Note

150 Years of Detox: How Inadequate Dietary Supplement Regulation Undermines Consumer Safety in the Weight Loss Industry

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Prior to the passage of the Pure Food and Drug Act of 1906, the American food and drug market was a proverbial "wild west," fraught with charlatans, snake oil salesmen, and manufacturers cutting costs at the expense of consumers. The Pure Food and Drug Act, along with the Food, Drug, and Cosmetics Act of 1938 took steps to address this problem, creating the modern food and drug regulatory scheme. While American food and drugs are markedly safer now than they were 150 years ago, the Dietary Supplement Health and Education Act of 1994 has prevented dietary supplement safety from keeping pace. A number of consumer crises over the past thirty years—particularly the ephedrine alkaloid crisis—demonstrate that the current dietary supplement regulatory scheme does not adequately protect consumers. This Note details the history of why dietary supplements are regulated as foods. This Note then parallels the current dietary supplement trend of weight loss and detox teas with the ephedrine alkaloid crises to demonstrate the dangers of lax safety regulations. Finally, this Note argues that the Dietary Supplement Health and Education Act obstructs the Food and Drug Administration's ability to protect American consumers,

* Articles Editor, *Minnesota Law Review*, Vol. 109; J.D. Candidate 2025, University of Minnesota Law School. My sincerest thanks to Professor Nadia Anguiano for her advice, feedback, and mentorship in the development of this Note and throughout my law school experience. Thank you to the staffers and editors of the *Minnesota Law Review* for their feedback and cite-checking efforts. I also want to extend my gratitude to my mother Jody, for being my first and favorite editor, and to my father Ross for his constant encouragement. My greatest thanks go to my husband, Mazen, for being my best friend, my unwavering support, and my biggest cheerleader. And finally, thank you to my dog Henry for being the best research assistant anyone could ask for.

contravenes the original purpose of food and drug regulation, and must be updated to effectuate these goals.

INTRODUCTION

"Get the boost you need to jumpstart your diet and get your skinny on."[1] "Reduce bloating[,] . . . speed metabolism, feelings of energy, and decrease gas."[2] "[F]eeling bloated and sluggish lately? Our Cleanse tea is just what you need!"[3] "Detox around-the-clock."[4] "Fuel your weight loss journey."[5] These claims are a small sampling of the bombardment consumers face if they venture into the tea aisle of most grocery stores. With names like "Detox Green,"[6] "Peach DeTox,"[7] "EveryDay Detox Lemon Tea,"[8] "Get Lean,"[9] and "Get Burning,"[10] in large, flashy letters, a reasonable consumer would be forgiven for overlooking the small print included on each product: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[11]

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1. *Skinny Boost Evening Detox Tea-14 Bags Total, Supports Detox and Cleanse, Reduce Bloating, 100% All Natural, Vegan, Non GMO*, WALMART, https://www.walmart.com/ip/Skinny-Boost-Evening-Detox-Tea-14-Tea-Bags-Total-Supports-Detox-and-Cleanse-Reduce-Bloating-100-All-Natural-Vegan-Non-GMO/492400174 (hover over the thumbnail showing an image of the back of the packaging) [https://perma.cc/8REQ-VAD7].

2. *Flat Tummy Tea*, FLAT TUMMY, https://flattummyco.com/products/flattummytea (click "Product Benefits") [https://perma.cc/K482-6ESF].

3. *Hey Girl Detox Tea Mint Chocolate - Colon Cleanse Herbal Detox Tea for Natural Body Cleansing - Caffeine-Free Chocomint Flavor - 20 Tea Bags*, WALMART, https://www.walmart.com/ip/Hey-Girl-Detox-Tea-Mint-Chocolate-Colon-Cleanse-Herbal-Detox-Tea-for-Natural-Body-Cleansing-Caffeine-Free-Chocomint-Flavor-20-Tea-Bags/816455578 [https://perma.cc/7PRW-PZUY].

4. *24/7 Day & Night Detox*, SKINNYFIT, https://skinnyfit.com/products/day-night-detox-bundle [https://perma.cc/77AE-LQR9].

5. *Get Lost® Stackable Tea Tin*, THE REPUBLIC OF TEA, https://www.republicoftea.com/get-lost-stackable-tea-tin/p/v20315 [https://perma.cc/FT8Q-7UZ8].

6. *Organic Detox Green SuperGreen Tea Bags*, THE REPUBLIC OF TEA, https://www.republicoftea.com/organic-matcha-green-tea-cleansing/p/v20458 [https://perma.cc/R5PF-2284].

7. *Peach DeTox Tea (16 Tea Bags)*, THE VITAMIN SHOPPE, https://www.vitaminshoppe.com/p/yogi-tea-peach-detox-cleansing-tonic-16-bag/yt-1021 [https://perma.cc/K79D-HWH2].

8. *EveryDay Detox® Lemon Tea*, TRADITIONAL MEDICINALS, https://www.traditionalmedicinals.com/products/everyday-detox-lemon-tea [https://perma.cc/LUW6-Z664].

9. *See Get Lost® Stackable Tea Tin*, *supra* note 5.

10. *Id.*

11. 21 C.F.R. § 101.93(c)(1) (2024); *see* Roseann B. Termini & Vincent A. Sannuti, *A Look Back at the DSHEA—Over 25 Years Later: The Dangers of a*

This disclaimer, while nominally warning consumers about weight loss and detox teas' lack of efficacy testing, obscures the full picture of shortcomings in dietary supplement regulation. Like all food products, dietary supplement packaging must include a list of all ingredients contained in the supplement.[12] The lack of any further disclaimers or warnings on the packaging suggests to consumers that while the tea may not have been tested for efficacy, it's at least as safe as any other food.[13] This is not always the case.[14]

Common ingredients of weight loss and detox teas can have potentially harmful effects. Licorice can cause hypertension.[15] Red clover may interact with hormonal medications like those used for treating osteoporosis and breast cancer.[16] Burdock root,[17] nettle leaf,[18] and dandelion[19] all have diuretic effects, meaning they increase urine output which can lead to

Reactionary Approach to Dietary Supplement Regulation, 22 QUINNIPIAC HEALTH L.J. 171, 175–76 (2019) ("Research shows that consumers more often associate dietary supplements with drugs rather than food. Therefore, they assume that supplements are regulated similar to the way drugs are regulated.").

12. *See* 21 C.F.R. § 101.36(c)(2) (2024). Common weight loss and detox tea ingredients include licorice, red clover, burdock root, nettle leaf, and dandelion. See, for example, ingredients of the products listed *supra* notes 1–9.

13. *See* Press Release, Council for Responsible Nutrition, CRN Reveals Survey Data from 2022 Consumer Survey on Dietary Supplements (Oct. 13, 2022), https://www.crnusa.org/newsroom/crn-reveals-survey-data-2022-consumer-survey-dietary-supplements [https://perma.cc/BCY8-TJXM] ("Trust in the dietary supplement industry also remains high. More than three-quarters of Americans (77%) find the industry trustworthy.").

14. *See* Termini & Sannuti, *supra* note 11, at 176 ("Consumers should expect a dietary supplement placed in a marketplace to be safe. However, this is not always the reality.").

15. Mikkel R. Deutch et al., *Bioactive Candy: Effects of Licorice on the Cardiovascular System*, FOODS, Oct. 2019, at 1, 3.

16. Anubhuti Tripathi et al., *Effect of Red Clover on CYP Expression: An Investigation of Herb-Drug Interaction at Molecular Level*, 76 INDIAN J. PHARM. SCIS. 261, 262 (2014).

17. Ie. V. Gladukh & Seguy Anael Marcelle, *The Study of Pharmacotechnological Parameters of Burdock (Arctium Lappa) Leaves*, 8 J. CHEM. & PHARM. RSCH. 260, 261 (2016).

18. Khuma Kumari Bhusal et al., *Nutritional and Pharmacological Importance of Stinging Nettle (Urtica Dioica L.): A Review*, HELIYON, June 2022, at 1, 5.

19. I. Hook et al., *Evaluation of Dandelion for Diuretic Activity and Variation in Potassium Content*, 31 INT'L J. PHARMACOGNOSY 29, 29 (1993).

dehydration.[20] None of these potential safety concerns from ingredients are referenced on the teas' packaging,[21] nor do regulations require recommended limits for daily intake.[22] An interested consumer would not only have difficulty finding readily available information about the risks and safe doses of the teas' ingredients,[23] but may also find it nearly impossible to determine the amount of each ingredient in any given product.[24] The Dietary Supplement Health and Education Act of 1994 (DSHEA) empowers manufacturers to shroud the effects, safety, recommended doses, and actual amount of any ingredient in a weight loss or detox tea from consumers by failing to require this information be disclosed on packaging or even be made available to consumers.[25]

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20. *Diuretics*, CLEVELAND CLINIC (last updated Oct. 1, 2021), https://my.clevelandclinic.org/health/treatments/21826-diuretics [https://perma.cc/7AP6-R8ND] (listing the risks and complications of diuretics, including dehydration).

21. *See supra* notes 1–9.

22. *See* 21 C.F.R. § 101.36(b)(2) (2024) (requiring that only ingredients with an established Reference Daily Intake or Daily Reference Value list the percent of the recommended daily intake of the ingredient on product packaging).

23. *See* Debra D. Burke & Anderson P. Page, *Regulating the Dietary Supplements Industry: Something Still Needs to Change*, 1 HASTINGS BUS. L.J. 119, 128 (2005) ("[T]he statutory presumption under DSHEA [is] that supplements are safe, which shifts the burden to prove otherwise to the government. . . . As a result, a dietary supplement . . . is presumed safe and unabashedly marketed as being effective by its manufacturer without the need to supply proof of such claims."); Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 207 (2009) ("Currently, there is a high level of scientific uncertainty over the safety and effectiveness of the vast majority of supplements, including those marketed for weight loss.").

24. *See* 21 C.F.R. § 101.36(c)(3) (2024) (stating that the individual weights of the component ingredients in a "proprietary blend" do not need to be listed on a product's packaging, only the total weight of the proprietary blend). Weight loss and detox teas frequently contain proprietary blends. See, for example, the products listed *supra* notes 1–2, 5–8.

25. *See infra* Part II.A; Kelly Ann Kaczka, Comment, *From Herbal Prozac to Mark McGwire's Tonic: How the Dietary Supplement Health and Education Act Changed the Regulatory Landscape for Health Products*, 16 J. CONTEMP. HEALTH L. & POL'Y 463, 488 (2000) ("Manufacturers are responsible for providing information to support their claims [of a reasonable likelihood of safety] and need not *prove* safety or effectiveness [of dietary supplements]. Instead, under DSHEA, the FDA bears the burden of proving the products are unsafe.") (emphasis added); Van Tassel *supra* note 23, at 241–42 ("[B]y virtue of the FDA's interpretation of DSHEA, weight loss supplements can now be placed directly

Dietary supplements are an enormously profitable industry. Global sales in 2020 topped $220 billion, with experts predicting this number will likely rise to $300 billion by 2028.[26] Consumer demand for dietary supplements, particularly those connected to weight loss, is not a new phenomenon,[27] nor is their potential for profitability. The predecessor industry to dietary supplements, "patent medicine," made an estimated $74.5 million over a century ago and was the largest advertiser in the country at the time.[28]

While consumer safety and information measures have drastically improved since the late nineteenth century, the dietary supplements of today share some startling similarities with the patent medicines of over 150 years ago.[29] "Purge then, ye wise . . . before your sickness is too far advanced" exclaimed an advertisement from the late-1800s selling Brandreth's Universal Vegetable Pills, meant to rid the body of "evil forces that might upset the digestion and render the blood impure."[30] A 2023 product description for "Get Clean" herbal tea asks: "Had too much of a good thing? Feeling out of balance, a bit heavy or puffy? Then it's time to get clean. . . . [The ingredients'] cleansing properties encourage healthy digestion and help to keep the kidneys flushed."[31] While the modern product description may lack the dire tone of its predecessor, both rely on the same notion of a need to "detox" the body. Additionally, neither product was subject to mandatory safety testing prior to being introduced to the

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on the market without any testing or premarket approval under a completely unsupported presumption of safety.").

26. Ouarda Djaoudene et al., *A Global Overview of Dietary Supplements: Regulation, Market Trends, Usage During the COVID-19 Pandemic, and Health Effects*, NUTRIENTS, July 2023, at 1–2.

27. *See infra* Part I.A.

28. JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION 110 (1961); Van Tassel, *supra* note 23, at 219. In 1904, $74.5 million had approximately the same purchasing power as $2.57 billion in 2024. *CPI Inflation Calculator*, https://www.officialdata.org/us/inflation/1904?amount=74500000 [https://perma.cc/J72X-NB6K].

29. *See infra* Part I.A.

30. YOUNG, *supra* note 28, at 79–80.

31. *Get Clean® - Herb Tea for Detoxing*, THE REPUBLIC OF TEA, https://www.republicoftea.com/get-clean-herb-tea-for-detoxing/p/v00731 [https://perma.cc/7FVS-HA3Q].

market.[32] Modern dietary supplements, unlike their nineteenth century counterparts, must disclose their constituent ingredients,[33] but they are not required to disclose how much of most ingredients are included in the product nor must they establish a safe daily limit for those ingredients.[34]

Dietary supplements are categorized as foods, which places them in a regulatory gray area resulting in a lack of safety testing and readily accessible ingredient information.[35] Because they are categorized as a food subsidiary, manufacturers are not required to include any warnings on product packaging besides an efficacy disclaimer,[36] leading consumers to regard dietary supplements as being safer than drugs.[37] This mismatch of consumer safety expectations and reality raises two questions: Why are dietary supplements regulated as foods? And are current dietary supplement regulations adequate to protect consumer safety?

This Note details the history of why dietary supplements are regulated as foods and concludes that the current regulations are inadequate to protect consumers. By examining the current trend in weight loss and detox teas through a historical lens, this Note will argue that the DSHEA obstructs the Food and Drug Administration's (FDA) ability to protect American consumers, contravenes the original purpose of food and drug regulation, and must be updated to effectuate these goals.

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32. *See* Van Tassel, *supra* note 23, at 219 ("Operating in an area almost completely devoid of regulation, vast fortunes were made as the quack medicine man was free to prey on the desperate and vulnerable."); YOUNG, *supra* note 28, at 76–77 (detailing how Brandreth's family made and sold his Vegetable Universal Pills out of their home); Burke & Page, *supra* note 23, at 130 ("[T]he statutory presumption under DSHEA that supplements are safe . . . shifts the burden to prove otherwise to the government.").

