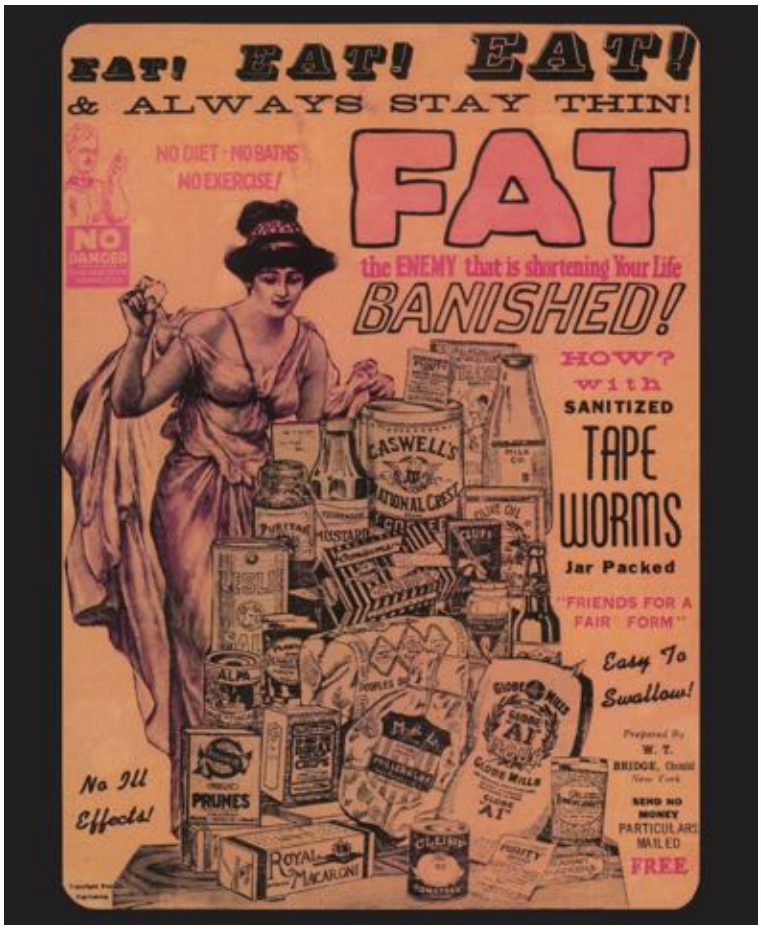
Dietary Suspects: Extracting the Truth from Dietary Supplements with a Standardized Federal Testing Seal

Nicholas A. Traver*



---

* Incoming Associate at Davis Wright Tremaine in Seattle, Washington; J.D. graduate from Sandra Day O'Connor College of Law Class of 2023. Thank you to Professor Andrew Carter, Renee Guerin, Dr. Preston Kramer, Gustaf Vanderdonck, my mother, and the exceptional team at the *Arizona State Law Journal* for their invaluable feedback and assistance.

INTRODUCTION

Are you fatigued, lethargic, or forgetful? Do you find it difficult to lose weight? Would you like to reduce your odds of cancer or even reverse the signs of aging? Considering the variety of common ailments many face every day, how empowered would you feel if you could address these, all on your own, with products widely available off the shelf? Would you take a magic pill, powder, or liquid that intimated quick relief? "Wellness culture" is thriving, and chances are more than half of the readers of this Comment take at least one dietary supplement regularly.[1] If this includes you, consider the following question: *Do you really know what's in your dietary supplement?*

Up to eighty percent of Americans regularly take at least one of over 85,685 dietary supplements available at the time of writing.[2] The global dietary supplement industry is expected to reach a global market size of $306.8 billion by 2026, with the U.S. market reaching $72 billion by the same year.[3] This is a staggering increase from the mere 4,000 products available in the $4 billion 1994 U.S. market.[4] The product range is incredibly vast: there are whey protein powders for bodybuilding;[5] KSM-66 ashwagandha capsules

---

1. *CRN Reveals Initial Data from 2021 Consumer Survey on Dietary Supplements*, COUNCIL FOR RESPONSIBLE NUTRITION (Oct. 21, 2021), https://www.crnusa.org/newsroom/crn-reveals-initial-data-2021-consumer-survey-dietary-supplements [https://perma.cc/H6HS-TH9T].

2. *Id.*; *Dietary Supplement Label Database (DSLD)*, NAT'L INSTS. OF HEALTH, OFF. OF DIETARY SUPPLEMENTS, https://dsld.od.nih.gov/search/*/bWFya2V0X3N0YXR1cz1vbl9tYXJrZXQvZW50cnlfZGF0ZT0yMDExLDIwMjIvc29ydD1uZXdlc3QvcGFnZV9zaXplPTIwLw== [https://perma.cc/9EH6-LRG4]. The DSLD tracks dietary supplement labels in the United States. *See also* SURUCHI MISHRA ET AL., NCHS DATA BRIEF NO. 399—DIETARY SUPPLEMENT USE AMONG ADULTS: UNITED STATES, 2017–2018 (2021), https://www.cdc.gov/nchs/data/databriefs/db399-H.pdf [https://perma.cc/6KLG-3T8P].

3. *Study on Dietary Supplements Market Size Estimated To Reach USD 306.8 Billion by 2026: Facts & Factors*, GLOBENEWSWIRE (Oct. 12, 2021, 9:38 AM), https://www.globenewswire.com/en/news-release/2021/10/12/2312740/0/en/Study-on-Dietary-Supplements-Market-Size-Estimated-to-Reach-USD-306-8-Billion-by-2026-Facts-Factors.html [https://perma.cc/VD4P-N925]; Nils Gerrit-Wunsch, *Value of the Dietary Supplements Market Worldwide in 2018 an 2020 with a Forecast to 2026, By Region*, STATISTA (Aug. 30, 2023), https://www.statista.com/statistics/1264459/region-global-dietary-supplement-market/ [https://perma.cc/QN73-QCC6]. For comparison, the OTC drug market is projected to reach $287.07 billion by 2027. *United States OTC Drugs Market Research Report*, MKT. DATA FORECAST (Jan. 2021), https://www.marketdataforecast.com/market-reports/united-states-over-the-counter-drugs-market [https://perma.cc/XS7B-NVAL].

4. COMM'N ON DIETARY SUPPLEMENT LABELS, REPORT OF THE COMMISSION ON DIETARY SUPPLEMENT LABELS 17 (1997), https://ods.od.nih.gov/pubs/DSHEA1997report.pdf [https://perma.cc/NJ7P-463H].

5. Lars L. Andersen et al., *The Effect of Resistance Training Combined with Timed Ingestion of Protein on Muscle Fiber Size and Muscle Strength*, 54 METABOLISM 151, 154 (2005).

for anxiety;[6] curcumin (turmeric) extracts designed to cross the blood brain barrier;[7] and even the swath of lab-derived "nootropics" designed to influence neurochemistry for depression, anxiety, ADHD, and the like.[8] Today, dietary supplements are directed at nearly every ailment a consumer could experience,[9] which seems to explain in part why so many people take them.[10] Although there are legitimate medical uses of dietary supplements,[11] consumers often turn to products to self-medicate.[12] Consumers are not provided drug-like assurances of quality for dietary supplements,[13] and contamination events are surprisingly common.[14] Many consumers

---

6. K. Chandrasekhar et al., *A Prospective, Randomized Double-Blind, Placebo-Controlled Study of Safety and Efficacy of a High-Concentration Full-Spectrum Extract of Ashwagandha Root in Reducing Stress and Anxiety in Adults*, 34 INDIAN J. PSYCH. MED. 255, 261 (2012).

7. *Longvida Optimized Curcumin*, VERDURE SCIS., https://vs-corp.com/longvida/ [https://perma.cc/7JTT-MG29].

8. Ruchi Malik et al., *Towards Better Brain Management: Nootropics*, 14 CURRENT MED. CHEMISTRY 123 (2007).

9. *See* FED. TRADE COMM'N, MIRACLE HEALTH CLAIMS & DIETARY SUPPLEMENTS: ADD A DOSE OF SKEPTICISM (2011).

10. CRN Reveals Initial Data from 2021 Consumer Survey on Dietary Supplements, supra note 1.

11. *See, e.g.*, John Yudkin, *Nutritional Deficiency in the Pathogenesis of Disease*, 1:4330 BRITISH MED. J. 5, 5–7 (1944), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2283209/?page=3 [https://perma.cc/YF2W-66VK]; Anne Schneyder, *Malnutrition and Nutritional Supplements*, 37:4 AUSTRALIAN PRESCRIBER 120, 122 (2014); *see also* Maria Isabel Toulson Davisson Correia et al., *Nutrition Therapy Cost-Effectiveness Model Indicating How Nutrition May Contribute to the Efficiency and Financial Sustainability of the Health Systems*, 45 J. PARENTERAL & ENTERAL NUTRITION 1542, 1544–48 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8697995/pdf/JPEN-45-1542.pdf [https://perma.cc/J893-GGCE] (demonstrating that use of dietary supplements leads to health care cost savings); CHRISTOPHER SHANAHAN & ROBERT DE LORIMIER, SMART PREVENTION—HEALTH CARE COST SAVINGS RESULTING FROM THE TARGETED USE OF DIETARY SUPPLEMENTS 1 (2013), https://www.crnusa.org/sites/default/files/pdfs-hccs/SmartPrevention-fullreport0913.pdf [https://perma.cc/X6D6-2653] (demonstrating use of dietary supplements can lead to reduced health care costs in the treatment of heart disease, diabetes, eye disease and osteoporosis).

12. Mark Nichter & Jennifer Jo Thompson, *For My Wellness, Not Just My Illness: North Americans' Use of Dietary Supplements*, 30 CULTURE, MED. & PSYCHIATRY 175, 187 (2006).

13. DEP'T OF HEALTH & HUM. SERVS., OFF. OF THE INSPECTOR GEN., ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS: AN INADEQUATE SAFETY VALVE 1 (2001), https://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf [https://perma.cc/3ZGL-7W6X] ("Unlike new prescription and over-the-counter drugs, the law does not require supplements to undergo premarket approval for safety and efficacy. Instead, FDA relies mainly on its adverse event reporting system to identify safety problems.").

14. *See Health Fraud Product Database*, FDA, https://www.fda.gov/consumers/health-fraud-scams/health-fraud-product-database [https://perma.cc/W5KR-FZQQ].

misunderstand the landscape of dietary supplement regulation,[15] often assuming the Food and Drug Administration ("FDA") exerts more control than is the case.[16] Compounding the issue, the FDA is severely underfunded, which stifles any enforcement of an already limited regulatory scheme.[17] The passage of the Dietary Supplement Health and Education Act ("DSHEA") in 1994,[18] fueled by decades of aggressive lobbying,[19] stripped the FDA of its prior ability to enforce stringent drug-like quality control requirements.[20] The DSHEA allows manufacturers to play on ambiguous legal distinctions between dietary supplements and pharmaceutical drugs to circumvent rigorous and expensive safety requirements.[21] Congress relaxed dietary supplement regulations in an attempt to increase access to "wellness."[22] But instead, these relaxed regulations effectively create an "anything goes" market of potentially harmful products that carry inadequate guarantees of safety and accuracy. After decades of market growth and transformation,[23]

---

15. Tonya Dodge, *Consumers' Perceptions of the Dietary Supplement Health and Education Act: Implications and Recommendations*, 8 DRUG & TESTING ANALYSIS 407, 408–09 (2016) (explaining that "two decades after DSHEA was enacted," physicians and consumers still misunderstand how dietary supplements are regulated and often assume they are approved for safety).

16. *Id.*; Aaron S. Kesselheim et al., *Mandatory Disclaimers on Dietary Supplements Do Not Reliably Communicate the Intended Issues*, 34 HEALTH AFFS. 438, 444 (2015).

17. Liz Richardson, *Funding Boost Should Be Followed by Reform of FDA Dietary Supplement Oversight*, PEW (Mar. 24, 2022), https://www.pewtrusts.org/en/research-and-analysis/articles/2022/03/24/funding-boost-should-be-followed-by-reform-of-fda-dietary-supplement-oversight [https://perma.cc/DW9E-6BGW].

18. Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4332 (1994) (codified as amended in scattered sections of 21 U.S.C.).

19. John P. Swann, *The History of Efforts To Regulate Dietary Supplements in the USA*, 8 DRUG TESTING & ANALYSIS 271, 277–79 (2016).

20. Food Drug & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

21. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective [https://perma.cc/E89L-BXNN]; Thomas Sullivan, *A Tough Road: Cost To Develop One New Drug Is $2.6 Billion*, POL'Y & MED. (Mar. 21, 2019), https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html [https://perma.cc/CU75-M2GY].

22. Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1038–39 (10th Cir. 2006); *see also Pharmanex v. Shalala,* 221 F.3d 1151, 1158–59 (10th Cir. 2000).

23. NAT'L CTR. FOR HEALTH STAT., NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY FOR 1971–1975 (NHANES I) 43 (1981), https://wwwn.cdc.gov/nchs/data/nhanes1/4701.pdf [https://perma.cc/SUH2-VQ93] (reporting 6,880 of 20,749 respondents (33%) stated they took dietary supplements); NAT'L CTR. FOR HEALTH STAT., NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY FOR 1976–1980 (NHANES II) 59 (1989), https://wwwn.cdc.gov/nchs/data/nhanes2/5701.pdf [https://perma.cc/7BNN-MA8S] (reporting 7,752 of 20,322 respondents (38%) stated they took

the DSHEA's castration of the FDA has left both consumers and manufacturers at greater risk of harm.[24]

Without required pre-market demonstrations of safety, consumers must determine a given product's quality on their own.[25] Even for the most skeptical consumer, successful verification of a supplement's quality is often unrealistic because of the difficulties in untangling the myriad of confusing and overlapping standards, seals, and regulations.[26] Because of this, consumers cannot adequately safeguard themselves against exposure to potentially toxic or misleading products.

Resolving these issues is a complex endeavor because dietary supplements exist in the middle of a policy paradox. Medical consumables, like drugs, demand upregulation by the FDA because of the potential for undisclosed harms. By contrast, foods and food-derivative consumables enjoy lower regulation as it is generally easier for consumers to appraise the quality of food than drugs. For instance, we can tell when produce is rotten, but poisoned Tylenol is harder to detect.[27] But dietary supplements exist in between foods and drugs, and rampant contamination events plague the industry as a result of this ambiguous regulatory regime.[28] Manufacturers have intentionally added undisclosed pharmaceuticals, mistakenly switched active ingredients, and carelessly allowed manufacturing debris, bacteria, and toxic heavy metals to be introduced into products.[29] The existence of harmful and inferior products in the dietary supplement marketplace places consumers at risk of physical harm while honest manufactures pay the cost of the resulting widespread reputational damage inevitably affiliated to the

---

dietary supplements); NAT'L CTR. FOR HEALTH STAT., NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY FOR 1988–1994 (NHANES III) 36 (1998), https://wwwn.cdc.gov/nchs/data/nhanes3/2a/PUVITMIN-acc.pdf [https://perma.cc/QTA3-G5MY] (reporting 17,408 of 33,994 respondents (51%) stated they took dietary supplements in the past month); MISHRA ET AL., *supra* note 2, at 5 (reporting that 57.6% of participants stated they took a dietary supplement in the past 30 days).

