

COMMENTS

SIPPING THE (DETOX) TEA: THE RISE IN ADVERTISEMENTS FOR NON-FDA APPROVED SUPPLEMENTS ON SOCIAL MEDIA & REGULATIONS (OR LACK THEREOF) THAT GOVERN

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Introduction	154
I. Background	158
A. What Are Supplements and Who Takes Them?	158
B. How Are Dietary Supplements Regulated?	160
C. How Are Dietary Supplements Advertised?	164
D. How are Prescription and Over-the-Counter Drugs Advertised?	167
II. Dangers of a Lack of Regulation	169
A. Why Should We Have Higher Standards for Supplements? ..	169
B. But What About the Other Side?	173
III. Recommendations	175
A. Updating the DSHEA: What New Legislation Could Look Like	175
B. Working Together: Issuing Joint Guidance	181
Conclusion	184

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INTRODUCTION

FitTea, FlatTummy Shakes, Sugar Bear Hair Vitamins—these are just a few of a myriad of “wellness” products flooding social media platforms through celebrity and influencer advertisements.¹ Companies who create, manufacture, and distribute these products rely heavily on famous users of social media platforms, some with millions of followers, to promote the company’s brand, individual products, or both.² However, the Food and Drug Administration (FDA) does not approve these “wellness” products and many social media advertisements for these products fail to notify consumers of the potentially harmful side effects.³ Thus, the upsurge of A-Listers routinely churning out promotional posts featuring non-FDA approved products is extremely troubling,⁴ especially when this category of products results in thousands of hospital visits per year.⁵

1. See Cheryl Wischhover, *Vitamins for Your Hair, Nails, and Skin are Everywhere on Instagram. Don't Fall for Them.*, VOX (Apr. 8, 2018), <https://www.vox.com/2018/4/9/17199164/beauty-vitamin-collagen-turmeric-biotin>; see also Tara Evans, *What Instagram-Famous 'Detox' Teas Actually Do for Your Health*, VICE (Dec. 9, 2015), https://www.vice.com/en_us/article/8qwpba/what-instagram-famous-detox-teas-actually-do-for-your-health.

2. See Joel Matthew, *Understanding Influencer Marketing and Why it is So Effective*, FORBES (July 30, 2018), <https://www.forbes.com/sites/theyec/2018/07/30/understanding-influencer-marketing-and-why-it-is-so-effective/#75ec58a071a9> (noting that influencer marketing has become a useful tool through the advent of social media and helps ensure that ads get in front of the relevant target audience on a continuous basis, especially since social media users can curate what content they view).

3. See generally *What You Need to Know About Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/buy-store-serve-safe-food/what-you-need-know-about-dietary-supplements> (last updated Nov. 29, 2017) (providing general answers to common questions a consumer may have about dietary supplements including the Food and Drug Administration’s (FDA’s) role); see also Evans, *supra* note 1 (providing examples of side effects including disruption in menstrual cycles and severe cramping in the abdominal area).

4. Sophie Lewis, *Instagram Posts That Promote Weight Loss will be Hidden from Users Under 18*, CBS NEWS (Sept. 18, 2019), <https://www.cbsnews.com/news/instagram-posts-that-promote-weight-loss-will-be-hidden-from-users-under-18/>. In response to promotional posts for non-FDA approved products, Instagram has set new policies that “are a direct reaction to the increase of influencer marketing and the promotion of diet teas, supplements and certain cosmetic surgeries on the app. Influencers have advertised weight loss products with increasing frequency over the years to an impressionable young audience.” *Id.*

5. Megan Smith-Mady, *Celebrity Drug Endorsements: Are Consumers Protected?*, 43 AM. J.L. & MED. 139, 143 (2017); see also Megan Thielking, *Unregulated Supplements Send Thousands to Hospital Each Year*, BOS. GLOBE (Oct. 14, 2015), <https://www.bostonglobe.com/metro/2015/10/14/diet-pills-and-other-unregulated-supplements-send-thousands-hospital-each-year/7HG6mwrdujYCB7ZMo5RHuM/story.html>.

Take a moment and scroll through your own social media feeds. There is a high probability that you, like millions of other users, will come across various miracle products that promise to flatten your stomach, build muscle, promote hair growth, or increase your sex drive; the list of miracle cures is seemingly endless.⁶ Seventy-four percent of social media users will ultimately decide to purchase one of these products based solely on an advertisement that catches their eye.⁷ But who are the individuals advertising these products? It runs the gamut and the group includes actors, fitness gurus, reality television stars, models, and YouTube vloggers to teens who have cashed in on the latest trendy app like TikTok—collectively these people are known as influencers.⁸ What exactly do these influencers promote? Among other things, dietary supplements. An industry that avails between 50,000 and 80,000 products to consumers and generates over \$40 billion in sales.⁹ To put those vast numbers into perspective, consider this: Three out of four

6. See *Beware of Products Promising Miracle Weight Loss*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/beware-products-promising-miracle-weight-loss> (last updated Jan. 5, 2015) [hereinafter *Beware of Products*] (noting that products guaranteeing a “quick fix,” such as “lose 10 pounds in one week,” can serve as a potential warning sign of a tainted product); see also *The FDA Warns That Biotin May Interfere With Lab Tests: FDA Safety Communication*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication> (last updated Nov. 28, 2017) (mentioning the existence of dietary supplements that are marketed for hair growth reasons, along with beneficial skin and nail growth as well); cf. *Tainted Sexual Enhancement Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/medication-health-fraud/tainted-sexual-enhancement-products> (last updated July 16, 2019) (alerting the public that products promoted for sexual enhancement purposes have increasingly contained hidden ingredients).

7. Alana Sandel, *Five Steps for Managing an Influencer Marketing Campaign*, FORBES (June 13, 2019), <https://www.forbes.com/sites/forbesagencycouncil/2019/06/13/five-steps-for-managing-an-influencer-marketing-campaign/#7ee17f9fa80c>.

8. *What is an Influencer?*, INFLUENCER MARKETING (Feb. 1, 2019), <https://influencermarketinghub.com/what-is-an-influencer/> (explaining that influencers on social media are individuals who have built a reputation by his or her association with a certain topic who then regularly post about that topic in order to generate and maintain a vast following); see, e.g., Khloe Kardashian (@khloekardashian), INSTAGRAM, <https://www.instagram.com/p/BxyGEcnB8OW/> (last visited Jan. 21, 2020) (posting an advertisement for FlatTummy Co.); Kyle Jenner (@kyliejenner), INSTAGRAM, <https://www.instagram.com/p/BtMODPMH4SH/> (last visited Jan. 21, 2020) (featuring an advertisement sponsoring the brand Sugar Bear Hair).

9. Press Release, U.S. Food & Drug Admin, 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 Oversight (Feb. 11, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>.

Americans take dietary supplements on a regular basis.¹⁰ Again, these are the very same supplements that result in over 20,000 emergency room visits each year in the United States.¹¹

The demonstrable, pervasive consumption of supplements and the increasing number of popular social media accounts constantly advertising these supplements,¹² perhaps because a majority of Americans use them,¹³ might lead one to assume there must be a stringent regulatory framework in place to ensure that these products are safe before they hit the shelves.¹⁴ However, the opposite is the case.

When it comes to supplemental products, the FDA takes a *laissez-faire* approach.¹⁵ Dietary supplements are available for consumers to buy and try without any prior approval from the agency.¹⁶ In fact, the FDA's role in regulating supplements is inherently contradictory; the FDA steps in and regulates only after these products enter the marketplace—the agency's relationship with supplements is one that is reactive rather than proactive.¹⁷ The only time manufacturers have to alert the FDA about the ingredients in a

10. *Id.*

11. See Thielking, *supra* note 5.

12. See Zara Stone, *The Enduring Menace of Detox Teas*, ELEMENTAL (Sept. 4, 2019), <https://elemental.medium.com/the-enduring-menace-of-detox-teas-9c4232eac50>.

13. See *New Data Reaffirm Trust and Confidence in Industry, Reveal Modern Trends and Habits of American Consumer*, COUNCIL FOR RESPONSIBLE NUTRITION (2018), <https://www.crnusa.org/CRNConsumerSurvey>. [hereinafter *New Data*].

14. Tonya Dodge, *Consumer's Perceptions of the Dietary Supplement Health and Education Act: Implications and Recommendations*, 2016 DRUG TESTING ANALYSIS 407–09 (“For example, in a sample of 185 undergraduates, about 75% erroneously believed that the FDA was responsible for ensuring the safety of supplements before they could be sold and nearly 50% believed that content of dietary supplements are not approved before they can be sold to consumers.”).

15. See generally *The FDA's Supplement Problem*, TRUTH IN ADVERT. (June 6, 2019), <https://www.truthinadvertising.org/the-fdas-supplement-problem/> (acknowledging the need for a new regulatory response to the supplement market).

16. See Morgan Gstalter, *NY City Council Bill Would Ban Sale of Celebrity-endorsed Detox Teas to Minors*, THE HILL (Apr. 11, 2019), <https://thehill.com/homenews/state-watch/438562-ny-city-council-bill-would-ban-sale-of-celebrity-endorsed-detox-teas-to>.

17. See generally *FDA 101: Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements> (last updated July 15, 2015) [hereinafter *FDA 101*] (“In general, FDA's role with a dietary supplement product begins after the product enters the marketplace. That is usually the agency's first opportunity to take action against a product that presents a significant or unreasonable risk of illness or injury, or that is otherwise adulterated or misbranded”).

dietary supplement is if it contains a new dietary ingredient (NDI).¹⁸ Consumer safety is central to the FDA's work, but the stunning lack of pre-approval required for this entire category of popular products is problematic.

Per the Dietary Supplement Health and Education Act of 1994 (DSHEA), the FDA's authority to regulate supplements differs drastically from the FDA's authority to regulate prescription and over-the-counter (OTC) drugs.¹⁹ Supplement manufacturers do not have to provide evidence that their products are safe unless the supplement contains an NDI.²⁰ Why is it that the FDA's regulatory standards regarding supplements are lacking when a majority of Americans, ranging from adolescents to the elderly,²¹ use these products on a daily basis?

Similar to the regulatory action taken when assessing the safety and effectiveness of prescription drugs, nonprescription drugs, and foods under the Food, Drug, and Cosmetic Act (FDCA), the FDA should implement an approval process for dietary supplements. Current regulatory efforts are underperforming; as of 2018, there are no requirements that supplement manufacturers must test their products in clinical trials.²² Instead, a manufacturer's self-proclaimed "reasonable evidence" that ingredients are safe is sufficient.²³ The FDA must be proactive in its regulatory efforts for

18. Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry; Availability, 81 Fed. Reg. 53,486, 53,486 (Aug. 12, 2016). The Food Drug & Cosmetic Act (FDCA) requires manufacturers and distributors of a dietary supplement with a new dietary ingredient (NDI) to submit a premarket notification to the FDA at least seventy-five days before introducing the product into interstate commerce. *Id.* at 53,487. "The notification must contain the information, including any citation to published articles, which is the manufacturer or distributor's basis for concluding that a dietary supplement containing the NDI will reasonably be expected to be safe." *Id.*; see also Megan Olsen & Andrew Shao, *New Dietary Ingredients (NDI) and Innovation in Dietary Supplements: A Call for New Compliance and Enforcement Strategies*, FOOD & DRUG LAW INST. (2019), <https://www.fdpi.org/2019/07/new-dietary-ingredients-ndi-and-innovation-in-dietary-supplements/> ("An NDI is an ingredient that was not marketed in the U.S. in a dietary supplement before October 15, 1994.")