33. 21 C.F.R. § 101.36(c)(1) (2024).

34. *Id.* § 101.36(c)(3) ("The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend and shall be placed on the same line to the right of the term 'Proprietary Blend' or other appropriately descriptive term or fanciful name . . . ."); *see infra* Part II.A.

35. *See infra* Part II.A.

36. *See infra* Part II.A.

37. *See* Aarika Nieto, Comment, *Supplementing DSHEA One Step at a Time: The FDA's Modernization Plan*, 70 DEPAUL L. REV. 115, 118 (2020) ("[T]he assumption [is] that because dietary supplements are not considered 'drugs,' they are risk-free . . . ."); Press Release, Council for Responsible Nutrition, *supra* note 13.

Part I of this Note will explore the history of patent medicine and the creation of "dietary supplements" as a regulatory category. It will provide an overview of major food and drug legislation, from the Pure Food and Drugs Act of 1906 to the DSHEA. It will also analyze the market conditions precipitating each change in the regulatory scheme, with particular focus on the shifting of the burden to prove product safety from manufacturers to the FDA.

Part II of this Note will survey the effects and pitfalls of contemporary food and drug law on the dietary supplement market. First, Part II will focus on untangling the current web of dietary supplement regulation. Second, Part II will examine a recent major consumer safety failure in dietary supplement regulation and how little has changed in the regulatory scheme since that failure.

Part III will propose a solution to the ineffective "safe until proven unsafe" model of dietary supplement regulation to realign the regulations with their original purpose of protecting consumers. This Part will discuss the differences in regulations between vitamin/mineral and herbal/botanical supplements, and it will suggest new regulations to close the consumer information gap between these categories. Part III will then argue that new dietary supplement ingredients should be subject to pre-market safety—but not efficacy—testing and that Recommended Daily Intake (RDI) values should be established for all dietary ingredients. Finally, Part III will propose strengthening the FDA's powers to remove unsafe products from the market and categorically ban dangerous ingredients.

I. THE HISTORY OF UNSAFE AND INEFFECTIVE "MEDICINES" AND EARLY CONSUMER PROTECTIONS

"Safety regulations are written in blood" is a common aphorism often associated with Occupational Safety and Health Administration (OSHA) regulations.[38] This statement, which encapsulates the idea that every safety regulation is precipitated by an accident or injury, also holds true for many food and drug regulations.[39] In order to understand the current regulatory framework governing dietary supplements and why it does not adequately protect consumers, it is essential to first examine why the regulations were created in the first place. The history of the food and drug industry in the United States is fraught with charlatans, snake oil salesmen, and manufacturers cutting costs at the expense of consumers.[40]

This Part places the current regulation (or lack thereof) of dietary supplements within its historical context to demonstrate that while much has changed over the past 150 years, consumers are still at risk of harm from the products they ingest. Section A surveys the predecessor industry to dietary supplements—patent medicines—and details the safety and efficacy problems faced by their nineteenth century consumers. Section B details the path to creating the nation's first food and drug regulations, which markedly increased consumer safety but left plenty of loopholes for the emerging dietary supplement industry to squeeze through. As this Part will demonstrate, food and drug

38. *See Safety Standards Slide as OSHA Guts Workplace Injury Tracking*, INT'L BHD. OF ELEC. WORKERS (Feb. 8, 2019), https://ibew.org/media-center/Articles/19Daily/1902/190208_Safety [https://perma.cc/W6N6-ADP4]; *Workplace Hazards: 'All Those Regulations Are Written in Blood'*, UC SAN DIEGO EXTENDED STUD. (May 9, 2014), https://extendedstudies.ucsd.edu/news-and-events/division-of-extended-studies-blog/may-2014/workplace-hazards-all-those-regulations-are-written-in-blood [https://perma.cc/K8VM-X2KK]; Michael Punke, *Written with the Blood of Miners*, OHIO ST. UNIV.: ORIGINS (June 2006), https://origins.osu.edu/history-news/written-blood-miners?language_content_entity=en [https://perma.cc/4VKU-A3YY].

39. *See infra* Part I.B.

40. *See generally* JAMES HARVEY YOUNG, THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN TWENTIETH-CENTURY AMERICA (1967) (examining historical examples of false drug advertisement in the United States); AM. MED. ASS'N, NOSTRUMS AND QUACKERY (2d ed., 1912) (detailing the problem of fraudulent medicine from a contemporary perspective).

regulations are indeed written in the blood—and bile[41]—of the American consumer.

A. PATENT MEDICINE AND SNAKE OIL SALESMEN

The United States has a long history of snake oil salesmen[42] peddling miracle cures, stemming from the English tradition of "patent" medicine.[43] English patent medicines slowly made their way to the American colonies throughout the early to mid-1700s.[44] A patent or "proprietary" medicine was simply a compound sold under a patented name; the actual compound was not patented because that would require the manufacturer to disclose its formula.[45]

One popular variety of patent medicine in the 1800s was the purgative.[46] Although most purgative patent medicines were laxatives, some were used to induce vomiting.[47] Laxatives were commonly used by doctors to cure the "almost universal prevalence of indigestion,"[48] but they were also widely used by the

41. *See infra* notes 46–58 and accompanying text (describing the historical use of purgatives).

42. *Snake Oil*, CAMBRIDGE DICTIONARY, https://dictionary.cambridge.org/us/dictionary/english/snake-oil [https://perma.cc/7XR6-EMBE] (defining snake oil as "a substance that is sold as a medicine but that is not at all effective and may be harmful"). A snake oil salesman is a person that sells snake oil.

43. *See generally* YOUNG, *supra* note 28, at 3–15 (describing the emergence of patent medicines in England).

44. *Id.* at 9. Popular English remedies like "Daffy's Elixir Salutis" gained steady traction through the mid-1700s. *Id.* at 7–8. The interruption in trade caused by the Revolutionary War provided the push American patent medicines needed to come into their own. *Id.* at 14.

45. Carrie Scrufari James, *FDA's Homeopathic Risk-Based Enforcement: Compromised Consumer Protection or Stepped-Up Scrutiny?*, 70 SYRACUSE L. REV. 1115, 1122 (2020) ("The phrase 'patent medicine' is misleading because the United States Patent Office did not regulate these products (such regulations would have required manufacturers to disclose their formulas, which they were loath to do). Manufacturers merely registered their trade names with the United States Patent Office, thereby preventing other snake oil salesmen from appropriating them.").

46. *See* YOUNG, *supra* note 28, at 78 ("Purges of various potencies were a popular prescription by regular physicians . . . . There were scores of remedies on the market 'whose chief mission,' as a pharmacist saw it, 'appear[ed] to be to open men's purses by opening their bowels.'").

47. *See id.* at 47. A famous example of this is Samuel Thomson's promotion of a mixture of lobelia, bay berry, cayenne pepper, and forty-proof brandy. *Id.*

48. *Id.* at 78.

general populace to cure a variety of other ailments.[49] The primary theory behind their use was that all illness was caused by impurities in the body, which had to be expelled to restore health.[50] The notion that impurities in the body were caused by environmental factors such as "bad food . . . grief . . . overwork, anxiety, impure water, [and] contagion"[51] was particularly effective with American consumers due to their growing reputation for having an unhealthy lifestyle.[52]

One purgative creator who capitalized on consumers' worries regarding their poor health was Benjamin Brandreth.[53] His Universal Vegetable Pills were comprised of sarsaparilla, aloe, gamboge, and colocynth—all ingredients with laxative properties.[54] Brandreth touted his Pills in grandiose language, stating "pergation" could prevent most premature deaths.[55] Brandreth's Pills spread across the country, aided by his 224-page treatise on the benefits of purgation[56] and the nearly $100,000 he spent on advertising in a single year.[57] Targeting the nation's interest in ridding the body of impurities served Brandreth well, with his

49. *See id.* at 79 (stating purgatives were used to cure "pleurisies, consumptions, dropsies, rheumatism, blotches, plagues, fevers, 'great nervousness and debility, accompanied with anxiety and dread that some sad event is about to occur'").

50. *See id*. at 79 ("[A]ll disease had but one cause. This was 'an alteration or vitiation of the blood.' Many were the evil forces that might upset the digestion and render the blood impure . . . . If the pollutions and decompositions could be gotten rid of with sufficient speed through [purgation], life went on and man was healthy.").

51. *Id.* at 79.

52. *See id*. at 77–78 ("Over-eating was a national scandal, as foreign visitors to the nation kept repeating . . . Americans also ate too fast. The national motto, one European traveler said, was 'gobble, gulp, and go.'").

53. *Id.* at 78.

54. *Id.*

55. *Id.* at 79 ("Premature death in nine hundreds and ninety nine [sic] cases out of a thousand is the consequence of disease being allowed to progress unchecked in the body, whereas by timely *pergation* [sic] it might have been successfully nipped in the bud, and finally removed.").

56. *Id.* at 80.

57. H.R. REP. NO. 30-52, at 31 (1849) ("The annual fee for publishing Brandreth's pills has amounted to one hundred thousand dollars."). In 1849, $100,000 had approximately the same purchasing power as $4.1 million in 2024. *CPI Inflation Calculator*, https://www.officialdata.org/us/inflation/1849?amount=100000 [https://perma.cc/E35E-D4RW].

business averaging $600,000 per year in sales between 1862 and 1883.[58]

Brandreth was far from the only commercial success story in patent medicine. From "Doctor Hostetter Celebrated Stomachic Bitters Tonic"[59] to the best-selling "Swaim's Panacea,"[60] the American patent medicine industry boomed into the late-1800s.[61] The creator of "Hamlin's Wizard Oil," promising a cure for rheumatism, used a portion of the fortune he made from the product to build Chicago's Grand Opera House.[62]

While many of these "cures" didn't do what they purported to, and many contained actual poison,[63] their sale continued. It was not concern about the safety of these patent medicines but rather an outcry over the lack of hygiene in the American food market that finally led to the creation of the first food and drug regulations.[64]

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58. YOUNG, *supra* note 28, at 88. In 1862, $600,000 had approximately the same purchasing power as $18.8 million in 2024. *CPI Inflation Calculator*, https://www.officialdata.org/us/inflation/1862?amount=600000 [https://perma.cc/J4YQ-P9SB].

59. YOUNG, *supra* note 28, at 126.

60. *Id.* at 62; Van Tassel, *supra* note 23, at 219 ("Swaim's Panacea claimed to cure 'cancer, scrofula, rheumatism, gout, hepatitis, and syphilis.'").

61. *See* YOUNG, *supra* note 28, at 110 ("On the eve of the [Civil War], in 1859, the proprietary medicine industry had an output valued in census figures at $3,500,000. By 1904 the sum had multiplied by more than twenty times.").

62. *See id.* at 193–94; KONRAD SCHIECKE, DOWNTOWN CHICAGO'S HISTORIC MOVIE THEATRES 50–51 (2012).

63. *See* YOUNG, *supra* note 28, at 65 (stating Swaim's Panacea purported to cure mercury poisoning while also containing mercury); Van Tassel, *supra* note 23, at 220 ("The problem involved toxic ingredients as well as harmless, but ineffective ingredients. If a proven remedy existed, a fake potion could divert or delay a consumer from seeking out necessary treatment.").

64. *See* DEBORAH BLUM, THE POISON SQUAD: ONE CHEMIST'S SINGLE-MINDED CRUSADE FOR FOOD SAFETY AT THE TURN OF THE TWENTIETH CENTURY 143 (2018) ("Beginning the first week of publication [of Upton Sinclair's *The Jungle* detailing the conditions of urban meat-packing plants], letters and telegrams of outrage arrived at the White House, demanding to know how [President] Roosevelt planned to fix the problem of the country's disgusting food supply.").

B. CONSUMER SAFETY AND REGULATORY WHACK-A-MOLE

The state of food safety in the late-1800s was little better than that of the patent medicine industry.[65] Many foods were produced in incredibly unhygienic conditions[66] or were not what they purported to be.[67] Manufacturers added substances to food in order to improve their marketability,[68] decrease the cost of production,[69] or lengthen their shelf-life.[70] Some additions were fairly innocuous, even if they were dishonest to the consumer, such as the inclusion of colored corn syrup in "honey"[71] or substituting saccharin for sugar.[72] However, many adulterants were not food at all. Floor sweepings and charred rope were passed off as various spices, and flour was mixed with crushed stone.[73] Other food adulterants veered into the category of disgusting and dangerous—brown sugar could contain crushed insects and meat could be preserved with formaldehyde.[74] While the food

65. *See id.* at 1 ("By the mid-nineteenth century . . . many foods and drinks sold in the United States had earned a reputation as often untrustworthy and occasionally downright dangerous.").

66. *See* Nieto, *supra* note 37, at 119 ("It was the vile condition of the meat-packing industry that was the final motivator behind the creation of a comprehensive food and drug law.").

67. BLUM, *supra* note 64, at 2 ("Fakery and adulteration ran rampant in other [than milk] American products as well.").

68. *See id.* at 3 ("Food manufacturers also adopted new synthetic dyes, derived from coal by-products, to improve the color of their less appealing products.").

69. *See id.* at 1 ("Dairymen . . . learned that there were profits to be made by skimming and watering down their product. The standard recipe was a pint of lukewarm water to every quart of milk—after the cream had been skimmed off.").

70. *See id.* at 2–3 ("The most popular preservative for milk—a product prone to rot in an era that lacked effective refrigeration—was formaldehyde, its use adapted from the newest embalming practices of undertakers.").

71. *Id.* at 2 ("'Honey' often proved to be thickened, colored corn syrup . . . .").

72. *Id.* at 3.

73. *Id.* at 2 ("Containers of 'pepper,' 'cinnamon,' or 'nutmeg' were frequently laced with a cheaper filler material such as pulverized coconut shells, charred rope, or occasionally floor sweepings. 'Flour' routinely contained crushed stone or gypsum as a cheap extender.").

