181 (2019).

⁴¹ See George Kennett, *Time for Change: Stepping up the FDA’s Regulation of Dietary Supplements to Promote Consumer Safety and Awareness*, 33 J.L. & HEALTH 47, 62 (2019); Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It’s Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 211-212 (2005).

⁴² See 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.⁴³ 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 that 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.⁴⁴ Dietary supplement manufacturers introducing an NDI into the market must notify the FDA, within seventy-five days of introducing the supplement into interstate commerce, of the basis on which the manufacturer relied to conclude the NDI was reasonably expected to be safe.⁴⁵ The dietary supplement containing the NDI is deemed adulterated if such pre-market notification is not submitted to the FDA.⁴⁶

What the FDA cannot do is require testing of a dietary supplement before marketing to confirm it contains only those ingredients that it advertises.⁴⁷ Manufacturers must affirm that they comply with dietary supplement safety standards prior to selling their products.⁴⁸ 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, cast doubt on the effectiveness of current recall and public notice measures. Research shows consumers continue to buy products after voluntary recalls are issued.⁴⁹ 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.⁵⁰ By contrast, only 3% of the products were voluntarily recalled by manufacturers following receipt of an FDA

⁴³ See *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).

⁴⁴ See 21 U.S.C. § 350b(a).

⁴⁵ See *New Dietary Ingredients in Dietary Supplements – Background for Industry*, *supra* note 43.

⁴⁶ See *id.*

⁴⁷ See FDA 101, FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements> (last updated June 2, 2022).

⁴⁸ See *id.*

⁴⁹ See Cohen, *supra* note 36; Pieter A. Cohen et al., *Prohibited Stimulants in Dietary Supplements After Enforcement Action by the US Food and Drug Admin.*, 178 JAMA NETWORK. 1721, 1721 (2018).

⁵⁰ See Cohen, *supra* note 36.

warning letter.⁵¹ Another study examining twenty-seven dietary supplements recalled from 2009 through 2012 found that two-thirds were still available for purchase post-recall.⁵² Some of those supplements contained both the pharmaceutical ingredient the FDA identified, *plus others*.⁵³ Yet another study examined the prevalence of one supplement, Pai You Guo, recalled in 2009 because it contained the pharmaceutical ingredients sibutramine and phenolphthalein.⁵⁴ Once again, voluntary recalls were deemed 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.⁵⁵

The FDA warned consumers, after testing seventy products sold on popular e-commerce platforms such as Amazon, eBay, and Walmart.com, that most products contained undeclared pharmaceutical ingredients, including fluoxetine [Prozac], an antidepressant.⁵⁶ The Dr. Reade supplement that touted its “100% natural” ingredients and scientific formulation contained lorcaserin [Belviq], a weight-loss drug the manufacturer voluntarily pulled from US markets at the FDA’s request after testing showed negative psychiatric and memory effects.⁵⁷ Without additional product and batch 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.”⁵⁸ Given that the FDA’s reactive measures

⁵¹ *See id.*

⁵² Pieter A. Cohen et al., *Presence of Banned Drugs in Dietary Supplements Following FDA Recalls*, 312 JAMA NETWORK 1691, 1691 (2014).

⁵³ *See id.*

⁵⁴ *See* 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).

⁵⁵ *See id.* at 53.

⁵⁶ *See Weight Loss, Male Enhancement and Other Products Sold Online or in Stores May be Dangerous*, *supra* note 11.

⁵⁷ *See Public Notification: Dr. Reade Slim Sense Contains Hidden Drug Ingredient*, *supra* note 1.

⁵⁸ *Tainted Sexual Enhancement Products*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/medication-health-fraud/tainted-sexual-enhancement-products> (last updated Aug. 22, 2023).

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.⁵⁹ Nationwide, over 23,000 emergency department visits per year are attributable to the use of dietary supplements.⁶⁰ Of those emergency department visits, 65.9% involved the consumption of herbal or complementary nutritional products.⁶¹ Herbal and dietary supplements now account for 20% of hepatotoxicity cases in the United States, with incidence on the rise.⁶² The greatest concern, however, is attributed to weight loss and energy supplements, which represented 71.8% of all supplement-related adverse events.⁶³

One of the most infamous dietary supplements removed from the market was DMAA (1,3-dimethylamylamine), an amphetamine derivative marketed as a tool to enhance sports performance and promote weight loss.⁶⁴ In 2012, the FDA issued warning letters to several manufacturers of DMAA-containing products to cease manufacture and sale after it received over one hundred reports of illnesses, including six deaths.⁶⁵ 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.⁶⁶ Out of the 114 adverse event reports received, 48%

⁵⁹ See Amy Hudson, et al., *A Review of the Toxicity of Compounds Found in Herbal Dietary Supplements*, 84 *PLANTA MEDICA* 613, 614-15, 625 (2018).

⁶⁰ See Andrew I. Geller, et al., *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, 373 *NEW ENG. J. MED.* 1531, 1533 (2015).

⁶¹ See *id.* at 1535.

⁶² See Victor J. Navarro, et al., *Liver Injury from Herbal and Dietary Supplements*, 65 *HEPATOLOGY* 363, 364-65 (2017).

