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I L L I N O I S B U S I N E S S L A W J O U R N A L

A BITTER PILL TO SWALLOW: AMERICA'S UNREGULATED SUPPLEMENT INDUSTRY AND THE COST TO CONSUMERS

❖ Note ❖

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I. INTRODUCTION

In 2021, the global dietary supplement market was worth USD 149 billion, and was projected to grow to USD 240 billion by 2028.[1] The U.S. alone was responsible for approximately thirty-two percent of the market.[2] This growth is attributable to a variety of societal changes including increased concerns over healthcare costs, skin health, shifts in lifestyle choices, celebrity endorsements, fears about immune system health resulting from COVID-19, greater self-care awareness, and sports and fitness trends.[3] Although supplement use within American society is rampant, with 57.6% of adults aged twenty and over consuming at least one dietary supplement within the past month, few people understand how they are produced,

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[1] Sagar Kumar, *Global Dietary Supplements Market Size In 2022: Growth Opportunities and Future Outlook 2028*, LINKEDIN (Sep. 14, 2023), https://www.linkedin.com/pulse/global-dietary-supplements-market-size-2022-growth-future-sagar-kumar/.

[2] Grand View Research, *U.S. Dietary Supplements Market Size, Share & Trends Analysis Report By Type (OTC, Prescribed), By Ingredient, By Form, By Application, By End-user, By Distribution Channel, And Segment Forecasts, 2023 – 2030*, https://www.grandviewresearch.com/industry-analysis/us-dietary-supplements-market-report (last visited Apr. 4, 2023).

[3] *Bone and Joint Health Supplements Global Market Report 2024 - Product Innovations and Strategic Acquisitions Fueling Market Dynamics*, PR NEWSWIRE (Feb. 7, 2024), https://www.prnewswire.com/news-releases/bone-and-joint-health-supplements-global-market-report-2024---product-innovations-and-strategic-acquisitions-fueling-market-dynamics-302056576.html; *Immune Health Supplements Market Pioneers Next-Gen Wellness Solutions, More than $14 Billion Opportunities in the Next 6 Years – Arizton*, PR NEWSWIRE (Jan. 31, 2024), https://www.prnewswire.com/news-releases/immune-health-supplements-market-pioneers-next-gen-wellness-solutions-more-than-14-billion-opportunities-in-the-next-6-years--arizton-302049387.html.

manufactured, and regulated.[4] A 2019 survey indicated that a majority of Americans overestimate the FDA's role in regulating supplements, assuming that the FDA tests supplements before sale or that supplement manufacturers must prove to the FDA that their products are safe or effective.[5] The law requires that every supplement bottle contains a label notifying consumers that "[t]his statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[6] This does little to clarify misinformation or counter consumer's assumptions.[7] As every single supplement label states, supplements are not evaluated by the Food and Drug Administration (FDA), but that does not mean they lack oversight altogether.[8]

The FDA's authority to intervene against supplement manufacturers is limited because supplements are regulated as a food, not a drug. This results in fewer safeguards and laxer requirements than what the layperson may expect from something sold under the guise of medical authority. As long as they refrain from making assertions to diagnose, mitigate, treat, cure, or prevent any disease, supplement producers are only required to inform the FDA if they plan on using novel ingredients within their supplement.[9] Thus, supplement manufacturers are not legally required to notify the FDA of the release of their supplement onto the market, submit any evidence regarding the safety or efficacy of the ingredients, get label approval, provide samples for regular testing, provide the amounts for each ingredient included, or confirm the identity of ingredients supplied to them.[10] While over-the-counter medication may take years to receive approval from the FDA, supplements are not legally required to get approval from the FDA at all.[11] Almost every aspect of efficacy, safety and quality control over the supplement industry is left to the discretion of the manufacturers.[12] Such policies result in outcomes like that of the now-banned Epehedra, which was a supplement that caused heart attack, seizure, stroke, and over 100 deaths prior to its ban by the FDA.[13]

Supplements are not regulated as rigorously as pharmaceuticals, yet the average consumer believes they are. The industry is largely opaque, yet it contributes

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[4] Suruchi Mishra, et al., *Dietary Supplement Use Among Adults: United States, 2017–2018*, NAT'L CTR. OF HEALTH STATISTICS DATA BRIEF (Feb. 2021), https://doi.org/10.15620/cdc:101131.