19. See *FDA 101*, *supra* text accompanying note 17.

20. *Dietary Supplements: Safe, Beneficial and Regulated*, COUNCIL FOR RESPONSIBLE NUTRITION (July 28, 2018), https://www.crnusa.org/system/files/2019-06/DSSafeRegulatedBeneficial_CRN2018.pdf; see also Olsen & Shao, *supra* note 18.

21. See *New Data*, *supra* note 13 (finding that 69% of individuals between ages eighteen and thirty-four take supplements, 77% of thirty-five to fifty-four-year-olds, and 78% of individuals fifty-five and over).

22. *FDA Regulation of Drugs Versus Dietary Supplements*, AM. CANCER SOC'Y, <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/fda-regulations.html> (last updated Mar. 31, 2015).

23. *Id.*

the dietary supplements industry, rather than maintain the current state of reactivity. A higher standard with pre-approval requirements is imperative, especially in a time where these untested supplements are taking social media platforms by storm and seem impossible to avoid.²⁴

Part I of this Comment provides background information on supplements including the prominent types, noting the recent rise in advertisements for supplements on social media platforms with a specific focus on diuretic teas. Part II surveys the current FDA involvement in supplement advertisements in comparison to advertisements for over-the-counter (OTC) and prescription drugs. Finally, Part III concludes by assessing how legislation has left a hole in the regulatory framework such that wellness products are introduced into the market via social media influencers without providing disclaimers and lacking FDA approval. Additionally, Part III will offer suggestions as to what the FDA can do to ensure that consumers are more informed than they currently are, as well as requirements the agency can impose on companies' use of social media influencers who promote unregulated products to high volumes of followers.

I. BACKGROUND

A. *What Are Supplements and Who Takes Them?*

The FDA defines dietary supplements as products that are taken orally and also contain some type of dietary ingredient.²⁵ Supplements come in myriad forms, "including tablets, capsules, powders, energy bars, and liquids."²⁶ Approximately 32% of all supplement users consume products that fall under the umbrella of sports nutrition.²⁷ Sports nutrition supplements, such as those used for bodybuilding, enhance the effects of exercise and often contain steroids or steroid-like substances.²⁸

24. See Kendra Auguste, *Detox Tea Advertising on Social Media: Examining the Content of Popular Detox Tea Brands on Instagram*, 51 J. NUTRITION EDUC. & BEHAV. 7S, S125 (2019) ("Advertisements for detox tea products in particular are widely prevalent on social media, with celebrity endorsements being the most notable.").

25. See *FDA 101*, *supra* note 17 ("Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals . . .").

26. *Id.*

27. *Dietary Supplement Use Reaches All Time High*, COUNCIL FOR RESPONSIBLE NUTRITION (Sept. 30, 2019), <https://www.crunusa.org/newsroom/dietary-supplement-use-reaches-all-time-high-available-purchase-consumer-reaffirms> [hereinafter *Dietary Supplement Use*].

28. See *Caution: Bodybuilding Products Can Be Risky*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/caution-bodybuilding-products-can-be-risky>

Supplements promising miracle weight loss are also very popular on social media platforms.²⁹ Weight-loss supplements, often referred to or characterized as detoxes and cleanses,³⁰ come in the form of teas and even lollipops.³¹ These products tend to “guarantee” rapid results that will help consumers shed weight in record time.³² Tellingly, approximately 20% of supplement users ages 18–34-years-old take them for weight management-related reasons.³³ These unregulated detoxes work as an appetite suppressant and contain ingredients that are known to induce weight loss, such as laxatives.³⁴ Because supplements have wide ranging effects on the body, consumers should consult a physician before taking them in order to truly understand what the

(last updated June 20, 2017) (“[M]any of these products are not dietary supplements at all; they are illegally marketed, unapproved drugs.”).

29. See, e.g., FitTea (@fittea), INSTAGRAM, <https://www.instagram.com/fittea/?hl=en> (last visited July 31, 2019) (1.5 million Instagram followers); Flat Tummy Co (@flattummyco), INSTAGRAM, <https://www.instagram.com/flattummyco/?hl=en> (last visited July 31, 2019) (1.7 million Instagram followers); Teami Blends (@teamiblends), INSTAGRAM, <https://www.instagram.com/teamiblends/?hl=en> (last visited July 31, 2019) (1 million Instagram followers).

30. See Julia Carrie Wong, *How Flat Tummy Co Gamed Instagram to Sell Women the Unattainable Ideal*, GUARDIAN (Aug. 29, 2018), <https://theguardian.com/media/2018/aug/29/flat-tummy-instagram-women-appetite-suppressant-lollipops>; see also *The Truth Behind Weight Loss Ads*, FED. TRADE COMM’N (Aug. 2019), <http://www.consumer.ftc.gov/articles/truth-behind-weight-loss-ads>.

31. Wong, *supra* note 30.

32. See U.S. FOOD & DRUG ADMIN., *supra* note 6; “Detoxes” and “Cleanses”, NAT’L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, <https://nccih.nih.gov/health/detoxes-cleanses> (last updated Sept. 24, 2017); see also *Beware of Products*, *supra* note 6.

33. See *Dietary Supplement Use*, *supra* note 27.

34. Amy O’Connor, *Should You Try a Teatox?*, CONSUMER REP. (May 15, 2018), <https://www.consumerreports.org/dieting-weight-loss/should-you-try-a-teatox/>; see also Claire Gillespie, *Do Detox Teas Really Work?*, WOMEN’S HEALTH (Nov. 1, 2018), <https://www.womenshealthmag.com/weight-loss/a24514728/do-detox-teas-work/> (common appetite suppressants include nettle leaf, dandelion leaf, and senna leaf); Cynthia Sass, M.P.H., R.D., *5 Things You Should Know About Detox Teas*, HEALTH (Jan. 8, 2019), <https://www.health.com/celebrities/5-things-you-should-know-about-detox-teas> (noting that according to the Natural Medicines Comprehensive Database, potential side effects of ingredients of natural laxative effects are: abdominal pain, bloating, gas, nausea, diarrhea, and severe dehydration, all of which can lead to muscle spasms and even abnormal heart rhythm); Letter from Sen. Blumenthal (Conn.) to FTC Chairman Simmons (June 4, 2019), <https://twitter.com/SenBlumenthal/status/1136059843285061632?s=20> (stating that although Senna is FDA approved, the agency cautions using products with Senna as an active ingredient for more than fourteen days because of its short-term side effects).

product is, what it is intended to do, and its potential side effects.³⁵ Recently, detox teas have faced backlash due to influencers' widespread promotion of such products on social media and the lack of regulation and public awareness regarding what is really inside the teas consumers are sipping.³⁶

In 2017, dietary supplements generated \$43 billion in revenue within the United States—a huge increase from the \$28 billion generated in 2010.³⁷ Consumers can purchase dietary supplements via mass merchandisers, drug stores, grocery stores, and online, among many other outlets.³⁸ Additionally, from 2003 to 2006, 49% of Americans reported that they used dietary supplements.³⁹ As of 2019, that number has increased to 75%.⁴⁰ This demonstrates that the individuals who routinely purchase and use supplements are extremely confident, perhaps wrongfully so, in the quality, effectiveness, and overall safety of the supplements they take.⁴¹

B. *How Are Dietary Supplements Regulated?*

Unlike prescription and nonprescription drugs, there are no federal laws in place that require the FDA to deem dietary supplements as safe before manufacturers may market products to millions and make these supplements available on numerous platforms.⁴² The scope of the FDA's regulation of

35. See *FDA 101*, *supra* note 17.

36. Vandana Rambaran, *Blumenthal Urges Probe of “Detox Teas” Touted as Weight Loss Miracles*, FOX NEWS (June 4, 2018), <https://www.foxnews.com/food-drink/blumenthal-urges-probe-of-detox-teas-touted-as-weight-loss-miracles>.

37. A. Elizabeth Sloan, *Supplements Signal a New Mix of Nutritional Priorities*, INST. OF FOOD TECHNOLOGISTS (Feb. 1, 2019), <https://www.ift.org/news-and-publications/food-technology-magazine/issues/2019/february/columns/consumer-trends-trends-in-supplement-usage>; Harvard Medical School, *Supplements: A Scorecard*, HARVARD HEALTH PUB. (Apr. 2012), <https://www.health.harvard.edu/staying-healthy/supplements-a-scorecard>.

38. *Who Takes Dietary Supplements*, COUNCIL FOR RESPONSIBLE NUTRITION (2016) <https://www.crnusa.org/sites/default/files/pdfs/CRN-WhoTakesDietarySupplements-2016data.pdf>.

39. Bailey RL et al., *Dietary Supplement Use in the United States, 2003-2006*, NAT'L CTR. FOR BIOTECH. INFO. (Dec. 22, 2010), <https://www.ncbi.nlm.nih.gov/pubmed/21178089>.

40. See Gottlieb, *supra* note 9; see also COUNCIL FOR RESPONSIBLE NUTRITION, *supra* note 38 (finding that 69% of individuals between ages eighteen and thirty-four take supplements, 77% of individuals thirty-five to fifty-four years old, and 78% of individuals fifty-five and over).

41. Jennifer Grebow, *Record Number of U.S. Adults are Taking Dietary Supplements, with Confidence in the Safety, Quality, and Efficacy of Supplements Remaining Steady – and High, CRN Poll Shows*, NUTRITIONAL OUTLOOK (Nov. 18, 2019), <https://www.nutritionaloutlook.com/trends-business/record-number-us-adults-are-taking-dietary-supplements-confidence-safety-quality-and-efficacy>.

42. See *FDA 101*, *supra* note 17.

supplements is embedded in the DSHEA.⁴³ Effective October 1994 during the Clinton Administration, the DSHEA put dietary supplements into their own category that was completely separate and unrelated to prescription and nonprescription drugs.⁴⁴ Under the DSHEA, manufacturers do all of the work to ensure the products they develop for the market are safe.⁴⁵ Additionally, manufacturers cannot claim that their products can cure and/or prevent illnesses or conditions, and all supplement packaging must contain a disclaimer that informs consumers the FDA has not evaluated the product.⁴⁶ The DSHEA's provisions shifted the burden of proving safe products from the FDA to manufacturers and companies.⁴⁷ For example, companies that produce and market supplements do not have to satisfy any type of pre-market notification requirements unless the supplement contains a NDI.⁴⁸ While the FDA's oversight of prescription and nonprescription drugs begins prior to market approval, it does not directly regulate dietary supplements until the product has entered the market.⁴⁹ Once the supplement reaches

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

44. 21 U.S.C. § 321(ff) (2012).