24. *See* Nisha Rao et al., *An Increase in Dietary Supplement Exposures Reported to U.S. Poison Control Centers*, 13 J. MED. TOXICITY 227, 227 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5570731/pdf/13181_2017_Article_623.pdf [https://perma.cc/GH8A-3BU4].

25. *See* Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4332 (1994) (codified as amended in scattered sections of 21 U.S.C.).

26. *See* discussion *infra* Subsection I.D.5.

27. Howard Markel, *How the Tylenol Murders of 1982 Changed the Way We Consume Medication*, PBS (Sept. 29, 2014, 11:30 AM), http://www.pbs.org/newshour/updates/tylenol-murders-1982/ [https://perma.cc/G2TB-BY6U].

28. *See* discussion *infra* Subsection I.A.1.

29. *See* discussion *infra* Subsection I.A.1.

entire product segment.[30] The demonstrated rise in dietary supplement consumption suggests a corresponding rise in the class of potential victims, and a growing need for change.[31]

Because overly restrictive regulatory approaches have failed and current approaches are inadequate,[32] the problem of quality control among dietary supplements requires novel and enforceable protections to eliminate inferior products and create a reliable market. The century-long public policy debate over the extent of the FDA's dietary supplement authority suggests any legitimate consumer protection interest must be balanced with the economic and free market interests.[33] Congress should address these issues by creating an optional standardized third-party testing certificate, paid for by participating manufacturers and guaranteed by verified third-party labs to give consumers the ability to quickly and accurately determine the quality of their dietary supplement purchases.

Such certification would bifurcate the dietary supplement market into certified and uncertified products, protecting quality manufacturers. Manufacturers of certified products would be insulated against the reputational harms resulting from dangerous uncertified products, increasing consumer trust.[34] The clearly recognizable certification label would provide the consumer with ingredient knowledge and enable them to make informed choices about the products they purchase. Like the influential USDA Organic seal used in the food market, this seal can effectively shift supplements toward higher quality and safety.[35]

This Comment proceeds in seven subparts. Section I.A describes the harms consumers and manufacturers face from contaminated dietary supplements. Section I.B exposes the ambiguities in the legal definition and characterization of dietary supplements as compared to foods and drugs.

---

30. *See* discussion *infra* Subsections I.A.1, I.A.3.

31. *See CRN Reveals Initial Data from 2021 Consumer Survey on Dietary Supplements, supra* note 1; *see also* sources cited *supra* note 23.

32. *See* Swann, *supra* note 19, at 276; DEP'T OF HEALTH & HUM. SERVS., *supra* note 13, at 1.

33. *See* Swann, *supra* note 19, at 279.

34. Ray L. Benedicktus et al., *Conveying Trustworthiness to Online Consumers: Reactions to Consensus, Physical Store Presence, Brand Familiarity, and Generalized Suspicion*, 86 J. RETAILING 322, 332 (2010); *see also* Guy Longworth, Book Review, 72 ANALYSIS 623, 624 (2012) (reviewing PAUL FAULKNER, KNOWLEDGE ON TRUST (2011)).

35. ELIAS MASHAO & NITA SUKDEO, IEOM SOC'Y INT'L, FACTORS THAT INFLUENCE CONSUMER BEHAVIOR IN THE PURCHASE OF DURABLE HOUSEHOLD PRODUCTS 1668, 1668 (2018), http://www.ieomsociety.org/paris2018/papers/320.pdf [https://perma.cc/UVD4-ZKN7]; *see also* Traci May-Plumlee & Trevor J. Little, *Proactive Product Development Integrating Consumer Requirements*, 18:1 INT'L J. CLOTHING SCI. & TECH. 53, 54 (2006); *infra* Section II.A.

Section I.C summarizes the history of the FDA's battle against dietary supplements and explains why drug-like regulations will never return. Section I.D lays out the current legal framework applicable to dietary supplements, and Section I.E exposes the deficiencies of this approach. Finally, Section II.A draws inspiration for a solution from the successful USDA Organic seal, and Section II.B develops the fundamental criteria of the proposed third-party testing certificate.

I. BACKGROUND

The potential for harmful consequences from dietary supplements begs the question: why do consumers take products with little to no scientific evidence to support their intended effects, especially considering the harms? If you believe the advertised claims, modern dietary supplements provide agency and autonomy over wellness.[36] We can hack our bodies, increase our wellness, and rein in our ailments.[37] At face value, these products are an attractive superpower against common fears such as aging, cancer, or general declines in health.[38] The modern development of wellness culture has created new health anxieties and shifted the public's attitude towards more holistic and preventative methods of medical care.[39] The mirage of dietary supplement claims delivers the key to controlling some of mankind's biggest fears.

This power is not lost on manufacturers, whose products often push the envelope with their imaginative advertising claims.[40] Many consumers also incorrectly believe all dietary supplements are safer than pharmaceutical drugs or that they are always "natural," and therefore safe.[41] For others, the doctor's office can be seen as a judgmental place and dietary supplements

---

36. *See* Nichter & Thompson, *supra* note 12, at 189, 194.

37. *See id.* at 177.

38. *Id.* at 181.

39. Nikolas Rose, *The Politics of Life Itself*, 18 THEORY, CULTURE & SOC'Y 1, 17 (2001) ("The very idea of health was re-figured—the will to health would not merely seek the avoidance of sickness or premature death, but would encode an optimization of one's corporeality to embrace a kind of overall 'well-being'—beauty, success, happiness, sexuality and much more.").

40. *See generally* FED. TRADE COMM'N, *supra* note 9.

41. Jacqueline S. Marinac, et al., *Herbal Products and Dietary Supplements: A Survey of Use, Attitudes, and Knowledge Among Older Adults*, 107 J. AM. OSTEOPATHIC ASS'N 13, 19 (2007) ("Two thirds of all respondents falsely believe that herbal products and dietary supplements pose no risk to the general population. The majority of participants incorrectly thought that the FDA tests these products and routinely regulates the herb and supplement industry.").

provide an alternative access to wellness.[42] Yet consumers often overestimate the FDA's authority and involvement in dietary supplement quality assurance,[43] and their reliance on these assumptions can be detrimental.[44] The spell dietary supplements cast over consumers and policymakers is germane to understanding (1) why harmful outcomes persist; (2) the intentionally ambiguous nature of dietary supplements' legal classification; (3) the ferocious lobbying that led to this current legislation; and (4) the tangled regulatory system that evolved as a result.

A. Harmful Outcomes from Dietary Supplements

Did *Advocare Arginine Extreme* destroy Jessica Hardy's Olympic career? Once projected as a gold medal contender in the 2008 Bejing Olympics, Hardy was instead banned from the Olympics and suspended for one year because she failed an anti-doping drug test.[45] Like many other athletes trying to emulate the Olympic motto "faster, higher, stronger,"[46] Hardy opted to supplement her diet with amino acids, a common and generally legal supplement by Olympics standards.[47] Aware of USADA's and WADA's strict policy prohibiting performance enhancing substances, Hardy thoroughly researched the product, contacted the company regarding its purity, and even consulted with qualified professionals on the product.[48] Despite her diligence, *Advocare Arginine Extreme* was found to be contaminated with *clenbuterol*, a prohibited substance similar to steroids that caused her to fail her mandated drug test.[49] Hardy, along with several other

---

42. *Id.*; Nichter & Thompson, *supra* note 12, at 200.

43. Dodge, *supra* note 15, at 231–32, 236 (2011) (despite the DSHEA being around for decades, "research shows that individuals [including physicians & consumers] do not understand how dietary supplements are regulated" often assuming they are "approved for safety").

44. *Id.*; DEP'T OF HEALTH & HUM. SERVS., OFF. OF THE INSPECTOR GEN., *supra* note 13; Nutraceutical Corp. v. Crawford, 364 F. Supp. 2d 1310, 1312 (D. Utah 2005).

45. Neilson M. Mathews, *Prohibited Contaminants in Dietary Supplements*, 10 SPORTS HEALTH 19, 19 (2018); World Anti-Doping Agency v. Hardy, CAS 2009/A/1870, Arbitral Award, at 4 (Haas & Bernasconi, Arbs.) (Ct. Arb. for Sport, May 2010), https://www.wada-ama.org/sites/default/files/resources/files/cas-2009-a-1870-hardy.pdf [https://perma.cc/6XFW-4BT7].

46. INTERNATIONAL OLYMPIC COMMITTEE, *What Is the Olympic Motto?*, OLYMPICS https://olympics.com/ioc.

47. Mathews, *supra* note 45; *World Anti-Doping Agency*, CAS 2009/A/1870, at 18.

48. *World Anti-Doping Agency*, CAS 2009/A/1870, at 6–7.

49. Hardy v. Advocare Int'l. L.P., No. 209CV01307JHNPJWX, 2010 WL 11509179, at *1, *2 (C.D. Cal. Dec. 10, 2010).

athletes,[50] was suspended because of the contaminated supplement.[51] She was unable to compete for the gold medal.

It is hard to imagine how a product with such innocuous perceptions as dietary supplements could ruin careers, erode profits, or even end lives. Unfortunately, negative outcomes concerning dietary supplements are very common. There were 274,998 dietary supplement exposures reported to U.S. Poison Control Centers (around one every twenty-four minutes) between 2000 and 2012.[52] The severe gaps within supplements' current regulatory framework allow negligent or malicious manufacturers to create deleterious products and introduce them into commerce, harming consumers physically, manufacturers economically, and society generally.

1. Physical Harm to Consumers

There are three major categories of contamination risk in dietary supplements. First, and arguably the worst, is intentional contamination.[53] In these cases, unscrupulous manufacturers add ingredients not listed on the label to the end-product to either lower costs or enhance a product's marketed effect.[54] The second type, accidental contamination, occurs when a

---

50. *U.S. Karate Athlete Joane Orbon Accepts Sanction for Anti-Doping Rule Violation*, USADA (Aug. 12, 2019), https://www.usada.org/sanction/joane-obon-accepts-doping-sanction/ [https://perma.cc/Z8J2-PXBA]; Rick Wright, *Sanchez Eligible Again After Serving Suspension*, ALBUQUERQUE J. (Jan. 31, 2020, 8:18 PM), https://www.abqjournal.com/1415793/sanche-zeligible-again-after-serving-suspension.html [https://perma.cc/LVP5-GRCD]; *Brazilian Jiu-Jitsu Athlete Kaynan Duarte Accepts Sanction for Anti-Doping Rule Violation*, USADA (Feb. 7, 2020), https://www.usada.org/sanction/kaynan-duarte-accepts-doping-sanction/ [https://perma.cc/8KLE-DS4Y].

51. *Hardy*, 2010 WL 11509179, at *2.

52. Nisha Rao et al., *An Increase in Dietary Supplement Exposures Reported to US Poison Control Centers*, 13 J. MED. TOXICOLOGY 227, 227 (2017), https://link.springer.com/content/pdf/10.1007/s13181-017-0623-7.pdf [https://perma.cc/62GA-A8JA].

53. Pieter A. Cohen et al., *Nine Prohibited Stimulants Found in Sports and Weight Loss Supplements*, 59 CLINICAL TOXICOLOGY 975, 975 (2021), https://www.tandfonline.com/doi/full/10.1080/15563650.2021.1894333 [https://perma.cc/3M9H-7W38].

54. Alison Young, *Makers of Tainted Supplements Have Criminal Pasts*, USA TODAY (Dec. 19, 2013), https://www.usatoday.com/story/news/nation/2013/12/19/dietary-supplements-executives-criminal-records-spiked/4114451/ [https://perma.cc/5UWY-AU7N] ("Consumers . . . are in some cases entrusting their health and safety to people with rap sheets for crimes involving barbiturates, crack cocaine, Ecstacy [sic] and other narcotics, as well as arrests for selling or possessing steroids and human growth hormone."); Jungmin Li, *Marketplace Analysis Demonstrates Quality Control Standards Needed for Black Raspberry Dietary Supplements*, 69 PLANT FOODS FOR HUM. NUTRITION 161, 161 (2014),

manufacturing facility lacks adequate quality control.[55] Foreign material can make its way into a finished product during any stage in the production lifecycle, making accidental contamination one of the most difficult to police.[56] The third risk, mislabeled ingredients, can be either intentional or unintentional. Mislabeled ingredient contamination is more common with herbal supplements and extracts and occurs when the finished product contains a different ingredient than the label reports.[57]

a. Intentional Pharmaceutical Contamination

The frequency with which manufacturers *intentionally* contaminate dietary supplements with prohibited substances is alarming.[58] A study of FDA warnings from 2007 to 2016 "showed that unapproved pharmaceutical ingredients were identified in 776 dietary supplements, . . . with 157 products (20.2%) containing more than 1 unapproved ingredient."[59] Manufacturers' apparent disregard for consumers creates two major problems. First, the undisclosed inclusion of prohibited substances directly harms consumers like Jessica Hardy. Second, the manufacturers can easily write off a contaminated product as a mistake and promise that it will not happen again, sometimes

---

https://link.springer.com/article/10.1007/s11130-014-0416-y [https://perma.cc/FP9C-7YQR]; Rachael Rettner, *The FDA Found Hundreds of Supplement Brands Tainted with Rx Drugs. Most Weren't Recalled*, LIVESCIENCE (Oct. 12, 2018), https://www.livescience.com/63815-dietary-supplements-tainted-drugs.html [https://perma.cc/SHV6-4XH6]; Mathews, *supra* note 45, at 22.

55. *See* Mathews, *supra* note 45, at 21.

56. *See id.*; *see also Church & Dwight Initiates Voluntary Recall of Select Vitamins Due to Isolated Manufacturing Issue*, U.S. FOOD & DRUG ADMIN. (Apr. 2021), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/church-dwight-initiates-voluntary-recall-select-vitamins-due-isolated-manufacturing-issue [https://perma.cc/D2KJ-5TUQ].

57. Mathews, *supra* note 45, at 25 ("Herbal preparations are a particularly difficult class to regulate and study due to the multiple, complex compounds found in herbs . . . . Botanicals represent 18% of the US dietary supplements market . . . . In a study using DNA barcoding to assess authentic contents of herbal preparations, 68% of samples had product substitution, and 59% contained plant species not listed on the label."); *see also* Junhua Zhanga et al., *Quality of Herbal Medicines: Challenges and Solutions*, 20 COMPLEMENTARY THERAPIES MED. 100, 104 (2012); Attila Hunyadi et al., *Ecdysteroid-Containing Food Supplements from Cyanotis Arachnoidea on the European Market: Evidence for Spinach Product Counterfeiting*, 6 SCI. REPS. 1, 1 (2016) ("A comparative analysis . . . provides evidence that [the supplements sold in Europe] were manufactured from Cyanotis [arachnoidea] extracts instead of spinach as stated.").