74. *Id.* at 2–3 ("Ground insects could be mixed into brown sugar, often without detection—their use linked to an unpleasant condition known as 'grocer's itch.'. . . Processors employed formaldehyde solutions . . . to restore decaying meats . . . ."). Formaldehyde is a strong-smelling, flammable substance often used to preserve mortuary specimens. *Formaldehyde*, NAT'L CANCER INST. (Aug. 6, 2024), https://www.cancer.gov/about-cancer/causes-prevention/risk/

manufacturing industry successfully blocked multiple legislative efforts to reign in their behavior throughout the 1800s,[75] Congress did allocate funding to create the Department of Agriculture in 1862 to investigate the contents of agricultural products.[76]

Dr. Harvey Washington Wiley was appointed as the Department of Agriculture's chief chemist in 1883 where he formed a task force of volunteers to test the safety of preservatives commonly found in the American food supply.[77] In 1904, the Department of Agriculture published Dr. Wiley's findings on the harmful effects caused by ingesting borax, a common preservative at the time.[78] In addition to safety testing, Dr. Wiley also examined

substances/formaldehyde [https://perma.cc/E847-R3T7]. High exposure to formaldehyde can cause various cancers, including leukemia. *Id.*

75. *See* BLUM, *supra* note 64, at 4 ("[Lobbying to prevent even modest food regulation] especially galled consumer safety advocates because governments in Europe *were* enacting protective measures; some foods and drinks sold freely in the United States were now banned abroad.").

76. Pub. L. No. 37-72, § 1, 12 Stat. 387 (1862) (establishing the Department of Agriculture); *see* BLUM, *supra* note 64, at 4–5 ("Decades before the federal government had even considered anything resembling a food and drug administration, the Department of Agriculture (created in 1862 by President Abraham Lincoln) was tasked with analyzing the composition of American food and drink. . . . An 1870s complaint from a Minnesota agricultural association asked the division to investigate the 'misapplication of science to deodorize rotten eggs, revive rancid butter, and dye pithy peas' green again.").

77. BLUM, *supra* note 64, at 5; *see also id.* at 88 ("The trial design was straightforward. Each compound would be studied during a six-week period, and the test subjects would be divided during that time into two different seating arrangements. For the first two weeks, those sitting at table 1 would receive untainted food and those at table 2 would be dosed with a given preservative. The scientists would track the health differences, if any, between the two groups."). Dr. Wiley received his M.D. from Indiana Medical College in 1871 and went on to study chemistry at Harvard University. *Id.* at 13. Prior to accepting the Department of Agriculture position, he worked as the only chemistry professor at Purdue University. *Id.*

78. *Id.* at 101 ("[A] steady diet of borax was shown to harm the human system."); *see id.* at 3 (describing borax as "a mineral-based material best known as a cleaning product"). Following the passage of the 1906 Pure Food and Drugs Act, Dr. Wiley successfully lobbied against borax's inclusion as an approved food additive. *Id.* at 202. It remains illegal to use borax as a food additive in 2024. *See Inventory of Food Contact Substances Listed in 21 CFR*, U.S. FOOD & DRUG ADMIN. (last updated Oct. 29, 2024), https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives&id=BORAX [https://perma.cc/MM5Z-LFTQ] (approving Borax for use only in packaging and adhesives); Elisabeth Anderson & Joe Zagorski, *Trending – Borax*, CTR. FOR RSCH. ON

samples of food for adulteration and published advice to consumers on how to identify fake ingredients.[79] The quantity of adulterated food on the market was staggering.[80] While Dr. Wiley pushed for food and drug safety regulations with his research,[81] it was the depiction of the meat-packing industry in Upton Sinclair's novel *The Jungle* that finally disgusted consumers enough to spur government action.[82] Faced with the public pressure caused by Sinclair's book and an independent investigation that painted a grim picture of the sanitary and labor conditions in the meat-packing industry,[83] President Theodore Roosevelt

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INGREDIENT SAFETY (July 31, 2023), https://www.canr.msu.edu/news/trending-borax [https://perma.cc/F4ZC-5RSM] ("[Borax] is NOT a food grade substance and the [FDA] has not approved it for human consumption as a food or beverage."). Today, borax is a common ingredient in household cleaners. *See* Madeline Buiano, *What Is Borax—And 15 Clever Ways to Use It Around Your Home*, MARTHA STEWART (Jan. 26, 2024), https://marthastewart.com/what-is-borax-8430570 [https://perma.cc/S59X-GWV7] ("Borax is safe to use as a household cleaner and laundry booster . . . . Borax is not meant for consumption . . . . 'When large doses of borax are consumed, kidney damage, anemia, and seizures can occur.'" (quoting Maryann Amirshahi, Co-Medical Director, Nat'l Cap. Poison Ctr.)).

79. BLUM, *supra* note 64, at 111–13 ("[T]he home cook could follow instructions to detect fakes and chemical additives in her groceries. . . . Macerate a tablespoon of chopped meat with hot water, press it through a bag, and then put two or three tablespoons into a sauce dish. Drip in fifteen to twenty drops of hydrochloric acid per tablespoon. Pour the liquid through the filter-paper-lined funnel. Then dip a piece of turmeric paper into the filtered liquid and dry the wet paper near a stove or lamp. 'If boric acid or borax were used for preserving the sample, the turmeric paper should turn a bright cherry red.'").

80. *See id.* at 112 ("Twelve of thirteen samples of sausage had been found to contain borax. Ten of nineteen additional samples were packed with more cornstarch than meat. Coffee continued to be only partly coffee. Spices continued to be adulterated with ground coconut shells, Indian corn, almond shells, olive pits, and sawdust.").

81. *See id.* at 117 (stating the food industry was alarmed by Dr. Wiley's crusade against chemical food additives).

82. *See* Termini & Sannuti, *supra* note 11, at 178 ("[A]uthor Upton Sinclair's novel, *The Jungle*, began to draw public attention to the deplorable conditions of the meatpacking industry. These circumstances [combined with Dr. Wiley's reports] were met with pressure and public outrage . . . .").

83. President Roosevelt sent two investigators to Chicago to find out what was really going on in the meat-packing industry. BLUM, *supra* note 64, at 145. Their report detailed the horrifyingly unsanitary conditions of meat processing: "'[W]e saw meat shoveled from filthy wooden floors, piled on tables rarely washed, pushed from room to room in rotten box carts . . . .' One dead hog had fallen out of a box cart and into a privy. Workers had simply dragged it out and sent it down the line with the other carcasses." *Id.* at 147. Sinclair leaked part

pressured Congress for reform.[84] The President's efforts resulted in the Pure Food and Drugs Act of 1906 (PFDA),[85] which was later strengthened by the Federal Food, Drug, and Cosmetic Act (FDCA).[86] With the enactment of the PFDA, the nation's first food and drug regulatory regime was born.

1. The 1906 Pure Food and Drugs Act

The stated purpose of the PFDA was to "prevent[] the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors."[87] More simply, it mandated producers be truthful when informing consumers what they were putting in their bodies. The PFDA specified different standards for what qualified as "adulterated" or "misbranded" depending on whether an item was a food or a drug.[88] Drugs were defined as "medicines and preparations recognized in the United States Pharmacopœia or National Formulary . . . and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease."[89] The definition of food was simpler: "[A]ll articles used for food, drink, confectionary, or condiment by man or other animals, whether simple, mixed, or compound."[90]

These definitions placed patent medicines in a nebulous position. If the patent medicines continued to make claims related to the cure, mitigation, or prevention of diseases or if they contained any ingredients recognized by the medical establishment, they could be classified as a drug.[91] To avoid being labeled "adulterated drugs," patent medicine makers would need to test their products for purity, strength, and quality and label them

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of this report to the *New York Times*, after which Roosevelt was forced to publish a summary of the report. *Id.* at 149.

84. *See id.* at 149–50 (stating that President Roosevelt was "exasperated" with the bad press surrounding the conditions in the meat-packing industry, and "he wanted meat-inspection legislation on his desk in short order").

85. Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

86. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–99g).

87. Pure Food and Drugs Act of 1906, ch. 3915, § 1, 34 Stat. 768, 768 (repealed 1938).

88. *Id.* §§ 7–8.

89. *Id.* § 6.

90. *Id.*

91. *Id.* §§ 7–8.

accordingly.[92] Additionally, other potentially dangerous ingredients included in patent medicines would need to be listed on the packaging for the medicine not to be deemed "misbranded."[93]

However, the industry soon found a loophole in the law. The government attempted to charge the manufacturer of "Dr. Johnson's Mild Combination Treatment for Cancer" with a violation of the PFDA, alleging that it was a misbranded drug because it purported to cure cancer.[94] However, in *United States v. Johnson* the Supreme Court held that false statements about the curative properties of a drug did not make it misbranded under the PFDA.[95] Only false statements about the contents, strength, purity, or quality of a drug could qualify as misbranding.[96] Because Dr. Johnson's Treatment correctly listed the contents of the drug on the packaging, it was not misbranded under the PFDA, even though the manufacturer knew the curative claims were false.[97] Thus, patent medicine makers could continue making wild claims about their products' curative effects as long as they were honest about their contents.

Congress acted quickly to close this loophole by passing the Sherley Amendments in 1912.[98] The Amendments updated the

92. *Id.* § 7.

93. *Id.* § 8 ("[A drug] shall also be deemed misbranded . . . First. If it be an imitation of or offered for sale under the name of another article. Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.").

94. United States v. Johnson, 177 F. 313, 314–15 (W.D. Mo. 1910) ("The charge is then made that [Dr. Johnsons' Mild Combination Treatment for Cancer's] label was false and misleading, in that it bears false statement that said drug is a part of the treatment for cancer, etc., whereby it held out and falsely claimed that said drug is efficacious in the treatment of cancer, etc., when in truth and fact the drug contained in said packages is worthless and ineffective for such purpose.").

95. United States v. Johnson, 221 U.S. 488, 497 (1911).

96. *See id.* at 497 ("[W]e are of opinion that the phrase is aimed not at all possible false statements, but only at such as determine the identity of the article, possibly including its strength, quality and purity, dealt with in [PFDA] § 7.").

97. *See id.* at 495 ("[The drug packaging] stated or implied that the contents were effective in curing cancer, the defendant well knowing that such representations were false.").

98. Act of Aug. 23, 1912, ch. 352, 37 Stat. 416.

standard for a misbranded drug to include products whose packaging or label contained "false and fraudulent" statements about the drug's curative properties.[99] The "false and fraudulent" standard was meant to curtail the wild claims of patent medicines.[100]

However, Congress's efforts were again blocked by the Supreme Court. In *Seven Cases of Eckman's Alternative v. United States*, the Court held that Eckman's claim to cure pneumonia was not a misbranding because the claim was not both false *and* fraudulent.[101] While the claim was likely false, a charge of fraud required intent to deceive the consumer, and the Court held the government had not proven Eckman's intent to deceive consumers by stating it cured pneumonia, among other diseases.[102] Following this defeat, further efforts to regulate the food and drug industry stalled until a subsequent crisis sparked new change.[103]

2. The Food, Drug, and Cosmetic Act of 1938 and the Birth of Dietary Supplements

Most significant changes to U.S. food and drug laws come on the heels of a tragedy, and the Food, Drug, and Cosmetic Act of 1938 is no different.[104] In 1937, the strep throat medication sulfanilamide was released in a new liquid form.[105] The new drug, "Elixir Sulfanilamide," was sold by the S.E. Massengill

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99. *Id.* at 417 (updating the definition of a misbranded drug to include products whose "package or label bear[s] or contain[s] any statement, design, or device regarding the curative or therapeutic effect of such [drug] or any of the ingredients or substances contained therein, which is false and fraudulent").

100. Van Tassel, *supra* note 23, at 221.

101. 239 U.S. 510, 518 (1916).

102. *Id.* at 513–14. The packaging stated Eckman's Alternative could be used "[f]or all throat and lung diseases including Bronchitis, Bronchial Catarrh, Asthma, Hay Fever, Coughs and Colds, and Catarrh of the Stomach and Bowels, and Tuberculosis (Consumption). . . . Effective as a preventative for Pneumonia. We know it has cured and that it has and will cure Tuberculosis." *Id.*

103. *See generally* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 2–19 (1939) (detailing the failed attempts to enact the Food, Drug, and Cosmetic Act starting in 1933).

104. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–99g); *see supra* Part I.B.1.

105. Sharon B. Jacobs, *Crises, Congress, and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States*, 64 FOOD & DRUG L.J. 599, 604 (2009).

Company[106] and was marketed for children.[107] It had a pink color and a raspberry flavor,[108] and it had been tested for color and taste prior to being released to the market.[109] The product killed 100 people, mostly young children, because the sulfanilamide was dissolved in diethylene glycol, a main component in antifreeze, which gave the product its sweet flavor.[110] Massengill Company had performed no pre-market safety testing or research on diethylene glycol.[111] The only legal recourse available under the PFDA to remove the product from shelves was for the government to declare the drug misbranded because it was not an "elixir," which is a solution made with alcohol.[112] The public outcry over the deaths provided the momentum needed in Congress to finally pass the FDCA, overhauling the PFDA to create the modern food and drug regulatory regime.[113]

The FDCA instituted the first safety requirements for drugs sold to American consumers.[114] It required drug manufacturers to send the Food and Drug Administration a New Drug Application (NDA) before bringing to market a new product that wasn't generally recognized as safe.[115] The application required the

106. Cavers, *supra* note 103, at 20.

107. Jacobs, *supra* note 105, at 604.

108. *Id.*

109. *See* Cavers, *supra* note 103, at 20 ("[T]he pharmacist on [Massengill's] staff checked the product merely for appearance, flavor, and fragrance.").

110. *See* Van Tassel, *supra* note 23, at 224 ("Within weeks, scores of infants suffered slow, painful death as the diethylene glycol—today's antifreeze—produced irreversible liver toxicity.").

111. *See* Cavers, *supra* note 103, at 20 ("Tests on animals or even an investigation of the published literature would have revealed the lethal character of [diethylene glycol].").

112. *See id.* ("[T]he preparation was not an 'elixir' since that term may properly be applied only to an alcoholic solution. The product was therefore misbranded. The label, incidentally, did not mention the presence of the fatal ingredient, diethylene glycol.").

113. *See* Van Tassel, *supra* note 23, at 223–24 ("It took the Elixir Sulfanilamide crisis of 1937, when over 100 people died—mostly children—to finally trigger the passage of a law to provide the FDA with the tools to begin its fight against quack medications. . . . In response to the public outcry over this tragedy, Congress enacted the Federal Food, Drug and Cosmetic Act in 1938 to replace the 1906 [PFDA].").

114. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 §§ 501–05 (1938) (codified as amended at 21 U.S.C. §§ 301–99g).

