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Time for Change: Stepping Up the FDA's Regulation of Dietary Supplements to Promote Consumer Safety and Awareness

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TIME FOR CHANGE: STEPPING UP THE FDA’S REGULATION OF DIETARY SUPPLEMENTS TO PROMOTE CONSUMER SAFETY AND AWARENESS

GEORGE KENNETT, CLEVELAND MARSHALL COLLEGE OF LAW, J.D. 2020

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I. A HISTORY AND BACKGROUND ON DIETARY SUPPLEMENTS

As the pace of life speeds up, a greater number of adults are looking for that “quick fix” when it comes to their health and wellbeing. Fifty years ago, resorting to a pill or shake for breakfast would have been questionable; yet nowadays, sitting down for a hearty, nutrient dense meal is a rarity. Adults across the country are turning to meal replacements and dietary substitutes to fuel their lifestyles. Population ageing, retiring baby boomers and a rising awareness of diet-health related disease (e.g. obesity, diabetes) are the major driving forces behind the expansion of preventative consumption of dietary supplements as a proactive way of maintaining good health.¹ Furthermore, there is a willingness to “try anything” in the search of managing ones chronic disease (patients with chronic diseases often take more supplements than the general population).² People as a whole have greater general awareness of diet-health issues and trends toward proactive health behaviours have increased consumers’ demand for more products with identifiable health benefits.³ Whether ordered online or purchased at the drug store, adults have easy access to dietary supplements without a prescription, and most consume them without their health care provider’s advice or knowledge.⁴

In 2016 the diet supplement business was responsible for employing more than 750,000 people. The industry alone was worth \$122 billion, and within the past two years “[that] number has continued to grow and prosper.”⁵ The effects on the U.S. economy are positive, but unfortunately, the public are at risk of suffering from the potential detrimental consequences that some of those supplements could have on one’s health. While there is an extensive use of dietary supplements, there is little quality standardization of these products, and it is difficult for health care professionals and consumers alike to discern their safety and quality.⁶ Although supplements cannot be marketed for the treatment or prevention of disease, they are often taken to address symptoms or illnesses, as well as to maintain or improve overall health.⁷ Even with this stipulation in place, “[a] 2003 review of claims made on 273 websites selling dietary supplements found that 55% of sites made unauthorized and illegal claims to treat, prevent, diagnose, or cure specific

¹ Gavura Scott, *Who Takes Dietary Supplements*, SCIENCE-BASED MEDICINE (Feb. 14, 2013), <https://sciencebasedmedicine.org/who-takes-dietary-supplements-and-why/>.

² Falci L, Shi Z, Greenlee H., *Multiple Chronic Conditions and Use of Complementary and Alternative Medicine Among US Adults: Results from the 2012 National Health Interview Survey* (May 5, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4858448/>.

³ Anders Sven, Schroeter Christiane, *The Impact of Nutritional Supplement Intake on Diet Behaviour and Obesity Outcomes* (Oct. 9, 2017), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0185258>.

⁴ Bailey Regan L., Gahche Jamie J., Miller Paige E., *Why US Adults Use Dietary Supplements* (Mar. 11, 2013), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1568520>.

⁵ *Economic Impact of the Dietary Supplement*, THE SCIENCE BEHIND THE SUPPLEMENTS, <https://www.crnusa.org/resources/economic-impact-dietary-supplement-industry>.

⁶ Akabas, Sharon R. et al, *Quality Certification Programs for Dietary Supplements*, J. OF THE ACAD. OF NUTRITION AND DIETETICS, Vol. 116, Issue 9, 1378-79 (Sept. 2016).

⁷ Bailey, *supra* note 4.

disease.”⁸ Furthermore, “[t]he Government Accountability Office found that one in five dietary supplements sold for weight loss or immune system support included prohibited disease-related claims on their labels.”⁹ Not only do such claims entice consumers to purchase the products, but they also put an unwarranted amount of risk on the consumer in putting their faith in the product when professional medical help may be the most beneficial avenue. Consumers often believe what they see on the label, and rely on those claims being made to them – when in reality, at best, such products are often just a band aid on the situation.¹⁰ Not only is there the possibility of falsified claims being made by manufacturers, but some companies have also contaminated their products with filler that were not listed within the ingredients. This came to fruition when investigators found powdered rice and laxatives in place of St John’s Wort,¹¹

⁸ Akshay Kapoor & Joshua M. Sharfstein., *Breaking the Gridlock: Regulation of Dietary Supplements in the United States*, WILEY ONLINE LIBR. (Nov. 2, 2015), <https://onlinelibrary.wiley.com/doi/full/10.1002/dta.1892>; see also CA Morris & J. Avorn, *Internet Marketing of Herbal Products*, PUBMED.GOV (Sept. 17, 2003), <https://www.ncbi.nlm.nih.gov/pubmed/13129992>.