58. Young, *supra* note 54; *see also Recalls, Market Withdrawals, & Safety Alerts*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts [https://perma.cc/Y2FQ-LSH6]

59. Jenna Tucker et al., *Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated with US Food and Drug Administration Warnings*, JAMA NETWORK OPEN 1, 1 (2018).

continuing to sell it under a new label because of the FDA's "would you kindly stop selling this" warning letter approach.[60] This game of whack-a-mole is burdensome to enforce, especially for an already underfunded FDA.[61]

Sexual enhancement supplements demonstrate manufacturers' evasive tactics well. These products, often sold online and at gas stations or adult shops nationwide, advertise that they are "all natural" when they in fact contain undisclosed drugs like Viagra.[62] The manufacturers of these supplements can be small and difficult to find or are located overseas.[63] For example, Nam Hyun Lee recently pled guilty in California for selling thousands of "Rhino" pills worth up to $3.5 million between 2016 and 2018, all of which were tainted with illegal erectile disfunction drugs Lee imported from China; he is serving a forty-six month sentence in prison.[64] In an email between Lee and his importer, the importer stated, "Regarding to the safe way for passing the customs, we will change the product name on the label and make it esaier [sic] to pass the USA customs. We will use FedEx just like we always do."[65] There have been several Adverse Event Reports affiliated with

---

60. *See* Amy Martyn, *Potent Rhino Pills Outlast Anything–Even the Arrest of Their Creator*, FAIRWARNING (Feb. 3, 2021), https://wayback.archive-it.org/16877/20210929152326/https://www.fairwarning.org/2021/02/potent-rhino-pills-outlast-anything-even-the-arrest-of-their-creator/ [https://perma.cc/VPX7-UHNY].

61. Mathews, *supra* note 45, at 21; Erin Brodwin, *A Batch of Contaminated Supplements Has Been Recalled — Here's How the Products Get into Stores*, BUS. INSIDER (Aug. 14, 2017), https://www.businessinsider.com/dangerous-supplements-vitamins-in-stores-2017-8 [https://perma.cc/B2MF-5UYJ].

62. *In re* Outlaw Lab'ys, LP Litig., No. 18CV840 GPC (BGS), 2020 WL 4436364, at *1 (S.D. Cal. Aug. 3, 2020).

63. *See* DANIEL R. LEVINSON, U.S. DEP'T HEALTH & HUM. SERVS., OFF. OF THE INSPECTOR GEN., OEI-01-11-00211, DIETARY SUPPLEMENTS: COMPANIES MAY BE DIFFICULT TO LOCATE IN AN EMERGENCY (2012).

64. Alma Fausto, *California Man Sentenced to Prison in Erectile Dysfunction Scheme*, MERCURY NEWS (Feb. 10, 2021, 4:48 AM), https://www.mercurynews.com/2021/02/10/fullerton-man-sentenced-to-prison-in-erectile-dysfunction-drug-smuggling-scheme/ [https://perma.cc/LFU3-WDCT].

65. Exhibits A–F in Support of Defendant Nam Hyun Lee's Position Re: Sentencing; Objections to PSI Report at 26, United States v. Nam Hyun Lee, No. 18-CR-00226-01-JVS (C.D. Cal. Dec. 29, 2020), https://ia800700.us.archive.org/17/items/gov.uscourts.cacd.726774/gov.uscourts.cacd.726774.55.1.pdf [https://perma.cc/Q7HC-74TE].

sexual enhancement supplements like these, including claims of neurological damage[66] and multiple deaths.[67]

When a product is found to be contaminated, the FDA will issue a warning letter.[68] However, the deliberate contamination demonstrates many manufacturers simply do not care. Several will slightly change the name of the item at issue or their whole brand and continue to sell the exact same product. The FDA can proceed with criminal charges, but this takes time, and the products often stay on the market for years.[69] A quick look at the FDA's list of supplements discovered to be contaminated shows these incidents are pervasive.[70]

Fraudulent supplements can be extremely lucrative, and the games manufacturers play are not exclusive to sexual enhancement supplements.[71] Workout supplements like DMAA and DMBA illustrate how manufacturers also rely on illegitimate arguments of "natural origin" to sell what are effectively pharmaceutical drugs as dietary supplements. DMAA (2-Hexanamine, 4-methyl-) was first developed by Eli Lilly in 1948 as a nasal decongestant drug, but its approval status as a drug was withdrawn in the 1970's.[72] In the 2000's, no longer holding drug status, DMAA made a

---

66. Bill Hetherman, *Man Injured Taking Enhancement Pills from Amazon.com Gets Favorable Ruling from Judge*, NBC L.A. (July 21, 2020, 11:06 PM), https://www.nbclosangeles.com/news/local/man-injured-taking-enhancement-pills-from-amazon-com-gets-favorable-ruling-from-judge/2399918/ [https://perma.cc/JAG6-NCE9].

67. "A FairWarning review of FDA data since 2018 found 49 reports of problems ranging from penile pain and heart palpitations to congestive heart failure and coma. One death was reported: a 31-year old man believed to have taken a pill called Rhino Male Enhancement before suffering a fatal heart attack." Martyn, *supra* note 60; *see also* Petition for Damages, Hale *ex rel*. McElwee v. Enlightened Reading LLC, No. 1316-CV22071 (Mo. 2016) [hereinafter Petition for Damages]. The case was settled for $1 million. *Potts Law Firm*, *Settlement Reached Over Death Alleged from Arousal Pills,* CISION (Oct. 6, 2016), https://www.prnewswire.com/news-releases/settlement-reached-over-death-alleged-from-arousal-pills-300340417.html [https://perma.cc/G29U-JSEG].

68. *About Warning and Close-Out Letters*, U.S. FOOD & DRUG ADMIN. (Apr. 29, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters [https://perma.cc/G7WL-BVPZ].

69. See Compliance & Enforcement, U.S. Food & Drug Admin. (Sept. 9, 2022), https://www.fda.gov/animal-veterinary/compliance-enforcement#enforcement [https://perma.cc/NZ7K-D9PM]; Indictment, United States v. Nam Hyun Lee, No. 8:18-cr-00226-JVS (C.D. Cal. Oct. 24, 2018), https://quackwatch.org/wp-content/uploads/sites/33/quackwatch/casewatch/doj/lee/indictment.pdf [https://perma.cc/PG2B-RHJQ].

70. *Recalls, Market Withdrawals, & Safety Alerts*, *supra* note 58.

71. *See* Indictment, *supra* note 69, at 2–3.

72. Pieter A. Cohen, *DMAA as a Dietary Supplement Ingredient*, 172 ARCHIVES INTERNAL MED. 1038, 1038 (2012).

resurgence in weight loss and athletic supplements, relying on a single study in a defunct medical journal claiming to find DMAA in geranium oil despite measuring only 0.7% of the compound.[73] But subsequent legitimate studies were unable to confirm DMAA's existence in geranium oil at all.[74] After DMAA was involved in several deaths, in April of 2013 the FDA justified banning the substance with the argument that DMAA was considered an unlawful "new dietary ingredient" because it was not sold as a dietary supplement prior to the DSHEA.[75] But unsurprisingly, clever manufacturers developed and sold new compounds like DMBA whose chemical properties are nearly identical to DMAA, differing by only one carbon chain.[76] Manufacturers were able to openly sell these products for over two years before the FDA finally banned the ingredient entirely.[77]

b. Accidental Manufacturing Contamination

Accidental contamination occurs when inadequate oversight of the manufacturing process allows contaminants to reach the finished product. In theory, the mandatory manufacturing quality standards put forward by the DSHEA, known as the Good Manufacturing Practices ("GMPs"), should eliminate the possibility for this type of contamination.[78] However, insufficient GMP compliance and enforcement ensures accidental contamination will continue to occur.[79]

---

73. *Id.*; Zang Ping et al., *A Study on the Chemical Constituents of Geranium Oil*, 25 J. GUIZHOU INST. TECH. 82, 84 (1996), https://blog.priceplow.com/wp-content/uploads/hi-tech-vs-fda-20161230-wenik-exhibit-53-ping-study-translated.pdf [https://perma.cc/3DHF-XNDV] (formula C7H17N).

74. Cohen, *supra* note 72, at 1038.

75. Mathews, *supra* note 45, at 24.

76. *Id.* ("What followed [the ban of DMAA] was a succession of chemically related compounds with structures and effects similar to DMAA and methamphetamines, with initials like DMBA, BMPEA, NADEP, and NN-DMPAA, each claiming to be occurring naturally from sources but later disproven . . . . [Some are] very closely related to one another; DMAA differs from DMBA by 1 carbon chain.").

77. *Id.*

78. *See* Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4332 (1994)*; see also Backgrounder on the Final Rule for Current Good Manufacturing Practices (CGMPs) for Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Dec. 27, 2017), https://www.fda.gov/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/backgrounder-final-rule-current-good-manufacturing-practices-cgmps-dietary-supplements [https://perma.cc/6FMU-RAGR].

79. *See* Press Release, N.Y. State Off. of the Att'y Gen., A.G. Schneiderman Asks Major Retailers To Halt Sales of Certain Herbal Supplements as DNA Tests Fail To Detect Plant Materials Listed on Majority of Products Tested (Feb. 3, 2015), https://ag.ny.gov/press-

Accidental contamination can occur at any stage of the manufacturing process. For example, in 2018 several protein powders were found to be contaminated with Bisphenol A ("BPA") and heavy metals.[80] The BPA likely came from the plastic packaging used towards the end of the manufacturing process while the heavy metals were assumedly introduced by the raw ingredients prior to manufacturing.[81] Plant-based products are especially likely to see heavy metal contamination because their raw materials are grown in regions with contaminated groundwater.[82] Accidental contamination has also occurred in the middle of production during the ingredient processing phase.[83] In 2021, one manufacturer recalled thirteen products, including children's gummy vitamins, because they were contaminated with a metal mesh material that could damage the digestive organs in severe cases.[84] Bacterial contaminations have occurred multiple times, and from otherwise reputable brands like NatureMade.[85]

c. Mislabeled Herbal Ingredients

Sometimes, a product may advertise ingredient X, but instead contain ingredient Y. Mislabeled ingredients are more common in herbal supplements and can be the result of either intentional or unintentional

---

release/2015/ag-schneiderman-asks-major-retailers-halt-sales-certain-herbal-supplements-dna [https://perma.cc/QCU5-CE44].

80. *The Hidden Dangers of Protein Powders*, HARV. HEALTH PUBL'G (Aug. 15, 2022), https://www.health.harvard.edu/staying-healthy/the-hidden-dangers-of-protein-powders [https://perma.cc/7MK7-JU5C]; *New Study of Protein Powders from Clean Label Project Finds Elevated Levels of Heavy Metals and BPA in 53 Leading Brands*, CLEAN LABEL PROJECT (Feb. 27, 2018), https://cleanlabelproject.org/blog-post/new-study-of-protein-powders-from-clean-label-project-finds-elevated-levels-of-heavy-metals-and-bpa-in-53-leading-brands/ [https://perma.cc/E5YK-QLVH].

81. CLEAN LABEL PROJECT, PROTEIN POWDER: OUR POINT OF VIEW 2 (2018), https://cleanlabelproject.org/wp-content/uploads/download-9-converted.pdf [https://perma.cc/8XXT-4D7C].

82. Zhanga et al., *supra* note 57, at 101 ("Contamination [of plant-based products] can occur due to: (1) the accumulation of heavy metals in the environment (e.g. from contaminated soil or atmosphere); (2) inadvertent pollution during the production process; (3) or deliberate addition.").

83. *See id.*

84. *Church & Dwight Initiates Voluntary Recall of Select Vitamins Due to Isolated Manufacturing Issue*, U.S. FOOD & DRUG ADMIN. (Apr. 20 2021), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/church-dwight-initiates-voluntary-recall-select-vitamins-due-isolated-manufacturing-issue [https://perma.cc/48FX-W9JM].

85. Melissa Jenco*, FDA: Nature Made Vitamins Recalled for Possible Contamination*, AAP NEWS (June 9, 2016), https://www.aappublications.org/news/2016/06/09/VitaminRecall060916 [https://perma.cc/8FBX-KANJ]; *see also* Brodwin, *supra* note 61.

conduct.[86] Sometimes manufacturers or raw-ingredient suppliers will substitute expensive ingredients with similar-looking, less expensive ingredients.[87] Other times, the ingredients can simply be confused.[88] Inconsistent nomenclature across the industry is a common culprit.[89]

Consider Wisconsin, which is the largest producer of ginseng in the United States.[90] In the years leading up to the Farm Security and Rural Investment Act of 2002, ginseng fraud ran rampant.[91] At the time, Wisconsin-grown ginseng was worth nearly three times the amount of Chinese grown ginseng, and importers would falsely label their inferior and often toxic product to command the higher prices demanded for the coveted Wisconsin labeling.[92] But what is ginseng exactly? There is American ginseng (*Panax quinquefolius*), Asian ginseng (*Panax ginseng*), Siberian ginseng (*Eleutherococcus senticosus*), Manchurian ginseng (*Eleutherococcus gracilistylus*), Peruvian ginseng (*Lepidium meyenii*), Indian ginseng (*Withania somnifera*), Malaysian ginseng (*Eurycoma longifolia*)—the list

---

86. Mathews, *supra* note 45, at 25; *see* Zhanga et al., *supra* note 57, at 101, 104.

87. Zhanga et al., *supra* note 57, at 103.

88. *See* Mariame Najem et al., *Vernacular Names of Plants Between Diversity and Potential Risks of Confusion: Case of Toxic Plants Used in Medication in the Central Middle Atlas, Morocco*, 9 J. PHARM. & PHARMACOGNOSY RSCH. 222, 223, 242 (2021), https://jppres.com/jppres/pdf/vol9/jppres20.950_9.2.222.pdf [https://perma.cc/MHN7-QEYY]; *see also Why Latin Binomials Are Important for Herbs*, AM. COLL. HEALTHCARE SCI. (Feb. 25, 2017), https://achs.edu/blog/2017/02/25/latin-binomials-are-important/ [https://perma.cc/EAF5-DJCZ] (explaining that "Lavandula angustifolia" is calming but "lavandin Lavandula intermedia" is stimulating, despite both being called "lavender").

89. Zhanga et al., *supra* note 57, at 104.

90. Taylor Schaefer, *Wisconsin-Grown Ginseng Is in Demand Around the World*, Wisconsin State Farmer (Sept. 5, 2022), https://www.wisfarmer.com/story/opinion/columnists/2022/09/05/wisconsin-grown-ginseng-demand-around-world/7997600001/ [https://perma.cc/ZWF8-KBAV] ("Today, Wisconsin Ginseng farmers produce 95 percent of the total cultivated American ginseng in the U.S.").