115. *See id.* § 505 (outlining the process for launching a new drug); *see also* 21 U.S.C. § 321(p)(1) (implying that a new drug is generally recognized as safe

manufacturer to demonstrate that the new drug was safe for its intended use before the FDA would permit its sale in the United States.[116] However, the FDA did not require any pre-market efficacy testing, meaning that while harmful drugs were kept off the market, approved drugs didn't always work as advertised.[117] Additionally, manufacturers often appealed the FDA's safety determinations.[118]

Unfortunately, the burden of proof on appeal favored the manufacturers. The government had the burden of proving in court a particular drug was unsafe, both for cases regarding new drugs and those previously released that the government wanted removed from the market.[119] Placing the burden on the government to prove a product was unsafe led to delays in removing products from the market because the FDA first had to conduct research to provide evidence the product was unsafe, which might take months or years.[120] While this appeal standard limited the safety enforcement mechanism for drugs, the FDCA did keep flagrantly unsafe products away from consumers—a marked improvement from the previous *caveat emptor* standard that governed the patent medicine era.[121]

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based on the scientific consensus "among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs").

116. *See* Jacobs, *supra* note 105, at 607 (describing the application as one of many provisions in the FDCA to strengthen food safety regulation).

117. *See* Van Tassel, *supra* note 23, at 225 ("[U]ntil 1962, there was no obligation to test a product prior to distribution for efficacy."); YOUNG, *supra* note 28, at 251 ("[U]nless scientific opinion universally condemns the promoter's claims [about the curative properties of a particular substance], his intent to deceive must be established.").

118. *See* Van Tassel, *supra* note 23, at 225 ("If the FDA refused approval of the new drug, it was likely that the manufacturer would appeal this decision to the courts.").

119. *Id.* ("The FDA still carried the burden at trial of demonstrating that a product was unsafe or ineffective by proving that it was harmful or that therapeutic advertisements were misleading. . . . [Thus] the FDA had to wait until the science had been sufficiently developed so that it could produce the evidence to meet its burden of proof.").

120. See *infra* Part II.B for discussion of how placing the burden to remove a product from the market on the FDA, in the context of dietary supplements, delayed the ban on ephedrine alkaloids by years.

121. *See* Termini & Sannuti, *supra* note 11, at 178–79 ("The overall intent behind the [FDCA] was to ensure that food and drug related companies focused on the safety of the American public.").

Dietary supplements made their first appearance as a concept in U.S. law with the passage of the FDCA, though under a different name.[122] Foods marketed for "special dietary uses" were explicitly listed under the types of foods that could be classified as misbranded if their label didn't contain "information concerning its vitamin, mineral, and other dietary properties."[123] Products making any claims about their ability to diagnose, cure, mitigate, treat, or prevent diseases were classified as drugs,[124] which would be expected to include the majority of old patent medicines.[125] The FDA pursued enforcement actions based on this definition that restricted the manufacturers of "special dietary" foods from making drug-like claims.[126] Special dietary food products making such claims would be classified as misbranded drugs.[127] Thus, the FDCA ended the era of patent medicine, at least in terms of products making curative claims.[128] However,

122. *See* Federal Food, Drug, and Cosmetic Act, ch. 675, § 403(j), 52 Stat. 1040, 1048 (1938).

123. *Id.* Current federal regulations define special dietary uses as:

> (i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
>
> (ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;
>
> (iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

21 C.F.R. § 105.3(a)(1) (2024).

124. 21 U.S.C. § 321(g)(1).

125. *See* YOUNG, *supra* note 28, at 251 ("The legal environment [after the passage of the FDCA] is fraught with perils to the unscrupulous or careless proprietor which Swaim selling his Panacea and Radam his Microbe Killer did not confront.").

126. Nieto, *supra* note 37, at 121 ("For example, in *United States v. Kordel*, the defendant, a distributor of healthy beverages and mineral tablets, was convicted of distributing misbranded drugs into interstate commerce.").

127. *See id.* ("[T]he [FDCA] provided for the regulation of 'food for special dietary uses,' by stating that food is misbranded: 'If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.'" (quoting 21 U.S.C. § 343(j))).

128. *See* Federal Food, Drug, and Cosmetic Act of 1938 § 201(g), 21 U.S.C. § 321(g) (defining drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals").

dietary supplements, the successor to patent medicines, were just getting started.

C. DISTINGUISHING DIETARY SUPPLEMENTS: SHIFTING THE SAFETY BURDEN

The first major shift in dietary supplement regulation came in 1958 when Congress passed the Food Additives Amendment, updating the language of the FDCA.[129] Dietary supplements were included in the "food additive" category, which required less pre-market safety screening than drugs but more than ordinary foods.[130] This pre-market screening shifted the burden for proving safety onto the manufacturers of dietary supplements.[131] However, the dietary supplement industry lobbied against this burden, and, in 1976, it was removed.[132]

The 1976 Health Research and Health Services Amendments, commonly called the Proxmire Amendments, shifted the burden back to the FDA to prove a particular dietary supplement was unsafe before it could be removed from the market.[133] The Proxmire Amendments also prohibited the FDA from setting maximum potency limits for vitamins and minerals used as dietary supplements[134] and from classifying vitamins and minerals

129. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified as amended in scattered sections of 21 U.S.C.).

130. *See* Termini & Sannuti, *supra* note 11, at 179 ("[I]f nutritional experts could not agree that a dietary supplement was safe, the supplement manufacturers were required to provide sufficient evidence that their dietary supplement was safe before it could be placed on the market.").

131. *See* Van Tassel, *supra* note 23, at 229 n.170 ("The FAAA placed the burden of proof on the manufacturers, rather than on the FDA, to show that a newly discovered substance added to food is safe if used within specified quantities. This change fixed a major flaw in the 1938 FDCA that had placed the burden of proof on the FDA to prove that a food additive was unsafe." (citations omitted)).

132. *See* Termini & Sannuti, *supra* note 11, at 180 ("In 1976, Congress passed the Health Research and Health Services Amendments in response to significant outcry from dietary supplement manufacturers.").

133. *Id.* ("[The Proxmire] amendments decreased the FDA's authority to regulate dietary supplements by placing the burden on the FDA to establish that a dietary supplement was unsafe for consumers before the agency could remove the product from the market. The decreased enforcement with a reduced burden on manufacturers attracted numerous businesses to enter the dietary supplement market.").

134. Health Research and Health Services Amendments of 1976, Pub. L. No. 94-278, § 411(a)(1)(A), 90 Stat. 401, 410 (codified as amended at 21 U.S.C. § 350(a)(1)(A)). The Proxmire Amendments did allow the FDA to set limits on

as drugs based solely on their potency.[135] This permissive regulatory scheme opened up the dietary supplement market, allowing manufacturers to sell supplements so long as there wasn't scientific evidence they were unsafe.[136]

The focus of supplement regulations up to this point had been on vitamins and minerals because they made up the majority of the supplement market.[137] The 1980s saw a shift in the dietary supplement market composition, with herbal and botanical ingredients increasing in popularity.[138] This led to another safety crisis in 1989.[139] The amino acid supplement L-tryptophan, which was popular with body builders looking to build muscle mass, was linked to thirty-seven deaths due to eosinophilia-myalgia syndrome, a painful condition of the muscles.[140] Following this tragedy, the FDA increased enforcement actions

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vitamin and mineral potency if they were "represented for use by individuals in the treatment or management of specific diseases or disorders, by children [under twelve years], or by pregnant or lactating women." 21 U.S.C. § 350(a)(2).

135. 21 U.S.C. § 350(a)(1)(B) ("[T]he Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful.").

136. *See* Van Tassel, *supra* note 23, at 235 ("With the passage of the [Proxmire] Amendments, the supplement industry took the first major step toward the recreation of a commercial playground where it could operate virtually free of regulation as long as scientific uncertainty existed over the health risks and benefits of its products.").

137. *Id.* at 235–36.

138. *See id.* ("Before the 1980s, vitamins made up the vast majority of the supplement market . . . the FDA ignored many of the herbal remedies that generally seemed harmless and focused its attention on the most dangerous and the ones that made the most outlandish disease curing claims. As a result, there was an explosive growth in the herbal remedy industry and the scope of health claims escalated.").

139. *See* Iona N. Kaiser, Comment, *Dietary Supplements: Can the Law Control the Hype?*, 37 HOUS. L. REV. 1249, 1255 (2000) (describing the L-tryptophan safety crisis and the FDA's inability to proactively prevent it due to the Proxmire Amendments).

140. *See id.* Eosinophilia-myalgia syndrome (EMS) is a rare, life-threatening condition "that causes white blood cells . . . to collect in . . . blood and tissues." *Eosinophilia-Myalgia Syndrome*, CLEVELAND CLINIC (last updated Feb. 13, 2023), https://my.clevelandclinic.org/health/diseases/24730-eosinophilia-myalgia-syndrome [https://perma.cc/AR85-E43K].

against supplement manufacturers in an attempt to protect consumers from untested herbal supplements.[141]

The passage of the National Labeling and Education Act (NLEA) in 1990 was the breaking point for the growing tension between the FDA and the supplement industry.[142] The NLEA would have required pre-market safety and efficacy testing for herbal supplements, aligning with the FDA's desire to reign in the supplement industry and protect consumers.[143] The supplement industry rallied massive public support against the new regulations,[144] cleverly linking vitamins and minerals, which would not have been subject to the NLEA's new testing requirement, with herbal remedies, which would have been covered by the law, to argue the NLEA was against consumer interests.[145]

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141. *See* Kaiser, *supra* note 139, at 1257 ("[T]he FDA questioned whether herbs used as traditional medicine should be regulated as drugs rather than as supplements based upon consumers' perceptions of their own supplement use. . . . The FDA further stated its intention to hold supplements whose labels made health claims to the same standard it applied to conventional food forms.").

142. *See* Van Tassel, *supra* note 23, at 239 ("[The NLEA] spurred a massive lobbying and public relations campaign [from dietary supplement manufacturers].").

143. *See id.* ("[T]he NLEA gave the FDA the long-awaited opportunity to finally put to rest the question of the proper method for regulating herbal remedies . . . . [Herbal supplements] would have to obtain premarket approval to establish that they were safe and effective for their claimed uses."); Termini & Sannuti, *supra* note 11, at 180 (describing successful industry lobbying against the FDA's attempts to assert its regulatory authority over dietary supplements in the early 1990s).

144. *See* Kaiser, *supra* note 139, at 1258 ("Thousands of dietary supplement retailers, in an effort to convince consumers that the FDA sought to destroy consumer access to dietary supplements, organized collectively to stage National Blackout Day. Supporters draped in black those supplements that would potentially be affected by the new FDA policy to illustrate what stood to be lost if the FDA was allowed unrestrained regulation of supplements. The Blackout Day message was simple yet inflammatory: 'The FDA is trying to take away your supplements and it will be successful if nothing is done.'"). One anti-supplement regulation commercial featured actor Mel Gibson being arrested for possessing vitamin C tablets. *See* Johnny Harris, *Your Supplements Are a Lie*, YOUTUBE, at 07:30 (Dec. 13, 2023), https://youtu.be/WIT5_SMIaHE?si=l75JY0LfTY42TaRw.

145. *See* Van Tassel, *supra* note 23, at 236 ("[T]he supplement industry had made a strategic transition in the nomenclature of their products from 'herbal remedies' to 'dietary supplements' to better argue that they should be minimally regulated like traditional food.").

Their lobbying efforts were successful.[146] Congress placed a one-year moratorium on the NLEA in 1992,[147] and in 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA), exempting dietary supplements from the pre-market testing the NLEA required and deregulating the industry.[148]

The current framework of regulations for dietary supplements has not drastically changed since the passage of DSHEA thirty years ago. With the historical context established in this Part, Part II of this Note will examine the permissive regulatory scheme established by DSHEA and how it has failed to adequately protect consumers from dangerous dietary supplements.

II. WHO BEARS THE BURDEN? CONSUMER SAFETY AND THE FAILURE OF THE DSHEA

Despite the vast improvements in food and drug safety over the past century and a half, gaps remain in the regulations that allow manufacturers to bring dietary supplements to market without testing their safety or efficacy. This Part will detail how dietary supplement regulations are out of step with the FDA's goal of consumer safety and why this mismatch is so dangerous. Section A will describe the current regulatory landscape and examine where the gaps in safety protections lie. Then, Section B will employ the example of ephedrine alkaloids, a dietary ingredient marketed as a weight loss aid, to demonstrate how

146. *See* Termini & Sannuti, *supra* note 11, at 180 ("Industry leaders joined forces to convince Congress to campaign for a law that would essentially deregulate dietary supplements. Despite the FDA's desire to increase the regulation of dietary supplements, these efforts were no match for the measures taken by the industry. Ultimately, Congress relaxed regulation of dietary supplements through the enactment of the DSHEA in 1994.").

147. Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4500; *see* Peter A. Vignuolo, *The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994*, 21 SETON HALL LEGIS. J. 200, 204 (1997) ("As a result, the Dietary Supplement Act of 1992 ('DSA') placed a one year moratorium on the enforcement of NLEA. A grass roots lobbying effort begun by the dietary supplement manufacturers provided the impetus for the moratorium.").

148. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21, 42 U.S.C.); *see* Vignuolo, *supra* note 147, at 205 ("Containing numerous provisions, including the modification of the labeling requirement for dietary supplements, DSHEA placed the burden of proof on the FDA in an action against a dietary supplement manufacturer."); *infra* Part II.A.

dangerous products have ended up in the hands of unsuspecting consumers.

A. THE CURRENT DIETARY SUPPLEMENT REGULATORY LANDSCAPE

Under the DSHEA, dietary supplements are categorized as a type of food.[149] They are broadly defined as products that are "intended to supplement the diet."[150] There are six general categories of ingredients that can be classified as dietary supplements: vitamins, minerals, herbs or botanicals, amino acids, "dietary substance[s] for use by man to supplement the diet by increasing the total dietary intake[,]" and any combination of these categories.[151]

Because dietary supplements are a subcategory of food, they are not subject to the same pre-market safety and efficacy testing as drugs.[152] When applying to sell a new dietary ingredient, manufacturers must disclose the amount of the new ingredient in a dietary supplement and the supplement's suggested conditions of use.[153] Manufacturers must also provide the FDA with any scientific articles or studies that support their assertion that the new dietary ingredient is reasonably expected to be safe.[154] These minimal requirements are a stark contrast to the

149. *See* 21 U.S.C. § 321(ff) (flush language) ("Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.").

150. *Id.* § 321(ff)(1).

151. *Id.* § 321(ff)(1)(A)–(F).

152. *See* Termini & Sannuti, *supra* note 11, at 181 ("[U]nlike pharmaceutical drugs, dietary supplements bypass the rigors of the premarket approval process, and thus have a significantly easier barrier to entry [into the market].").