⁶³ See Geller, *supra* note 60, at 1536.

⁶⁴ See *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>.

⁶⁵ See 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).

⁶⁶ See Karl C. Klontz et al., *The Role of Adverse Event Reporting in the FDA Response to a Multistate Outbreak of Liver Disease Assoc. 'ed with a Dietary Supplement*, 130 *PUB. HEALTH REP.* 526, 526 (2015).

of OxyELITEPro consumers described signs and symptoms of liver damage.⁶⁷ Of those, 60% were hospitalized and three underwent liver transplantation.⁶⁸ The FDA issued warning letters to USPlabs, urging them to initiate a voluntary recall of their products.⁶⁹ In response to those warning letters, USPlabs replaced DMAA with aegeline, an NDI with a similar composition to DMAA, failing to notify the FDA as required by law.⁷⁰ USPlabs introduced the aegeline-containing OxyELITEPro into the market and continued to sell OxyELITEPro until USPlabs voluntarily removed it from the market in November 2013.⁷¹

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 in criminal forfeiture.⁷² The two former USPlabs executives were found guilty of conspiracy to introduce misbranded food into interstate commerce after they imported substances into the US from China with false and misleading labeling to avoid law enforcement and regulatory attention.⁷³

Despite well-documented reports of harmful dietary supplements sold on US markets, Congress has been reluctant to introduce new legislation granting pre-market authority to the FDA to ensure the safety of dietary supplements before they become available to consumers.⁷⁴ Antiquated legislation and congressional inaction have resulted in numerous calls for legislative reform by scholars, health care professionals, and industry officials.⁷⁵ 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

⁶⁷ See *id.* at 529.

⁶⁸ See *id.*

⁶⁹ See Natasha Singer & Peter Lattman, *F.D.A. Sends Warning Letters to 10 Marketers of 'Workout Boosters'*, N.Y. TIMES, Apr. 12, 2012 (§ B), at 2.

⁷⁰ Klontz et al., *supra* note 66, at 527.

⁷¹ See *id.*

⁷² See *Two Individuals and Two Cos. Sent'ed in Scheme to Fraudulently Sell Popular Dietary Supplements*, U.S. DEP'T OF JUST. (Oct. 15, 2020), <https://www.justice.gov/opa/pr/two-individuals-and-two-companies-sentenced-scheme-fraudulently-sell-popular-dietary>.

⁷³ See *id.*

⁷⁴ See *AMA Policy Calls for Increased Regulation of Dietary Supplements*, AM. MED. ASS'N. (Nov. 18, 2020), <https://www.ama-assn.org/press-center/press-releases/ama-policy-calls-increased-regulation-dietary-supplements>.

⁷⁵ See *id.*

increase costs for consumers.⁷⁶ 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 available dietary supplements, 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.

Undoubtedly, this proposal will require resources and political will to implement. Nonetheless, public need and desire for greater oversight appears to be mounting⁷⁷ 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 about which the FDA previously warned consumers, including links to those warnings.⁷⁸ Moreover, the industry's seemingly exponential growth and real risk of harm provide sufficient justification for implementing greater controls.

⁷⁶ See *Dietary Supplement Indus. Argues 2016 Guidance Contrary to DSHEA*, NAT. PRODS. INSIDER (Dec. 4, 2016),

<https://www.naturalproductsinsider.com/supplement-regulations/dietary-supplement-industry-argues-2016-guidance-contrary-to-dshea>.

⁷⁷ See Kathy Talkington, *Stronger Fed. Oversight of Dietary Supplements Will Protect Consumers from Unsafe Prods.*, 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>.

⁷⁸ See *FDA Launches New Directory of Ingredients Used in Prods. Marketed as Dietary Supplements*, FOOD & DRUG ADMIN. (Mar. 26, 2023), <https://www.fda.gov/food/cfsan-constituent-updates/fda-launches-new-directory-ingredients-used-products-marketed-dietary-supplements>.

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 hinders the FDA's ability to promulgate new rules.⁷⁹ 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.⁸⁰ Specifically, the FDA needs express 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 each administration.

Congress should also consider amending the Food, Drug, and Cosmetics Act (FD&C Act) provision on “new dietary ingredients” to apply to all dietary supplements, not just those marketed after October 1994.⁸¹ Doing so will explicitly deem dietary supplements adulterated if they contain any dietary ingredients not “present in the food supply”—a distinction which clearly and unequivocally would put drug-laced supplements into the “adulterated” category.⁸² This amendment would place nearly 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.”⁸³ In addition to dietary ingredients, “other ingredients”—“such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders”—must be listed below the label.⁸⁴ The proposed statutory amendment would not only provide the FDA authority to review ingredient labels prior to their marketing, but it would also provide the FDA an avenue to

⁷⁹ See *FDA 101: Dietary Supplements*, *supra* note 47.

⁸⁰ See Ilisa B. Bernstein & Karin L. Bolte, *Is My Patient Taking an Unsafe Dietary Supplement?*, 24 AM. MED. ASS'N J. ETHICS 390, 392 (2022).