[5] *Americans Support Requiring Supplement Makers to Tell FDA About Their Products*, THE PEW CHARITABLE TRUSTS (Dec. 18, 2019), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2019/12/americans-support-requiring-supplement-makers-to-tell-fda-about-their-products.

[6] 21 C.F.R. § 101.93(a)(3)(c).

[7] *See id.*

[8] *21* U.S.C. § *343(r)(6).*

[9] *Id.*

[10] *Id.*

[11] The Editors, *We Need to Better Regulate Nutraceuticals*, 328 SCI. AM., 1, 8 (2023), https://www.scientificamerican.com/article/we-need-to-better-regulate-nutraceuticals/.

[12] *Id.*

[13] *Ephedra*, NAT'L INST. OF HEALTH: NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, https://www.nccih.nih.gov/health/ephedra (last updated Jul. 2020).

over USD 158 billion to the U.S. economy. How can supplement businesses continue to be competitive in such a market while promoting consumer awareness and safety?[14] This article will offer solutions by analyzing the consequences of the current regulatory scheme and considering possible changes on three levels—federal regulation, business accreditation, and consumer discretion. In Part II, I will describe the history of the supplement industry. In Part III, I will discuss the positive and negative outcomes that result from the current regulatory scheme. In Part IV, I will provide recommendations for changes to increase business and consumer protections.

II. BACKGROUND

To fully understand the weaknesses of the current regulatory framework employed to control the supplement market, it is important to first understand the history of the industry and how it came to be regulated the way that it is today. To this end, this section will describe: (1) the Dietary Supplement Health and Education Act's (DSHEA) early attempts to regulate the supplement industry, (2) the evolution of supplement regulation laws, and (3) the self-regulation requirements for supplement manufacturers.

A. The DSHEA and its Reliance on Trust

Large supplement retailers like GNC will prominently display ads for supplements and supplement combinations with text such as: "no prescription. no sky-high costs. no hassle."[15] In less than ten words, the retailor was able to encapsulate the current draw consumers have towards supplements and shed light on the purpose of the 1994 Dietary Supplement Health and Education Act.[16] The DSHEA amended the Federal Food, Drug, and Cosmetic Act (FD&C) and ensured that the FDA's only place in regulating the supplement market was after health and safety problems had been reported.[17] The FDA encourages individuals to report adverse effects caused by supplements, but only when the FDA has compiled

[14] Claudia Adrien, *New report highlights $158 billion U.S. economic impact of supplement companies*, NUTRAINGREDIENTS USA (Jan. 26, 2024), https://www.nutraingredients-usa.com/Article/2024/01/26/Economic-impact-by-supplement-companies-158-billion.

[15] *Id.*

[16] *Dietary supplements*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/food/dietary-supplements (last visited Mar. 5, 2024).

[17] *Questions and Answers on Dietary Supplements*, U.S. FOOD AND DRUG ADMIN., https://web.archive.org/web/20240327121553/https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements (last visited Mar. 3, 2024).

sufficient evidence of adulteration, fraud, or violations of the law can it intervene.[18] The FDA was provided with the ability to define current "Good Manufacturing Practices," or "cGMP," for the production of dietary supplements by the DSHEA, but these are focused on the purity and consistency of a supplement as opposed to the inherent safety or efficacy of the ingredient itself.[19]

The DSHEA was the product of efforts by Utah senator Orrin Hatch. Although the alleged purpose of the DSHEA was to provide consumers with the ability to take their health into their own hands with the use of a flexible and responsive supplement market, its passive regulation model was more likely related to Utah's standing as the leading supplement manufacturer in the United States.[20] Utah still has a vested interest in maintaining the current status-quo in regards to supplement manufacturing, as the dietary supplement industry is the largest industry in Utah as of 2023.[21] The changes caused by Orrin Hatch resulted in a highly dynamic industry that is able to adapt quickly to fads and consumer whims, as well as an industry that is fiercely protected by lobbyists.[22]

In 1994, when the DSHEA was enacted, it was estimated that the dietary supplement market only contained approximately 4,000 products.[23] Today there are almost 90,000.[24] Supplements are statutorily defined as any product intended to supplement the diet that contains a vitamin, mineral, herb, botanical, amino acid, any "substance used to supplement the diet by increasing the total dietary intake," or a concentrate, constituent, extract, or combination of any of the previously listed items.[25] The supplements on the market today range in type and purpose and can be found in a variety of forms, from pills to IVs. [26]

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[18] *FDA 101: Dietary Supplements,* U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements (last visited Mar. 3, 2024).