⁹ Morris, *supra* note 8, see also Office of Inspector Gen., *Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements*, DEPT. OF HEALTH AND HUMAN SERVICES DIETARY SUPPLEMENTS, (Oct. 2012), <https://oig.hhs.gov/oei/reports/oei-01-11-00210.pdf>; see also Nadel Mark V., *Committee on Labor and Human Resources*, <https://www.gao.gov/assets/90/83193.pdf> (“[T]his was an issue even thirty years ago when dietary supplements were not widely used. From fiscal year 1989 to 1992, FDA had taken action against about 290 companies that manufactured or marketed dietary supplements. FDA took action against about 250 of the companies because I determined that their products’ labelling contained unsubstantiated drug claims and, thus, the products were new drugs that were misbranded. FDA took action against the remaining companies because it considered the substances in their products to be unsafe food additives because they were not generally regarded as safe and had not been approved by FDA for use in foods or their products’ labelling did not contain a complete list of ingredients.”)

¹⁰ See generally Bill Fay, *Average Doctor Visit Cost*, DEBT.ORG, <https://www.debt.org/medical/doctor-visit-costs/> (last updated Apr. 2, 2019).

¹¹ Steven G. Newmaster, et al., *DNA Barcoding Detects Contamination and Substitution in North America Herbal Products*, BMC MEDICINE (Oct. 11, 2013), <https://doi.org/10.1186/1741-7015-11-222> (“[H]erbal products available to consumers in the marketplace may be contaminated or substituted with alternative plant species and fillers that are not listed on the labels. According to the World Health Organization, the adulteration of herbal products is a threat to consumer safety. Our research aimed to investigate herbal product integrity and authenticity with the goal of protecting consumers from health risks associated with product substitution and contamination.”)

black walnut in place of Ginkgo biloba,¹² and various species of Asian actae in place of black cohosh.¹³

Nevertheless, strictly speaking about dietary supplements, consumers rely on the claims on the label and put their faith into the stipulated ingredients because they are not necessarily aware that dietary supplements - often sold within the same vicinity as FDA approved over-the-counter drugs - are not tested for safety or efficacy prior to market entry.¹⁴ However, the perception of many is that anything on sale within the same purview of those over-the-counter drugs are as safe and as widely regulated.¹⁵

A. Weight-Loss Supplements

With the current obesity epidemic around the world, and particularly in the U.S.,¹⁶ many Americans turn to supplements to aid and accelerate their weight loss journey.¹⁷ The reason that many turn to supplements, is because not enough doctors treat obesity as a disease, and even those who do, cannot prescribe drugs

¹² *Id.*, (Within the experiment, “[m]ost of the herbal products tested were of poor quality, including considerable production substitution, contamination and use of fillers. These activities dilute the effectiveness of otherwise useful remedies, lowering the perceived value of all related products because of a lack of consumer confidence in them. We suggest that the herbal industry should embrace DNA barcoding for authenticating herbal products through testing of raw materials used in manufacturing products. The use of an SRM DNA herbal barcode library for testing bulk materials could provide a method for ‘best practices’ in the manufacturing of herbal products. This would provide consumers with safe, high quality herbal products.”)

¹³ *Id.*; see also DA Baker, et al., *DNA Barcode Identification of Black Cohosh Herbal Dietary Supplements*, PUBMED.GOV, (last visited Sept. 8, 2019), <https://www.ncbi.nlm.nih.gov/pubmed/22970567>.

¹⁴ Joanna K. Sax, *Dietary Supplements are Not all Safe and Not all Food: How the Low Cost of Dietary Supplements Preys on the Consumer*, AM. J. OF L. & MED. (Sept. 21, 2015), <https://doi.org/10.1177%2F0098858815591523>.

¹⁵ *Id.*; see also U.S. FOOD & DRUG ADMIN., *Mixing Medications and Dietary Supplements Can Endanger Your Health*, FDA, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm420349.htm> (last updated Oct. 27, 2014).