⁸¹ 21 U.S.C. § 350b.

⁸² 21 U.S.C. § 350b(a)(1).

⁸³ 21 C.F.R. § 101.36 (2016).

⁸⁴ 21 C.F.R. § 101.4(g) (2016).

catalogue all dietary supplements currently sold in the US—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.⁸⁵

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 Prescription Drug User Fee Act (PDUFA) reauthorization package, embraced a similar proposal.⁸⁶ Generally, the policies required manufacturers to register their supplements with the FDA, disclosing the supplement’s name, ingredients, and health claims prior to marketing a product.⁸⁷ 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. § 321.⁸⁸ Though PDUFA VII passed “clean”—without any policy amendments or riders⁸⁹—the mere consideration of two bills aimed at bolstering supplement regulation suggests that the requisite political will for greater industry oversight exists.

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.⁹⁰ As of mid-August 2023, the FDA issued twenty-four public notifications, warning consumers that several dietary supplements were tainted

⁸⁵ See *Summary of FY 2024 Legislative Proposals*, *supra* note 12.

⁸⁶ See FDASLA Act of 2022, S. 4348, 117th Cong. (2022).

⁸⁷ See Pieter A. Cohen et al., *Institutionalizing Misinformation—The Dietary Supplement Listing Act of 2022*, 387 NEW ENG. J. MED. 3, 3 (2022).

⁸⁸ See FDASLA of 2022, S. 4348, 117th Cong. (2022).

⁸⁹ Nicholas Choate, et al., *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/>.

⁹⁰ See *Questions and Answers*, FOOD & DRUG ADMIN. (Oct. 26, 2022), <https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements>.

with undeclared drugs, including sildenafil [Viagra], tadalafil [Cialis], and sibutramine [Meridia].⁹¹

It is unlikely that a more stringent labeling requirement would be sufficient to stop manufacturers from sneaking drug ingredients into dietary supplements after entering the market, but requiring manufacturers to submit evidence of supplement ingredients might. Thus, the FDA should require manufacturers to prove the composition of their supplement matches the ingredients listed on the Supplement Label, such that their products are safe for human consumption. 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-registered laboratory.

Our proposal grants authority to the FDA to require that all dietary supplement manufacturers submit products for pre-market composition testing and post-market randomized composition testing. This new regulatory authority will be more effective 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 of this Article, 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.⁹² DSHEA's voluntary-recall-first approach allows adulterated dietary supplements to remain available to consumers for extended periods of time while presenting a safety risk, as evidenced by the history of OxyELITEPro sales in the United States.

Instead, this proposal would allow the FDA to bypass the voluntary recall step and mandate a product's removal from the

⁹¹ See *Health Fraud Product Database*, FOOD & DRUG ADMIN. (May 11, 2023), <https://www.fda.gov/consumers/health-fraud-scams/health-fraud-product-database>.

⁹² Rahi Azizi, "Supplementing" the DSHEA: Congress Must Invest the FDA with Greater Regul. Auth. Over Nutraceutical Mfrs. by Amending the Dietary Supplement Health and Education Act, 98 CAL. L. REV. 439, 441 (2010).

market when the FDA's investigation finds that a dietary supplement contains prohibited or hidden dietary ingredients, is unsafe, or is misbranded or mislabeled. This proposal shifts the burden to the manufacturer to affirmatively prove its product is safe before it can be reintroduced into the market. By shifting the onus to manufacturers, the FDA can conserve limited financial and human resources. While the harms associated with non-pharmaceutical dietary ingredients might garner 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 & Airway Trust Fund (AATF) as the primary source of funding for the Federal Aviation Administration (FAA).⁹³ To replenish the trust fund, the Act levies an excise tax on users of the National Airspace System.⁹⁴ The revenue collected from the excise tax is deposited into the AATF.⁹⁵

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

We recognize dietary supplement manufacturers may attempt to pass those costs on to consumers via higher prices. To avoid unintended consequences, particularly disparate access, dietary supplements with legitimate medical uses—such as prenatal vitamins

⁹³ *Airport & Airway Trust Fund Act of 1970*, U.S. DEP'T OF TRANSP. (Feb. 21, 2023), <https://www.faa.gov/about/budget/aatf>.

⁹⁴ *See id.*

⁹⁵ *See id.*

or calcium/vitamin D supplements—should be exempted from tax-related price increases.

V. Conclusion

The dietary supplement industry has grown exponentially since the passage of DSHEA nearly thirty years ago. The industry's boom, however, has left the FDA nearly powerless to regulate the industry—to the extent that the FDA 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.⁹⁶

The FDA urgently 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 whether consumers are willing to sacrifice unfettered access to dietary supplements in exchange for greater assurances of safety.

⁹⁶ See S. Res. S5823C, 2023 Leg., Reg. Sess. (N.Y. 2023), <https://www.nysenate.gov/legislation/bills/2023/S5823>; Assemb. A5610A, 2023 Leg., Reg. Sess. (N.Y. 2023), <https://www.nysenate.gov/legislation/bills/2023/a5610/amendment/a>.