91. Zhang Yu, *The Herbal Fraud*, GLOBAL TIMES (June 10, 2014), https://www.globaltimes.cn/content/864916.shtml [https://perma.cc/KE3J-AUEW] ("Chen said that even back in the late 1990s, only 5 percent of the American ginseng in China's ginseng market was actually produced in America"); Joanne M. Haas, *Illegal Harvest of Wild Ginseng on the Rise: Warden Seeks Public Help*, WIS. DEP'T OF NAT. RES. (Aug. 23, 2012), https://dnr.wi.gov/topic/WardenWire/WardenWire_Lookup.asp?id=122 [https://perma.cc/QF55-P3M9]; Frank Shyong, *American Ginseng Has a Loyal Chinese Clientele*, L.A. TIMES (Feb. 28, 2015, 7:32 PM), https://www.latimes.com/local/california/la-me-adv-ginseng-american-20150301-story.html#page=1 [https://perma.cc/DA7B-QW3T] (the "Wisconsin Ginseng Board . . . inspected dozens of Wisconsin-branded ginseng products at the Asian American Expo" and found that "less than 12% of the products were actually from Wisconsin").

92. 147 CONG. REC. 22,059–60 (2001) (statement of Sen. Feingold) ("The smugglers know that while Chinese-grown ginseng has a retail of about $5–$6 per pound, while Wisconsin-grown ginseng is valued at roughly $16–$20 per pound.").

goes on.[93] However, only Asian and American ginseng are of the genus *Panax* and contain *ginsenosides*, the active ingredients responsible for ginseng's benefits.[94] Legislation in 2002 addressed the ginseng issue in America by requiring any product sold as common "ginseng" to be of the *Panax* species or otherwise be deemed "adulterated" and thus actionable under the Food Drug & Cosmetic Act.[95] However, nomenclature confusion is not unique to ginseng.[96]

The frequency of this ingredient "confusion" within herbal supplements is high. In 2015, the attorney general of New York launched an investigation into herbal supplements and ultimately sent cease & desist letters to several big-name retailers including GNC, Target, Walmart, and Walgreens.[97] Only twenty-one percent of the products tested were accurately labeled.[98] Products sold at Walmart were the worst offenders, with only four percent containing the listed ingredients.[99]

2. Other Consumer Harms

Other quality harms exist parallel to contamination.[100] When consumers are taking supplements for drug-like purposes, it is essential that the active ingredients be consistent.[101] Oxidation, for example, affects supplements like

---

93. Dennis V.C. Awang, *What in the Name of* Panax *Are Those Other "Ginsengs"*, 57 J. AM. BOTANICAL COUNCIL 30, 31–32 (2003), https://www.herbalgram.org/resources/herbalgram/issues/57/table-of-contents/article2447/ [https://perma.cc/C7C7-9CPR]; *see also Medicinal Plant Names Services Portal, V11.0,* ROYAL BOTANIC GARDENS, KEW, http://mpns.kew.org/mpns-portal [https://perma.cc/9HHA-CWKN] (MPNS found over nineteen plants affiliated with "Ginseng").

94. *American Ginseng*, MOUNT SINAI, https://www.mountsinai.org/health-library/herb/american-ginseng [https://perma.cc/BZP9-5DWX].

95. 21 U.S.C. § 343 (u); 21 U.S.C. § 321d (b)(1); 21 U.S.C. § 331; 147 CONG. REC. 22,060 (2001) (statement of Sen. Feingold) ("We must ensure . . . [consumers] are getting the real thing, not a cheap imitation.").

96. Mutong, for example, refers to both "Chuan Mutong" (*caulis akebiae*) and "Guan Mutong" (*caulis aristolochiae manshurienis*). Both have been labeled as "Mutong" despite being completely different. The mix up has caused serious problems of "aristolochic acid nephropathy." *See* Zhanga et al., *supra* note 57, at 104.

97. *See* Press Release, *supra* note 79.

98. *Id.*

99. *Id.*

100. Lisa L. Gill, *10 Supplements To Always Avoid*, CONSUMER REPS. (Dec. 8, 2022), https://www.consumerreports.org/vitamins-supplements/15-supplement-ingredients-to-always-avoid/ [https://perma.cc/8WV9-C4LH].

101. *Cf.* Amy K. Eichner et al., *Essential Features of Third-Party Certification Programs for Dietary Supplements: A Consensus Statement*, 18 CURRENT SPORTS MED. REPS. 178, 178–79 (2019).

fish oil and causes them to change over time, creating new chemicals which can be potentially harmful.[102] Some manufacturers will add greater amounts of an active ingredient than labeled, in anticipation of a declining potency.[103] This is permitted by the DSHEA's GMPs; however, no set standard exists for just how much extra should be added, creating a potential for harm.[104] The GMPs also do not regulate the proper dosage for dietary supplements.[105] A recent 2014 case demonstrates this issue where Pure Caffeine powder sold as a pre-workout supplement on Amazon killed Logan Stiner, a high school senior in Ohio, when he accidentally exceeded the incredibly small recommended dose of an eighth of a teaspoon.[106] The dosage problem can also apply to herbal extracts, where slight procedural variations can render an extract too weak to be effective or too strong to be safe, despite being identified as the same on the label.[107]

In sum, consumers lack adequate assurances that their dietary supplements are what they purport to be. Inadvertent and deliberate contamination, mislabeled ingredients, and potency concerns spotlight a gap in the DSHEA's ability to protect consumers. For the lucky, the harm is minimal. But for consumers like Jessica Hardy and Logan Stiner, the harm is much more severe.

---

102. Stefan A. Jackowski et al., *Oxidation Levels of North American Over-the-Counter n-3 (omega-3) Supplements and the Influence of Supplement Formulation and Delivery Form on Evaluating Oxidative Safety*, 4 J. NUTRITIONAL SCI. e30, 2 (2015); *see also* Monique Heller et al., *Oxidation of Fish Oil Supplements in Australia*, 70 INT'L J. FOOD SCIS. & NUTRITION 540, 541 (2019).

103. Dietary supplements "shall be deemed to be misbranded . . . unless . . . the nutrient content of the composite is at least equal to that value for that nutrient declared on the label." 21 C.F.R. § 101.9(g)(4); s*ee also* Stephen R. Cammarn, *Managing Overages in Vitamins, Minerals & Dietary Supplements*, COUNCIL FOR RESPONSIBLE NUTRITION (Oct. 30, 2020), https://www.crnusa.org/CRN-Daily-Supplement/Spotlight-EAS-Consulting [https://perma.cc/H84X-6HV3].

104. Cammarn, *supra* note 103.

105. *Questions and Answers on Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Oct. 26, 2022), https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements [https://perma.cc/ZBB6-58WQ] ("Other than the manufacturer's responsibility to meet the safety standards and labeling requirements for dietary supplements and to comply with current good manufacturing regulations, there are no laws or regulations that limit the serving size of a dietary supplement or the amount of a dietary ingredient that can be in a serving of a dietary supplement. This decision is made by the manufacturer and does not require FDA approval.").

106. Stiner v. Amazon.com, Inc., 164 N.E.3d 394, 395–97 (Ohio 2020).

107. Cammarn, *supra* note 103; *see also* S. Guillon et al., *Hairy Roots of Catharanthus Roseus: Efficient Routes to Monomeric Indole Alkaloid Production*, *in* BIOACTIVE MOLECULES AND MEDICINAL PLANTS 285, 310–13 (K.G. Ramawat & J.M. Merillon eds., 2008).

3. Economic Harms for Honest Manufacturers and the Need for Consumer Trust: The "Market for Lemons" Theory

There is a cost to bear for dishonest products. When these inferior products exist in the market, the resulting "quality uncertainty" experienced by consumers affects their collective appraisal of the entire market segment, rather than of any one producer, and honest manufacturers pay for this "cost of dishonesty."[108] George Akerlof, a Nobel Memorial Prize-winning economist and creator of the "Market for Lemons" theory, explained how this asymmetric information about product quality between consumers and producers leads to low quality products overall and creates financial disadvantages for honest producers:

> There are many markets in which buyers use some market statistic to judge the quality of prospective purchases. In this case there is incentive for sellers to market poor quality merchandise, since the returns for good quality accrue mainly to the entire group whose statistic is affected rather than to the individual seller. . . . [For example,] bad cars must still sell at the same price as good cars – since it is impossible for a buyer to tell the difference between a good and a bad car . . . only the seller knows . . . . [Q]uality may be represented, or it may be misrepresented. The purchaser's problem, of course, is to identify quality. The presence of people in the market who are willing to offer inferior goods tends to drive the market out of existence – as in the case of our automobile "lemons." [109]

Producers of high-quality dietary supplements have an incentive to market their product's superior quality. However, other less-honest producers can make the same high-quality claims despite having a low-quality product.[110] Supplement consumers have no reliable way to verify the quality claims of products.[111] Some producers have attempted to insulate their products from dietary supplements' negative reputation by creating pharmaceutical versions, like *Vascepa*, the prescription version of fish oil, that ensure

---

108. George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECONS. 488, 488, 495–96 (1970).

109. *Id.* at 488.

110. *Public Notification: Alpha Male Plus Contains Hidden Drug Ingredient*, U.S. FOOD & DRUG ADMIN. (Feb. 24, 2021), https://www.fda.gov/drugs/medication-health-fraud/public-notification-alpha-male-plus-contains-hidden-drug-ingredient [https://perma.cc/5BWP-LBRB] (explaining that male sexual enhancement product "Alpha Male Plus" claimed to have safe and natural ingredients, but FDA lab analysis uncovered that it in fact contained tadalafil, active ingredient in FDA-approved prescription drug *Cialis*, used to treat erectile dysfunction).

= 111. Eichner et al., *supra* note 101, at 179.

adequate quality control.[112] But prescription *Vascepa* is nearly ten times as expensive as popular dietary supplement versions of fish oil,[113] likely due to the tremendous expenditure and unique liability exposure incurred in bringing verified pharmaceuticals to market.[114] This is a functional solution for those who can afford this multi-billion-dollar development, but it is not a practicable approach for the majority.

Oversaturation of unverified quality claims turns consumers into skeptics.[115] As Akerlof states, "[t]he purchaser's problem, of course, is to identify quality,"[116] and without a recognizable and objective signifier of quality, consumers will remain wary of manufacturers' advertisements and their potential incentive to convince or deceive the consumer into a sale.[117] This skepticism is very difficult to overcome and weakens honest manufactures' ability to market their products.[118]

Negative reviews and consensus opinions compound the issue. When a consumer has encountered an inferior product after anticipating a superior one, they often mistakenly develop opinions about the entire class of products and may avoid buying that type of product ever again. In the age of e-commerce, these negative consumer opinions are often promulgated through online comments and reviews and negatively affect other new first-time purchasers' appraisals of efficacy and quality of the entire product class. Those new purchasers may then choose not to buy a product, even if it is

---

112. The market has responded by creating a pharmaceutical grade fish oil (*Vascepa*®) that comes with the higher safety and efficacy guarantees of drugs. *See* ERIC C. COLMAN, CTR. FOR DRUG EVALUATION & RSCH., APPLICATION NUMBER: 202057ORIG1S000, SUMMARY REVIEW (2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202057Orig1s000SumR.pdf [https://perma.cc/Z8BC-5G5R].

113. *C*ompare How Much Is Vascepa Without Insurance?, CHECKUP BY SINGLECARE (Feb. 1, 2022), https://www.singlecare.com/blog/vascepa-without-insurance/#:~:text=The%20average%20price%20of%20a,run%20about%20%2415%20per%20day [https://perma.cc/596V-ZBFD] (average price of Vascepa was $461.78 as of February 2022), *with Nordic Naturals Ultimate Omega*, AMAZON, https://www.amazon.com/dp/B0739KKHWL?ref_=cm_sw_r_cp_ud_dp_EXZ9DFHZPH7F6DW5DSNS [https://perma.cc/CNX7-ZJKZ] ($32.49 for a forty-five day supply).

114. *See* Sullivan, *supra* note 21.

115. *See* Benedicktus et al., *supra* note 34, at 329; *see also* Scott Koslow, *Can the Truth Hurt? How Honest and Persuasive Advertising Can Unintentionally Lead to Increased Consumer Skepticism*, 34 J. CONSUMER AFFS. 245, 245 (2000).

116. Akerlof, *supra* note 108.

117. *See* Benedicktus et al., *supra* note 34.

118. *See, e.g.*, Koslow, *supra* note **Error! Bookmark not defined.**, at 246 ("[C]onsumers may sometimes be so vigilant against potentially misleading advertisers, that even after claim verification has occurred, consumers sometimes remain skeptical.").

made by a different manufacture because they assume the product offering is generally ineffective.

The retailers face similar problems. In a California case where Amazon was sued for selling a tainted dietary supplement made by a third party, the defense attorney put it well: even "the FDA didn't know, so how did Amazon know?"[119] Because retailers cannot verify the quality of their dietary supplement products, consumers may generate negative assumptions about a retailer's offering after reading reviews of select negative encounters with inferior products. Ultimately, consumer skepticism and negative consensus opinions prevent consumers from reaching quality products and hinder honest manufacturers' and retailers' abilities to sell them.

For example, *Rhodiola rosea* is an herbal supplement believed to be pharmacologically effective because of a compound within the plant called *rosavin*.[120] Certain products will advertise that their *rosavin* content is standardized to a percentage per gram of weight; however, many are simply measured by total weight without mention of concentration.[121] This is problematic because there is no scientific consensus on how to best extract *rosavin*, so significant potency variability can occur between extracts of the same gram weight.[122] Additionally, if certain procedural variables like extraction temperature are slightly off, it can render the entire extract ineffective.[123] Without testing to confirm the presence and concentration of *rosavin* content, consumers of *Rhodiola rosea* supplements may unknowingly encounter a large spread of products with a range of rosavin content. Consumers of the inert or low potency products may have inferior experiences and then formulate opinions about *Rhodiola rosea* supplements generally based on those inferior experiences. They may assume *Rhodiola rosea* is ineffective and transmit this belief through comments and reviews

---

119. Hetherman, *supra* note 66.

120. Z. Węglarz et al., *Roseroot (*Rhodiola rosea *L.): Effect of Internal and External Factors on Accumulation of Biologically Active Compounds*, *in* BIOACTIVE MOLECULES & MEDICINAL PLANTS 297, 297 (K.G. Ramawat & J.M. Merillon eds., 2008).

121. *Compare Rhodiola Rosea*, GAIA HERBS, https://www.gaiaherbs.com/products/rhodiola-rosea [https://perma.cc/RBR5-MEQX] ("Each 1-capsule serving delivers 6 mg rosavins from 850 mg dry herb."), *with Full Spectrum Rhodiola Rosea Root*, SWANSON, https://www.swansonvitamins.com/swanson-premium-rhodiola-rosea-root-400-mg-100-caps [https://perma.cc/E8C6-6VE3] (advertising 400 mg of "Full Spectrum" root powder, which indicates it was formulated "without unnecessary processing").