45. *Id.*

46. 21 C.F.R. § 101.93(c)–(e) (2019) (regulating the specific language, placement, and font for the required disclaimer); see also *FDA 101*, *supra* note 17.

47. See *The FDA's Supplement Problem*, *supra* note 15 (explaining that the Dietary Supplement Health and Education Act of 1994 (DSHEA) requires companies to notify the FDA about the circulation of new dietary supplements).

48. See *Dietary Supplement Labeling Guide: Chapter VII*, U.S. FOOD & DRUG ADMIN., DOCKET NO. 2004D-0487, (Apr. 2005), <https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-vii-premarket-notification-new-dietary-ingredients> (outlining process for providing premarket notification to FDA, with reference to relevant regulations and statutory authorities); cf., e.g., *510(k) Pre-market Notification*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> (last updated July 29, 2019) (featuring an online tool that allows individuals to search the FDA's database for information regarding a medical device's premarket approval status). “Premarket notification” is a submission made to the FDA, before a product is put into the market, in order to prove that the product in question is at least as safe as a product that is already legally marketed that is also not subject to premarket approval. *Id.*; see also *Is it Really FDA Approved?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved> (last updated Jan. 17, 2017). If a supplement contains a new dietary ingredient that was not marketed prior to October 1994, the manufacturer must notify the FDA approximately seventy-five days prior to putting the supplement on the market.

49. *FDA 101*, *supra* note 17; see also *Dietary Supplements Products & Ingredients*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/dietary-supplements/dietary-supplement-prod>

the marketplace, the FDA is responsible for overseeing on the supplement and resolving any issues that arise.⁵⁰ When the FDA learns a supplement is unsafe, it investigates and, if warranted, pulls the product from the market.⁵¹ Also, the FDA releases public notifications and advises consumers not to purchase the unsafe dietary supplement.⁵² The Office of Criminal Investigations (OCI) within the FDA investigates criminal activity involving dietary supplements and other products, and makes recommendations to the Department of Justice (DOJ) regarding potential prosecution.⁵³

Since Congress passed the DSHEA provisions, members of Congress have made several efforts to keep the 75% of Americans who take supplements safe and well-informed.⁵⁴ For instance, the 2006 Dietary Supplement and Nonprescription Drug Consumer Protection Act mandated that supplement and nonprescription drug manufacturers inform the FDA of products that

ucts-ingredients (last updated June 19, 2019) (providing examples of claims that supplements may not include, such as “reduces pain” or “treats heart disease”).

50. See *FDA 101*, *supra* note 17 (describing the FDA’s safety oversight responsibilities after a dietary supplement enters the market).

51. *Beware of Fraudulent Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-dietary-supplements> (last updated Mar. 15, 2011); see also Press Release, U.S. Food & Drug Admin., FDA Takes Action Against 17 Co.s for Illegally Selling Prod.s Claiming to Treat Alzheimer’s Disease (Feb. 11, 2019), <https://www.fda.gov/news-events/press-announcements/fda-takes-action-against-17-companies-illegally-selling-products-claiming-treat-alzheimers-disease> (announcing that the FDA posted twelve warning letters and five online advisory letters to companies, both domestic and foreign, that had illegally marketed dietary supplements as a way to prevent and treat Alzheimer’s Disease).

52. Public Notification, U.S. FOOD & DRUG ADMIN., *GoLean Detox Contains Hidden Drug Ingredients* (Jan. 28, 2019), <https://www.fda.gov/drugs/medication-health-fraud/public-notification-golean-detox-contains-hidden-drug-ingredients> (advising the public to not purchase or use GoLean Detox, a weight-loss product, after the FDA confirmed it contained sibutramine, which is known to substantially increase blood pressure and overall heart rate; and phenolphthalein, which is not an active ingredient in *any* approved drug, as studies indicate it increases the risk of cancer).

53. *About OCI*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/about-oci> (last updated Mar. 12, 2018). The Office of Criminal Investigations (OCI) was founded in 1991, in response to a generic drug scandal, to coordinate and conduct investigations into violations of the FDCA, Federal Anti-Tampering Act, and related violations of Title 18 of the U.S. Code. *Id.* The office is comprised of special agents who receive instruction in FDA law and have the authority to enforce U.S. criminal law. *Id.*

54. See Gottlieb, *supra* note 9 (underscoring that the use of dietary supplements expanded drastically after Congress passed the DSHEA).

may have caused any adverse effects.⁵⁵ Ten years after the act passed, the FDA formed the Office of Dietary Supplement Programs (ODSP) with the sole purpose of keeping tabs on the constant flow of supplements onto the marketplace.⁵⁶ Efforts to improve supplement regulation continue today, especially with the advent of social media and the influx of supplement-related advertisements. In February 2019, FDA Commissioner Scott Gottlieb, M.D., detailed his plan to modernize, reform, and strengthen the FDA's regulation of dietary supplements.⁵⁷ Striving to achieve a balance between maintaining consumers' access to supplements, protecting consumers from unsafe and questionable supplements, and holding manufacturers accountable, Commissioner Gottlieb proposed the following steps: notifying the public as soon as a supplement has posed a concern;⁵⁸ guaranteeing a flexible regulatory framework that ensures both product safety and incentivizes innovation;⁵⁹ maintaining relationships with industry partners;⁶⁰ focusing on implementing new enforcement strategies;⁶¹ and engaging in public dialogue with stakeholders who have an interest in supplements.⁶²

Despite recent efforts to revitalize the FDA's regulation of supplements, the FDA ultimately lacks jurisdiction to implement standards applicable to supplement advertisements.⁶³ Similar to advertisements for OTC drugs, the

55. Donna V. Porter, CONG. RES. SERV., RS22480, DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG CONSUMER PROTECTION ACT (Pub. L. 109-462), 120 Stat. 3469 1 (2007).

56. *FDA Creates the Office of Dietary Supplement Programs and Announces New Nutrition Office Leadership*, U.S. FOOD & DRUG ADMIN. (Dec. 21, 2015), <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm478303.htm> [<http://wayback.archive-it.org/7993/20171114120120/https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm478303.htm>].

57. See Gottlieb, *supra* note 9.

58. *Id.* (describing a new rapid-response tool that alerts the public to unlawful and potentially dangerous ingredients).

59. *Id.* (offering the “submission of new dietary ingredient (NDI) notifications,” updating the compliance policy regarding NDIs, and organizing a public meeting about “responsible innovation in the dietary supplement industry”).

60. *Id.* (promoting the FDA's collaboration with industry partners on developing novel methodologies for evaluating the safety of compounds in dietary supplements).

61. *Id.* (emphasizing that the FDA is “making . . . internal processes more efficient,” issuing warnings to companies, and actively ensuring companies are in compliance).

62. *Id.*

63. See *The FDA's Supplement Problem*, *supra* note 15 (reporting that many criticize the FDA for relying solely on self-reporting to learn about new supplements entering the market, given the belief that companies find ways to circumvent the reporting process); see also *FDA 101: Dietary Supplements*, *supra* note 17 (noting that the Federal Trade Commission (FTC) has jurisdiction over dietary supplement advertising).

Federal Trade Commission (FTC) is primarily responsible for all advertisements that promote dietary supplements.⁶⁴

C. *How Are Dietary Supplements Advertised?*

As of 2019, 79% of Americans have at least one social media profile, making the United States the third largest social network base.⁶⁵ Facebook remains the top platform, while YouTube comes in at a close second.⁶⁶ However, the young adult population, ranging from ages eighteen to twenty-nine, tends to be more active on Instagram and Snapchat.⁶⁷ Although these social media platforms differ in structure and function, one commonality is that they all feature advertisements and brand interaction.⁶⁸ Because the social media presence in the United States is exorbitantly high and users are active on these platforms multiple times a day,⁶⁹ companies turn to social media as an avenue to market products effectively.⁷⁰ To enhance advertisement effec-

64. See FED. TRADE COMM'N, *DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY* (2001), <https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf> [hereinafter *FTC ADVERTISING GUIDE*] (distinguishing between the FDA's and FTC's regulatory responsibilities with respect to dietary supplements).

65. J. Clement, *Social Media Usage in the United States*, STATISTA (Mar. 29, 2019), <https://www.statista.com/topics/3196/social-media-usage-in-the-united-states/> (estimating that the number of social media users in the United States will be approximately 257 million by 2023).

66. Andrew Perrin & Monica Anderson, *Share of U.S. Adults Using Social Media, Including Facebook, is Mostly Unchanged Since 2018*, PEW RES. CTR. (Apr. 10, 2019), <https://www.pewresearch.org/fact-tank/2019/04/10/share-of-u-s-adults-using-social-media-including-facebook-is-mostly-unchanged-since-2018/>.

67. *Id.*

68. See Lisette De Vries et al., *Popularity of Brand Posts on Brand Fan Pages: An Investigation of the Effects of Social Media Marketing*, 26 J. INTERACTIVE MKTG. 83, 83 (2012) (“Social media outlets constitute excellent vehicles for fostering relationships with customers.”).

69. J. Clement, *Daily Time Spent on Social Networking by Internet Users Worldwide from 2012 to 2018 (in minutes)*, STATISTA (Aug. 14, 2019), <https://www.statista.com/statistics/433871/daily-social-media-usage-worldwide/> (finding that the average daily social media usage of Internet users worldwide amounted to 136 minutes, or nearly two-and-a-half hours per day).

70. Lauren Meltzer, *Social media “influencers” add a new twist to advertising*, CBS NEWS: MONEYWATCH (Feb. 8, 2018), <https://www.cbsnews.com/news/social-media-influencers-brand-advertising/>; Mark Goodrich & Jason Howell, *Influencers: What Every Brand and Legal Counsel Should Know*, LANDSLIDE, AM. B. ASS'N SEC. OF INTELL. PROP. L., vol. 2, no. 1, Sept./Oct. 2018, at 1 (“[A] 2017 study found that 86 percent of marketers surveyed now use influencer marketing, and 92 percent of those marketers found it effective.”) (citing *The State*

tiveness even further, companies partner with influencers in efforts to increase consumer engagement with the brand and its products.⁷¹ Influencer marketing is a popular technique that has proven successful, with 86% of marketers using influencers to promote entire brands as well as individual products.⁷² Ninety-two percent of those marketers found the use of influencers to have a tremendous positive effect.⁷³ Influencers are individuals who have both a large following and high engagement rates; they can range from beauty gurus to fitness bloggers to foodies.⁷⁴ Social media and influencer marketing typically functions within a basic framework: companies hire and pay influencers to endorse products or services on their profiles by posting photos and videos. An influencer's post acts as a word-of-mouth opinion, comparable to a close friend's opinion that a consumer might want to hear prior to making a purchase.⁷⁵ Because consumers value influencer opinions, they are more inclined to purchase the product that is advertised.⁷⁶

The FTC regulates advertisements that influencers post on behalf of brands to ensure that consumers are aware of the existing relationship between the two parties.⁷⁷ To guarantee effective disclosures of paid partnerships, the FTC provides guidelines for influencers, including that they must clearly and conspicuously note somewhere in the post that it is not solely the result of the influencers' desire to post about it, but because there is an incentive behind it.⁷⁸ By including "#ad" in a post to denote an advertisement,

of Influencer Marketing 2018, LINQIA INC. (2017), <http://www.linqia.com/wp-content/uploads/2017/12/Linqia-The-State-of-Influencer-Marketing-2018.pdf>.