153. *See* 21 C.F.R. § 190.6(b)(3) (2024) (requiring the manufacturer or distributor of a dietary supplement with a novel ingredient to disclose "[t]he level of the new dietary ingredient in the dietary supplement; and the conditions of use recommended or suggested in the labeling of the dietary supplement, or . . . the ordinary conditions of use of the supplement.").

154. *See id.* § 190.6(b)(4) (requiring dietary supplement manufacturers to provide "[t]he history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe").

extensive safety and efficacy testing required of new drugs.[155] While drug manufacturers bear the burden of proving their products are both safe *and* effective for their intended use,[156] supplement manufacturers need only show a "reasonable" expectation of safety when the supplements are used as recommended.[157]

Although dietary supplement manufacturers may not claim their products diagnose, treat, cure, or prevent any disease,[158] they may still make statements about "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans . . . or describe[] general well-being from consumption."[159] This "structure and function" exemption is what allows weight loss and detox teas to make claims like "[the tea] *supports* the body's natural detoxification process to help reduce bloating for a flatter-looking tummy."[160] "Support" is the key term because it makes no promises that drinking the tea will have any particular effect on the consumer, only that the ingredients contained have some sort of link to the body's "natural detoxification process."[161] Dietary supplements making structure or function claims must display a disclaimer that the FDA has not evaluated the claims and the supplements are not intended to diagnose, treat, cure, or prevent any disease.[162] Because no efficacy testing

155. *See* 21 U.S.C. § 355 (detailing pre-market safety and efficacy testing required of new drugs).

156. *See id.* § 355(b)(1)(A)(i) (requiring new drug applications to contain "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use."). *See generally* Burke & Page, *supra* note 23, at 125–30 (explaining the extensive testing process new drugs must pass before being released to the market).

157. 21 C.F.R. § 190.6(b)(4) (2024).

158. 21 U.S.C. § 343(r)(6) (flush language).

159. *Id.* § 343(r)(6)(A).

160. *Flat Tummy 2-Step Detox Tea – 1.06oz*, TARGET, https://www.target.com/p/flat-tummy-2-step-detox-tea-1-06oz/-/A-86874104?ref=tgt_adv_xsf&AFID=google&CPNG=Health&adgroup=94-8 [https://perma.cc/9GUK-WD3Q] (emphasis added).

161. *See Structure/Function Claims*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2024), https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/structurefunction-claims [https://perma.cc/B2V4-Z8KX] (stating "calcium builds strong bones," "fiber maintains bowel regularity," and "antioxidants maintain cell integrity" are all examples of acceptable structure or function claims).

162. 21 C.F.R. § 101.93(c)(2) (2024); *see supra* Introduction.

is required for dietary supplements, only claims straying into "drug-like" territory generally spark agency action.[163]

Manufacturers are required to disclose on product packaging all the ingredients contained in a particular dietary supplement.[164] For ingredients with an established "Reference Daily Intake" (RDI), such as calcium, manufacturers must disclose the total weight of the ingredient and the percentage of the recommended "Daily Value" included per serving.[165] They are not required to disclose how much of any ingredient is contained in a product if it is part of a "proprietary blend" and no RDI has been established.[166] Manufacturers can avoid disclosing the quantity of any ingredient that does not have an RDI by claiming the ingredient is part of a proprietary blend.[167] It also creates a

163. § 101.93(g)(2) (providing criteria that will lead FDA to conclude a statement is a "disease claim"); *see, e.g.*, Kevin McCarthy, *FDA Sinks Cheerios Health Claims; Calls Cereal an 'Unapproved Drug'*, CONSUMER REPS. (May 13, 2009), https://www.consumerreports.org/cro/news/2009/05/fda-sinks-cheerios-health-claims-calls-cereal-an-unapproved-drug/index.htm [https://perma.cc/H27X-SHZG] (reporting that General Mills was warned by the FDA about making drug-like claims in advertisements for Cheerios, including that "you can lower your cholesterol 4 percent in 6 weeks"); *cf.* Burke & Page, *supra* note 23, at 131 ("Many of the claims asserted by sellers of dietary supplements contain extraordinary claims of effectiveness . . . . If the product itself is not subject to pre-market proof of safety and effectiveness, is the regulation of truthfulness in advertising sufficient to deter marketing supplements based on deceptive claims?").

164. *See* § 101.36(c)(2) ("Dietary ingredients contained in the proprietary blend that [do not have an established Reference Daily Intake] shall be declared in descending order of predominance by weight . . . ."). Manufacturers must disclose the total weight of the included proprietary blend but not the percentage or weight of each constituent ingredient. § 101.36(c)(3) ("The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend . . . .").

165. *See* § 101.36(b)(2)(i). "Daily Value" is a term generally used to encompass both RDIs and Daily Reference Values (DRVs). Both are calculations of how much of a particular nutrient a person needs per day based on their age. Various vitamins, minerals, and amino acids have RDIs, while other nutrients like fat, cholesterol, and protein have DRVs. The term, "% Daily Value," as listed on product packaging, is calculated using the applicable DRV as applied to the average adult. *Frequently Asked Questions for Industry on Nutrition Labeling Requirements*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/99069/download [https://perma.cc/3KZR-5H87].

166. § 101.36(c).

167. Currently, nutrition labels for foods and supplements must disclose the amount and % Daily Value for: total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, and some vitamins and minerals. *Daily Value on the Nutrition and Supplement*

reporting discrepancy between different types of dietary supplement ingredients. Vitamins and minerals are both types of dietary supplement ingredients, and many of the common vitamins and minerals included in foods have RDIs—meaning manufacturers are required to report the percentage of the recommended Daily Value present in a serving.[168] Herbal or botanical supplements, however, do not generally have RDIs,[169] and, therefore, manufacturers must only report the amount present in a dietary supplement[170] or note their presence in a "proprietary blend."[171]

The DSHEA also shifted the burden to the FDA to prove a supplement should be removed from the market.[172] The FDA can only step in when a supplement "presents a significant or unreasonable risk of illness or injury" to consumers when used as recommended or if the supplement is adulterated or misbranded.[173]

Facts Labels, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2024), https://www.fda.gov/food/nutrition-facts-label/daily-value-nutrition-and-supplement-facts-labels [https://perma.cc/9UDW-GXRW].

168. § 101.36(b)(2)(iii)(B); *see* § 101.36(b)(2)(i)(B) (stating the order vitamin and mineral dietary ingredients must be reported on supplement packaging: "Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate and folic acid, vitamin B12, biotin, pantothenic acid, choline, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, potassium, and fluoride.").

169. *See* § 101.36(b)(3)(ii)(B) (using "fresh dandelion root" as an example of a dietary ingredient without an RDI).

170. § 101.36(b)(3)(i)–(ii).

171. § 101.36(c)(3).

172. *See* Van Tassel, *supra* note 23, at 242 ("Currently, in order to remove an unsafe or ineffective weight loss supplement from the market, the FDA carries the burden of demonstrating that the product poses a 'significant or unreasonable risk of illness or injury.'" (quoting Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1038 (10th Cir. 2006)).

173. 21 U.S.C. § 342(f)(1)(A)(i); § 342(f)(1)(D). An adulterated product is one that:

> [B]ears or contains any added poisonous or added deleterious substance . . . pesticide chemical residue . . . any food additive that is unsafe . . . a new animal drug . . . or if it consists in whole or in part of any filthy, putrid, or decomposing substance, or if is otherwise unfit for food; or if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or . . . if it has been intentionally subjected to radiation . . . .

Supplement manufacturers are, however, required to report any "serious" adverse reactions caused by their products to the FDA.[174]

The FDA's relatively weak regulatory control of the dietary supplement market compared to the drug market has led to several serious failures in consumer safety in recent years.[175] The most significant of these failures was the ephedrine alkaloid crisis,[176] which exemplifies the need for both pre-market safety testing of dietary supplements and increased authority to remove unsafe products from the market.

B. EPHEDRINE ALKALOIDS: A CONSUMER SAFETY FAILURE

Weight loss supplements have been a consistently popular type of dietary supplement with American consumers.[177] In a

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21 U.S.C. § 342(a)(1). In other words, an adulterated product contains harmful ingredients that were not disclosed by the manufacturers or were not intentionally included. *See id.*

174. *See* 21 U.S.C. § 379aa-1(b)(1) (detailing FDA reporting requirements for supplement manufacturers). A "serious" adverse event is constrained to "death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly or birth defect; or requires . . . a medical or surgical intervention to prevent [the above outcomes]." *Id.* § 379aa-1(a)(2).

175. *See* Termini & Sannuti, *supra* note 11, at 191 ("Despite [removing ephedrine alkaloids from the product formula], Hydroxycut products continued to be linked to adverse side effects, including liver toxicity and rhabdomyolysis—a condition which may lead to kidney failure."); *see also id.* at 200–01 (detailing the FDA's concerns about the new dietary supplement kratom).

176. *See* Kaiser, *supra* note 139, at 1265 (discussing "[t]he current state [in 2000] of FDA regulation of ephedrine supplements" to illustrate DSHEA's detrimental effect on the FDA's ability to protect consumers); Van Tassel, *supra* note 23, at 242–43 (describing the "numerous complaints of heart attacks, strokes, seizures and deaths associated with the consumption of products containing ephedrine-alkaloid supplements," leading to a widespread public health crisis); Termini & Sannuti, *supra* note 11, at 188–91 (describing the circumstances that led to the FDA's ban on dietary supplements containing ephedrine alkaloids).

177. *See* Maggie Dickens, Comment, *Safe Until Proven Unsafe: Solving the Growing Debate Around Dietary Supplement Regulation*, 15 WAKE FOREST J. BUS. & INTELL. PROP. L. 576, 577 ("Society often idolizes weight loss, but not through the traditional approach of diet and exercise. Instead, Americans spend $40 billion on weight-loss programs and products annually, as supplement manufacturers capitalize on the market's lack of regulation."). The popularity of the weight loss industry is not a new phenomenon. In 1961, Young observed: "Allied to the food supplement business is the weight reduction craze. . . . Americans

search for a quick fix to their weight struggles, American consumers became the unwitting test subjects for a new dietary supplement—ephedrine alkaloids.[178]

Ephedrine alkaloids are produced by plants of the ephedra family.[179] Ephedrine alkaloids derived from herbal ephedra sources were marketed in dietary supplements as a weight loss aid,[180] which some studies support.[181] Ephedrine alkaloids may promote weight loss because they "work as stimulants and fall into the same category as the street drug referred to as 'speed.'"[182] This stimulant effect is also what makes ephedrine alkaloids so dangerous,[183] with adverse effects including heart

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have been wealthy enough to pay for expensive drugs and devices which their promoters promise will take off fat without dieting or exertion. To stop the most dangerous and deceptive of reducing racketeers has been a high-priority concern of regulatory agencies." YOUNG, *supra* note 28, at 259.

178. *See* Van Tassel, *supra* note 23, at 242 ("An example of the implications of switching the burden of proof onto the FDA to prove that weight loss supplements are unsafe and ineffective is the case of a product called Ephedra.").

179. Khaoula Elhadef et al., *A Review on Worldwide Ephedra History and Story: From Fossils to Natural Products Mass Spectroscopy Characterization and Biopharmacotherapy Potential*, EVIDENCE-BASED COMPLEMENTARY & ALT. MED., Apr. 30, 2020, at 1, 2. Legal scholarship on this issue often conflates the terms "ephedra" and "ephedrine alkaloid." *See* Termini & Sannuti, *supra* note 11, at 188 (using ephedra and ephedrine alkaloid interchangeably); Nieto, *supra* note 37, at 137–38 (same). Ephedra is a genus that contains the plant known as ephedra sinica; it is also commonly referred to as ma huang. *Id.* at 1–2. Ephedrine alkaloids are derived from the ephedra sinica plant. *Id.* at 2. While "ephedra" is often used as shorthand, ephedrine alkaloids are the substance specifically banned from use in dietary supplements by the FDA. 21 C.F.R. § 119.1 (2024).

180. *See* Van Tassel, *supra* note 23, at 242 ("Products containing ephedrine-alkaloid supplements were marketed for weight loss and to enhance sports performance.").

181. *See* C.N. Boozer et al., *Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial*, 26 INT'L J. OBESITY 593, 601 (2002) ("[Ephedra] administered with diet and exercise counseling for a 6 month period, promoted significantly greater reductions in body weight, body fat and waist and hip circumferences in overweight subjects compared with similarly counseled placebo-treated subjects.").

182. Van Tassel, *supra* note 23, at 242; *see Drug Fact Sheet: Amphetamines*, U.S. DRUG ENF'T ADMIN. (Oct. 2022), https://www.dea.gov/factsheets/amphetamines [https://perma.cc/QXK3-8ENM] (identifying "speed" as a slang term for amphetamines, a type of stimulant).

183. *See* Vignuolo, *supra* note 147, at 201 ("[E]phedra products, like the drugs they mimic, may cause a variety of adverse reactions, including death, if taken in excessive quantities.").

attacks, strokes, seizures, and death.[184] These supplements became popular throughout the 1980s and 1990s,[185] and by mid-2003, the FDA had received 2,277 serious adverse event reports related to herbal ephedrine alkaloids—fifteen times more than the number of reports for any other herbal dietary supplement.[186] The deaths of several college and professional athletes, including Baltimore Orioles pitcher Steve Bechler, due to complications from ephedrine alkaloid use drew national attention to the issue.[187] However, despite the damning evidence against ephedrine alkaloids, it took the FDA until 2004 to totally ban the substance's use in dietary supplements.[188]

This delay was directly caused by herbal ephedrine alkaloids' classification as a dietary supplement; the FDA could only remove a dietary supplement from the market if it presented a "significant or unreasonable risk of illness or injury" when used at the recommended dose.[189] The FDA first proposed restricting the use of herbal ephedrine alkaloids in dietary supplements in

184. U.S. GOV'T ACCOUNTABILITY OFF., GAO-03-1042T, DIETARY SUPPLEMENTS CONTAINING EPHEDRA: HEALTH RISKS AND FDA'S OVERSIGHT 1 (2003) ("Medical experts have expressed concerns about the safety of dietary supplements containing ephedra. Reports of adverse health events associated with such supplements, including reports of heart attack, stroke, seizure, and death, have been received by the Food and Drug Administration (FDA) and others . . . .").