[19] *See generally* INSTITUTE OF MEDICINE AND NATIONAL RESEARCH COUNCIL COMMITTEE ON THE FRAMEWORK FOR EVALUATING THE SAFETY OF DIETARY SUPPLEMENTS, DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY. NAT'L ACAD. PRESS (2005), https://www.ncbi.nlm.nih.gov/books/NBK216048.

[20] Michael Hiltzik, *Column: Orrin Hatch is leaving the Senate, but his deadliest law will live on*, L.A. TIMES (Jan. 5, 2018), www.latimes.com/business/hiltzik/la-fi-hiltzik-hatch-20180105-story.html.

[21] Stephen Daniells, *Dietary supplements become Utah's #1 industry, topping $7.2 billion*, NUTRAINGREDIENTS USA (May 22, 2012), https://www.nutraingredients-usa.com/Article/2012/05/23/Dietary-supplements-become-Utah-s-1-industry-topping-7.2-billion.

[22] *See* Bobby Hewitt, *The U.S. Supplement Market*, CREATIVE THIRST (May 30, 2023), https://creativethirst.com/blog/united-states-supplement-market/.

[23] *Id.*

[24] *Id.*; Ranjani Starr, *Too Little, Too Late: Ineffective Regulation of Dietary Supplements in the United States*, 105 AM. J. PUBLIC HEALTH 478 (2015).

[25] 21 U.S.C. § 321(f)(1).

[26] U.S. FOOD AND DRUG ADMIN., *supra* note 19.

These products are more readily available than they were in 1994, as the internet has become a key tool in selling supplements to the public.[27] Unfortunately, regulatory policies have not adapted to these more recent changes, resulting in incomplete coverage. Supplement labels are required by 21 U.S.C. § 343(q)(5)(F) to list any ingredient in "significant amount," as well as their quantities. 21 C.F.R. § 101.93(a)(3)(c) further requires that all supplement bottles featuring statements regarding the benefits or safety of the supplement bear the disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[28] Although this is required to be placed at the end of such statements they are often listed at the bottom of packages or on the back of the bottle.[29]

These requirements have not been adapted to the sale of supplements on the internet. Such warnings may now be nested within drop-down menus, accompanied with motivational photos, and buried within more text than could fit on the box or bottle.[30] 21 U.S.C. § 343–2 has addressed attempts to augment label information with misleading or false claims published to the public by incorporating publications regarding supplements to be construed as labeling if they are used in connection with the sale of supplements to consumers, contain false information, promote a brand or manufacturer, or are displayed in proximity to the bottles.[31] However, this has no impact on the promulgation of false information associated with these products that is often provided to consumers within reviews of products or on blogs and other websites.[32] The FTC in its limited authority over advertising requires that claims regarding efficacy or safety of supplements be supported with "competent and reliable scientific evidence," but has only recently begun expanding its scope beyond solely cases of fraud.[33]

In 1994, only approximately two in five people used supplements, while today that number has doubled to four in five people.[34] Ten percent of people report

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[27] *How is E-Commerce Impacting the Global Supplement Market?*, GLANBIA NUTRITIONALS (Jun. 7, 2021), https://www.glanbianutritionals.com/en/nutri-knowledge-center/insights/how-e-commerce-impacting-global-supplement-market.

[28] 21 C.F.R. § 101.93(c)(1).

[29] *Id.* § 101.93(a)(3)(c).

[30] GNC, gnc.com (last visited Mar. 31, 2024).

[31] 21 U.S.C. § 343–2.

[32] Artur Bjelica, et al., *Internet Marketing of Cardioprotective Dietary Supplements*, MARY ANN LIEBERT, INC., PUBLISHERS (Mar. 2020), https://www.liebertpub.com/doi/full/10.1089/acm.2019.0128.