71. See Goodrich & Howell, *supra* note 70 (referencing a study finding that 86% of marketers surveyed now use influencer marketing and discussing influencer promotion of brands and products).

72. Goodrich & Howell, *supra* note 70.

73. Goodrich & Howell, *supra* note 70.

74. Meltzer, *supra* note 70 (discussing what it means to be a social media influencer).

75. See Meltzer, *supra* note 70 (using demographic, contextual and psychological information to create the voice of the influencer to ensure that each post is getting the right type of sentiment across to the intended audience).

76. See Meltzer, *supra* note 70 (relying on the personal connection that influencers make with their audience through industry and value specific posts, companies are able to track how much each influencer is able to "move the needle on followers' purchasing decisions").

77. Lesley Fair, *Influencers, are your #materialconnection #disclosures #clearandconspicuous?*, FTC: BUS. BLOG (Apr. 19, 2017), <https://www.ftc.gov/news-events/blogs/business-blog/2017/04/influencers-are-your-materialconnection-disclosures>.

78. Letter from Mary K. Engle, Assoc. Dir., Fed. Trade Comm'n, to Mark King, President, Adidas Group North America (Mar. 20, 2017), <https://www.ftc.gov/system/files/doc>

an influencer signals to followers that he or she has a relationship with a brand.⁷⁹ Although FTC guidelines say that influencers cannot be ambiguous, the agency does not provide detailed instructions regarding what is required to meet this standard.⁸⁰ For example, although it is recommended, there is no requirement that an influencer must put “#ad” at the beginning of the post where consumers would see it almost immediately.⁸¹ Social media platforms have introduced various tools to permit brand influencers to disclose their paid partnership status in compliance with FTC guidelines. For example, Instagram allows influencers to use “Paid Partnership with” tags on their posts (e.g., #paid, #ad).⁸²

Paid partnerships amongst influencers and detox teas are rampant on social media.⁸³ Popular unregulated diuretic drinks like FitTea, FlatTummy Shakes,

uments/foia_requests/lb-2017-00799_instagram_influencers_327_pgs.pdf (including several other letters to other individuals in order to ensure companies are following the Endorsement Guidelines set forth by the FTC published in 16 C.F.R. Pt. 255).

79. *See id.* (“To be both ‘clear’ and ‘conspicuous’ the disclosure should use ambiguous language and stand out.”).

80. *See* FED. TRADE COMM’N, .COM DISCLOSURES: HOW TO MAKE EFFECTIVE DISCLOSURES IN DIGITAL ADVERTISING 6 (2013), <https://www.ftc.gov/tips-advice/business-center/guidance/com-disclosures-how-make-effective-disclosures-digital> (stating there is no set formula for a clear and conspicuous disclosure and the key to evaluating the disclosure is the overall net impression of the ad by the consumers). *See generally* *FTC Rules for Influencers—Here are the Key Takeaways for Brands*, GRIN (Apr. 8, 2019), <https://www.grin.co/blog/ftc-rules-for-influencers> (highlighting key takeaways from the FTC disclosure guidelines such as using “Paid Partnership with” tags on Instagram posts, the Branded Content Tool on Facebook, and the Content Declaration on option on YouTube).

81. *See* FTC ADVERTISING GUIDE, *supra* note 64, at 6–7 (stating that disclosures should be clearly and prominently presented so that it is actually noticed and understood by the consumers and recommending “use [of] clear language, avoid small type . . .”).

82. *Branded Content on Instagram* (dropdown option “About Branded Content”), INSTAGRAM, <https://help.instagram.com/116947042301556> (last visited Jan. 5, 2020). Facebook introduced the Branded Content Tool that places a “About This Partnership” mouseover option on influencers’ posts. *What Branded Content Posts Look Like*, FACEBOOK, <https://www.facebook.com/business/help/1859041471004169?id=1912903575666924> (last visited Jan. 21, 2020) (dropdown menu option displaying examples of branded content). YouTube, a Google owned platform, requires consumers who upload paid product placements to use the “Content Declaration” tool that informs viewers of the paid partnership status. *Google Support, Paid product placements and endorsements*, YOUTUBE HELP, <https://support.google.com/youtube/answer/154235?hl=en> (last visited Jan. 21, 2020) (noting that YouTube will use this information not only to ensure FTC compliance, but also to avoid placing ads that conflict with the paid partnership).

83. Richard Blumenthal (@SenBlumenthal), TWITTER (June 4, 2019, 4:59 PM),

SkinnyTea, and BooTea are just a few of the many brands that use influencers to promote products to the masses.⁸⁴ On Instagram, it is common for the post to feature the influencer holding the product alongside a caption detailing how great the product is, how good it makes the influencer feel, and more often than not include a promotional code for consumers to buy the product at a discounted rate.⁸⁵ While these ads often include the #ad per FTC guidelines, as well as “Paid Partnership with” the brand, influencers do not have to mention that the product they are promoting has not been approved by the FDA.⁸⁶ By posting advertisements of this nature, influencers are compensated a drastic amount (up to six figures) depending on the influencer’s popularity.⁸⁷ With the constant rise in social media usage, it is fair to say that influencer marketing is a technique that supplement companies will continue to implement to increase widespread recognition of the brand and products.

D. *How are Prescription and Over-the-Counter Drugs Advertised?*

The FDA implements an in-depth process for potential prescription drugs to go through before professionals can prescribe them, and also regulates the advertising of prescription drugs.⁸⁸ If a pharmaceutical company wants to

<https://twitter.com/SenBlumenthal/status/1136059843285061632?s=20> (“Unfortunately, manufacturers of these products are taking advantage of young people’s insecurities and the power of celebrities on social media platforms to endorse their products.”).

84. *Id.* (“The nearly \$70 billion weight loss industry includes a wide range of pills and supplements promising a simple path to slimming down . . . ‘detox teas.’ Manufacturers of these teas—including brands such as Flat Tummy Co, Lyfe Tea, Boo Tea, MateFit, and Dit Tea . . .”).

85. *Id.* (discussing the role of influencers and celebrities in the detox tea industry social media marketing); see, e.g., Cardi B (@iamcardib), INSTAGRAM (Nov. 23, 2018), <https://www.instagram.com/p/BqioLC8lFjk/>; Skinny Mint (@skinnymintcom), INSTAGRAM (May 30, 2015), https://www.instagram.com/p/3U8ePkG_Hy/?utm_source=ig_embed.

86. Engle, *supra* note 78; cf. Krystin Arneson, *Kourtney Kardashian is Promoting Flat Tummy Shakes on Instagram, and Followers Aren’t Happy*, GLAMOUR (Jan. 5, 2019), <https://www.glamour.com/story/kourtney-kardashian-flat-tummy-shakes-instagram-reactions>. The Kardashian family has an affiliation with FlatTummy products and posts promotional advertisements on FlatTummy’s behalf detailing how life-changing the teas, shakes, and lollipops are for their waistslines. *Id.* However, the Kardashians fail to mention that the shakes they are holding have not been evaluated for safety or quality. *Id.*

87. Sarah Karmali, *This is How Much the Kardashians Get Paid for One Instagram Post*, HARPER’S BAZAAR (Mar. 17, 2017), <https://www.harpersbazaar.com/uk/culture/culture-news/news/a40474/this-is-how-much-the-kardashians-get-paid-for-one-instagram-post/>.

88. See generally Agata Dabrowska & Susan Thaul, CONG. RES. SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS (2018),

advertise a prescription drug, the FDA requires that the advertisement include the drug's generic name, at least one approved use for the drug, as well as all risks associated with using the drug.⁸⁹

Although the FDA is involved in prescription drug advertisements, the agency is not responsible for OTC drug advertisements.⁹⁰ Instead of the FDA, the FTC is the agency that is responsible for regulating advertisements for OTC drugs.⁹¹ In order to guarantee that advertisements for OTC drugs are truthful and not misleading to the public, the FTC sets three standards for OTC advertisements.⁹² First, advertisers need confirmation that claims in an advertisement are true before they can publish the advertisement.⁹³ Next, under its deception policy, the FTC looks to real life situations to determine how consumers would interpret a certain advertisement.⁹⁴ Even if certain aspects of an advertisement are technically truthful, if the overall advertisement misleads consumers through misrepresentations, the FTC takes action against the advertiser.⁹⁵ Additionally, under its unfairness policy, the FTC acts against advertisements causing substantial consumer harm or where a consumer could not reasonably avoid the harm.⁹⁶ The FDA's lack of involvement in OTC drug advertisements drastically differs from the agency's contribution to prescription drug advertisements.⁹⁷

<https://fas.org/sgp/crs/misc/R41983.pdf>; see also U.S. FOOD & DRUG ADMIN., PRESCRIPTION DRUG ADVERTISING: QUESTIONS AND ANSWERS (2015), <https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers> [hereinafter PRESCRIPTION DRUG ADVERTISING] (detailing that in addition to prescription drugs, the FDA also oversees advertisements for medical devices, such as hearing aids and vision-related procedures).

89. See PRESCRIPTION DRUG ADVERTISING, *supra* note 88.

90. See PRESCRIPTION DRUG ADVERTISING, *supra* note 88 (“The FDA *does not* oversee the advertising of over-the-counter (OTC) drugs.”).

91. *Id.*

92. *OTC Drug Advertising*, CONSUMER HEALTHCARE PRODS. ASS'N, <https://www.chpa.org/OTCDrugAdvertising.aspx> (last visited Jan. 21, 2020).