¹⁶ CTRS. FOR DISEASE CONTROL AND PREVENTION, *Obesity is Common, Serious, and Costly*, CDC, (Aug. 13, 2018), <https://www.cdc.gov/obesity/data/adult.html> (“[T]he prevalence of obesity was 39.8% among adults and 18.5% among youth in the United States in 2015-2016. Obesity prevalence increased in both adults and youth during the 18 years between 1999-2000 and 2015-2016”); see also NAT’L CTR. FOR HEALTH AND STATISTICS, *Prevalence of Obesity Among Adults and Youth: United States, 2015-2016*, (Oct. 2017) <https://www.cdc.gov/nchs/data/databriefs/db288.pdf> (“Obesity prevalence increased in both adults and youth during the 18 years between 1999-2000 and 2015-2016.”).

¹⁷ Edward McKinley, *As Obesity Rates in America Soar New Weight Loss Drugs are in the Offing that Offer Hope*, CNBC (Dec. 22, 2018, 9:00 AM), <https://www.cnbc.com/2018/12/12/new-obesity-drugs-are-coming-but-doctors-and-insurers-are-hurdles.html> (“In general, the way obesity medication works is either by affecting the brain or the gut. It can work on your brain to make you feel less hungry, on your intestines and gut to make you digest food more slowly, or some combination of the two.”).

to all but their wealthiest patients; with few insurers, and no government insurance program, offering coverage.¹⁸ In an industry-sponsored study, 3,500 Americans were surveyed about their use of dietary supplements for weight loss.¹⁹ The results of the study were worrying. A majority believed that not only were the weight-loss supplements approved for safety and efficacy, but that these type of supplements were actually safer than over the counter or prescription medications.²⁰ Based on these findings, it is not surprising that thousands of American's are reluctant to seek medical advice about their weight and instead rely on manufacturers who claim to be the quick fix that they are looking for.²¹

B. Dangers: Emergency Department Visits

The obese population are not the only ones at risk. A recent study published in the *New England Journal of Medicine* found that adverse effects of dietary supplements were responsible for an average of about 23,000 emergency department (ED) visits per year.²² Dietary supplements are best known for providing benefits to the human body; they should not put an unjustifiable amount of risk of those who are taking it.²³ Weight-loss products accounted for one quarter of all single-product ED visits and disproportionately affected women,

¹⁸ *Id.*

¹⁹ See Janine L. Pillitteri et al., *Use of Dietary Supplements for Weight Loss in the United States: Results of a National Survey*, WILEY ONLINE LIBR. (Sept. 6, 2012), <https://onlinelibrary.wiley.com/doi/epdf/10.1038/oby.2007.136> (One noticeable result from the survey was that a higher proportion of African Americans and Hispanics used dietary supplements than did whites and additionally, those with less education, lower incomes, and no health insurance were more likely to use supplements. Finally, dietary supplements were more likely to be used by those who reported a greater number of lifetime weight-loss attempts, tried a greater number of weight loss products and methods, and reported greater willingness to see a doctor for assistance with weight loss.)

²⁰ *Id.*

²¹ *Id.*, (“[C]ertain groups that were surveyed were more likely to believe that dietary supplements are safe, efficacious, and regulated before marketing. These groups included younger respondents (aged 18-24 and 25-34 years vs. older age groups); African Americans, Hispanics, and other ethnicities (compared to whites); those with less education; and those without health insurance.”)

²² Andrew I. Geller et al., *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, N. ENG. J. MED. 373;16 (Oct. 15, 2015), <https://www.nejm.org/doi/pdf/10.1056/NEJMsa1504267> (“[S]uch visits commonly involved cardiovascular manifestation from weight-loss or energy products among young adults and swallowing problems, often associated with micronutrients, among older adults.”)

²³ *Id.*, (“[W]orryingly, unsupervised ingestions by children caused more than one fifth of all estimated emergency department visits for supplement-related adverse events, with almost two thirds involving micronutrients. Child-resistant packaging is not required for dietary supplements other than those containing iron”); see also Susan Farrell., *Harmful Effects of Supplements Can Send you to the Emergency Department*, HARV. MED. SCH. (Oct. 15, 2015), <https://www.health.harvard.edu/blog/harmful-effects-of-supplements-can-send-you-to-the-emergency-department-201510158434>.

while men were more likely to experience adverse effects from products advertised for sexual enhancement and body building.²⁴

Apart from rapid weight loss, dietary supplements are often marketed to those individuals who work-out.²⁵ These people are not looking for a quick fix in terms of their health; rather they are looking for an increase in their performance.²⁶ Unfortunately, those in that position often are young adults,²⁷ and as demonstrated, those within that category are among the most likely to believe that dietary supplements go through the same rigorous regulation and testing by the FDA as do over-the-counter drugs.²⁸

1. Case Study: Matthew Dana

Unfortunately, that lack of knowledge had detrimental effects on a young bodybuilder – Matthew Dana. In August 2017, Dana, a 27-year-old New York State Sergeant died after overdosing on a dietary supplement common in the bodybuilding field - Kratom.²⁹ Known as an energizer and pain reliever, it has been extensively used in the bodybuilding community to help lifters feel focused and energized.³⁰ In 2017, Kratom was regarded as a dietary supplement and

²⁴ Farrell, *supra* note 23.