[33] Christine Wilson, *Dissenting Statement of Commissioner Christine S. Wilson Regarding the Issuance of a Notice of Penalty Offenses on Substantiation of Product Claims*, FED. TRADE COMM'N (Mar. 31, 2023), https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/dissenting-statement-commissioner-christine-s-wilson-substantiation.

[34] Jamie Gahche, et al., *Dietary supplement use among U.S. adults has increased since NHANES III (1988-1994)*, 61 NAT'L CTR. OF HEALTH STAT. DATA BRIEF 1, 5, 8 (2011).

taking five or more supplements daily, meaning the number of people potentially harmed by supplements before the FDA can intervene is higher than ever.[35]

B. The Evolution of Supplement Regulation Laws

Due to the immense growth in the supplement market, there has been growing pressure to enforce greater restrictions.[36] Only in 2006 did the Dietary Supplement and Nonprescription Drug Consumer Protection Act mandate that supplement manufacturers report serious adverse effects to the FDA.[37] This required the reporting of deaths, life-threatening events, hospitalizations, disabilities, permanent impairments, congenital anomalies, birth defects, or other serious medical events.[38] On January 4, 2011, the FDA was granted mandatory recall authority over supplements.[39] Prior to 2011, the FDA could only make recommendations to consumers or to the manufacturers found to be in violation of the law and request that they remove the supplement from the market, often with little effect.[40] Of the warnings the FDA issued to manufacturers between the years 2007 and 2016, only approximately forty-six percent complied and voluntarily removed the product from the market.[41]

C. Self-Regulation Within the Supplement Industry

The focus on self-regulation within the industry and the subsequent lack of quality throughout has borne several opportunities for proponents of supplements to stand out. Trade organizations within the industry have joined forces to improve the industry's reputation by focusing on product quality and consumer safety.[42] Other trade organizations focus on the industry's code of ethics, including truthful advertising.[43] Additionally, third-party companies like Consumerlab, US Pharmacopeia, or NSF (National Sanitation Foundation International) are available

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[35] Starr, *supra* note 24.

[36] The Editors*, We Need to Better Regulate Nutraceuticals*, 328 SCI. AM., 8, 8 (Jun. 2023).

[37] Starr, *supra* note 24.

[38] *Id.*

[39] Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls, 85 Fed. Reg. 55551 (Nov. 06, 2018).

[40] Jenna Tucker, et al., *Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated with US Food & Drug Administration Warnings*, 1 JAMA 2, 11 (2018).

[41] *Id.*

[42] *Leading Dietary Supplement Trade Organizations Commemorate 100th Meeting of the Dietary Supplement Trade Associations*, CONSUMER HEALTHCARE PRODUCTS ASS'N (Apr. 26, 2021), https://www.chpa.org/news/2021/04/leading-dietary-supplement-trade-organizations-commemorate-100th-meeting-dietary.

[43] Jodie Bernstein, The FTC and Dietary Supplements, FED. TRADE COMM'N. (Nov. 13 1997), https://www.ftc.gov/news-events/news/speeches/ftc-dietary-supplements.

to provide accreditation to supplement manufacturers whose products contain accurate ingredient labels.[44]

III. ANALYSIS

Despite past attempts to protect consumers through legislation such as the DSHEA and the Dietary Supplement and Nonprescription Drug Consumer Protection Act, consumers still fall through the gaps. To protect consumers while maintaining business interests, it is necessary to understand: (1) the gaps in the current regulatory framework, (2) attempts to remedy the gaps and how they have been unsuccessful, (3) recent legislation drafted to address these issues, and (4) how consumers can protect themselves.