185. *See* Termini & Sannuti, *supra* note 11, at 188 ("Throughout the 1980s and 1990s, supplement manufacturers promoted the use [of] dietary supplements containing ephedrine alkaloids to achieve weight loss and improve athletic performance."); Gene Emery, *FDA Ban Nearly Wiped Out Deaths, Poisonings from Ephedra*, REUTERS (May 27, 2015), https://www.reuters.com/article/idUSKBN0OC2SQ [https://perma.cc/2ZLW-HK6W] ("Prior to the ban [in 2006], industry groups were saying the substance had been used by 12 million people.").

186. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 184, at 2.

187. *See* Dave Sheinin, *Athletes' Deaths Led to Ephedra Ban*, WASH. POST (Dec. 31, 2003), https://www.washingtonpost.com/archive/sports/2003/12/31/athletes-deaths-led-to-ephedra-ban/bbb0a6d9-fbdc-46ae-8c4e-ca24195245ec [https://perma.cc/VP48-AVRJ] ("It took the death of a baseball player, Baltimore Orioles pitcher Steve Bechler, on a cool February morning last spring to thrust ephedra deep into the public consciousness—a process that concluded yesterday with the Bush administration announcing a federal ban on the controversial stimulant.").

188. *See* 21 C.F.R. § 119.1 (2024) (banning the use of ephedrine alkaloids in dietary supplements). The regulation went into effect February 11, 2004. *Id.*

189. Vignuolo, *supra* note 147, at 227; 21 U.S.C. § 342(f)(1)(A).

1997,[190] and it implemented a final rule banning them altogether in 2004, collecting an administrative record of nearly 130,000 pages along the way.[191] Supplement manufacturers were not pleased with this decision and sued to invalidate the rule, alleging the FDA did not have the authority to completely ban ephedrine alkaloids, and it had not met its burden that they presented a significant or unreasonable risk when used as recommended.[192]

The manufacturer's argument highlights the primary flaws of placing the burden on the FDA to prove dietary supplements are unsafe for consumers. First, the FDA must prove the supplement presents not just any risk, but one that is "unreasonable in light of its potential benefits."[193] Second, the FDA must prove there is an unreasonable risk, specifically when the product is used as recommended.[194] This means that if the FDA wishes to ban a dietary supplement ingredient entirely, they must prove that *any* use of the ingredient presents an unreasonable risk to consumers because each ban applies only to supplements that contain as much or more of the ingredient as the FDA has specifically proven to be harmful.[195] Because of the "recommended

190. Dietary Supplements Containing Ephedrine Alkaloids, 62 Fed. Reg. 30,678, 30,678 (proposed June 4, 1997) (proposing adding a warning label to dietary supplements containing more than eight mg of ephedrine alkaloid per serving).

191. *See* Van Tassel, *supra* note 23, at 242 ("The FDA compiled an administrative record of 130,000 pages, 19,000 adverse event reports and engaged in extensive notice and comment before it passed a regulation banning the sale of ephedrine-alkaloid supplements in 2004.").

192. *See* Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1035 (10th Cir. 2006) ("In its published decision, the district court determined that the risk-benefit analysis employed by the FDA to support an [ephedrine alkaloid] ban was contrary to the intent of Congress and that the FDA had failed to prove by a preponderance of the evidence that [ephedrine alkaloids] pose an unreasonable risk of illness or injury at 10 milligrams ('mg') or less a day.").

193. *Id.* at 1038, 1040; 21 U.S.C. § 342(f)(1)(A).

194. *See* § 342(f)(1)(A) (stating that a dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury under—(i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use").

195. *See* Nieto, *supra* note 37, at 132 ("To classify a supplement as adulterated, the FDA must show the supplement is unsafe when taken at the manufacturer's recommended dosage (or if no dosage is provided) at the dosage ordinarily taken. While the FDA may be able to show a supplement is harmful at

usage" provision, the FDA had to produce evidence showing ephedrine alkaloids were unsafe at the dose currently on the market.[196] Manufacturers then produced supplements with a lower dose of ephedrine alkaloids, forcing the FDA to conduct more studies to prove the new, lower dosage was also harmful.[197]

Nutraceutical Corporation, a manufacturer of ephedrine alkaloid dietary supplements, challenged the FDA's total ban on exactly those grounds.[198] The company argued that the agency had not met its burden of showing ephedrine alkaloids presented an unreasonable risk to consumers in doses less than ten milligrams.[199] The absence of any premarket testing requirements for ephedrine alkaloid supplements contributed to the initial scarcity of scientific evidence, which made the FDA's evidentiary task particularly burdensome.[200] While the court ultimately held that the FDA had proven, by a preponderance of the evidence, that ephedrine alkaloids were unsafe for use in dietary

some dosages, if that dosage is higher than the recommended amount by just one percent, there is essentially nothing the FDA can do to prevent that product from being marketed to consumers." (internal citations omitted)).

196. *Id.* at 137–38 ("Although the FDA was aware of these harmful effects, it still took over ten years for the FDA to implement an effective ban on the dangerous herb. This is largely due to the DSHEA requirement that the FDA prove the product is unsafe at the recommended dose.").

197. *See id.* ("Once the FDA banned ephedra at a specific dose, manufacturers would come out with supplements containing the product at a lower dose, which in turn would require the FDA to conduct more studies in order to prove the new dosage was still harmful.").

198. *See* Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1035 (10th Cir. 2006) (stating that an issue raised on appeal was "whether the FDA satisfied its burden of proving that dietary supplements containing [ephedrine alkaloids] present an unreasonable risk of illness or injury when doses of 10 mg or less per day are suggested or recommended in labeling").

199. *See id.* at 1041–42 (noting Nutraceutical Corporation's argument that the FDA provided insufficient evidence).

200. *See id.* at 1036 ("Given the fact that dietary supplement manufacturers are not required to submit scientific data on their products, the body of scientific literature on [ephedrine alkaloids] was limited.").

supplements in any amount,[201] it took nearly a decade and thousands of ephedrine alkaloid-related adverse events to do so.[202]

The eventual ban on ephedrine alkaloids in dietary supplements has been a consumer safety success.[203] There have been no deaths caused by ephedrine alkaloids reported since 2008, and poisonings have decreased by over ninety-eight percent.[204] Although the ephedrine alkaloid ban has had a demonstrably positive impact on consumer safety, thousands were injured and over one hundred people died from ephedrine alkaloid-related injuries prior to the ban.[205] This was caused both by the lack of pre-market safety testing for dietary supplements and by the FDA's lack of meaningful authority to remove dangerous supplements from the market. Part III proposes a solution to this problem. To prevent consumers from becoming unwitting guinea pigs for dietary supplements, new dietary ingredients must be subject to basic pre-market safety testing, there must be uniform ingredient disclosure requirements, and the FDA's powers to ban dietary supplement ingredients must be strengthened.

III. REALIGNING DIETARY SUPPLEMENT REGULATION TO PRIORITIZE CONSUMER SAFETY

The passage of the Pure Food and Drugs Act in 1906 and the Food, Drug, and Cosmetic Act in 1938 were critical milestones in the history of consumer food and drug protection. American

201. *See id.* at 1043 ("The FDA reasonably concluded that there is no recommended dose of [ephedrine alkaloids] that does not present an unreasonable risk. The FDA was not arbitrary or capricious in its Final Rule; the FDA met its statutory burden of justifying a total ban of [ephedrine alkaloids] by a preponderance of the evidence." (citations omitted)).

202. *See* Michele Zell-Kanter et al., Correspondence, *Reduction in Ephedra Poisonings After FDA Ban*, 372 NEW ENG. J. MED 2172, 2173 (2015) ("The number of calls to poison centers related to ephedra poisonings peaked at 10,326 in 2002 . . . .").

203. *See* Emery, *supra* note 185 ("A 13-year tally of deaths and poisonings from ephedra show a spectacular decline after the U.S. Food and Drug Administration banned the sale of weight loss products containing the herb in 2004.").

204. Zell-Kanter et al., *supra* note 202 ("The number of deaths peaked at 7 in 2004, and there have been no reported ephedra-related deaths since 2008. . . . The number of poisonings resulting in major effects or deaths has decreased by more than 98% since 2002.").

205. Nieto, *supra* note 37, at 137 ("For example, the herb ephedra, which was used to treat symptoms of bronchial asthma, colds, influenza, allergies, and induce weight loss, was responsible for 155 deaths and thousands of additional injuries.").

consumers are far more protected now from unsafe products than they were in the days of patent medicine,[206] but the current regulatory scheme still leaves consumers exposed to harm because of the gaps surrounding dietary supplements.[207] These gaps can be seen clearly through the lens of weight loss and detox teas, which are not tested for safety prior to being introduced to the market and whose manufacturers do not have to disclose how much of any dietary supplement ingredient each serving contains if the ingredient does not have an established RDI.[208] The deaths and injuries related to ephedrine alkaloid weight loss supplements are a clear example of how the current regulatory scheme leaves consumers vulnerable.[209]

Part III proposes updating the framework established by the DSHEA to better reflect the mission of the FDA—protecting consumers[210]—in three ways. First, Section A proposes that all dietary supplements must be required to report their dietary ingredient contents by weight on their packaging. Second, Section B argues basic pre-market safety testing and RDIs for dietary ingredients must be established, either by manufacturers or the FDA. And third, Section C advocates for the enhancement of the FDA's authority to remove dangerous dietary ingredients from the market categorically.

A. CLOSING THE INFORMATION GAP BETWEEN DIETARY SUPPLEMENT INGREDIENT CATEGORIES

One way to improve consumer safety in the dietary supplement market is to require disclosure of how much of each dietary supplement ingredient one serving of a product contains. Until the 1980s, vitamins and minerals comprised the majority of the

206. *See supra* Part I.B.

207. *See supra* Part II.B.

208. *See supra* Part II.A.

209. *See supra* Part II.B.

210. *See What We Do: FDA Mission*, U.S. FOOD & DRUG ADMIN. (Nov. 21, 2023), https://www.fda.gov/about-fda/what-we-do [https://perma.cc/5SRC-PDW4] ("The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.").

dietary supplement market.[211] Manufacturers of herbal or botanical supplements purposefully started using the phrase "'dietary supplements' to better argue that they should be minimally regulated like traditional food."[212] This merging of vitamins and minerals with herbs and botanicals under the umbrella term "dietary supplement" was codified in the DSHEA, establishing the same safety requirements for all dietary supplement ingredients.[213] While all new dietary supplement ingredients have the same threshold safety requirement of a "reasonabl[e]" expectation of safety,[214] there are different reporting requirements based on whether the ingredient has an RDI.[215] If an ingredient is part of a "proprietary blend" and has no RDI, manufacturers are not required to disclose how much of the ingredient is in the dietary supplement, only the name of the ingredient and the total weight of the "proprietary blend."[216]

This reporting discrepancy presents an informational gap for consumers. Most dietary ingredients with an RDI are vitamins, minerals, and amino acids.[217] Consumers can easily find information about how much of any ingredient with an RDI a product contains and the "% Daily Value" on the product's packaging.[218] There are also plentiful resources from reputable institutions, such as the National Institute of Health, Mount Sinai, the Mayo Clinic, and other official public health websites, available for consumers to find out exactly what these ingredients are, what they do, what the recommended dose is, how much of the ingredient is safe to ingest, and what interactions they may

211. *See* Van Tassel, *supra* note 23, at 235–36 ("Before the 1980s, vitamins made up the vast majority of the supplement market. Relative to today, herbal remedies played only a small role compared to the market for vitamins.").

212. *Id.* at 236.

213. 21 U.S.C. § 321(ff)(1) (explaining the requirements for dietary supplement ingredients).

214. 21 C.F.R. § 190.6(b)(4) (2024).

215. *See id.* § 101.36(b)(2)–(3). Ingredients with RDIs are primarily vitamins, minerals, and amino acids. *Id.* Ingredients without RDIs must only report the ingredient's presence in the product and the amount by weight. *Id.*; *see also supra* notes 165–71 and accompanying text.

216. *Id.* § 101.36(c)(1)–(3) (detailing compliance measures for "proprietary blends").

217. *Id.* § 101.36(b)(2)(i)(B).

218. *See id.* § 101.36(e) (requiring RDI ingredient and "% Daily Value" labeling to appear on dietary supplement packaging in no smaller than six-point font).

have with various medications.[219] Because they lack an RDI, the same cannot be said for many herbal supplements.

Licorice root is a prime example of a common weight loss and detox tea ingredient that does not have an RDI.[220] It must be listed on the tea's packaging as an ingredient, but because it is often part of a "proprietary blend,"[221] there is no way for consumers to know exactly how much licorice root a tea contains. Additionally, because licorice root has no RDI, consumers must look elsewhere to discover how much is safe to consume.[222] Information about the safe daily intake amount of licorice root or how it reacts with other medications is also less readily available than most vitamins and minerals, so omitting information about how much licorice root is contained in a product from its packaging keeps consumers completely in the dark.[223]

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219. *See, e.g.*, *Vitamin A*, HARVARD T.H. CHAN SCH. OF PUB. HEALTH: THE NUTRITION SOURCE (Mar. 2023), https://nutritionsource.hsph.harvard.edu/vitamin-a [https://perma.cc/2LTM-2Y3G] (explaining Vitamin A's purpose, recommended daily intake, toxicity level, common sources, and dangers of deficiency and toxicity); *Vitamin B1 (Thiamine)*, MOUNT SINAI, https://www.mountsinai.org/health-library/supplement/vitamin-b1-thiamine [https://perma.cc/2XD7-VK6T] (detailing the uses of Vitamin B1, its sources in food, daily recommended intake for different age groups, possible drug interactions, and supporting research); Mayo Clinic Staff, *Calcium and Calcium Supplements: Achieving the Right Balance*, MAYO CLINIC (Nov. 1, 2022), https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/calcium-supplements/art-20047097 [https://perma.cc/TX8D-Y3G7] (discussing the importance of calcium in the diet for bone health, risks of calcium deficiency, recommended daily intake for different age groups and sexes, types of calcium supplements, and risks of over-ingestion); *Iodine: Fact Sheet for Health Professionals*, NAT'L INSTS. OF HEALTH: OFF. OF DIETARY SUPPLEMENTS (May 1, 2024), https://ods.od.nih.gov/factsheets/Iodine-HealthProfessional [https://perma.cc/74TC-KQP9] (reporting recommended daily iodine intake for different age groups and sexes, food sources of iodine, risks of deficiency and excessive intake, medication interactions, and supporting research); *Chromium*, HARVARD T.H. CHAN SCH. OF PUB. HEALTH: THE NUTRITION SOURCE (March 2023), https://www.hsph.harvard.edu/nutritionsource/chromium [https://perma.cc/AA3Y-GCQU] (describing chromium uses in the body, recommended daily intake and maximum safe dose, signs of deficiency and toxicity).