²⁵ Karimian, Jahangir, Esfahani, Parrivash S., *Supplement Consumption in Body Builder Athletes*, J. OF RES. AND MED SCI. (Oct. 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3430026/> (In this study, a substantial number of bodybuilders took vitamins, minerals, and/or other supplements. “Among national-level Sri Lankan athletes, it was reported that 94% of the subjects had used supplements. In University students in U.S., 89% used dietary supplements. Additionally, like many other studies, men were more likely to take supplements than women.”)

²⁶ *Id.*; see also Frolad K., Koszewski W., Hingst J., Kopecky L., *Nutritional Supplement use Among College Athletes and Their Sources of Information*, INT’L J. OF SPORT NUTRITION AND EXERCISE METABOLISM (Oct., 2004), <https://www.ncbi.nlm.nih.gov/pubmed/15129934> (Reasons for supplement intake include; include increasing energy, enhancing performance, improving health, prevention of nutritional deficiencies, prevention of illness, increasing muscle mass, and improving recovery.)

²⁷ Kristiansen M., Levy-Milne R., Barr S., Flint A., *Dietary Supplement use by Varsity Athletes at a Canadian University*, INT’L J. OF SPORT NUTRITION AND EXERCISE METABOLISM (Apr. 2015), <https://pdfs.semanticscholar.org/cbb8/351840c623cbe4f626b998f1e5b80735d983.pdf> (Among Canadians, 94.3% of young athletes were reported to have one or more supplement use.)

²⁸ CTRS. FOR DISEASE CONTROL AND PREVENTION, *supra* note 16.

²⁹ Danielle Zickl, *This Healthy 27-Year-Old Bodybuilder Died After Using a Common Supplement*, MENS HEALTH (Oct. 3, 2017), <https://www.menshealth.com/trending-news/a19537222/police-officer-matthew-dana-kratom-bodybuilding-supplement-overdose/>.

³⁰ *Id.*; see also Joel Balsam, *Police Sergeant Matt Danas’s Death Ruled A Kratom Overdose*, ASK MEN (Oct. 2017), <https://www.askmen.com/news/sports/police-sergeant-matt-dana-s-death-ruled-a-kratom-overdose.html> (“In 2017, six states had banned Kratom and the Drug Enforcement Agency considered making it illegal nationwide, but decided to delay its decision in 2016 due to protests from Congress and the American Kratom Association.”)

therefore it had not been tested in the same clinical trials that other drugs are subjected to. Ultimately that means that the dietary supplement world had no idea exactly what would happen if someone were to take it over a long period of time or ingest a lot of it.³¹ It was not until September 2018 that the FDA released a statement regarding the ongoing concerns about the supplement.³² The Matthew Dana death revived the movement for Kratom to be labelled as an illegal substance; but this example shows that it should not require a death or a significant adverse health effect for the FDA to respond to such dietary supplements before removing them and banning them from production.³³ This death could have been avoided if the proper science and testing had gone into regulating the dietary supplement before it was available to the public.

II. THE FDA'S CURRENT REGULATION

Dietary supplements are classified as food. As defined in the U.S. Code, the term dietary supplement means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; a herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)³⁴ The classification as a food rather than a drug is a huge problem and is one of the major reasons why the current standard in place is lacklustre when it comes to regulation, safety, and efficacy. Being classified as food is important for the FDA because there is no requirement that each supplement goes through the extensive regulatory process that prescription drugs do. That is not to say that dietary supplements are unregulated, and it is a free for all market - they are just not regulated to the degree that they should be.

³¹Zickl, *supra* note 29.

³² FDA Statement, *Statements from FDA Commissioner Scott Gottlieb, M.D., on new warning letters FDA is issuing to companies marketing Kratom with unproven medical claims; and the agency's ongoing concerns about Kratom* (Sept. 11, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620106.htm> (“[M]itragyna speciosa, known more commonly as Kratom, is a plant native to Thailand, Malaysia, Indonesia and Papua New Guinea. There is evidence that certain substances found in Kratom are opioids and data suggest that one or more may have a potential for abuse. The FDA is not alone in its concern about the opioids found in Kratom – it’s already illegal or controlled in several other countries including Australia, Denmark, Germany, Malaysia and Thailand. The substance is also banned in a number of states and municipalities in the U.S.”)