A. Gaps in the Current Regulatory Framework

Although the intended purpose of the current regulatory framework is to create an industry that is flexible and responsive to current needs, it is clear that the balance between innovation within the industry and consumer safety is not being struck.[45] The FDA's central reporting system (the Center for Food Safety and Applied Nutrition AE Reporting System or "CAERS") between 2004 and 2013 received over 15,000 reports of adverse health effects, of which included 4,000 hospitalizations and 339 deaths.[46] Such numbers likely do not reflect the true scale of the issue, as adverse effects often go unreported.[47] The FDA itself admits that consumers only report between one to ten percent of adverse health events.[48]

The FDA's additional tool, the inspection of manufacturing facilities, is also wholly underused due to lack of resources.[49] Of the 4,000 manufacturers covered by cGMP regulations, the FDA only inspected 416 in 2013.[50] These only amount to 2.8% of all supplement manufacturers registered with the FDA, as the rest are domestic and international dietary supplement firms that are not covered by the

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[44] Tod Cooperman, *7 Red Flags to Watch Out for When Buying Vitamins & Supplements*, CONSUMERLAB (May 16, 2023), https://www.consumerlab.com/answers/what-to-watch-out-for-when-buying-vitamins-and-supplements/vitamin-and-supplement-red-flags.

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

[46] *See generally* Elizabeth Richardson, et al., *What Should Dietary Supplement Oversight Look Like in the US?* 24 AM. J. ETHICS 402 (2022).

[47] *Id.*

[48] *CDERLearn Training and Education*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/training-and-continuing-education/cderlearn (last visited Apr. 28, 2024).

[49] Starr, *supra* note 24.

[50] *Id.*

cGMP regulations.[51] In 2011, of those inspected by the FDA, 73% failed to adhere to regulations.[52] The serious adverse effects reporting mandate also went unheeded. In 2006, it was estimated that around 50,000 adverse effects impacted consumers in the United States alone, but only "596 serious and 352 mild or moderate" reports were ever filed by manufacturers.[53] Additional studies identified approximately 23,000 emergency department visits within the U.S. between 2004 and 2013 as a result of adverse effects of dietary supplements.[54] One diet product alone resulted in forty-seven hospitalizations, three liver transplants, and one death in 2014.[55] Muddying the waters even further, when the FDA analyzed their adverse effects reports, they found that 64% of those listed as mild or moderate were misclassified by manufacturers and were actually severe.[56]

B. Attempts to Remedy the Gaps and Why They Have Been Unsuccessful

The FDA has indicated it is aware it has been failing consumers.[57] In 2019, the FDA committed to "cracking down" on supplement retailers and manufacturers for making illegal health claims but made no indications it will address the extreme inconsistencies found within the industry.[58] In 2022, the FDA expressed an interest in promoting transparency and consumer safety by producing a draft guidance that, if published, would allow supplement manufacturers and distributors who had previously failed to disclose new supplement ingredients to the FDA to "correct past failures" and submit this information with a presumably lower likelihood of being penalized.[59] The existence of this draft guidance is an indication that the FDA is aware that supplement manufacturers are not being faithful in complying with the FD&C Act and that there is currently no way for consumers to know of these new ingredients without the assistance of consumer watch groups or other outside agencies.[60]

In 2010, the U.S. Government Accountability Office reported that ninety-three percent of dietary supplements it tested contained trace amounts of lead, arsenic, mercury, cadmium, or pesticides.[61] The supplement Oxy ELITE Pro Super

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[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] Andrew Geller, et al.*, Emergency Department Visits for Adverse Events Related to Dietary Supplements*, 373 NEW ENG. J. MED. 1531 (Oct. 15, 2015).

[55] Hiltzik, *supra* note 20.

[56] Starr, *supra* note 24.

[57] Gottlieb, *supra* note 45.

[58] *Id.*

[59] Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-Market Notification, 87 Fed. Reg. 30843 (May 20, 2022).

[60] *See id.*

[61] Starr, *supra* note 24.

Thermogenic, which was advertised to promote weight loss, was found to contain the SSRI Fluoxetine.[62] Tainted supplements or misleading labels are unfortunately not uncommon within the industry.[63] This includes bottles containing none of the active ingredient they purport to contain, inaccurate estimates of ingredient amounts, and entirely unlisted ingredients that "raise serious questions about [their] safety."[64]