122. *Rhodiola rosea* extract is difficult to stabilize. *See* Węglarz et al., *supra* note 120, at 303, 310, 313 (noting that differences in rosavin content in raw material varied by region up to 400%, and that "[d]ata concerning the recommended solvent and extraction method for standardisation of roseroot is contradictory").

123. *Id.* at 313.

online. The weakening of this consensus opinion for *Rhodiola rosea* weakens the value of the entire class of products,[124] and this can result in lost profits for manufacturers with a superior product.[125]

This issue is not specific to *Rhodiola rosea*;[126] the same consensus data harms occur when any specific product among a class is diluted, contains mislabeled ingredients, causes adverse reactions, or is otherwise undesirable for a product-specific quality issue. This demonstrated variability within the dietary supplement market creates a veil of generalized suspicion that weakens its profitability.[127]

So long as there is a "market for lemons," generalized suspicion will harm honest producers who create legitimate, high-quality products.[128] While their positive brand identity may combat this, consumers' generalized suspicion may be so pervasive so as to remain even after an honest manufacturer's product claim has been verified to the consumer.[129] Though consumers continue to purchase supplements, the logic behind the "Market for Lemons" begs the question of just how much further the market could grow without consumer skepticism. In order to reduce economic harm, honest manufacturers need a way to distinguish themselves from dishonest manufacturers and immunize their products from the class-wide assumptions resulting from inferior "lemon" products.[130]

B. What Is a Dietary Supplement Anyways?

Any effort to rid the industry of inferior products must first resolve the ambiguity between what is, and more importantly, what is not a dietary supplement. Back in the 1970s, the public opinion that dietary supplements

---

124. *See* Benedicktus et al., *supra* note 34; Akerlof, *supra* note 108.

125. Akerlof, *supra* note 108, at 489–90.

126. The same is true for ginseng products, where a recent analysis found the concentrations of the desired ingredients to vary between 15–200 fold. M.R. Harkey et al., *Variability in Commercial Ginseng Products: An Analysis of 25 Preparations*, 73 AM. J. CLINICAL NUTRITION 1101, 1101 (2001).

127. *See* Akerlof, *supra* note 108, at 489–90.

128. *See id.*; Benedicktus et al., *supra* note 34, at 332 ("[G]eneralized suspicion led to a reduction in both the benevolence and reliability of a retailer and thereby undermined purchase intentions concerning a different product sold by an unrelated firm.").

129. *See* Benedicktus et al., *supra* note 34, at 329.

130. Sharmila C. Chatterjee & Arjun Chaudhuri, *Are Trusted Brands Important?*, 15 MKTG. MGMT. J. 1, 12 (2005) ("[T]rust has a direct positive relationship with brand outcomes. Brands enjoying higher levels of trust are associated with higher market share as well as with greater advertising efficiency.").

were innocuous compounds used to supplement the diet held some merit.[131] At that time, most supplements on the market were in fact alternatives to vitamins and minerals found in regularly consumed foods, like calcium or Vitamin C, ingested to benefit the diet.[132] However, the same is no longer true today: a new, undefined grey area has emerged where certain products are much more akin to drugs based on the consumers' intended use.[133]

Trying to draw the line between supplements and drugs is difficult, and the results are often ambiguous. One might say supplements are only natural or low risk, while synthetic or high-risk compounds would be classified as drugs, but this is not the case. The natural versus synthetic argument fails because many dietary supplement compounds are lab created and many pharmaceuticals are of natural origin: penicillin from mold, *Epidiolex* from the cannabis plant,[134] or *Vascepa* from fish oil.[135] Similarly, attempting to distinguish drugs from supplements based on their potential risk for harm or abuse is also unhelpful. While some high-risk natural compounds are indeed classified as drugs, such as *AtroPen*, which is derived from deadly nightshade (*Atropa belladonna*),[136] there have also been numerous dietary supplements that are just as harmful without being classified as a drug. Most famously, the heavily litigated, sometimes lethal, and eventually banned dietary supplement ephedra came from the evergreen shrub of the same name and was a common ingredient in weight loss products in the 1990s.[137]

---

131. *See* Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 257–58 (1994).

132. *Id.*

133. *See* Nichter & Thompson, *supra* note 12, at 210–11 ("There is little doubt that North Americans use supplements to treat and prevent disease. . . ."); *see also, e.g.*, *A Beginner's Guide to Nootropics*, *supra* note 12.

134. *Epidiolex*, EPIDIOLEX, https://www.epidiolex.com [https://perma.cc/5UB6-FMQ3] ("EPIDIOLEX is the first and only FDA-approved prescription cannabidiol (CBD) to treat seizures . . . .").

135. *See* COLMAN, *supra* note 112, at 2 (describing Vascepa as a "drug substance . . . derived from fish oil").

136. MERIDIAN MED. TECHS., INC., ATROPEN® AUTO-INJECTOR 1 (2020), [https://perma.cc/55KP-KCSQ] (explaining that the active ingredient in AtroPen is "Atropine, a naturally occurring belladonna alkaloid, . . . commonly classified as an anticholinergic or antiparasympathetic (parasympatholytic) drug"); *see also Atropine,* NAT'L LIBR. MED.: PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/compound/Atropine [https://perma.cc/CS4E-WWSW].

137. *See Ephedra*, NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, https://www.nccih.nih.gov/health/ephedra [https://perma.cc/8BQS-5MBU].

Instead, dietary supplements are generally distinguished from pharmaceutical drugs based on the stated purpose of the manufacturer.[138] Under the FDCA, a drug is defined as a substance "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."[139] A supplement is defined as "a product taken by mouth that contains a 'dietary ingredient'[140] intended to supplement the diet."[141] Thus, under the current rules, dietary supplements may not make "disease claims," which refer in some way to a specific disease,[142] but may make "structure/function claims," which describe the nutrient's role or mechanism for supporting or maintaining the structure or function of the human body.[143] However, the limits to what constitutes a structure/function claim are broad enough to allow consumers to make implicit inferences, even if technically incorrect, that lead them to draw conclusions about a product that are effectively "disease claims."[144] If a manufacturer intends to use the product "in the diagnosis, cure, mitigation, treatment, or prevention of disease,"[145] it will be classified as a drug and will be subject to a more stringent set of quality control regulations.[146] For example, prescription *Vascepa* is designed to "reduce the risk of heart attack, stroke and certain types of heart issues" and is therefore classified as a drug.[147] By contrast, *UnoCardio* X2, a fish oil dietary

---

138. *See, e.g.*, United States v. Hakim, 462 F. Supp. 3d 418, 429 (S.D.N.Y. 2020) ("The key factor in whether a product may be regulated as a drug is the 'vendor's intent in the sale of the product to the public.'" (quoting Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 333 (2d Cir. 1977))); *id.* at 429 ("the intended use of a product may be deduced" from packaging and advertising).

139. 21 U.S.C. § 321(g)(1).

140. 21 U.S.C. § 321(ff) (defining "dietary supplement" as a product "intended to supplement the diet that bears or contains one or more of" six listed "dietary ingredients").

141. FOOD & DRUG ADMIN., WHAT YOU NEED TO KNOW ABOUT ADMINISTRATIVE DETENTION OF FOODS: SMALL ENTITY COMPLIANCE GUIDE 4 (2013), https://www.fda.gov/media/85381/download [https://perma.cc/A8GZ-V4DZ].

142. 21 C.F.R. § 101.93(g)(2) (2022); *see also* 21 U.S.C. § 343(r)(6).

143. 21 U.S.C. § 343(r)(6)(A), (C).

144. Frank R. Kardes et al., *Consumer Inference*, *in* HANDBOOK OF CONSUMER PSYCHOLOGY 167–68 (Curtis P. Haugtvedt et al. eds., 2008) (arguing that consumers make implicit inferences about a product's features); Nichter & Thompson, *supra* note 12, at 177 ("[T]he 'structure and function' regulation has become a coded means of communicating health and disease claims.").

145. Under the FDCA, a product's classification as a drug depends upon its intended use by the vendor. *See* 21 U.S.C. § 321(g)(1)(B); *see also* 21 C.F.R. § 201.128.

146. 21 U.S.C. § 355(a)–(b)(1)(A). Pre-market approval of drugs is required prior to introduction into interstate commerce, and applications for the sale of drugs must include reports showing that the drug is safe for public use and effective. 21 U.S.C. § 360e(a).

147. *Vascepa*, VASCEPA, https://www.vascepa.com/cardiovascular-risk/protect-against-another-heart-attack-or-stroke/ [https://perma.cc/B6B5-C5F3].

supplement, instead helps "keep the heart functioning well" and "maintain normal blood pressure."[148]

Surprisingly, the consumer's intended use is disregarded. Supplements today often have a disconnect between their advertised purpose and the consumer's actual use.[149] Patients who take medications prescribed by their doctors naturally share their physician's intention to achieve "diagnosis, cure, mitigation, treatment, or prevention of disease." However, the consumer can carry the same intent for taking dietary supplements.[150] Efficacy aside, when consumers take dietary supplements like *dehydroepiandrosterone* (*DHEA*) to raise testosterone,[151] *L-theanine* for ADHD,[152] or *curcumin* (turmeric) extracts for depression,[153] they do not intend to supplement their dietary intake. Their intent is the same as patients who take prescription *AndroGel*,[154] *Adderall*,[155] or *Zoloft*.[156] Consumers regularly opt to self-diagnose, cure, mitigate, treat, or prevent disease with questionably marketed dietary supplements.[157] Contamination is especially concerning for these "grey-area" products

148. *UnoCardio® 1000*, WHC, https://nutrogenics.be/product/unocardio-1000/?lang=en [https://perma.cc/A8JA-NGTH].

149. Nichter & Thompson, *supra* note 12, at 211.

150. *Id.* at 210–11.

151. Jason R. Kovac et al., *Dietary Adjuncts for Improving Testosterone Levels in Hypogonadal Males*, 10 AM. J. MEN'S HEALTH N109, N115 (2016) ("More men are turning to oral prohormone supplements and dietary adjuncts to improve muscle mass and appearance or combat the decreased energy, libido associated with hypogonadism and low testosterone.").

152. Michael R. Lyon et al., *The Effects of L-Theanine (Suntheanine®) on Objective Sleep Quality in Boys with Attention Deficit Hyperactivity Disorder (ADHD): A Randomized, Double-Blind, Placebo-Controlled Clinical Trial*, 16 ALT. MED. REV. 348, 348 (2011).

153. Adrian L. Lopresti & Peter D. Drummond, *Efficacy of Curcumin, and a Saffron/Curcumin Combination for the Treatment of Major Depression: A Randomised, Double-Blind, Placebo-Controlled Study*, 207 J. AFFECTIVE DISORDERS 188, 188 (2017) ("[D]oses of curcumin and combined curcumin/saffron were effective in reducing depressive and anxiolytic symptoms in people with major depressive disorder.").

154. U.S. FOOD & DRUG ADMIN., JATENZO (TESTOSTERONE UNDECANOATE) CAPSULES 1 (2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/206089s000lbl.pdf [https://perma.cc/X7QB-UYH2] ("JATENZO . . . is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.").

155. U.S. FOOD & DRUG ADMIN., ADDERALL LABEL 3 (2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/011522s043lbl.pdf [https://perma.cc/ZGA4-YXHT] ("Adderall® is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) . . . .").

156. U.S. FOOD & DRUG ADMIN., ZOLOFT (SERTRALINE HYDROCHLORIDE) LABEL 3 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019839S74S86S87_20990S35S44S45lbl.pdf [https://perma.cc/VW4U-DH3U] ("Zoloft is indicated for the treatment of . . . [m]ajor depressive disorder.").

157. Nichter & Thompson, *supra* note 12, at 176.

because they are often not taken under the supervision of a trained medical professional, despite known harms.[158] While public policy demands products used for medical purposes are guaranteed safe, these products do not get sufficient assurances.

The same harms that the FDCA is so cautious to police in drugs occur with dietary supplements. Yet, because of dietary supplements' conflicting and ambiguous definitions, two different quality standards are applied to products with near-identical *consumer* objectives; drugs require rigorous assurances of both efficacy *and* quality while supplements receive little oversight and are often easily contaminated. The fight for efficacy demonstrations of dietary supplements is an already-lost battle, and understandably so: people want agency and demand the freedom to experiment. However, consumers deserve assurances that their supplements are accurately labeled and free from contamination harms just the same. Considering the unwavering demands for economic freedom and consumer access, an appropriate solution must balance these economic interests with the goal of consumer protection.

The extent of the harms in existence today begs the question: why do we not regulate the quality of these products as drugs? This question has been the subject of debate for decades, culminating in the passage of the DSHEA in 1994. Practical problems arise with drug-equivalent regulation. Unreasonable economic burdens would be cast all over the industry; innovation, consumer access, and wellness autonomy would be impeded. The effects this would have on a $300+ billion industry almost guarantee Congress will never return to the explicit regulations that existed prior to the DSHEA.

C. The Evolution of Conflict Within the Dietary Supplement Industry

People seeking to profit from selling untested, alternative remedies have been circumventing trained medical professionals for centuries.[159] As many remember from *Carlill v. Carbolic Smoke Ball Co.*, which involved a disputed flu remedy that shot puffs of acid into the nose, history is indeed riddled with dubious products available for direct purchase despite their

---

158. *Id.* at 200.

159. *See, e.g.*, S.D. POWERS, THE UGLY-GIRL PAPERS, OR, HINTS FOR THE TOILET, *reprinted from* HARPER'S BAZAAR 201 (1874) (discussing alternative beauty tips like sulphur-vapor baths and noting that physicians "ought to moderate the charges for these remedial agents"); *80 Years of the Federal Food, Drug, and Cosmetic Act*, FDA (July 11, 2018), https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act [https://perma.cc/9CZG-3UQ4].

unverified claims and quality.[160] Regulation of the medical and wellness industries has in fact been strengthened dramatically since the 1800s[161] when, as British legal scholar Brian Simpson puts it, "no human orifice was safe from the assaults of Victorian medical science."[162]

Still today, questionable, unverified, and sometimes dangerous products do exist in the market.[163] An overwhelming preference and demand for an unrestricted market has shaped our current regulatory landscape.[164] As a result, for certain products like dietary supplements, initial quality policing is left primarily up to the manufacturers, with the FDA only getting involved once harms are discovered.[165] This reactive legislative framework allows consumers to be harmed.[166]

While regulating dietary supplements as drugs may provide the most consumer protections, the FDA's history of failed attempts to strong-arm the dietary supplement industry suggests any advocacy for stringent regulation is a fruitless endeavor. Indeed, dietary supplements retain their perception as natural, relatively innocuous compounds that are less dangerous or risk-bearing than pharmaceutical drugs, despite modern changes.[167] To people who hold this view, stringent regulation is an infringement on their access to wellness.[168] Therefore, any attempts to increase product safety are met with tremendous backlash.[169]

This war on dietary supplements is one of the oldest public policy debates involving the FDA, and it began in 1906 with the passage of the Pure Food and Drugs Act.[170] A few years prior, Upton Sinclair published his novel *The Jungle*, which detailed the filthy conditions of Chicago's meatpacking

---

160. Carlill v. Carbolic Smoke Ball Co. [1893] 1 QB at 256 (Eng.).

161. *Compare* Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906), *with* Food, Drug & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938), *and* Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

162. A. W. B. Simpson, *Quackery and Contract Law: The Case of the Carbolic Smoke Ball*, 14 J. LEG. STUD. 345, 366 (1985).