220. *See* sources cited *supra* notes 2–3, 7 (exemplifying weight loss and detox teas that utilize licorice root).

221. *See* sources cited *supra* notes 2–3, 7; 21 C.F.R. § 101.36(c)(1)–(3) (2024).

222. *See* 21 C.F.R. § 101.36(a)(2)(i) (2024) (providing a list of ingredients with RDIs, which does not include licorice root).

223. *See* Michael T. Murray, *Glycyrrhiza Glabra (Licorice)* (describing licorice's use in medicine from a scientific perspective), *in* 1 TEXTBOOK OF NATURAL MEDICINE 641 (Joseph E. Pizzorno & Michael T. Murray eds., 5th ed. 2021)

The lack of easily accessible information for consumers to determine how much of a substance they're putting in their bodies is particularly troubling in relation to medication interactions and dosage. For example, there is evidence that licorice root interacts with high blood pressure medications, oral contraceptives, and insulin.[224] Licorice root can also be dangerous if consumed in excess,[225] and some scientists have called on the FDA to more closely regulate its use.[226] A consumer drinking tea containing licorice root would have no way of knowing how much of the ingredient each serving contains, and, therefore, no way to calculate how many servings they can safely consume.

To help close the information gap, all dietary supplement ingredients must be subject to the same reporting standards, regardless of whether an RDI has been established. The cost to manufacturers to implement this change would amount to no more than the cost of modifying product labels. Consumers must have access to enough information to make decisions about their own health related to their supplement consumption, including

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(ebook); *Licorice*, MOUNT SINAI, https://www.mountsinai.org/health-library/herb/licorice [https://perma.cc/SB3Y-D7PM] (documenting potential uses and medication interactions of licorice). The research surrounding ingredients without RDIs is often sparse or virtually non-existent. While researching for this Note, the author spent considerably more time attempting to find reputable scientific research about a single example ingredient (licorice root), than for all the ingredients with established RDIs *supra* note 219.

224. *See Licorice*, *supra* note 223 ("Licorice may interfere with several medications, including . . . ACE inhibitors and diuretics . . . corticosteroids . . . insulin or drugs for diabetes . . . laxatives . . . oral contraceptives . . . Warfarin . . . .").

225. *See id.* ("Too much glycyrrhizin [licorice's active ingredient] causes a condition called pseudoaldosteronism, which can cause a person to become overly sensitive to a hormone in the adrenal cortex. This condition can lead to headaches, fatigue, high blood pressure, and even heart attacks. It may also cause water retention, which can lead to leg swelling and other problems."); *Licorice Root*, NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH (Aug. 2020), https://www.nccih.nih.gov/health/licorice-root [https://perma.cc/Q9HP-G9HK] ("The effects of licorice on potassium and blood pressure are a particular concern for people with hypertension (high blood pressure) or heart or kidney disease.").

226. *See* Hesham R. Omar et al., *Licorice Abuse: Time to Send a Warning Message*, 3 THERAPEUTIC ADVANCES ENDOCRINOLOGY & METABOLISM 125, 134 (2012) ("The FDA should start regulating the use of [licorice] and create public awareness through the media about its health hazards. We aim to send a warning message that licorice is not just a candy and that serious life-threatening complications can occur with excess use.").

tracking the amount of each ingredient they consume. This information is available for ingredients that have RDIs;[227] it must also be available for those that do not. Providing consumers with the same information about dietary supplement ingredients, whether vitamin, mineral, herbal, or botanical, is one way to prevent potential adverse health events from ingredient overdose or medication interactions.

B. ESTABLISHING PRE-MARKET SAFETY TESTING AND RDIS FOR DIETARY SUPPLEMENT INGREDIENTS

A second way to improve consumer safety in the dietary supplement industry is to mandate basic pre-market safety testing for dietary supplement ingredients and to establish RDIs for new and previously approved dietary ingredients. Prior to the FDCA, there was no requirement for manufacturers to prove any product was safe before introducing it to the market.[228] Now, new drugs must undergo rigorous safety and efficacy testing before the FDA will approve them for sale, including several phases of clinical trials.[229] This stringent process is logical in the context of drugs because not only must they be safe for their intended use, but they must also effectively treat the targeted condition.[230]

In contrast, dietary supplements are not subject to pre-market safety testing.[231] Manufacturers must merely submit evidence to establish that a new dietary ingredient is reasonably

227. *See* 21 C.F.R. § 101.36(b)(2)(ii) (2024) (requiring dietary ingredients with an RDI to report the percentage of the recommended daily intake of that ingredient present in the product).

228. *See supra* Part I.B.

229. *See* 21 U.S.C. § 355 (establishing the information that a manufacturer must include in its application for FDA approval of a new drug); *The Drug Development Process*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process [https://perma.cc/H48W-8SZQ]; *see also* Sandeep Sinha & Divya Vohora, *Drug Discovery and Development: An Overview* (detailing the "time and cost intensive" process by which new drugs are approved by the FDA), *in* PHARMACEUTICAL MEDICINE AND TRANSLATIONAL CLINICAL RESEARCH 19, 19 (Divya Vohora & Gursharan Singh eds., 2018).

230. *See* 21 U.S.C. § 355(b)(1)(A)(i) (requiring evidence in a New Drug Application that the drug "is safe for use and whether such drug is effective in use").

231. *See supra* Part II.A.

expected to be safe.[232] This requirement is only for new dietary ingredients; dietary ingredients already on the market require no approval prior to sale.[233] This presents a major safety problem for consumers. While the requirement to prove a reasonable expectation of safety protects consumers from obviously harmful ingredients—such as antifreeze[234]—being introduced to the market, it does not protect against ingredients already on the market that may have had minimal research into possible adverse effects at the time they were approved, such as ephedrine alkaloids.[235]

Requiring basic pre-market safety testing and establishing safe daily consumption amounts for dietary ingredients would help protect consumers from potentially adverse interactions or toxicities.[236] Establishing safe daily limits for dietary ingredients instead of requiring only that they be reasonably safe for the recommended use would provide consumers vital information to protect their health.[237] It would allow consumers to track their consumption of an ingredient across products to ensure they don't exceed the safe maximum. Safe daily limits could be established either by manufacturers wishing to bring a new

232. *See* 21 C.F.R. § 190.6(b)(4) (2024) (requiring dietary supplement manufacturers to submit "[t]he history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe").

233. *See* 21 C.F.R. § 190.6(a) (2024) (requiring that a manufacturer *notify* the FDA "[a]t least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food" but providing no requirement that the FDA issue any approval before the new ingredient is sold to consumers).

234. *See supra* Part I.B.2.

235. *See, e.g.*, Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1039 (10th Cir. 2006) ("[Ephedrine alkaloid dietary supplements] were allowed to enter the market without findings of safety or effectiveness. The FDA did not impose a pre-market requirement for the sale of [ephedrine alkaloids].").

236. *See* Termini & Sannuti, *supra* note 11, at 205 ("By implementing [a premarket] approval process, the FDA would be able to halt the production of unsafe supplements prior to entering the marketplace. This preventative measure alone would prevent numerous consumers from being harmed by unsafe dietary supplements.").

237. *See supra* Part III.A.

dietary ingredient to market or by the FDA for dietary ingredients already in circulation.[238] This would place the safety burden on manufacturers with regards to new dietary ingredients, but it would limit this burden for already approved products. This approach mirrors that for drugs, but the much lower threshold reflects the comparatively lesser likelihood of adverse events from consumption of dietary supplements.[239]

In the context of weight loss and detox teas, establishing pre-market safety testing and recommended daily amounts for ingredients could potentially protect consumers from unintended overuse of herbal laxatives and diuretics. Overuse of laxatives and diuretics can result in serious health problems, including kidney damage.[240] They are also common ingredients in weight loss and detox teas.[241] Because there are no RDIs for these ingredients, it would be difficult for a consumer to know when their consumption of teas containing diuretic or laxative ingredients may become dangerous. Coupled with the lack of information about exactly how much of each ingredient is in a serving of tea, there is no way for consumers to safely judge their intake of such products. Laxatives also interact with a plethora of medications, including antibiotics and heart medication.[242]

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238. *See* Nieto, *supra* note 37, at 151 (proposing the FDA conduct trials of dietary supplement ingredients).

239. The FDA has created a combined online portal for consumers and healthcare professionals to report adverse events for most of the products in its purview, including food, drugs, dietary supplements, cosmetics, and medical devices. *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, U.S. FOOD & DRUG ADMIN. (last updated Oct. 25, 2024), https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program [https://perma.cc/9BZN-BFPZ].

240. *See* Amy Baker Dennis, *Laxative Misuse*, NAT'L EATING DISORDER ASS'N, https://www.nationaleatingdisorders.org/laxative-misuse [https://perma.cc/X6LH-K743] (detailing consequences of laxative overuse such as severe dehydration, which "may cause tremors, weakness, blurry vision, fainting, kidney damage, and in extreme cases, death"); Craig G. Smollin, *Diuretics* (describing the presentation of symptoms resulting from diuretic overuse, including "nausea, vomiting, and diarrhea" and "[l]ethargy, weakness, hyporeflexia, and dehydration"), *in* POISONING & DRUG OVERDOSE § 2-63 (Kent R. Olson & Craig G. Smollin eds., 8th ed. 2022) (ebook).

241. See *supra* notes 1–8 for examples of teas containing these ingredients.

242. *Nonprescription Laxatives for Constipation: Use with Caution*, MAYO CLINIC (Jan. 26, 2024), https://www.mayoclinic.org/diseases-conditions/constipation/in-depth/laxatives/art-20045906 [https://perma.cc/TC4A-7LDQ] ("Laxatives can interact with many medicines including certain antibiotics,

Mandating pre-market safety testing, including establishing RDIs, for laxative and diuretic dietary ingredients would allow consumers to make more informed decisions about how much of any substance is safe for them to ingest given their personal health circumstances.

Pre-market efficacy testing, on the other hand, should not be a requirement for dietary supplements. Unlike drugs, dietary supplements do not claim to cure or treat any particular illness—they are expressly forbidden from doing so.[243] Manufacturers are also mandated to include a disclaimer of such curative effects on dietary supplement packaging.[244] This disclaimer provides consumers clear warning that dietary supplements have not been tested or proven to diagnose, treat, cure, or prevent diseases. A weight loss tea may state it "promote[s] healthy digestion, helps . . . reduce water weight, and helps reduce inflammation to soothe bloating,"[245] but these statements must include the required disclaimer. Contrast this with an FDA-approved weight loss drug, which may tout its efficacy in helping users lose weight because this result was borne out by required clinical testing.[246] Because dietary supplements may not make any substantive claims as to their efficacy, it is not necessary for them to undergo pre-market efficacy testing.

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heart and bone medicines."); *see Laxative (Oral Route)*, MAYO CLINIC (last updated Sept. 1, 2024), https://www.mayoclinic.org/drugs-supplementslaxative-oral-route/before-using/drg-20070683 [https://perma.cc/8SLT-RWQS] (listing over one hundred medications not recommended for use while taking laxatives).

243. *See* 21 C.F.R. § 101.93(f) (2024) ("If the label or labeling of a product marketed as a dietary supplement bears a disease claim . . . the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.").

244. *See id.* § 101.93(c) (requiring dietary supplement packaging to contain the disclaimer that the product is "not intended to diagnose, treat, cure, or prevent any disease").

245. *Detox: Superfoods Tea*, SKINNYFIT, https://skinnyfit.com/products/detox [https://perma.cc/VBC3-H4GX].

246. *See Weight Loss with Saxenda*, SAXENDA, https://www.saxenda.com/about-saxenda/weight-loss-with-saxenda.html (click "Saxenda Adult Study Results") [https://perma.cc/Y9G9-E89F] ("Saxenda was clinically tested and proven in a study of 3,731 adult patients in which 85% of people taking Saxenda lost some weight."); Mayo Clinic Staff, *Prescription Weight-Loss Drugs*, MAYO CLINIC (Oct. 29, 2022), https://www.mayoclinic.org/healthy-lifestyle/weight-loss/in-depth/weight-loss-drugs/art-20044832 [https://perma.cc/UK6X-XWJY] (listing the six weight loss drugs currently approved by the FDA).

Pre-market safety testing of dietary supplements will likely raise the cost of development for manufacturers. The same is true for the testing required to establish RDIs for new dietary ingredients. However, the benefit of ensuring that dietary supplements available to consumers are safe at their recommended dosages far outweighs the cost. Ephedrine alkaloid supplements never underwent pre-market safety testing,[247] and numerous lives were lost as a result.[248] Pre-market safety testing could also prove more profitable for manufacturers in the long run if it prevents consumers from being injured by unsafe products. Just a few publicly reported damages awards from ephedrine alkaloid-related cases total $27 million.[249] This doesn't account for the cost of defending such lawsuits.[250] Pre-market safety testing would protect dietary supplement manufacturers by preventing unsafe products from entering the market in the first place, thus decreasing the likelihood manufacturers would face litigation from injured consumers. Additionally, many laxative and diuretic ingredients used in weight loss teas, such as senna, are also

247. *See* Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1039 (10th Cir. 2006) ("[Ephedrine alkaloid dietary supplements] were allowed to enter the market without findings of safety or effectiveness.").

248. *See supra* Part II.B.

249. *See Woman Awarded $13.3 Million for Ephedrine-Induced Stroke*, SUPPLY SIDE SUPPLEMENT J. (Feb. 28, 2001), https://www.supplysidesj.com/supplement-regulations/woman-awarded-13-3-million-for-ephedrine-induced-stroke [https://perma.cc/KAV5-TVPL] ("A woman who suffered a stroke after taking a supplement containing ephedrine was awarded $13.3 million Feb. 7, more than has been paid in any previous settlement for an ephedra or ephedrine lawsuit."); *First Settlement in Diet Supplement Case*, CBC NEWS (Nov. 25, 2002), https://www.cbc.ca/news/canada/first-settlement-in-diet-supplement-case-1.306509 [https://perma.cc/NM7Y-E2G3] ("A jury in Alabama has awarded more than $4 million to four people who suffered strokes and cardiac problems after taking a dietary supplement [containing ephedrine alkaloids]."); *Jury Awards $7.4 Million in Ephedra Lawsuit*, NBC NEWS (June 24, 2004), https://www.nbcnews.com/id/wbna5288323 [https://perma.cc/2983-Y44G] ("A jury awarded $7.4 million to a woman who suffered brain damage in a stroke two years ago after taking a diet supplement that contained the now-banned herbal stimulant ephedra."); Guy Gugliotta, *Ephedra Lawsuits Show Big Increase*, WASH. POST (July 23, 2000), https://www.washingtonpost.com/archive/politics/2000/07/23/ephedra-lawsuits-show-big-increase/3cf0e1e6-5585-4271-b39f-32833dcb1303 [https://perma.cc/YJ9K-ME8L] ("In 1998, the [ephedrine alkaloid manufacturers] settled for $2.5 million . . . .").