Worse, while some companies mislabel their products by mistake due to lack of oversight and proper testing, others take advantage of legal loopholes to do so intentionally.[65] Supplement manufacturers are required to list a product's ingredients by weight, "except when the ingredients are a part of a proprietary blend," in which case they only need to list the quantity of the proprietary blend itself.[66] When supplements use terms like "blend," "complex," "matrix," and "proprietary formula," they may be obscuring very low doses of active ingredients combined with filler materials like rice or wheat flour, or they may be leading the consumer to ingest significantly higher amounts of active ingredients than they anticipated.[67] This is particularly dangerous when done with stimulants, but such practices are currently appropriate under 28 U.S.C. § 343(q)(5)(F), which explicitly allows the use of proprietary blends.[68] Proprietary blends are simply combinations of ingredients that remain confidential as they are considered trade secrets.[69]

However, not every instance of intentional ingredient manipulation is done with ill intent.[70] The shelf life of dietary supplements can vary dramatically depending on environmental conditions like temperature, moisture, ultraviolet light, and exposure to oxygen.[71] Some ingredients will degrade over time while others become more potent.[72] However, in part due to the temperament of the products and in part due to the FDA's requirements that supplements list their active ingredients based on the amount present upon expiration, it is common for supplements to contain

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[62] *Public Notification: Oxy ELITE Pro Super Thermogenic Contains Hidden Drug Ingredient*, U.S. FOOD AND DRUG ADMIN. (Feb. 28, 2015), https://www.fda.gov/drugs/medication-health-fraud/public-notification-oxy-elite-pro-super-thermogenic-contains-hidden-drug-ingredient.

[63] Robert Shmerling, *What's in your supplements?* HARVARD HEALTH PUBL'G (Feb. 15, 2019), https://www.health.harvard.edu/blog/whats-in-your-supplements-2019021515946.

[64] *Id.*

[65] Operation Supplement Safety, *Proprietary Blends: What Does This Mean?*, https://www.opss.org/article/proprietary-blends-what-does-mean (last updated Mar. 28, 2018).

[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] *Proprietary blends in dietary supplements protect trade secrets and foster innovation*, COUNCIL FOR RESPONSIBLE NUTRITION (Oct. 2021), https://www.crnusa.org/sites/default/files/Proprietary%20Blends/CRN-ProprietaryBlends-DietarySupplements1021.pdf.

[70] *See* Regan Bailey, *Current Regulatory Guidelines and Resources to Support Research of Dietary Supplements in the United States*, 60 CRITICAL REVIEWS IN FOOD SCI. AND NUTRITION 298 (2020).

[71] *Id.*

[72] *Id.*

either more or less of the ingredient than is listed on the bottle based on how close it is to expiring.[73] Supplements that are anticipated to degrade will have higher amounts than listed, while those anticipated to sublimate will have lower amounts than listed.[74] Although the FDA has allowed an eighty-percent variation rate for naturally occurring dietary ingredients, independent studies indicate that this suggestion is rarely followed. A 2013 study on the concentrations of vitamin D found that pill potency varied from nine percent to 146% of the concentration listed on the label.[75] In 2020, a review of dietary supplements claiming to aid brain health found that of the twelve tested, eight were missing an ingredient listed on their label, and ten contained unreported ingredients.[76] Another study in 2022 found that of thirty dietary supplements purchased online, only thirteen contained accurate labels, while thirteen were missing from one to six ingredients listed on their label and nine had substances detected that were not accounted for on the label.[77]

C. Recent Attempts to Increase Supplement Regulation

There have been attempts to increase regulation of the supplement market, most recently in the form of the Dietary Supplement Listing Act of 2022 (DSLA).[78] Most notably, the DSLA would require supplements entering into the market to be pre-registered with the FDA and would force the FDA to create a publicly accessible electronic database for consumers to access important information on all supplements registered.[79] However, the DSLA is receiving intense resistance from lobbyists who think the more restrictive measures will prove too expensive and difficult to implement.[80] The resulting risk-based regulatory scheme currently in force in the United States has been described by some as a large-scale clinical trial, one in which unwitting participants taking dietary supplements are being exposed to "new, untested ingredients, without their knowledge or consent."[81]

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[73] *Id.*

[74] *Id.*

[75] Starr, *supra* note 24.

[76] Cindy Crawford, et al., *A Public Health Issue: Dietary Supplements Promoted for Brain Health and Cognitive Performance*, 26 J. ALT. COMPLEMENTARY MED. 265 (2020).

[77] Cindy Crawford, et al., *Analysis of Select Dietary Supplement Products Marketed to Support or Boost the Immune System*, 5 JAMA 3–5, 9 (2022).