163. *See* discussion *infra* Section I.D.

164. *See* Swann, *supra* note 19, at 272 (noting that the public quickly embraced advances in nutrition and supplements in late 1800s).

165. *See* Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

166. *See* discussion *infra* Section I.D.

167. *See* Nichter & Thompson, *supra* note 12, at 176 (discussing the general public's attraction to dietary supplements).

168. *Id.* at 215–16.

169. *See* RIMA APPLE, VITAMANIA: VITAMINS IN AMERICAN CULTURE (1996) (discussing the public interest in vitamins constructed by the supplement industry).

170. Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

industry.[171] *The Jungle* left the public incensed.[172] In response, President Theodore Roosevelt formed a special investigative committee which revealed Sinclair's stories were less fictitious than initially thought.[173] The unearthed horrors in *The Jungle* resulted in the passage of both the Meat Inspection Act and the Pure Food and Drug Act in 1906.[174] Under the Pure Food and Drug Act, the FDA was born and it was granted the authority to restrict "adulterated or misbranded or poisonous or deleterious" products from the market.[175] But the 1906 Act effectively operated as a transparent ingredient labeling requirement and did little to protect consumer safety.[176] These limitations allowed manufacturers to use creative loopholes and precluded the government from intervening when disturbingly harmful and misleading products affected consumers.[177] Numerous attempts were made to solve the problem, but Congress was not entirely interested. This changed after the 1937 Elixir Sulfanilamide tragedy, where a manufacture's liquid reformulation of a popular antibiotic used diethylene glycol, better known as anti-freeze, as a carrier solvent and killed over 100 people. The FDA was only able to prosecute the manufacturer for mislabeling, rather than the resulting deaths, leading Congress to finally enact the Food, Drug, & Cosmetic Act ("FDCA") in 1938. Replacing the 1906 Act, the FDCA granted the FDA slightly stronger regulatory powers largely still in effect today.[178]

Without a category of their own, products we now call dietary supplements were then classified as either a food, drug, food additive, or

---

171. *See* UPTON SINCLAIR, THE JUNGLE (1906).

172. Const. Rts. Found., *Upton Sinclair's* The Jungle: *Muckraking the Meat-Packing Industry*, 24 BILL OF RTS. IN ACTION 6 (2008).

173. *Id.* at 8.

174. *See* Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906); Meat Inspection Act, Pub. L. No. 59-242, 34 Stat. 1256 (1907).

175. Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

176. *See id.*

177. Notorious examples from the FDA's 1933 traveling exhibit "American Chamber of Horrors," all found to be legal despite their harms include: *Dinitrophenol*, sold as a weight loss product legally despite causing "fatal blood disorders, cataracts, and other serious side effects"; *Mamola*, another weight loss supplement containing dried thyroid tissue causing hyperthyroidism; *Radithor*, sold to treat erectile disfunction despite being nothing other than highly radioactive water, which made headlines after causing the horrifying death of businessman and athlete Eben Byers; and *Pabst's Okay Specific*, an "elixir" for STD's that did absolutely nothing and was unsuccessfully challenged by the FDA twenty-three times! The landscape of harms was *terrifying*, to say the least. *80 Years of the Federal Food, Drug, and Cosmetic Act*, *supra* note 159.

178. *Id.*; Food, Drug & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938); FOOD & DRUG ADMIN., FDA STAFF MANUAL GUIDES, VOLUME I—ORGANIZATIONS AND FUNCTIONS (2020), https://www.fda.gov/media/96655/download [https://perma.cc/HK6U-6YFQ].

some combination of the three.[179] Each product's designation would determine the quality standards for which a product would have to satisfy before reaching the market.[180] This was a form of "proactive" regulation, and it was not at all popular.[181]

The FDA had it out for dietary supplements. Almost immediately after the passage of the FDCA, the FDA's mission was to determine the "appropriate daily intakes of vitamins and minerals to ensure that minimum nutritional needs were being met,"[182] and the FDA spent several decades addressing vitamin regulation.[183] In 1966, the FDA took the position that people should get their vitamins and minerals from foods first, and proposed the following label be added to dietary supplements:

> Vitamins and minerals are supplied in abundant amounts in the foods we eat. The Food and Nutrition Board of the National Research Council recommends that dietary needs be satisfied by foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.[184]

This was met with predictable backlash by manufacturers,[185] but even nutritionists and the Association of Food and Drug Officials were opposed to the labeling.[186] In response, and without many alternatives, the FDA stayed the proposed 1966 labeling requirement, and it never took effect.[187]

---

179. Food, Drug & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

180. *See* United States v. Vitasafe Formula M, 226 F. Supp. 266, 278 (D.N.J. 1964) (explaining "Vitasafe" was both a food and a drug "because its labeling recommends its use as and represents it to be of value as a dietary and nutritional supplement, and . . . as a curative or preventive of disease conditions in man affecting the structure and function of the body").

181. *See* APPLE, *supra* note 169.

182. *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act: Hearings on H.R. 2493 Before the Subcomm. of the Comm. on Appropriations*, 103d Cong. 88 (1993) [hereinafter *1993 Hearings*] (statement of David Kessler, Comm'r of Food and Drugs).

183. *See* APPLE, *supra* note 169, at 126–27; Swann, *supra* note 19, at 273–75 (discussing the FDA's efforts to regulate vitamins since 1938).

184. Dietary Supplements of Vitamins and Minerals; Identity; Label Statements, 31 Fed. Reg. 8521, 8525 (June 18, 1966), https://www.govinfo.gov/content/pkg/FR-1966-06-18/pdf/FR-1966-06-18.pdf [https://perma.cc/9DCS-U9X2].

185. *See Part 1—Review of the Results of the White House Conference on Food, Nutrition, and Health: Hearings Before the Select Comm. on Nutrition & Hum. Needs*, 92d Cong. 205–07 (1971) [hereinafter *1971 Hearings*], https://babel.hathitrust.org/cgi/pt?id=uc1.31210017990746&view=1up&seq=219 [https://perma.cc/J4LA-7AQP] (letter from Miles Laboratories, Inc.); *see also* APPLE, *supra* note 169, at 132–34.

186. *1993 Hearings*, *supra* note 182, at 89.

187. *Id.*; APPLE, *supra* note 169, at 106, 132–33.

Switching gears in the 1970s, the FDA turned its attention to high potency vitamins.[188] They attacked these products on the grounds that their potency was "nutritionally irrational" for a dietary product, and that unless the dosage was reduced, these high potency vitamins should be regulated as drugs.[189] To the FDA, these products were not foods or food additives, but something entirely different, and as such should be regulated accordingly. However, Congress shut down the FDA's position with the Vitamin-Mineral Amendments of 1976, also known as the Proxmire Amendments, which forbid the FDA to limit potency on grounds of nutritional rationality.[190] This back-and-forth as to how these products should be regulated continued, with manufacturers and the public favoring a free market approach, and the FDA and scientific community insisting on higher safety standards.[191]

Towards the early 1990s, the FDA found themselves in increasingly hot water with the public, fueled primarily by supplement manufacturers' fearmongering.[192] In 1992, Senator Orrin Hatch proposed the Health Freedom Act to suffocate the FDA's power to prohibit supplements that made misleading health claims.[193] Though it did not pass, it prompted the FDA to assemble a committee and write a secret report addressing the dietary supplement issue. In this report, the FDA outlined how the agency thought supplements should be regulated. Feeling pressure from the industry, the FDA released the secret report in 1993.[194] The public was outraged.[195] The FDA's report appeared to propose exclusive regulation of supplements as drugs.[196]

---

188. Swann, *supra* note 19, at 277.

189. *Id.* at 276.

190. *Id.* at 277; Health Research and Human Services Amendments of 1976, Pub. L. No. 94-278, 90 Stat. 401 (1976).

191. *See* Swann, *supra* note 19 (discussing the FDA's historical attempts to regulate dietary supplements); *1993 Hearings*, *supra* note 182, at 88–117; Zhanga et al., *supra* note 57, at 105 (recommending a rigorous screening process for herbal products to minimize contamination and adulteration).

192. *See* Swann, *supra* note 19, at 278 (discussing the FDA's actions in the 1990s to regulate the dietary supplement industry).

193. S. 2835, 102d Cong. (1992).

194. 58 Fed. Reg. 33690, 33690–700 (proposed June 18, 1993).

195. *Dietary Supplement Health and Education Act: Is the FDA Trying To Change the Intent of Congress?*, *Hearing Before the H.R. Comm. on Gov. Reform*, 106th Cong. 2 (1999) [hereinafter *1999 Hearing*], https://www.govinfo.gov/content/pkg/CHRG-106hhrg57333/pdf/CHRG-106hhrg57333.pdf [https://perma.cc/YTG7-8JBT].

196. Food Labeling; General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances, 58 Fed. Reg. 33751 (June 18, 1993) (codified at 21 C.F.R. § 101).

Consumers became paranoid that the FDA would take dietary supplements away from them, despite the FDA's efforts to demonstrate their only goal was to protect consumers from harm.[197] A massive campaign was launched against the FDA's proposal. Thousands of retailers nationwide participated in "Blackout Day" and refused to sell dietary supplement products or covered them with "black dots, crepe-paper, black ribbons, or any other means" to (falsely) illustrate what the FDA was trying to do.[198] These campaigns were successful: more than 2.5 million letters were written to Congress in support of "health freedom," making the movement one of the largest and most successful grassroots efforts in the country.[199]

The FDA's fate was sealed. The DSHEA was passed in 1994; thereafter, any product previously marketed as a dietary supplement, or any ingredient found within a food, was allowed to be labeled as a dietary supplement and regulated accordingly.[200] Under the DSHEA, dietary supplements, including vitamins, minerals, herbs, amino acids, and other dietary substances, are regulated as foods rather than drugs.[201] Thus, they do not require pre-market approval.[202] Unlike drugs, supplement harms are addressed reactively,[203] rather than proactively.[204] The FDA is authorized to prevent "adulterated" products from entering the marketplace, though they carry the burden of proof and must make a sufficient demonstration that the supplement or ingredient is unsafe. This, of course, requires the product to already be unsafe and in commerce. It is reactive.

The Dietary Supplement Health & Education Act's ("DSHEA") modifications to the FDCA remain the controlling legislation regarding

---

197. APPLE, *supra* note 169, at 173–75.

198. *Dietary Supplement Blackout Day To Support Hatch/Richardson Bills*, GENERICS BULL. (Aug. 9, 1993). The movement provided stores with "pre-arranged congressional meetings and lobbying kits" full of information on the bill. The "blackout" was intended to "mobilize consumer support for the Hatch/Richardson bills by widely disseminating the industry's message that many products that consumers regularly purchase . . . [would] no longer be available" if the FDA's proposal took effect. *Id.* Campaign posters included phrases like "Don't Let Health Freedom Follow the Dinosaur" and "What do Dietary Supplements and Dinosaurs Have in Common? Nothing . . . YET! Tell Congress to Keep it That Way! Write Your Elected Representative NOW." *Id.*; APPLE, supra note 169, at 175.

199. *1999 Hearing*, *supra* note 195 ("More letters and faxes were received on this topic than any other single piece of legislation in U.S. history.").

200. *See* Dietary Supplement Health and Education Act, Pub. L. 103-417, 108 Stat. 4332 (1994).

201. *Id.*

202. *Id.*

203. *Id.*

204. *See* Food Drug & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

dietary supplements today.[205] The FDA has several tools to enforce quality within the industry: Good Manufacturing Practices ("GMPs") set forth requirements for manufacturers to ensure product quality;[206] the FDA conducts inspections and issues notices of violations if detected; adverse event reports alert the FDA to harms when they arise;[207] certain non-compliant ingredients can be labeled as a new dietary ingredient and have premarket requirements;[208] and if an ingredient is adulterated,[209] misbranded,[210] or fails to meet labeling requirements,[211] it can be removed from the market.[212] When all else fails, the FDA can inspect and investigate

---

205. *See* Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4332 (1994).

206. 21 U.S.C. § 342 ("The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology.").

207. *See* Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462 (2006). Adverse Event Reports can be filed by manufacturers and consumers to notify the FDA of harm. *See id.* In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act requiring manufacturers to register and report all serious events resulting from dietary supplements. *Id.*

208. *Questions and Answers on Dietary Supplements*, FDA (July 22, 2019), https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements [https://perma.cc/8HCG-ULGG]. A "new dietary ingredient" includes those which were not identified to be in use prior to October 15, 1994, around the time of the passage of the DSHEA. *Id.*

209. 21 U.S.C. § 342. The FDA has the authority to prevent "adulterated" foods from entering commerce. *Id.* A dietary supplement is classified as an "adulterated" food if it has been prepared, packed, or held in violation of GMPs, is a "new dietary ingredient" with insufficient safety information, or if the Secretary declares it to be imminently hazardous. *Id.*

210. Food Drug & Cosmetic Act, Pub. L. 75-717, 52 Stat. 1040 (1938). If any dietary supplement is "misbranded," the FDA can take action to remove it from the market. *Id.* A dietary supplement is deemed misbranded if it the label is false or misleading in some way. *Id.* This includes inaccurate and insufficient representations of the ingredients, failure to identify the product as a dietary supplement, failure to include required labels, or any other failure to meet required standards of "identity, strength, quality, purity, or compositional specifications." *Id.*

211. *Label Claims for Conventional Foods and Dietary Supplements*, FDA (Mar. 7, 2022), https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements [https://perma.cc/4JPE-X4S9] ("FDA regulations require that certain information appear on dietary supplement labels. Information that must be on a dietary supplement label includes: a descriptive name of the product stating that it is a 'supplement;' the name and place of business of the manufacturer, packer, or distributor; a complete list of ingredients; and the net contents of the product. In addition, each dietary supplement (except for some small volume products or those produced by eligible small businesses) must have nutrition labeling in the form of a 'Supplement Facts' panel. This label must identify each dietary ingredient contained in the product.").

212. *See supra* note 210.

facilities,[213] issue warnings and recalls,[214] seize products,[215] and proceed with criminal charges against those in violation of the FDCA.[216] Comprehensive in theory, these tools are underused and over-abused, leaving consumers substantially under-protected.