250. *See Facts + Statistics: Product Liability*, INS. INFO. INST., https://www.iii.org/fact-statistic/facts-statistics-product-liability [https://perma.cc/N8D5-NYCT] (showing the cost of products liability defense and cost containment is, on average, over forty percent of incurred losses).

used in over-the-counter medications.[251] For ingredients already used in FDA-approved drugs, the burden on dietary supplement manufacturers in proving their safety would be minimal because the necessary research already exists. As described in Part III.A, updating dietary supplement packaging to explicitly inform consumers of ingredients' RDI would incur a minimal cost.

Establishing RDIs for dietary supplement ingredients already on the market would also cost money. However, it would be fundamentally unfair to any particular dietary supplement manufacturer to mandate they conduct research on an ingredient that is already used throughout the industry if there are no reports of serious adverse events relating to the ingredient.[252] Placing the research burden on the FDA is not without its own cost considerations. The FDA's budget in recent years has not kept pace with the agency's workload,[253] particularly in the realm of food safety.[254] A string of reports documenting dietary

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251. *Compare, e.g.*, *Dr. Tea Slender You With Senna – Pomegranate Flavor*, SNS HEALTH, https://snshealth.com/products/dr-tea-slender-you-with-senna-pomegranate-flavor [https://perma.cc/Z6X2-TNFW], *and Super Dieter's Tea – Caffeine Free All Natural Botanicals (30 Tea Bags)*, THE VITAMIN SHOPPE, https://www.vitaminshoppe.com/p/laci-le-beau-super-dieter-tea-natural-botanical-30-bag/lb-1001 [https://perma.cc/TZ8D-J5UG], *with Senna Laxative Tablets – 100ct – up&up*, TARGET, https://www.target.com/p/senna-laxative-tablets-100ct-up-38-up-8482/-/A-11031083 [https://perma.cc/MD7T-VXML]. Senna is listed as the primary ingredient in both the dietary supplement teas and the over-the-counter drug.

252. *See infra* Part III.C (advocating for dietary supplement manufacturers to bear the burden for proving an ingredient is safe when consumers report serious adverse events relating to the ingredient).

253. *See* Judith Alphonse et al., *The FDA Funding Crisis*, 30 J. PHARMACY TECH. 57, 59 (2014) ("Our review of FDA responsibilities makes it abundantly clear that the FDA budget is being burdened with increased contemporary demands beyond traditional safeguards and approvals laws, executive directives, and public expectations.").

254. *See* Laura Reiley, *Scathing Report Urges Major Changes at FDA, Including Possibly Breaking Up Agency*, WASH. POST (Dec. 6, 2022), https://www.washingtonpost.com/business/2022/12/06/fda-food-safety-formula [https://perma.cc/HTR2-XFS5] ("Food safety experts have long complained that [the FDA's] food oversight arm has been chronically understaffed and underfunded. . . . More broadly, experts say, the agency has prioritized the drug and medicine side, frequently drawing leaders with medical backgrounds and without food industry knowledge.").

supplements contaminated with lead,[255] steroids,[256] unapproved drugs,[257] and bacteria and fungus[258] highlight the agency's currently ineffective enforcement power.[259] The problem of contaminated food is so prevalent it even caught the attention of talk show host John Oliver, who produced a widely-viewed segment on food safety.[260] While the FDA has requested a $7.2 billion budget increase for 2024, the medical product safety sector would receive nearly three times the funding as the food safety sector.[261] The safety of the American food supply, which

255. *See* Julia Calderone, *FDA Warns About Lead Poisoning from Dietary Supplements*, CONSUMER REPS. (Aug. 30, 2016), https://www.consumerreports.org/vitamins-supplements/lead-poisoning-from-dietary-supplements [https://perma.cc/UCL4-6KNT] ("A dietary supplement has been linked to a cluster of lead poisoning cases in the Chicago area . . . . The FDA found that it contains 56 times more lead than the amount known to pose a health risk in children.").

256. *See Tainted Body Building Products*, U.S. FOOD & DRUG ADMIN. (Sept. 12, 2023), https://www.fda.gov/drugs/medication-health-fraud/tainted-body-building-products [https://perma.cc/52PU-TCPZ] ("FDA testing found [body building supplements] to contain active ingredients not listed on the product labels, including some with ingredients found in prescription drugs.").

257. *See* Jenna Tucker et al., *Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated with US Food and Drug Administration Warnings*, JAMA NETWORK OPEN, Oct. 2018, at 1, 9 ("[F]rom 2007 through 2016 [the study's analysis] showed that unapproved pharmaceutical ingredients were identified in 776 dietary supplements, and these products were commonly marketed for sexual enhancement, weight loss, or muscle building.").

258. *See* Jolanta Dlugaszewska et al., *Are Dietary Supplements Containing Plant-Derived Ingredients Safe Microbiologically?*, 27 SAUDI PHARM. J. 240, 245 (2019) ("The results of this study implicate an impending danger for consumers. The presence of even low levels of pathogenic microorganisms, higher levels of opportunistic pathogens or toxic microbial metabolites, which persist even after the elimination of primary contaminants, may result in products being ineffective. Microbial infections, not only regarding the physical presence of microorganisms but also their metabolites/toxins, could produce harmful effects even at low levels.").

259. *See* C. Michael White, *Analysis: Some Natural Supplements Can Be Dangerously Contaminated*, PBS NEWS (Feb. 19, 2020), https://www.pbs.org/newshour/health/analysis-some-natural-supplements-can-be-dangerously-contaminated [https://perma.cc/H7E3-PHSG] ("[T]he FDA can't fully protect you from quality issues in dietary supplements . . . .").

260. Last Week Tonight with John Oliver, *Food Safety*, YOUTUBE (Oct. 16, 2023), https://www.youtube.com/watch?v=Za45bT41sXg (explaining the FDA's "serious shortcomings" over the previous fifty years).

261. FOOD & DRUG ADMIN., *Justification of Estimates for Appropriations Committees*, DEP'T OF HEALTH & HUM. SERVS. 5 (2024), https://www.fda.gov/media/166182/download?attachment [https://perma.cc/K7ZT-WKF2] (allocating $1.7 billion for food safety and $4.6 billion for medical product safety).

currently includes dietary supplements, must be funded adequately as a whole. The additional cost of establishing RDIs for products already on the market should be included in a holistic budget increase for the agency to enforce the current standards and to protect consumers with continuing research.

The DSHEA should be updated to subject dietary supplements to pre-market safety testing in order to protect consumers from potentially dangerous ingredients.[262] The FDA and supplement manufacturers should also conduct research to establish a safe daily dosage for dietary supplement ingredients—the FDA for ingredients currently on the market and manufacturers for new ingredients they wish to bring to market. This would allow consumers to monitor their intake of ingredients against the recommended daily values to prevent overuse of potentially harmful substances, such as herbal laxatives and diuretics used in weight loss and detox teas.

C. CLOSING THE "UNREASONABLE" LOOPHOLE

A third way to protect dietary supplement consumers from harm is to shift the burden of proving the safety of suspect supplements already on the market from the FDA to the manufacturer. The ephedrine alkaloid crisis was so disastrous to consumer safety because the DSHEA prevented the FDA from taking swift action to remove the substance from the market.[263] The "under conditions of use recommended" clause stymied their efforts because it required a showing that *any* amount of ephedrine alkaloids in dietary supplements presented an "unreasonable" risk of injury.[264] This places the burden on the FDA to prove a product is harmful in order to remove it from the market entirely, even when injuries caused by higher doses create a strong inference that a supplement is harmful in any quantity.

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262. The European Union has already implemented regulations requiring dietary supplements to be safety tested prior to being sold. *See* Termini & Sannuti, *supra* note 11, at 204 ("[U]nder the Food Supplements Directive, the manufacturer has the burden of proving to the European Union's regulatory body that the supplement is safe, before it ever reaches the marketplace.").

263. *See supra* note 196.

264. *Id. See generally* 21 U.S.C. § 342(f)(1) (categorizing a dietary supplement as "adulterated," or failing to meet legal standards, if it "presents a significant or unreasonable injury under . . . conditions of use recommended or suggested in labeling").

The ephedrine alkaloid crisis was in some ways a mirror to the Elixir Sulfanilamide incident prior to the enactment of the FDCA, where the ingredient diethylene glycol (a main component in antifreeze) killed nearly 100 people.[265] In that case, the FDA did not have the authority to remove the product from the market for being highly dangerous; it could only be removed as "misbranded" for failing to adhere to the standard of "elixir."[266] The FDA could not even ban the use of diethylene glycol in future medications because it did not possess the authority to wholly ban an ingredient from the market.[267] Similarly, while the FDA nominally had the authority to remove ephedrine alkaloids from the market, the high bar to do so prevented it from exercising this authority effectively, with the delay costing lives.[268]

To protect consumers from a repeat of these failures, Congress should update the DSHEA and place the burden on the manufacturer to prove that dietary supplement ingredients already on the market are safe when consumers report serious adverse events. Manufacturers are already required to report any serious adverse events stemming from their products to the FDA.[269] The FDA should be given the authority to act quickly based on these reports and place a temporary freeze on the sale of products containing suspected dangerous ingredients—a kind of administrative preliminary injunction. This would immediately protect consumers from harm in the case that the dietary ingredient is actually dangerous.[270] Following a temporary freeze, the burden should fall to the manufacturer to prove their

265. *See* Cavers, *supra* note 103, at 20 (stating at the time "at least 75, perhaps over 90, persons in various parts of the country, although chiefly in the South, died as a result of taking" Elixir Sulfanailamide).

266. *Id.*

267. *See* Pure Food and Drugs Act of 1906, ch. 3915, §§ 7–8, 34 Stat. 768, 769–71 (1906) (repealed 1938). The PFDA only gave the FDA the authority to remove "misbranded" or "adulterated" products from the market.

268. *See* Van Tassel, *supra* note 23, at 243 ("The total time and expense involved in [banning ephedrine alkaloids], including the cost of the harm suffered by consumers, was tremendous."); *supra* Part II.B.

269. *See* 21 U.S.C. § 379aa-1(b)(1) ("The manufacturer, packer, or distributor of a dietary supplement . . . shall submit to the Secretary any report received of a serious adverse event associated with such dietary supplement . . . .").

270. *See* Kaiser, *supra* note 139, at 1273 ("[T]he FDA should be re-empowered to act against a supplement as a class, instead of merely against an individual product. One major handicap visited upon the FDA by the DSHEA was the requirement that the FDA act against not only each individual product, but also against the specific formulation of that product.").

product is safe for its intended use, instead of on the FDA. If the manufacturer meets this bar, then the burden could shift to the FDA to rebut. By placing the initial burden of safety on the manufacturer, the manufacturer would be required to produce research affirming a product's safety, in contrast to the current scheme which places the burden on the FDA to prove the product is unsafe. Shifting the burden to the manufacturers to prove safety could also provide an incentive to conduct more thorough research and testing prior to launching a new product, both to prevent unsafe products from entering the market and to have evidence proving the new product's safety in preparation for litigation.

In the case of ephedrine alkaloids, halting the sale of the products and giving the manufacturers the burden of proving safety could have prevented injuries and saved lives.[271] It would then have fallen to the manufacturers to prove that ephedrine alkaloids were safe at their recommended dosages, which they were not. While a temporary freeze on the sale of a dietary supplement ingredient would cost manufacturers money, the scale of the potential harm to consumers from letting dangerous products remain on the market far outweighs this burden.[272] Placing the interests of supplement manufacturers before the interests of consumers is antithetical to the FDA's mission and endangers consumers.[273] The past failures of regulating weight loss dietary supplements, such as ephedrine alkaloids, should serve as a warning; the FDA must have the authority to act against potentially dangerous weight loss and detox supplements to avert the next crisis.

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271. *See* Termini & Sannuti, *supra* note 11, at 207 ("Under a more proactive regulatory approach, the FDA would have been able to prevent past tragedies, such as those involving ephedrine alkaloids . . . ."); Van Tassel, *supra* note 23, at 242 (stating the ephedrine alkaloid crisis was "[a]n example of the implications of switching the burden of proof onto the FDA to prove that weight loss supplements are unsafe and ineffective"); Burke & Page, *supra* note 23, at 134–35 ("[I]t is estimated that at least one percent of the U.S. adult population had taken a supplement that contains ephedrine, thus putting them at risk for ischemic and hemorrhagic strokes, until the FDA banned its use for safety concerns.").

272. *See supra* Part II.B.

273. *See What We Do: FDA Mission*, *supra* note 210; Kaiser, *supra* note 139, at 1273 (stating changes to DSHEA must be made to "restore the FDA's power to regulate any supplement that becomes a recognized health threat. Any other solution would place the public in a dangerous position").

CONCLUSION

The history of dietary supplements and their predecessors, patent medicines, teaches us two important lessons. First, the American obsession with "detoxing" and weight loss is not a new trend[274] and is unlikely to go away anytime soon.[275] Second, dietary supplement manufacturers cannot be trusted to voluntarily place the interests of consumers over their own profits.[276] As the ephedrine alkaloid crisis demonstrates, manufacturers will continue to sell weight loss supplements to make a profit, regardless of the evidence that they are dangerous to consumers. To protect consumers from harm, basic safety mechanisms must be put in place to prevent potentially dangerous products from entering the market, to remove unsafe products from the market more easily, and to increase dietary supplement transparency so consumers know exactly what they are putting in their bodies. This can be done by updating the DSHEA to require manufacturers to report dietary ingredient contents by weight on product packaging and to engage in pre-market safety testing for new dietary ingredients, including establishing RDIs, and to provide the FDA with more authority to remove dangerous dietary ingredients from the market. If changes are not made, it is only a matter of time before consumers, in their perennial quest for weight loss, once again find themselves the unwitting victims of another untested dietary supplement.

274. *See supra* Part I.A.
275. *See supra* notes 1–8, 31.
276. *See supra* Parts I.A, II.B.