[78] Dietary Supplement Listing Act of 2022, S.4090, 117th Cong. (2022).

[79] *Id.*

[80] Nicholas Florko, *As Congress takes up FDA oversight of dietary supplements, a lobbying showdown looms*, STAT (May 17, 2022), https://www.statnews.com/2022/05/17/dietary-supplements-reform-fda-oversight-lobbying; Dan Mitchell, *Why the Supplements Industry is So Powerful*, TIME (Mar. 11, 2015), https://time.com/3741142/gnc-vitamin-shoppe-supplements.

[81] Starr, *supra* note 24.

D. Consumer Education

With the evidence piling up against the supplement industry, it can be difficult to assess if consumers are truly in the dark or if it can be more accurately described as willful blindness. Those who have been disillusioned by the dietary supplement industry have offered advice to others: buyer beware. [82] In fact, countless resources remarking on the unsafe nature of supplements and the ineffectiveness of the current regulatory structure ultimately close their discussions with how-to guides for a consumer to safely participate in the market.[83] Advice includes watching out for misleading or meaningless claims, coming to terms with the knowledge that what is on the bottle is likely not reflective of the contents, talking to your doctor before taking any supplements, being skeptical of endorsements and testimonials and trying to purchase products verified by outside companies.[84] Others have simply suggested that health-conscious consumers purchase their supplements from countries with stricter supplement regulation regimes like Canada, China, and countries within the European Union.[85]

While numerous factors play into the spread of misinformation within the U.S. regarding the health benefits of dietary supplements, inappropriate labeling undoubtedly plays a role. Bottles boast that they are "verified," "approved," or made in an "FDA-Approved Facility," leading consumers to confirm their preexisting beliefs without doing further research.[86] Bottles purporting to contain "clinically tested ingredients" are equally deceptive, as consumers are prone to assuming they mean the efficacy of the contents has been proven, when in reality it means no more than what it says—that it has been clinically tested with no mention as to what for or with what result.[87] Similarly, bottles claiming to contain "pharmaceutical grade" ingredients give the consumer the impression of a higher-quality product by leaning on the credibility of the drug industry to achieve an artificially elevated status for an ingredient that is, in truth, not a drug.[88] The only accreditation of dietary supplements that can be trusted are those provided by reputable third-party

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[82] *Supplements: A Scorecard*, HARVARD HEALTH PUBLISHING (Sept. 22, 2021), https://www.health.harvard.edu/newsletter_article/supplements-a-scorecard; Curtis Haas, *Dietary Supplements: Buyer Beware*, UNIV. OF ROCHESTER MED. CTR. (Oct. 14, 2015), https://www.urmc.rochester.edu/news/publications/health-matters/dietary-supplements-buyer-beware; Cooperman, *supra* note 44.

[83] HARVARD HEALTH PUBLISHING, *supra* note 83; Haas, *supra* note 83; Cooperman, *supra* note 44.

[84] Karen Asp, *What's Hiding in Your Vitamin Supplement? The Ingredients to Avoid*, THE BEET (Mar. 25, 2022), https://thebeet.com/watch-out-for-whats-hiding-in-your-supplement; HARVARD HEALTH PUBLISHING, *supra* note 83.

[85] *See generally* Valeriya Zayets, *Comparing Dietary Supplement Regulations in the U.S. and Abroad*, 74 FOOD & DRUG L.J. 613 (2020).

[86] Consumer Reports, *What Supplement Labels Mean, and Don't*, YAHOO! FINANCE (Jul. 27, 2016), https://finance.yahoo.com/news/supplement-labels-mean-dont-100048438.html.

[87] Cooperman, *supra* note 44.

[88] *Id.*

companies, and even those only test for ingredient accuracy, not safety or efficacy.[89] Additionally, while all supplement manufacturers are *supposed* to follow the FDA's GMP guidelines regarding the manufacturing, packaging, labeling, and holding of supplements, only those that actually do so and can prove it become GMP certified (GMPs).[90]

IV. RECOMMENDATION

Given the lack of effective regulations on supplements, it is clear that the supplement industry needs change. Consumers are largely unaware of the industry's regulation practices, causing countless deaths and injuries. To better balance business interests and consumer protection, changes can be made by legislatures, supplement manufacturers, and consumers. Legislatures need to provide the FDA with greater authority and resources to identify dangerous supplements prior to their introduction into the market. Supplement manufacturers must invest in greater safety standards and verify the identities and quantities of the ingredients they are using. Lastly, consumers should research the products they consume, spread awareness of any adverse effects they experience, and remain skeptical of manufacturers promises.