This century-long fight between the FDA and the dietary supplement industry demonstrates the unavoidable parameters any successful regulation must operate within. Dietary supplements will never again be regulated as drugs. While clear and convincing arguments can be made that consumers would be better protected if they were, the FDA has repeatedly lost this battle with the public. Consumers want autonomy to experiment and make their own wellness decisions.[217] Manufacturers want to sell these products and have tremendous power to influence the debate. We are left then to accept nonregulation of the *efficacy* of dietary supplements, but what about their quality? The gas station Viagra will stay; but can we at least know what's really in that pill?

D. Critiques of the Current Regulations

"Dietary supplements" as defined by the FDCA is an overinclusive category that affords drug-like products ineffectual regulations and creates consumer harms. Manufacturers have perverse incentives to classify their

---

213. Tara Lin Couch, *Current Status and Future FDA Enforcement of Dietary Supplements*, REGUL. FOCUS (June 2021), https://www.raps.org/News-and-Articles/News-Articles/2021/6/Current-status-and-future-FDA-enforcement-of-dieta. When a manufacturer is found to be non-compliant with FDCA requirements like GMP's, a formal "FDA Form 483" is issued documenting the observations and outlining the required remedies. *Id.* But because of the COVID-19 pandemic, the FDA was not performing on-site inspections or issuing any Form 483's to manufacturers, opting instead to perform remote observations. *Id.*

214. 21 C.F.R. § 7.45. Manufacturers can recall a product themselves, or the FDA can request the manufacturer to initiate a recall. *Id.* These requests are technically voluntary, though the FDA can initiate a mandatory recall under the Food Safety Modernization Act if the product is adulterated or misbranded food and will cause serious adverse health consequences or death. Food Safety Modernization Act, Pub. L. No. 111-353, § 206, 124 Stat. 3885, 3939–44 (2011).

215. *See FDA Announces Seizure of Adulterated Dietary Supplements Containing Kratom*, FDA (May 21, 2021), https://www.fda.gov/news-events/press-announcements/fda-announces-seizure-adulterated-dietary-supplements-containing-kratom [https://perma.cc/Z25C-JVBQ]. The FDA has the power to seize and destroy dietary supplements in limited circumstances. *See id.* Kratom is a recent example. *Id.*

216. *See* Indictment, United States v. Lee, No. 8:18-cr-00226-JVS (C.D. Cal. Oct. 24, 2018), https://quackwatch.org/wp-content/uploads/sites/33/quackwatch/casewatch/doj/lee/indictment.pdf [https://perma.cc/8FJ8-V4BL].

217. *See* Nichter & Thompson, *supra* note 12.

product as a dietary supplement by any means possible to avoid the more stringent and expensive requirements for pharmaceutical drugs.[218] Additionally, manufacturers have tremendous input and influence over the regulation of dietary supplements because the DSHEA shifts several burdens onto them, rather than shifting them onto a disinterested third party or a government agency. Even if compliance was perfect, the regulatory framework of dietary supplements is predominantly a process standard, rather than an end-product standard; it creates several gaps in quality control where contamination events can occur. This ineffectual legislation is enforced by an underfunded and understaffed FDA, so it comes as no surprise that contamination events occur with such frequency.[219] The quality uncertainty that exists for dietary supplements gives potentially legitimate and innovative products a bad reputation to start, and many medical professionals are hesitant to prescribe them.

1. Manufacturer Non-Compliance

Incredibly, about seventy percent of manufacturers do not comply with Good Manufacturing Practices.[220] In 2013, 444 of the 626 FDA inspected manufacturers received written violations.[221] Non-compliance includes obvious violations like manufacturing defects or sanitation violations, but some manufacturers will simply fail (perhaps intentionally) to supply accurate or complete contact information.[222] Without this information, when adverse events occur, the FDA cannot reach the manufacturer to coordinate a solution.

In theory, every adulterated product produced by a non-compliant manufacturer should be pulled from the market. Any dietary supplement is deemed "adulterated" if its production is not compliant with the GMPs.[223] The FDA does not need to make a demonstration that an adulterated product

---

218. *See* Sullivan, *supra* note 21.

219. *See* Brodwin, *supra* note 61.

220. LEVINSON, *supra* note 63.

221. Josh Long, *FDA GMP Inspectors Cite 70% of Dietary Supplement Firms*, NAT. PRODS. INSIDER (May 20, 2013), https://www.naturalproductsinsider.com/regulatory/fda-gmp-inspectors-cite-70-dietary-supplement-firms [https://perma.cc/R8AJ-HTCW].

222. LEVINSON, *supra* note 63.

223. 21 U.S.C. § 342(g)(1).

is necessarily dangerous or contaminated, and any adulterated dietary supplement may not be introduced into interstate commerce.[224]

Frequent and routine inspections of manufacturing plants would ideally mitigate contamination harms; however, the FDA's lack of funding and manufacture's resistance effectively precludes required swift action against adulteration from applying to all products. Additionally, the significant number of foreign manufacturers and importers create additional challenges for enforcement. As a result, often only the most severe cases get investigated,[225] leaving numerous harmful products on the shelves. The question then becomes: can we have unfettered access without rampant adulteration?

2. The Process Standard Includes Too Much Manufacturer Influence

The final issue with GMPs is that they generally regulate the quality of the manufacturing processes, rather than the quality of a final product. Manufacturers develop and follow their own standards for quality assurance, and this leads to conflict regarding what standard is sufficient. Process standards like GMPs create many opportunities for unintentional contamination events.

Manufacturers of dietary supplements are required by law to ensure their products are safe before they are marketed.[226] But what does "safe" mean? Under the DSHEA, several quality control standards are left to the manufacturer to decide. Manufacturers, not the FDA, must design and implement their own system of "quality" and "production and process controls covering all stages of manufacturing, packaging, labeling, and holding of the dietary supplement to ensure the quality of the dietary supplement."[227] This is a classic example of the fox guarding the hen house.

---

224. *See* John D. Copanos & Sons, Inc. v. FDA, 854 F.2d 510, 514 (D.C. Cir. 1988); *see also* 21 U.S.C. § 331(a).

225. DANIEL R. LEVINSON, OFF. OF INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERVS., DIETARY SUPPLEMENTS: STRUCTURE/FUNCTION CLAIMS FAIL TO MEET FEDERAL REQUIREMENTS 20 (2012). The FDA commented that it will continue to focus primarily on disease claims because they pose the greatest threat to public health but that it will continue to address situations in which products fail to meet dietary supplement labeling requirements, including the use of structure/function claims without a disclaimer. *Id.*

226. *Questions and Answers on Dietary Supplements*, *supra* note 105.

227. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, FDA-2010-D-0605*,* SMALL ENTITY COMPLIANCE GUIDE: CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS (Dec. 2010), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-

Manufacturers are aware of this and routinely take advantage, putting consumers in harm's way.

3. Bottlenecked FDA Results in Total Oversight

Between 2009 and 2012 the FDA issued recalls for 237 dietary supplements.[228] Alarmingly, they all contained banned drugs.[229] Even worse, two-thirds of those recalled products still contained the banned drugs only six months later.[230] Because the FDA does not have the finances or manpower to test every batch of every product at every stage of manufacturing, they must conservatively allocate their resources to the most pressing harms.[231] Manufacturers take advantage of the FDA's limited resources, often playing games to continue to sell their product.

The FDA only recently created the Office of Dietary Supplement Programs in 2016.[232] In 2017, the Office of Dietary Supplement Programs had a budget of $5 million, a team of twenty-six people, and was responsible for policing a multi-billion-dollar industry.[233] Despite dietary supplements being around for decades, the division only recently received its own office.[234] The circumstances today have only marginally improved.[235] They are, as then-director Steven Tave put it, "doing the best [they] can."[236]

Aware of its own limitations, the FDA has published on its website that it is "unable to test and identify all products marketed as dietary supplements that have potentially harmful hidden ingredients" and warns consumers to

---

compliance-guide-current-good-manufacturing-practice-manufacturing-packaging-labeling#IX [https://perma.cc/AN2M-6LYH]; *see also* 21 C.F.R. § 111.70.

228. Pieter A. Cohen et al., *Presence of Banned Drugs in Dietary Supplements Following FDA Recalls*, 312 J. AM. MED. ASS'N 1691, 1691 (2014).

229. Brodwin, *supra* note 61.

230. Pieter A. Cohen et al., *Presence of Banned Drugs in Dietary Supplements Following FDA Recalls*, 312 J. AM. MED. ASS'N 1691, 1691 (2014).

231. *Questions and Answers on Dietary Supplements*, *supra* note 105 ("FDA has limited resources to analyze the composition of food products, including dietary supplements, and, therefore, focuses its resources first on public health emergencies and products that may have caused injury or illness. Priority then goes to products suspected to be adulterated, fraudulent, or otherwise in violation of the law. The remaining resources are used to analyze product samples collected during inspections of manufacturing firms or pulled from store shelves as part of FDA's routine monitoring of the marketplace.").

232. 81 Fed. Reg. 6524 (Feb. 8, 2016), https://www.govinfo.gov/content/pkg/FR-2016-02-08/pdf/2016-02444.pdf [https://perma.cc/PDM5-3NQS].

233. Brodwin, *supra* note 61.

234. *Id.*

235. *Id.*

236. *Id.*

"exercise caution before purchasing" dietary supplements.[237] Without adequate funding, the FDA will never be able to sufficiently ensure safety within dietary supplements no matter how comprehensive manufacturer requirements may be.

Male sexual enhancement pills are a common repeat offender routinely identified as contaminated with prescription medications.[238] Despite numerous warnings from the FDA, manufacturers have simply renamed the aberrant product to deceitfully pacify the FDA's warnings, falsely claiming it has been reformulated when, in fact, it is still contaminated.[239] The already overextended FDA generally must then begin the process all over again with the new product, leaving consumers in harm's way in the interim and exhausting the FDA's resources.[240] What is worse is the sheer amount of time it can take to halt the sale or enforce compliance of a non-compliant supplement. Many cases have illustrated this issue. For example, in *United States v. Hakim*, after nearly eight years from the FDA's first inspection for noncompliance, an FDA investigator discovered that non-compliant products were still being sold despite numerous warnings and return promises of compliance.[241] Meanwhile, consumers are generally unable to bring suit on their own for manufacturer violations because enforcement of the FDCA is exclusive to the FDA and there is no private right of action.[242]

---

237. *Public Notification: Vigour 800 mg Contains Hidden Drug Ingredient*, FDA (July 16, 2019), https://www.fda.gov/drugs/medication-health-fraud/public-notification-vigour-800-mg-contains-hidden-drug-ingredient [https://perma.cc/8NZX-5WM4].

238. For example, the FDA maintains a running list of nearly 400 tainted sexual enhancement pills known to contain hidden and potentially harmful ingredients. *Tainted Sexual Enhancement Products*, FDA (Feb. 7, 2023), https://www.fda.gov/drugs/medication-health-fraud/tainted-sexual-enhancement-products [https://perma.cc/3PGM-8PQN].

239. For example, "Rhino" male enhancement products were declared to contain hidden and harmful drug ingredients by the FDA. *Public Notification: RHINO 7 Platinum 5000 Contains Hidden Drug Ingredient*, FDA (Feb. 23, 2018), https://www.fda.gov/drugs/medication-health-fraud/public-notification-rhino-7-platinum-5000-contains-hidden-drug-ingredient [https://perma.cc/3EU8-C8GY]. However, the product is still for sale with the addition of a "V" in front of the "7." *Rhino V7 Platinum 5000*, BOOM HEADSHOP, https://boomheadshop.com/products/rhino-v7-platinum-5000 [https://perma.cc/2AAM-L9WF].

240. *See* Brodwin, *supra* note 61 (noting the FDA will receive a report about adverse health effects of a product before investigating the product for adulteration or misbranding); *see also* Petition for Damages, *supra* note 67, at ¶¶ 21–34 (claiming that a manufacturer's sale of a product previously declared misbranded by the FDA resulted in the wrongful death of a consumer).

241. United States v. Hakim, 462 F. Supp. 3d 418, 425 (S.D.N.Y. 2020).

242. 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.").

When the FDA has, on an incredibly rare basis, taken final action and banned a deleterious compound from the market, manufacturers have simply changed the chemical makeup of the ingredient just enough for it to fall outside the restriction, despite having the same effects or even converting into the banned substance post-digestion.[243]

4. Over-Inclusive Category Creates Perverse Incentives for Manufacturers

Fish, Fish Oil, or *Vacsepa*? If you need to supplement your diet with omega-3 fatty acids, all three will deliver. On the other hand, if you are preparing dinner, odds are you would not opt for either of the capsules. This is an easy distinction to make and explains the FDCA's drug versus food distinction quite well, but what about the dietary supplement? Generally, one can tell when fish is rotten, but rotten medication is not easily detectable by the consumer; thus public policy demands rigorous assurances. However, the same issues apply to dietary supplements for medical consumption, which are not afforded the same quality protections.

Around the passage of the DSHEA, dietary supplements for medical consumption were not as visible or prevalent and they were generally considered more food-like from both consumer and manufacturer perspectives.[244] Accordingly, it was reasonable to regulate these products as foods.[245] However, modern innovation creates a new problem: today there are many more food-derivative health products, classified as dietary supplements, that have medicinal uses.[246] The controlling public policy arguments thus create a paradox for these products: on the one hand strict regulation for food derived products is disfavored, but at the same time, protections against undisclosed harms must be afforded to medical consumption. The resulting in-between zone for dietary supplements with medical functions perversely incentivizes manufacturers to represent their product as a dietary supplement when it arguably should be a drug.

Fertility tea, among other herbal remedies, illustrates these perverse incentives well. Although it is an herbal beverage crafted from soaking leaves in hot water, it is not equivalent to Earl Grey. The entire point of fertility tea is to increase fertility. Thus, the tea has a legitimate medical purpose, and

---

243. Neilson M. Mathews, *Prohibited Contaminants in Dietary Supplements*, 10 SPORTS HEALTH 19, 24 (2018).

244. *See* APPLE, *supra* note 169.

245. Federal Food, Drug, & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

246. *See* Nichter & Thompson, *supra* note 12, at 195.

prescription drugs like *Clomid* aim to achieve similar goals.[247] Knowing this purpose, the manufacturer has two choices. They could market the tea as a drug, which would require premarket approval and demonstrations of efficacy and safety, as well as meeting the highest quality standards at a tremendous cost. Alternatively, the manufacturer could market the product as a dietary supplement. After all, the leaves are found in nature, they are edible, why not compare them to Earl Grey? The manufacturer would have to make no pre-market demonstrations, which would reduce the expertise, cost, and time needed to get the product to market. For manufacturers of fertility tea, and the thousands of supplements with medical uses, the choice is clear.