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

97. See Dabrowska & Thaul, *supra* note 88, at 25–26.

II. DANGERS OF A LACK OF REGULATION

A. *Why Should We Have Higher Standards for Supplements?*

There are several reasons why the United States should have higher standards for regulating supplements. The first reason is due to the history of manufacturers being untruthful about their products' ingredients.⁹⁸ Seventy percent of supplement companies violated FDA rules between 2008 and 2013.⁹⁹ Over the course of a decade, there were 700 warnings for dietary supplements containing unapproved and hazardous ingredients, with 41% related to weight loss supplements.¹⁰⁰ Of the 700 warnings, 98% of the supplements in question did not publish any of the potentially dangerous ingredients on their respective labels.¹⁰¹ Whether it is adding fillers or including potent drugs to exacerbate intended effects, companies take advantage of the fact that they do not have to provide the FDA with concrete evidence of what is inside their products.¹⁰² Putting so much trust into the hands of manufacturers has proven to be problematic across other agencies as well.¹⁰³ The Federal Aviation Administration (FAA) is currently facing severe backlash for

98. Alan Mozes, *Many Supplements Contain Unapproved, Dangerous Ingredients: Study*, MED. EXPRESS (Oct. 13, 2018), <https://medicalxpress.com/news/2018-10-supplements-unapproved-dangerous-ingredients.html>; see also *Herbal Supplements Filled with Fake Ingredients, Investigators Find*, CBS NEWS (Feb. 3, 2015), <https://www.cbsnews.com/news/herbal-supplements-targeted-by-new-york-attorney-general/> (discussing an investigation conducted by the New York Attorney General on a variety of herbal supplements from four major retailers which found that only 21% of the dietary supplements cited the correct DNA from the plants advertised on labels).

99. Delthia Ricks, *FDA Official: 70% of Supplement Companies Violate Agency Rules*, NEWSDAY (Aug. 23, 2013), <https://www.newsday.com/news/health/fda-official-70-of-supplement-companies-violate-agency-rules-1.5920525>.

100. Mozes, *supra* note 98.

101. Mozes, *supra* note 98.

102. Mozes, *supra* note 98; see Ricks, *supra* note 99 (“A report in the Journal of the American Medical Association in April noted that potent drugs are sometimes purposely added to supplements to increase strength, usually weight loss remedies and sleep aids.”); see also *Supplement Maker Admits to Lying About Ingredients*, FOX NEWS (Oct. 26, 2015), <https://www.foxnews.com/health/supplement-maker-admits-to-lying-about-ingredients>. Sibutramine—an appetite suppressant taken off the market in 2010 due to cardiovascular risks—was cited in nearly 85% of weight-loss supplements. See Mozes, *supra* note 98.

103. See Sinéad Baker, *FAA Boss Says it Let Boeing Partly Self-Regulate the Software Thought to be Behind Both Fatal 737 Max Crashes*, BUS. INSIDER (Mar. 28, 2019), <https://www.businessinsider.com/faa-let-boeing-self-regulate-software-believed-737-max-crashes-2019-3>.

allowing a private airline, Boeing, to oversee the certification of its own software that was linked to two fatal crashes.¹⁰⁴ Generally, the FAA allows aircraft manufacturers to be involved in aspects of the plane-certification process.¹⁰⁵ Several members of Congress have since expressed their concern with manufacturers having a role in ensuring safety in the plane-certification process.¹⁰⁶ Evidently, giving manufacturers control over product safety poses a concern for consumers—from dietary supplements to airplanes.

Second, the FDA should hold supplements to a higher standard of regulation because of the potential side effects of taking them. In detox teas specifically, the ingredient list is full of laxatives—the two most common are senna and guarana.¹⁰⁷ Although senna is FDA-approved, it is not approved for use over an extended period of time; yet there are detox teas that recommend consumers drink them twice a day for twenty-eight days straight.¹⁰⁸ Side effects of guarana include: “Nervousness, restlessness, stomach irritation, nausea, vomiting, headache, anxiety, agitation, ringing in the ears, and fast heart and breathing rates.”¹⁰⁹ Additionally, there have been cases of extreme health consequences stemming from guarana, such as liver failure.¹¹⁰ The human body can build up a tolerance to laxatives and recent studies have shown a

104. *Id.*

105. *Id.* (explaining how the policy of aircraft manufacturers aiding with their products’ certification began in 2003 to speed up the certification process and reduce costs).

106. *Id.* (“Democratic Sen. Richard Blumenthal saying he would introduce legislation to reform the system and describing it as ‘fatally riddled with flaws’ . . . Republican Sen. Ted Cruz said that the ‘close relationship between industry and regulators’ threatened to erode the public’s trust in the aviation industry . . . Democratic Sen. Tom Udall also said that the relationship needed to be questioned and that changes were necessary to ensure that safety ‘remains the paramount interest, not the quarterly profits of this company.’”).

107. JR Thorpe, *Detox Teas’ Health Effects Are Incredibly Dangerous & This is Why*, BUSTLE (Nov. 29, 2018), <https://www.bustle.com/p/detox-teas-health-effects-are-incredibly-dangerous-this-is-why-13201173>.

108. *Id.*; see also *28 Day Tea Detox*, FITTEA, <https://www.fittea.com/products/28-day-tea-detox> (last visited Nov. 22, 2019), and Blumenthal, *supra* note 83 (“While senna is approved by the U.S. Food and Drug Administration (FDA) as an over-the-counter laxative for occasional use, the National Institutes of Health (NIH) cautions against this product for more than 14 days . . .”).

109. See Thorpe, *supra* note 107.

110. *Id.*; see also Keerthana Kesavarapu et al., *Yogi Detox Tea: A Potential Cause of Acute Liver Failure*, HINDAWI CASE REP. IN GASTROINTESTINAL MED. (2017), <https://doi.org/10.1155/2017/3540756> (presenting a case of acute fulminant liver failure associated with an individual who consumed Yogi Detox Herbal Tea three times a day, for fourteen days for cleansing purposes).

link between high dosages of laxative teas and colorectal cancer.¹¹¹ Supplements also hinder the effectiveness of prescription medications when users take the two concurrently.¹¹² Diuretic supplements, like detox teas, can alter the effectiveness of oral contraceptives.¹¹³ Since detox teas contain laxatives and can cause vomiting and diarrhea, the effectiveness of birth control pills is at risk, and users may require another form of contraception.¹¹⁴

Additionally, there should be heightened standards for supplements because companies can, and do, use celebrity influencers to publicize these products at alarming rates on social media, especially when the age group most active on social media platforms is younger and more impressionable. Seventy-two percent of teenagers ranging from ages thirteen to seventeen are active on Instagram.¹¹⁵ There are over half a million accounts on Instagram categorized as influencers.¹¹⁶ These statistics, in addition to the vulnerability of adolescents to advertisements of attractive influencers marketing detox teas on Instagram, underlie the concerns surrounding teenagers' consumption of appetite suppressants.¹¹⁷ Recently, members of both state and federal governments pushed to protect young adults from drinking unapproved detox teas.¹¹⁸ Young populations are not the only target audience for many of

111. Christine Ro, *Let's Call 'Detox Teas' What They Really Are*, VICE (Mar. 11, 2018, 6:00 PM), https://www.vice.com/en_us/article/mb5p7n/lets-call-detox-teas-what-they-really-a-re-laxatives.

112. Paula Gardiner, M.D., M.P.H. et al., *Herbal and Dietary Supplement—Drug Interactions in Patients with Chronic Illnesses*, AM. FAM. PHYSICIAN (Jan. 1, 2008), <https://www.aafp.org/afp/2008/0101/p73.html>.

113. *What is Skinny TeaTox?*, SKINNY TEATOX, <https://skinny-teatox.com/pages/what-is-skinny-teatox> (last visited Jan. 21, 2020) (“Skinny TeaTox can potentially reduce the effectiveness of birth control if you take your pill within 4–5 hours of the laxative effect.”).

114. The Sun, *Celeb-backed 'Detox Teas' Could Lead to Unplanned Pregnancy*, N.Y. POST (May 23, 2017), <https://nypost.com/2017/05/23/celeb-backed-detox-teas-could-lead-to-unplanned-pregnancy/>.

115. Monica Anderson & Jingjing Jiang, PEW RES. CTR., TEENS, SOCIAL MEDIA & TECH. 2, 11, 14 (2018), https://www.pewinternet.org/wp-content/uploads/sites/9/2018/05/PI_2018.05.31_TeensTech_FINAL.pdf.

116. Blake Drosch, *Is Everyone on Instagram an Influencer?*, EMARKETER (Mar. 5, 2019), <https://www.emarketer.com/content/is-everyone-on-instagram-an-influencer>.

117. See Morgan Gstalter, *NY City Council Bill Would Ban Sale of Celebrity-Endorsed Detox Teas to Minors*, THE HILL (Apr. 11, 2019), <https://thehill.com/homenews/state-watch/438562-ny-city-council-bill-would-ban-sale-of-celebrity-endorsed-detox-teas-to> (discussing concerns over young adolescents' vulnerability to marketing of celebrity-endorsed detox teas and appetite suppressants on social media).

118. *Id.* (reporting that the New York City Council has introduced legislation that would

these products. Flat Tummy Tea, a popular diuretic tea brand, has created a Pregnancy Tea designed specifically for pregnant women to reduce bloat and nausea.¹¹⁹ Although Flat Tummy claims that the product is safe for women to take while pregnant or breastfeeding, the FDA has yet to evaluate the product.¹²⁰ Influencers who promote this line of tea through paid advertisement posts on social media are severely criticized.¹²¹

The majority of supplement users want stronger FDA oversight for dietary supplements to ensure safety.¹²² After being informed that the FDA does not approve dietary supplements for them to reach the market, nine out of ten individuals were in favor of setting higher standards for manufacturers.¹²³ The growing concern towards dietary supplements is comparable to the recent apprehension towards vaping and related products.¹²⁴ Many individuals, especially adolescents, who use vaping products like electronic cigarettes

ban the sale of appetite suppressants to minors and fine any person or establishment that did so); *see also* Blumenthal, *supra* note 83 (voicing his concern with deceptive supplement advertising targeted towards young adults).

119. *Organic Pregnancy Tea*, FLAT TUMMY CO., <https://flattummyco.com/products/organic-pregnancy-tea#product-detail-1560759663751> (last visited Jan. 21, 2020).

120. *See id.* (claiming that the product is safe to consume while pregnant, yet also noting, at the bottom of the webpage under “Important Product Information,” that these statements have not been evaluated by the FDA and that products on the site should not be used while pregnant or breastfeeding).

121. *See, e.g.*, Yahoo Lifestyle Videos, *Pregnant Amber Rose Slammed for Promoting Detox Tea*, YAHOO! FIN. (June 19, 2019), <https://finance.yahoo.com/video/pregnant-amber-rose-slammed-promoting-143309535.html> (critiquing influencers who promote these teas); *see also* Blumenthal, *supra* note 83 (referencing actress Jameela Jamil’s criticism on detox teas and the negative impacts such products have on young populations).

122. Liz Richardson, *Most Supplement Users Back Enhanced FDA Oversight of These Products*, THE PEW CHARITABLE TRUSTS (Oct. 1, 2019), <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/10/01/most-supplement-users-back-enhanced-fda-oversight-of-these-products>.