First, numerous steps should be taken to curb the damages and dangers resulting from the current risk-based regulatory scheme deployed in the United States. Beginning with the systems that are already in place, the FDA needs to secure more authority to appropriately deal with the unreliability and depth of deception occurring within the supplement industry.[91] Although adopting the regulatory scheme currently adopted for medications would be a thorough means of ensuring consumer safety, it would demolish the innovation of the industry that has allowed it to thrive for the past few decades.[92] Instead, a more moderate approach would be appropriate, one that bridges the gap by (1) forcing supplement manufacturers to receive FDA pre-approval with a focus on proving the quality and amounts of ingredients within their products, (2) enforcing more transparency when confronted with proprietary blends, and (3) granting the FDA with the authority to regularly test supplements in the market for label accuracy and greater resources to be able to inspect supplement manufacturing facilities for GMPs as well as follow up on adverse effects reported to them.[93] Additionally, the DSLA would not be sufficient on its own to address the current issues in the supplement industry regulatory

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[89] *Id.*

[90] *Federal GMPs for Dietary Supplements*, NAT. PRODUCTS ASSOC., https://www.npanational.org/regulatory/federal-gmps-dietary-supplements (last visited Mar. 3, 2024).

[91] Starr, *supra* note 24.

[92] Hewitt, *supra* note 22.

[93] Starr, *supra* note 24.

scheme, but providing an online database would aid in the spread of accurate information that currently lacking.[94]

Second, dietary supplement manufacturers must do better as well.[95] The system in place gives manufacturers and producers immense discretion in enforcing the guidelines provided by the FDA, and too many are falling short.[96] The DSHEA was created in 1994, when the supplement market looked significantly different than it does today.[97] With the immense influx of internet usage, the days of insufficient adverse effect reporting to the FDA are numbered. Individuals have turned to the internet to purchase their supplements at an alarming rate and will continue to use the internet should they experience any negative side effects.[98] The best option to survive a change in public opinion about supplements is to get ahead of the misinformation and become registered with a third-party agency to become verified.[99] This will serve the dual purpose of making the supplement manufacturer durable against shifts of public opinion and the market as well as set them apart from competitors.[100]

Third, the recommendation for consumers to navigate the dietary supplement industry is clear: buyer beware.[101] Researching various supplement providers prior to ingesting them will go a long way.[102] With the prominence of online supplement shops, it is important to remain vigilant and question the reputation of the producers and websites consumers rely upon, while staying wary of the different ways supplement providers may deceive consumers by nesting important warnings within tabs and hidden segments of websites.[103] Ultimately, even if a supplement provider is completely transparent about what is contained within its product, ingredient effects still vary person by person.[104] Consumers must discuss taking supplements with their healthcare provider prior to making any decisions, because although many of the ingredients may be natural, that does not mean that they are inherently healthy.[105]

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[94] Consumer Reports, *supra* note 87.
[95] Starr, *supra* note 24.
[96] *Id.*
[97] Hewitt, *supra* note 23.
[98] Glanbia Nutritionals, *supra* note 28.
[99] Cooperman, *supra* note 44.
[100] *Id.*
[101] *Id.*
[102] Asp, *supra* note 84.
[103] GNC, *supra* note 30.
[104] Asp, *supra* note 84.
[105] *Id.*

V. CONCLUSION

Although stricter enforcement of current FDA regulations would curtail some of the damaging conduct running rampant within the supplement industry, this is by no means the most effective way to increase transparency and consumer safety. Changes are coming within the supplement industry, with or without the consent of manufacturers, sellers, and producers. Such changes should instead be made by the legislature, supplement manufacturers, and consumers. Legislatures need to provide the FDA with greater authority and resources, supplement manufacturers need to adopt safer business practices, and consumers need to remember—buyer beware.