If the FDA adequately enforced the DSHEA's safety requirements, there would be little issue here. GMPs would ensure a quality product and protect the consumer from harm. However, as noted earlier, these protections are underenforced, and the tremendous input manufacturers have in setting their own quality standards leaves little for the consumer to trust. To protect themselves, consumers must first recognize these issues and then venture out into the marketplace to wade through the sea of confusing labels and claims in the hopes that they land on something of quality.

5. Myriad of Labels: Confused Consumers Must Fend for Themselves

Shopping for quality dietary supplements is unreasonably difficult for the consumer. Wading through the litany of claims, guarantees, and badges suggesting quality leaves consumers highly skeptical and rightly so.[248] These do not point to any specific sources and are unreliable.

While savvy consumers are understandably skeptical, other less-savvy consumers incorrectly assume dietary supplements are approved for safety by some government agency.[249] They may give these claims some credence despite a product's mandatory disclaimer it has not been evaluated by the FDA.[250] Consumers often disregard or are unaware of this disclaimer, making it ineffective.[251] Because most consumers are unaware of how the DSHEA

---

247. Sanofi-Aventis U.S. LLC, *Clomid (Clomiphene Citrate Tablets USP)*, FDA (Oct. 2012), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/016131s026lbl.pdf [https://perma.cc/WLU7-CD67].

248. *See* Eichner et al., *supra* note 101, at 179 ("It is difficult for athletes, military members, and their support professionals to assess whether a particular certification adequately reduces the risks in their setting.").

249. Dodge, s*upra* note 15, at 236; Nichter & Thompson, *supra* note 12, at 177.

250. Nichter & Thompson, *supra* note 12, at 177.

251. Kesselheim et al., *supra* note 16, at 444.

operates, they are exposed to veiled risks that otherwise would be better appreciated with a proper understanding of the FDA's limits.[252]

Labels of compliance are a step above bogus guarantees. GMP compliance is required by the FDCA, and manufacturers may advertise that their product was made in a GMP compliant facility.[253] However, because so many manufacturers are not compliant despite the requirement, such claims are unverifiable and untrustworthy.

Select manufacturers will advertise that their finished product has been tested and that this ensures its quality.[254] The availability of tested products is progress in the right direction. However, the current approaches to testing are inconsistent and flawed. In-house testing, when manufacturers choose to test their products themselves, is inherently prone to bias.[255] Third-party testing is the best current approach because it relies on an external, disinterested third party. But results vary from lab to lab, and consumers cannot be expected police the differences.[256] Both types of testing lack a consensus procedure: there is no standard for what to test for, how frequently to test it, and with what methods. The best and most comprehensive third-party certification available today is likely the "NSF" badge from NSF International ("NSF").[257] However, because it is an independent organization not overseen by the FDA, situations could arise where a manufacturer was certified under NSF but non-compliant under the FDCA. Because of these issues, quality assurances from testing claims are not absolute.

II. PROPOSAL

Absolute regulation is untenable in today's political climate and the consumer protection strategies in effect today are insufficient because they effectively ignore the consumer's intended medical use of certain dietary supplements and do not provide the same assurances of quality as those afforded to drugs despite this. All consumers are at risk for physical harm and

---

252. Dodge, s*upra* note 15, at 236.

253. *Best Naturals Zinc Supplement*, AMAZON, https://www.amazon.com/dp/B00HYIABBY?ref_=cm_sw_r_cp_ud_dp_QF6T0YNX8XSN771MDSA3 [https://perma.cc/CXV9-94E9] (product carries an unofficial badge denoting GMP compliance).

254. Eichner et al., *supra* note 101, at 178.

255. *See id.* at 180 ("Third-party certification programs also must have written conflicts of interest policies that ensure no part of the program or analytical testing is biased.").

256. *Id.* at 178.

257. *See Health Certification Services*, NSF, https://www.nsf.org/testing/health [https://perma.cc/UAB4-NXAP].

honest manufacturers pay for this. The dietary supplement industry needs a workable solution that balances the interests of economic freedom with consumer safety. A successful solution must satisfy four requirements. First, it must not impede economic growth or consumer access to dietary supplements. Second, the solution must offer safety assurances and increase consumer trust. Third, the FDA should be able to sufficiently enforce the solution. Finally, any solution must be both economically feasible and easily implemented by the manufacture. The creation of a "FDA Certified" label for products whose quality meets or exceeds certain criteria will satisfy these requirements. This Comment will propose a general framework of this proposed FDA certification, a foothold into the issue, by drawing inspiration from USDA Organic's success.

A. Pulling Inspiration from USDA Organic

USDA Organic is a process standard for organic products sold in the United States.[258] Though not officially created until 2002, the movement behind organic standards can be traced all the way back to the writings of Sir Albert Howard in the 1940s.[259] In his writings, Howard expressed concern over unfit practices in agriculture like the use of pesticides and chemical fertilizers on crops.[260] Similar to the debate over dietary supplement regulation, the organic movement faced tremendous backlash and criticism for being too restrictive and progressive.[261] However, today, products certified as organic must meet the USDA's strict requirements to bear their seal of approval.

The regulatory framework of "USDA Organic" satisfies the proposed requirements for a successful approach for dietary supplements and is thus a great starting point. Because the organic standard is optional, it does not directly impede any producer of agriculture and consumers are free to select other products. Therefore, there is no economic restraint for the manufacturer

---

258. *See* Valerie J. Watnick, *The Organic Foods Production Act, the Process/Product Distinction, and a Case for More End Product Regulation in the Organic Foods Market*, 32 UCLA J. ENV'T L. & POL'Y 40, 54 (2014).

259. *See* J. Heckman, *A History of Organic Farming: Transitions from Sir Albert Howard's* War in the Soil *to USDA National Organic Program*, 21 RENEWABLE AGRIC. & FOOD SYS. 143 (2006) (discussing the writings of Sir Albert Howard and how he contributed to the organic farming movement); *see also* ALBERT HOWARD, AN AGRICULTURAL TESTAMENT (1940); ALBERT HOWARD, THE WAR IN THE SOIL (1946).

260. Heckman, *supra* note 259, at 149.

261. *See id.* at 147 (discussing the political tension arising between organic and non-organic farming practices).

and consumer autonomy is maintained. USDA Organic is proactive: products must first demonstrate compliance to bear the seal.[262] This preemptive standard ensures consumers are adequately protected from undesired harms. Organic compliance requires a product to be free from or contain less than set thresholds for certain deleterious substances like pesticides or chemical fertilizers. These safety assurances increase consumer trust. Organic products are generally adequately enforced, though there are concerns regarding imported products with the label. These issues stem from USDA Organic also being a process standard, rather than an end-product standard as proposed here for dietary supplements. The success and growth of the organic foods industry suggests the framework is also economically feasible and easily implemented by the manufacture.[263]

B. Designing the Standard

Regulation for dietary supplements can take inspiration from and expand upon the "USDA Organic" framework. A proper solution must balance the four mentioned factors, essentially preserving economic freedom while ensuring consumer protection. One way to do this would be with a voluntary certification label that represents a finished product as meeting sufficient standards of quality. To prevent the contamination that can occur between manufacturing ingredients and the finished product, the certification should verify the product in its finished state. Compliance with the standard should be enforced externally by a third-party lab, rather than by the manufacturer in-house. Additionally, this end-product verification should not be handled directly by the FDA because rigorous testing has been shown to be too burdensome for the FDA's limited resources.[264] Instead, the FDA should determine a process for certifying and overseeing a third-party testing facility, issue guidelines to the third party for testing products in compliance with the FDA's label requirements, and issue certification approval contingent on the lab's findings.

This method of nested management would mean the FDA would only have to ensure the labs were compliant with testing guidelines, and the labs would

---

262. Unlike the proposal for dietary supplements, USDA Organic is a process standard, not an end-product standard. Watnick, *supra* note 258, at 43. As such, there are legitimate issues with quality control. *Id.* at 59–60. However, the proposal for dietary supplements would not be subject to these issues because the end product would be tested instead.

263. *Organic Agriculture: Overview*, USDA ECON. RSCH. SERV., https://www.ers.usda.gov/topics/natural-resources-environment/organic-agriculture/ [https://perma.cc/9V7Z-S6LM].

264. *See* discussion *supra* Subection I.D.3.

then ensure the products were compliant. The cost of lab testing would be passed to the manufacturer who would be seeking the optional certification to improve its brand reputation and separate its products from inferior products.[265] If a manufacturer is not compliant, its product will not be certified. If a lab falsely certifies the product, the FDA can revoke the lab's power to test under the standard and either bring direct action against the lab or allow for a consumer private right of action. These consequences for both manufacturers and testing facilities will ensure legitimate compliance and guarantee that consumers receive trustworthy information. Additionally, this regulatory structure would satisfy the four requirements outlined above.

6. The Certification Process Must Not Impede Economic Growth, Consumer Autonomy, or Access

The certification process would not significantly impede manufacture's profitability and overall economic growth because: (1) it is entirely optional; (2) once popularity and awareness grow, product prices could be increased commensurate with demand; and (3) the third-party labs would be regulated by the FDA, so reasonable pricing policies could be enforced.

An optional standard would allow manufacturers to implement the standard if and when it is reasonable for them. For manufacturers who currently utilize third-party testing for their products, switching to the FDA certification standard would likely not carry any significant increase in costs, but may even increase the economic benefit because of the wider recognition. After these pioneering manufacturers deploy the certification, the increase in consumer awareness would reduce the financial risk to other non-testing manufacturers. The manufacturer may even choose to never certify their product; however, as the certification grows in popularity and recognition, non-compliant manufacturers may lose consumer popularity and revenue. Consumer autonomy and access to dietary supplements are also preserved. Because manufacturer compliance is optional, consumers are still free to choose whatever product they want, certified or not.

The certification would likely increase economic growth by reducing skepticism that may reduce consumer purchase power. The resulting standardization of quality would separate "lemons" within the market and the average perceived efficacy of any given type of product within the certified

---

265. *See* Akerlof, *supra* note 108, at 499–500 (noting the impact of brand names on consumers' belief of product quality).

segment would rise. This increase in quality may correlate to an increased demand, potentially justifying price increases.

7. Offer Reliable Consumer Protection & Increase Consumer Trust

End-product standards offer inherently more reliable assurances of quality to a consumer than process standards because they eliminate the possibility of undiscovered contamination occurring before completion of a product. The most comprehensive standard to assure quality in dietary supplements is to verify each capsule in every bottle, but this would be prohibitively expensive and destroy each capsule in the process. Instead, sufficiently frequent batch-lot style testing would offer statistically similar assurances of quality for the finished product, not just ingredients at one point in time prior to completion. Batch-lot testing is recommended by the GMPs; however, the standard proposed herein would eliminate clumsy enforcement by shifting the costs to manufacturers and quality assurance responsibilities to certified labs.

Third-party testing facilities would compare a manufacture's product to established FDA testing criteria. Like USDA's National List of Allowed and Prohibited Substances,[266] the FDA would maintain a database of required quality thresholds and prohibited substances that third-party facilities would use to compare tested products against. For herbal products, the database could include standardization requirements of herbal constituents to reduce product variability.

The proposed seal should also list the year in which the product was certified and feature a QR code that directs customers to an FDA web page displaying the certification results. As a more comprehensive evolution of USDA's Organic Integrity Database, the QR code would prevent fraudulent manufacturers from using illegitimate seals on their products.[267] Because relevant testing criteria evolves over time, the certification page should situate the current testing standards next to those used at the time the product was tested to highlight any relevant changes. This use of a QR code would greatly increase product transparency and consumer trust.

---

266. *The National List of Allowed and Prohibited Substances*, USDA, https://www.ams.usda.gov/rules-regulations/national-list-allowed-and-prohibited-substances [https://perma.cc/H2XM-HZ6R].

267. *Organic Integrity Database*, USDA, https://organic.ams.usda.gov/integrity/ [https://perma.cc/8V76-JZPM].

8. Be Sufficiently Enforceable by the FDA

Under the proposed label program, rather than policing individual products, the FDA would issue testing procedures and thresholds to certified testing facilities. These labs would then charge manufacturers who wish to apply for certification. The FDA could exclude participating manufacturers' voluntarily-submitted products from the random quality audits. This would reduce both the costs incurred in random audits and the size of the pool of products to be audited, increasing the chances of discovering GMP non-compliant manufacturers. Of course, audits would still need to be performed on submitting manufacturers for the remaining GMP criteria like facility sanitation and record keeping, but these audits have successfully been performed remotely and any offset in responsibility will lead to a better allocation of resources.

9. Be Economically Feasible & Easily Implementable by Manufacturers

Any new standard must be economically feasible to be functional. Third-party testing already meets this requirement because several manufacturers successfully employ third-party testing. The new FDA standard would not create any significant increase in costs for these manufacturers because it only consolidates testing criteria under one label. These manufacturers may even experience an increase in profits further offsetting existing costs because of the improved recognition the seal would provide over the current variety.

For other manufacturers, the FDA's resulting monopolization of testing facilities would permit lower testing costs due to an increase in scale and the FDA's potential ability to regulate costs. As the label becomes more widely recognized, consumer demand may further encourage non-participating manufacturers to adopt the label. Like the rising demand for USDA Organic products, the perceived quality differences between certified and uncertified products may justify higher prices.[268] To encourage smaller manufacturers to participate, a cost shifting or cost reduction program could be implemented. This would function similarly to the USDA's National Organic Certification Cost Share Program where eligible producers' certification costs are subsidized by up to fifty percent.[269] Tax incentives could be directed towards participating manufacturers to further encourage participation. Tax penalties

---

268. *Organic Agriculture: Overview*, *supra* note 263.

269. *Organic Certification Cost Share Program (OCCSP)*, USDA FARM SERV. AGENCY, https://www.fsa.usda.gov/programs-and-services/occsp/index [https://perma.cc/REQ3-FVJH].

could be applied to non-participating large-scale manufacturers to further encourage participation and offset government expenditure.

The large number of manufacturers who already implement third-party testing indicates the cost is feasible and implementable. For other manufacturers, incentive programs can be developed to encourage participation.

III. CONCLUSION

Dietary supplements exist within a public policy paradox. On the one hand, medical consumables require strong regulations. But on the other hand, public policy demands relaxed regulations for food-derivative consumption. We can tell when lettuce is rotten, but contaminated drugs are harder for the consumer to identify. Dietary supplements have both food-derivative qualities and medical purposes, and the conflicting policy goals surrounding these intended uses create a nebulous regulatory landscape. As a result, the FDA is forced to use a reactive approach, correcting harms only after they occur. Consumers therefore face the risk of ingesting contaminated supplements while manufacturers face the risk of economic loss due to the uncertainty on the market. Enhancements in the regulation of dietary supplements are needed to create a more efficient market with less risk of consumer harm while maintaining consumer autonomy. The proposed FDA certified seal would allow consumers to distinguish verified, quality products from the rest and protect honest manufacturers from economic loss.