123. *Id.* The survey also found that one in eight adults had experienced serious side effects, or who had a family member who did; this includes heart, kidney, or liver problems, from supplements. *Id.* Moreover, 74% of respondents considered supplements geared towards weight loss as “not too” or “not at all” safe. *Id.*

124. *See* Hannah Knowles & Leah H. Sun, *What We Know About the Mysterious Vaping-Linked Illnesses and Deaths*, WASH. POST (Nov. 8, 2019), <https://www.washingtonpost.com/health/2019/09/07/what-we-know-about-mysterious-vaping-linked-illnesses-deaths/>; *see also* Elizabeth Lawrence, *Vaping, Juice Cleanses, Fitness Trackers: Some ‘Healthy’ Trends Are Riskier Than You Might Think*, USA TODAY (July 4, 2019), <https://www.usatoday.com/story/news/health/2019/07/04/healthy-fads-like-vaping-and-juice-cleanses-have-some-serious-risks/1584101001/> (giving additional examples of social trends that may negatively impact consumers’ health).

are unaware of what exactly they are inhaling, quite similar to the lack of awareness regarding detox tea ingredients and overall safety.¹²⁵

B. But What About the Other Side?

But what about the consumers? Many lay people rely on the ability to buy supplements simply by clicking a button on a smartphone or taking a quick trip to the drug store. One of the most attractive qualities of supplements is that they are easily obtainable and readily available—all because there is no pre-market approval requirements under the DSHEA.¹²⁶ In fact, many consumers prefer using supplements instead of prescription medication because supplements are easier to purchase and do not require a visit to a medical professional or a prescription.¹²⁷ Supplements also tend to be less expensive than prescription drugs, and because consumers have a say in which supplements they want to use, they gain a sense of control over what they are putting into their own bodies.¹²⁸ Consumers are not fond of the government interfering with products they consume as part of their daily routines.¹²⁹ After its initial passing, the DSHEA faced lobbying efforts based on similar criticism, which included commercials warning citizens that the government was trying to take away access to vitamins.¹³⁰

125. See Lawrence, *supra* note 124 (stating that e-cigarettes contain high levels of nicotine and that many kids who use such devices are unaware of the amount of nicotine inhaled when vaping).

126. See *Dietary Supplements—Safe, Beneficial and Regulated*, *supra* note 20 (“FDA never had pre-market approval over dietary supplements, and DSHEA did not change that fact.”).

127. Reilley Michelle Dunne, Note, *How Much Regulation Can We Swallow? The Ban on Ephedra and How It May Affect Your Access to Dietary Supplements*, 31 J. LEGIS. 351, 365 (2005).

128. *Id.*

129. See James Hamblin, *Why Vitamins and Other “Dietary Supplements” Can Contain Anything*, ATLANTIC (June 26, 2016), <https://www.theatlantic.com/health/archive/2016/06/supplements-make-tobacco-look-easy/488798/> (recounting the intensity of lobbying efforts in response to FDA attempts to increase regulation of supplement producers).

130. *Id.*; see also Susan Katz Miller, *The Return of the Medicine Show*, NEWSIDENTIST (Aug. 7, 1993), <https://www.newscientist.com/article/mg13918851-800-the-return-of-the-medicine-show/> (“The Nutritional Health Alliance, an industry lobby group, sponsored a campaign in health food shops implying that the FDA is trying to take vitamins and minerals off the market. One FDA official has received death threats.”), and John Schwartz, *Next Week, FDA Will Take Vitamins*, WASH. POST (Dec. 7, 1993), <https://www.washingtonpost.com/archive/politics/1993/12/07/next-week-fda-will-take-vitamins/8d0e57d6-243f-4008-b235-acd89861b2ca/>.

Success of the supplement industry is attributed in-part to how fast production is in comparison to prescription drugs.¹³¹ Manufacturers and companies rapidly market and sell supplements because the FDA does not require manufacturers to test supplements or provide results of clinical trials as steps before supplements can become available.¹³² A process that requires pre-market approval may stunt the industry's upward trend.¹³³

Consumer and manufacturer considerations aside, the FDA is the government agency in charge of overseeing and ensuring efficacy of human and veterinary drugs, medical devices, and biological products, as well as certifying that foods and cosmetics are safe.¹³⁴ The FDA's responsibilities stretch far and wide, but its resources are limited just as any other government agency.¹³⁵ The rapid growth of the dietary supplement industry severely restricts the degree to which the FDA can inspect products, which is why the FDA only requires a safety approval process for supplements that contain a new ingredient not previously marketed.¹³⁶

In order to keep providing for the 75% of Americans that take supplements on a daily basis, the liberal nature of the DSHEA ensures that manufacturers can create and distribute products promptly.¹³⁷

131. See Jennifer Prince, *Contract Manufacturing: One Step Ahead*, NUTRITIONAL OUTLOOK 62 (Jan.–Feb. 2018), <http://www.nutritionaloutlook.com/sites/default/files/legacy/mm/digital/media/1801%20nutritional-outlook-january-2018-New.pdf> (suggesting increases in production timelines have the potential to lead to overall industry growth).

132. See 21 U.S.C. § 321(g), (p), (ff) (2018) (classifying dietary supplements as distinct from drugs); see also Prince, *supra* 131, at 62 (suggesting that lack of regulation equates to faster development).

133. See Prince, *supra* note 131, at 62 (discussing concerns of supplement industry insiders that industry growth could be diminished by a slower NDI process).

134. *What We Do*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/what-we-do> (last updated Mar. 28, 2018).

135. Amy Norton, *Banned Stimulant Found in U.S. Dietary Supplements*, WEBMD (Apr. 7, 2016), <https://www.webmd.com/vitamins-and-supplements/news/20160407/stimulant-banned-from-sports-found-in-dietary-supplements-in-us#>; see also Korin Miller, *The FDA Will Finally Crack Down on Dietary Supplements—Here's What Experts Have to Say*, SELF (Feb. 11, 2019), <https://www.self.com/story/fda-dietary-supplements-regulations> (noting the backlog that already exists); Priyanka Boghani, *Can Regulators Keep Up With the Supplements Industry?*, FRONTLINE (Jan. 19, 2016), <https://www.pbs.org/wgbh/frontline/article/can-regulators-keep-up-with-the-supplements-industry> (stating that the FDA's limited resources restrict the amount of inspections it can perform).

136. See Boghani, *supra* note 135 (stating that the FDA struggles to keep pace with the industry and inspects a relatively small number of facilities when compared to the size of the supplement market).

137. T. Jiang, Letter to the Editor, *The New Law: Public Law 109-462 for Dietary Supplements*, 63 EUR. J. CLINICAL NUTRITION 300, 300 (2009).

III. RECOMMENDATIONS

A. *Updating the DSHEA: What New Legislation Could Look Like*

Although the FDA Commissioner's recent press release highlights various changes that the agency is on course to implement, the problem remains within the DSHEA itself.¹³⁸ Currently, supplements are available for consumers to buy and try all without FDA approval, and it is only after the products hit the shelves that the FDA reacts to any and all issues that arise with the dietary supplements.¹³⁹ This is especially problematic with products like detox teas that have a history of negative health effects on the body.¹⁴⁰ To truly guarantee that supplements are safe and effective, the FDA must thoroughly regulate supplements from the start, prior to mass production and marketing.¹⁴¹ Pre-market approval requirements are especially important since there have been numerous instances where improper ingredients have been found in supplements.¹⁴²

138. See Gottlieb, *supra* note 9 (announcing agency steps to advance product safety, product integrity, and informed consumer decisionmaking, but without upsetting the balance struck by the DSHEA).

139. *Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/dietary-supplements> (last updated Aug. 16, 2019).

140. See Smith-Mady, *supra* note 5; see also Kesavarapu et al., *supra* note 110; Thorpe, *supra* note 107.

141. See also Richard E. Nowak, Note, *DSHEA's Failure: Why a Proactive Approach to Dietary Supplement Regulation is Needed to Effectively Protect Consumers*, 2010 U. ILL. L. REV. 1045 (proposing a middle-ground approach for supplement regulation combining the lax nature of the DSHEA and the restrictive nature of the European Union's Food Supplements Directive to achieve a proactive approach to supplement regulation).

142. Robert King, *Faulty Supplements Could Relaunch Debate Over Regulation*, WASH. EXAMINER (Feb. 17, 2015), <https://www.washingtonexaminer.com/faulty-supplements-could-relaunch-debate-over-regulation> ("New York Attorney General Eric Schneiderman earlier this month pulled supplements sold by those four retailers from their stores in New York state. Schneiderman performed DNA testing on nearly 400 samples of store-brand supplements such as ginkgo biloba, ginseng and St. John's wort and found seventy-nine percent didn't include the right active ingredient."); see also *Backgrounder on the Final Rule for Current Good Manufacturing Practices (CGMPs) for Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/current-good-manufacturing-practices-cgmps/backgrounder-final-rule-current-good-manufacturing-practices-cgmps-dietary-supplements> (last updated Dec. 27, 2017) ("Products have been recalled because of microbiological, pesticide, and heavy metal contamination and because they do not contain the dietary ingredients they are represented to contain or they contain more or less than the amount of the dietary ingredient claimed on the label.").

The FDA should also require companies to provide the agency with evidence that the supplement actually contains the claimed ingredients, and that it is completely safe for use and free of troublesome additives. Putting such a vast amount of trust into the manufacturers and companies who want to capitalize on the supplement industry and ultimately yield a market advantage is quite troublesome.¹⁴³ Companies that produce and market dietary supplements may not always have the public's best interest in mind, and therefore, the FDA must revamp its lack of pre-approval requirements for supplements to truly ensure products are safe for human consumption.¹⁴⁴ Pre-market approval requirements will incentivize companies to provide thorough and honest products to consumers because the only way to get on the market would be after evidence of safety and effectiveness is validated. Perhaps there will be fewer cases of companies placing consumers at risk, less distribution of dangerous or illegal products, and fewer fraudulent claims if the FDA regulates supplements from the start rather than at the end when it is too late.

If the FDA proposed new regulations for dietary supplements, the agency goes through a series of steps to determine whether the proposed regulation is needed, guided by the Administrative Procedure Act (APA).¹⁴⁵ This process, known as notice-and-comment rulemaking, allows for the agency to explain the basis of the proposed rule and for the public to weigh in on the potential regulation.¹⁴⁶ After the FDA receives public comment, the agency can either end the rulemaking process, issue a new proposed rule, or issue a final rule that is published in the Federal Register.¹⁴⁷ The rule goes into effect

143. See King, *supra* note 142 (discussing consumer and government action (i.e., class action lawsuits and mandated product removal) taken against retailers selling supplements with incorrect ingredients).

144. See *supra* Section II (discussing the history of improperly marketed supplements, potential side effects of supplements, and the use of social media to supplements to teenagers, as reasons supporting higher regulation standards).

145. 5 U.S.C. § 706 (2018). See generally Maeve P. Carey, CONG. RES. SERV., RL32240, THE FEDERAL RULEMAKING PROCESS: AN OVERVIEW (2013), <https://fas.org/sgp/crs/misc/RL32240.pdf> (providing an overview of the way that the Administrative Procedure Act (APA) applies to notice-and-comment rulemaking); see also *FDA Rules and Regulations*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/fda-rules-and-regulations> (last updated May 7, 2019) [hereinafter *FDA Rules and Regulations*].

146. See *FDA Rules and Regulations*, *supra* note 145; see also *Regulations and the Rulemaking Process*, EXECUTIVE OFF. PRESIDENT OFF. INFO. & BUDGET, <https://www.reginfo.gov/public/jsp/Utilities/faq.myjsp> (last visited Jan. 21, 2020). The APA governs how federal agencies propose and establish new regulations and, generally, the APA requires agencies to provide public notice and seek comment on potential regulations prior to enactment. *Id.*

147. See *FDA Rules and Regulations*, *supra* note 145.

approximately thirty days after its publication date in the Federal Register and creates binding obligations.¹⁴⁸ The current FDA rule, “Current Good Manufacturing Practice (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” establishes minimum CGMPs essential to manufacturing, packaging, and labeling dietary supplements.¹⁴⁹ However, even with the established rule in place for over ten years, FDA investigators still find that supplement manufacturers are deficient in compliance with CGMPs.¹⁵⁰ Establishing CGMPs is undoubtedly an important measure, yet gaps in compliance still remain.¹⁵¹ Yet another reason to subject manufacturers to pre-market approval requirements prior to shipping products out.

Although a divided legislative branch has made passing regulations quite difficult,¹⁵² Congress should amend the DSHEA to allow for a third-party program to assess whether dietary supplement manufacturers are truthful and accurate about what they are putting on the market.¹⁵³ A third-party program has the capacity to control private resources and knowledge in methods that make regulation more effective and less expensive.¹⁵⁴ Third-party programs allow regulated entities to contract with third parties for the

148. See *A Guide to the Rulemaking Process*, OFF. OF THE FED. REG. (2011), https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf. If an agency wants a rule to go into effect prior to thirty days, the agency must cite “good cause,” or persuasive reasonings, as to why incorporating the rule sooner would benefit the public. *Id.*

149. See 21 C.F.R. § 111 (2018).

150. Josh Long, *FDA Still Finding Same CGMP Deficiencies at Dietary Supplement Facilities*, NAT. PRODUCTS INSIDER (Nov. 1, 2018), <https://www.naturalproductsinsider.com/regulatory/fda-still-finding-same-cgmp-deficiencies-dietary-supplement-facilities> (revealing that in 2018, “75 inspections—or about 24 percent of firms that received a Form 483 inspection report for ‘observations,’ or alleged CGMP violations—were cited for failing to establish product specifications for the identity, purity, strength and composition of the finished dietary supplement.”).

151. *Id.*

152. See Adia Robinson, *Nearly Halfway Through the Year, Congress has Only Passed 17 Laws*, ABC NEWS (May 25, 2019), <https://abcnews.go.com/Politics/halfway-year-congress-passed-17-laws/story?id=63258594>.

153. U.S. ADMIN. CONFERENCE, 2012-7, *Agency Use of Third-Party Programs to Assess Regulatory Compliance* (Dec. 6, 2012), <https://www.acus.gov/sites/default/files/documents/Recommendation%202012-7%20%28Third-Party%20Programs%20to%20Assess%20Regulatory%20Compliance%29.pdf> [hereinafter *Agency Use of Third-Party Programs*]. The Collaborative Governance Committee (which has since been disbanded) adopted this recommendation in 2012. *Id.*

154. *Id.* at 2.

purpose of carrying out product testing, facility inspections, and other regulatory compliance assessments.¹⁵⁵ Additionally, third-party programs are able to assess product compliance more frequently since the third-party relationship is developed for that exact reason and for a set of specific products.¹⁵⁶ By initiating a third-party program, the FDA can obtain results of technical tasks that allow for pre-market approval.

The FDA already implements a third-party program in regard to medical device manufacturers.¹⁵⁷ The FDA created the 510(k) Third Party Review Program in order to yield timelier decisions, specifically for low-to-moderate-risk medical devices.¹⁵⁸ During this third-party partnership, a 510(k) pre-market proposal is submitted to an accredited Review Organization instead of the FDA.¹⁵⁹ Review organizations utilize the same criteria that the FDA uses regarding pre-market submissions for medical devices and the Review Organization may also meet with the FDA prior to its review in order to ensure standards are up-to-date.¹⁶⁰ After the Review Organization completes its evaluation, it sends all documentation to the FDA, which then makes the final determination on the pre-market submission based on the Review Organization's evaluation and recommendation.¹⁶¹ The FDA named several organizations, both public and private, as accredited Review Organizations for medical devices.¹⁶²

155. *Id.* at 1.

156. *Id.* at 2.

157. *510(k) Third Party Review Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/510k-third-party-review-program> (last updated July 31, 2019).

158. *Id.*; see also 63 Fed. Reg. 28,388 (May 14, 1998). This third-party review program originated in 1996 after the FDA solicited public comments in the Federal Register a year prior. *Id.*

159. See *510(k) Third Party Review Program*, *supra* note 157; see also *How to Become a Third-Party Review Organization*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/510k-third-party-review-program/how-become-third-party-review-organization> (last updated July 31, 2019). In order to become an accredited Review Organization, an interested third party submits an application to the FDA containing the following: name and address of persons or organization, administrative information, organizational information, required documentation and standard operating procedures, and good documentation. *Id.*

160. See *510(k) Third Party Review Program*, *supra* note 157.

161. See *510(k) Third Party Review Program*, *supra* note 157.

162. *Current List of Accredited Persons for 510(k) Review Under the FDA Modernization Act of 1997*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm> (last updated Nov. 11, 2019) (providing a list of accredited Review Organizations including but not limited to Third Party Review Group, LLC and New York State Department of Health).

The FDA also works with third parties to ensure food safety of foreign producers.¹⁶³ Finalized in 2015, the FDA Food Safety Modernization Act (FSMA) rule on Accredited Third-Party Certification establishes a voluntary program that accredits third-party certification bodies to conduct food safety audits and issue certifications for foreign entities that produce food products.¹⁶⁴ The accreditation bodies have authority to accredit third-party certification bodies.¹⁶⁵ Foreign governments, cooperatives, or other third parties are eligible for accreditation from a recognized accreditation body, or with authority directly from the FDA.¹⁶⁶ The rule proscribes different requirements for both parties involved—the accredited body and the third party.¹⁶⁷ Overall, the FDA’s purpose for implementing the rule on Accredited Third-Party Certification is to support the agency’s goal to ensure imported foods are in accordance with the same safety standards required in the United States and to address any potential hazards before the food comes into the United States.¹⁶⁸ The FDA expects that the use of accredited third-party auditors and certification bodies will increase the agency’s efficiency by diminishing the number of excess food safety audits.¹⁶⁹ When the FDA initially proposed the rule in 2013, the agency included a cost-benefit analysis

163. See *FSMA Final Rule on Accredited Third-Party Certification*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-accredited-third-party-certification> (last updated Sept. 21, 2018) [hereinafter *FSMA Final Rule*].

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.* Accreditation bodies are required to: assess third-party certification bodies for accreditation, monitor third-party certification performance, correct any problems within the accredited body’s own performance, submit monitoring and self-assessment reports to the FDA, and maintain and provide the FDA access to records related to the program. *Id.* Third-Party Certification bodies are required to perform unannounced facility audits, notify the FDA upon discovering a condition that could be a risk to public health, ensure audit agents are competent, verify effectiveness of corrective actions to address deficiencies, assess their own performance, and maintain and provide the FDA access to records related to the program. *Id.*; see also *What is Third-Party Certification?*, PUB. HEALTH & SAFETY ORG., <http://www.nsf.org/about-nsf/what-is-third-party-certification> (last visited Jan. 28, 2020) (defining third-party certification as when “an independent organization has reviewed the main manufacturing process of a product and has independently determined that the final product complies with specific standards for safety, quality or performance. This review typically includes comprehensive formulation/material reviews, testing and facility inspections.”).

168. See *Accredited Third-Party Certification Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program> (last updated Sept. 21, 2018).

169. 78 Fed. Reg. 45,782 (July 29, 2013).

and concluded that the greater the compliance, the greater reduction in illnesses, deaths, and other associated costs.¹⁷⁰ While the FDA summarized the annual cost of the program to be over \$70 million, the FDA found the benefit to the public health substantial enough for the rule to come into effect.¹⁷¹

A third-party partnership should be implemented for supplements as well. Take FitTea for example. Founded in 2013, FitTea manufactures, markets, and supplies detox teas and related products.¹⁷² Currently, the FDA puts all of its trust into FitTea and allows consumers to purchase the company's products without undergoing a full evaluation.¹⁷³ While it seems impossible for the FDA to sift through every type of detox tea that is on the market, partnering with an accredited third-party could make that notion more conceivable.¹⁷⁴ Therefore, the FDA should establish third-party programs with either a private or public entity that is solely dedicated to dietary supplements, just like the FDA has for medical devices and foreign food sources.¹⁷⁵ While third-party partnerships are admittedly an added cost, such partnerships are established with the intention that ensuring compliance proactively will decrease the latter costs and potential harmful effects on consumers.¹⁷⁶ The FDA cannot delegate all of its regulatory authority to a third party; but it can, and should, allow a third party to facilitate product testing, inspect manufacturing facilities, evaluate the validity of labels, and any other tasks the FDA deems necessary for consumer protection.¹⁷⁷ This approach will ensure the FDA is adequately performing its central role: protecting consumers.¹⁷⁸

Members of Congress have called for third-party review in response to recent aircraft accidents.¹⁷⁹ As previously mentioned, the FAA allows for

170. *Id.* at 45,784.

171. *See id.* (“[W]e account for its public health benefits in the economic analyses for those proposed rules and other applicable food safety regulations . . .”).

172. Fit Products, LLC, Articles of Incorporation (June 25, 2013); *About Us*, FITTEA, <https://www.fittea.com/pages/about-us> (last visited Jan. 28, 2020).

173. *See supra* Section I(B).

174. *See Agency Use of Third-Party Programs, supra* note 153, at 1–2 (“[A]gencies are faced with assuring the compliance of an increasing number of entities and products without a corresponding growth in agency resources.”).

175. *See FSMA Final Rule, supra* note 163.

176. *See Agency Use of Third-Party Programs, supra* note 153, at 1–2, 6 (recommending evaluating costs incurred and potential benefits and efficiencies gained when partnering with a third party).

177. *Agency Use of Third-Party Programs, supra* note 153, at 1.

178. *Agency Use of Third-Party Programs, supra* note 153, at 3.

179. *See* Press Release, U.S. House Comm. On Transp. & Infrastructure, Chairs DeFazio, Larsen Urge FAA to Conduct Third-Party Review into Boeing 737-MAX, (Mar. 26,

private airlines to play an important role in ensuring safety and efficacy of its own aircrafts—a system that is proven to have fatal consequences.¹⁸⁰ Airline industry analysts have agreed that partnering with a private third party could help with identifying potential unnoticed issues as well as conducting assessments without airline business pressures.¹⁸¹ Although the current congressional climate is not promising,¹⁸² allowing for third-party review could improve the current system of appointing manufacturers to oversee aspects of certification.¹⁸³

B. Working Together: Issuing Joint Guidance

In addition to revitalizing the regulation of supplements by incorporating a third-party partnership, the FDA must increase its involvement in supplement advertisements, especially because of the influx of social media platforms where influencers are profiting from posting on behalf of popular unapproved products. The FDA and FTC have a long-standing partnership when it comes to the dietary supplement industry; however, since the FTC's primary responsibility includes overseeing advertising claims, the FDA is not the agency that imposes requirements on advertisements.¹⁸⁴ The FDA and FTC should jointly issue guidance and advise that more than “#ad” be included in social media posts for supplements. Government agencies issue joint guidance with other agencies when respective interests and concerns overlap—especially in the context of consumer-related issues.¹⁸⁵ Moreover,

2019) (including Press Release from House Committee on Transportation and Infrastructure Peter DeFazio (D-OR) and Chair of the Subcommittee on Aviation Rick Larsen (D-WA) addressed to Acting Administrator Daniel K. Elwell of the Federal Aviation Administration (FAA), “urging the FAA to engage an independent, third-party review composed of individuals with the technical skills and expertise to objectively assess the corrective measures proposed for the 737 MAX by Boeing.”).

180. See Baker, *supra* note 103; see also Jon Hemmerdinger, *Boeing Chair Talks Certification Reform, Stands With Muilenberg*, FLIGHTGLOBAL (Nov. 7, 2019), <https://www.flightglobal.com/news/articles/boeing-chair-talks-certification-reform-stands-wi-462045/> (“The FAA certifies aircraft using a delegation process under which it appoints manufacturers and employees at manufacturers to oversee some aspects of certification.”).

181. See Hemmerdinger, *supra* note 180.

182. See Hemmerdinger, *supra* note 180 (noting that although Congress could mandate changes, the current administration has shifted away from increased regulation).

183. See Hemmerdinger, *supra* note 180.

184. See *Dietary Supplements: An Advertising Guide*, *supra* note 64.

185. See 82 Fed. Reg. 192 (Oct. 5, 2017) (guidance jointly issued by the FDA and Environmental Protection Agency (EPA) clarifying jurisdiction over mosquito related products); see also U.S. DEP'T OF JUST. & U.S. FED. TRADE COMM'N, *Antitrust Guidelines for Collaborations*

the FDA and FTC have worked in conjunction to issue warning letters to companies with concerning business practices regarding supplements and tobacco-related products.¹⁸⁶

In addition to “#ad,” the FDA and FTC should issue joint guidance recommending that advertisements for dietary supplements include “#nonFDAapproved” or at least a statement of similar character and value somewhere in the post. The inclusion of “#nonFDAapproved” will ensure that consumers no longer assume that all the benefits a celebrity claims about a detox tea on Instagram are true.¹⁸⁷ Instead, consumers can see the hashtag and decide whether to further research the product before buying it. Additionally, if there are any common side effects associated with the supplement, the guidance should detail how influencers should note potential side effects in the post as well.

Issuing guidance for advertisements to include a certain phrase could demonstrate too much government intrusion.¹⁸⁸ In fact, there have been several cases in which pharmaceutical companies have invoked First Amendment defenses to combat FDA restrictions placed on prescription drug advertisements.¹⁸⁹ However, in regard to dietary supplements, the FDA and

Among Competitors (2000), and U.S. DEP'T OF JUST. & U.S. FED. TRADE COMM'N, Antitrust Guidelines for Human Resources Professionals (2016).

186. See Letter from William A. Correll Jr., Director, Center for Food Safety & Applied Nutrition, and Mary K. Engle, Associate Director, Fed. Trade Comm'n, to TEK Naturals (Feb. 5, 2019), https://www.ftc.gov/system/files/attachments/press-releases/ftc-fda-send-warning-letters-companies-selling-dietary-supplements-claiming-treat-alzheimers-disease/tek_naturals_warning_letter_wl_565026.pdf. A warning letter from the FDA and FTC to TEK Naturals raised concerns over the company's practice of making unsubstantiated advertising claims and multiple FDCA violations. *Id.*; see also Press Release, Fed. Trade Comm'n, FTC, FDA Take Action Against Companies Marketing E-liquids That Resemble Children's Juice Boxes, Candies, and Cookies (May 1, 2018), <https://www.ftc.gov/news-events/press-releases/2018/05/ftc-fda-take-action-against-companies-marketing-e-liquids>.

187. See Bill Connolly, *Why Digital Influencers Are Winning the Battle for Consumer Trust*, OLAPIC (FEB. 3, 2016), http://www.olapic.com/resources/why-digital-influencers-winning-battle-consumer-trust_plaw_g1lo/ (“Digital influencers have become more powerful than traditional celebrities.”).

188. See Smith-Mady, *supra* note 5, at 158 (suggesting that the FDA would have to equate an act such as “liking” a post as a form of conduct and not speech).

189. See Smith-Mady, *supra* note 5, at 153–55. In *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011), Vermont authorized the Prescription Confidentiality Law, which prevented pharmaceutical companies from utilizing prescription-related data for marketing purposes. *Id.* at 153. Pharmaceutical companies responded to the legislation by filing suit—arguing that the law restricted the companies' First Amendment speech. *Id.*; see, e.g., *United States v. Caronia*,

FTC could argue that including “#nonFDAapproved” in a social media post is no different than requiring supplement labels that bear statements of dietary support to prominently display a prescribed advisory statement, per the DSHEA.¹⁹⁰ Additionally, the FDA could emphasize that its central priority is to protect consumers; thus, the agency has a vital interest in issuing guidance in conjunction with the FTC for purposes of safeguarding customers from being misled in any way, shape, or form, including by social media posts.¹⁹¹ Simply put, including “#ad” is not enough.

Recently, Instagram announced a new policy to combat companies advertising unhealthy dietary supplements to younger age groups.¹⁹² The application will now block, and sometimes remove, content that promotes weight-loss to users known to be under the age of eighteen—a major change stemming from the impact of influencers promoting diet teas and other supplements.¹⁹³ With platforms like Instagram and Facebook protecting vulnerable users, the FDA and FTC should form a public-private partnership with social media platforms to advance their collective interest in controlling posts that promote unregulated products. A public-private partnership, or consortium, is a collective group managed by a coordinating organization and involves several stakeholders, including at least one nonprofit or government organization and at least one for-profit company.¹⁹⁴ Organizations form public-private partnerships to tackle problems that are outside the capability

703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). The U.S. Supreme Court held that the law was an impermissible restriction on protected First Amendment speech because it was not narrowly tailored enough to advance Vermont’s goals of “maintaining physician confidentiality, protecting public health, and lowering health care costs.” *Smith-Mady*, *supra* note 5, at 153–54.

190. See *How Dietary Supplements Are Regulated*, NATURE MADE (2015), http://www.naturemade.com/~media/Images/NatureMade/PDF/Health%20Care%20Professionals/PID8742%20NM%20How%20Supplements%20are%20Regulated%20Handout_C5_FNL.ashx (featuring a nonprescription OTC product label and identifying laws and requirements for companies that manufacture and market such products).

191. See *Smith-Mady*, *supra* note 5, at 157.

192. See Gabrielle Sorto, *Instagram Will Block Content that Promotes Weight-Loss Products or Cosmetic Procedures to Anyone Under 18*, CNN (Sept. 20, 2019), <https://www.cnn.com/2019/09/19/business/instagram-posts-cosmetic-surgery-diet-products-trnd/index.html>.

193. *Id.* (outlining that Instagram’s new feature that allows users to report a post they believe violates the new policy; Instagram content reviewers will subsequently review the post and take appropriate action).

194. See *Scientific Public Private Partnerships and Consortia*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/science-research-drugs/scientific-public-private-partnerships-and-consortia> (last updated May 5, 2019).

and resources of a single organization.¹⁹⁵ The FDA and FTC are familiar with public-private partnerships; both agencies are involved in public-private partnerships that align with each agency's objectives.¹⁹⁶ A public-private partnership between the two government agencies and social networking platforms would be beneficial to achieve a common goal.¹⁹⁷ Again, it would not be the first time the FDA and FTC have collaborated on a consumer-related issue.¹⁹⁸ Adding a private company, like Instagram, with public government agencies can result in a mutually beneficial collaboration because of the complementary influence in the public and private sectors. Together, the collaboration can accomplish certain goals that they may not be able to when working alone.¹⁹⁹

CONCLUSION

The FDA, by way of an act of Congress, must change its permissive approach to the regulation of supplements. The DSHEA has failed in its refusal to subject supplements to an approval process in order to ensure that the companies who produce and market supplements are accurate and safe.²⁰⁰ The lack of proactive regulation is concerning, especially when most Americans regularly take supplements as part of a daily routine.²⁰¹ The lack of regulation is even more concerning with the advent of a new mass marketing approach involving influencers, who post on popular social media websites and applications. The FDA must reclaim oversight power over manufacturers by introducing proactive presale measures to ensure supplements are safe for consumers before they hit the shelves, instead of targeting after-the-fact

195. *Id.*

196. *Id.* (describing the FDA's partnership with "other government agencies, global organizations, academia, industry, patient advocacy groups and other stakeholders" in promoting innovative techniques for drug development); see also Brandon Gobel, *Relief From Those Annoying Robocalls*, AARP (Aug. 3, 2017), <https://www.aarp.org/money/scams-fraud/info-2017/ftc-phone-carriers-tackle-robocalls-fd.html> (providing example of a public-private partnership between the FTC and cellphone providers created to accomplish a joint interest in blocking robocalls).

197. Peter V. Schaeffer, *Towards an Understanding of Types of Public-Private Cooperation*, 26.2 PUB. PERFORMANCE & MGMT. REV. 169, 180 (2001) https://researchrepository.wvu.edu/cgi/viewcontent.cgi?article=1154&context=rri_pubs.

198. See *FTC and FDA Send Warning Letters to Companies Selling Flavored E-liquids About Social Media Endorsements without Health Warnings*, U.S. FED. TRADE COMM'N (June 7, 2019), <https://www.ftc.gov/news-events/press-releases/2019/06/ftc-fda-send-warning-letters-companies-selling-flavored-e-liquids>.

199. See Schaeffer, *supra* note 197, at 171.

200. See *FDA 101*, *supra* note 17.

201. See *New Data*, *supra* note 13.

through third-party review. Additionally, the FDA must work with the FTC to issue strong guidance for supplement advertisements on social media platforms that inform potential consumers that an official authority has not evaluated the teas and shakes.