³³ Nat’l Ctr. for Complementary and Integrative Health, *In the News: Kratom (Mitragyna speciosa)*, NCCIH (Jun. 29, 2018), <https://nccih.nih.gov/news/kratom> (“[I]n June the FDA completed its investigation of Kratom. However, because of proponents of the plant, the banning of the substance all together did not carry forward. Therefore the FDA continues to actively evaluate all available scientific information on the issue and continues to warn consumers not to use any products labeled as containing the botanical substance Kratom or its psychoactive compounds. According to the most recent statement by Commissioner Gottlieb, the “FDA stands ready to evaluate evidence that could demonstrate a medicinal purpose for Kratom; however, the agency has received no such submissions and is not aware of any evidence that would meet the agency’s standard for approval.””)

³⁴ See 21 U.S.C. § 321 ff (2010).

A. *A History of the Regulation*

Prior to any legislation, dietary supplements were regulated under the general food provisions of the FDA. “[T]he Pure Food and Drug Act of 1906 dealt with unsafe foods, unregulated elixirs, and misbranded products.”³⁵ In 1941 the FDA promulgated the first recommended daily allowance regulations for vitamin and mineral supplements and other foods for special dietary needs containing added vitamins or minerals. “[However] these regulations placed no restriction on the amount or variety of nutrients that could be included in a supplement or a fortified food.”³⁶ Furthermore, between 1962 and 1974, the FDA attempted to revise these regulations to replace the minimum daily requirements (MDR), with a new reference standard – the U.S. Recommended Daily Allowance (U.S. RDA) – and to establish a standard of identity restricting the amounts of combinations of vitamins and minerals that could be marketed as dietary supplements. The FDA also “proposed to require a label disclaimer on vitamin or mineral supplements.”³⁷

The nineties saw a huge reform and restructuring of dietary supplement regulation. In 1990, “Congress passed the Nutritional Labelling and Education Act (hereinafter ‘NLEA’), which affected the labelling of food and dietary supplements. The significance of the NLEA was that it mandated that virtually all food labels not only had to contain specific information on nutrient content, but they could also make claims relating to specific diseases or disorders.”³⁸ “In 1992, Congress passed the Dietary Supplement Act which essentially prohibited the implementation of NLEA with respect to dietary supplements except for the approved health claims.”³⁹

In 1994, Congress passed, and President Clinton signed, the Dietary Supplement Health Education Act.⁴⁰ The Act was established to “[t]o amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.”⁴¹ In signing such legislation, President Clinton stated:

After several years of intense efforts, manufacturers, experts in nutrition, and legislators – acting in a conscientious alliance with

³⁵ HEALTH.GOV, *Report of the Commission on Dietary Supplements* 11-17 (1997) <https://health.gov/dietsupp/final.pdf>.

³⁶ *Id.*

³⁷ *Id.*, (“The disclaimer would state: ‘Vitamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.’”)

³⁸ *Id.*, (“Such “health claims” were to be based on significant scientific agreement on the validity of the claimed relationship between the nutrient and the disease. In response to this, the FDA established standards for the types and levels of evidence necessary to meet the criteria for approval of health claims.”)

³⁹ *Id.*, (“The following year the FDA published an extensive ANPR which was to pinpoint the current standards of regulation in the use of dietary supplements. This ANPR was a significant factor for the development and passage of the DSHEA in 1994.”)

⁴⁰ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325

⁴¹ *Id.*

consumers at the grassroots level – have moved to successfully bring common sense to the treatment of dietary supplements under regulation and law.⁴²

However, under the DSHEA, supplement manufacturers still not need demonstrate safety or efficacy; “rather, the DSHEA purposefully minimizes oversight by the FDA and focuses on the value of the industry for the US economy.”⁴³

Manufacturers of dietary supplements containing ingredients that were introduced after October 15, 1994, (the enactment date of the DSHEA), were required to notify the FDA before marketing and to provide a rationale for the safety of the ingredients, such as historical use. However, neither safety testing nor FDA approval was required before the marketing of dietary supplements.⁴⁴ For those ingredients that were introduced before October 15, 1994, dietary supplement manufacturers were only responsible for establishing the safety and quality of a product, but they were not required to share that information with the FDA before the product entered the market.⁴⁵ Because the “FDA has limited resources to ascertain harmful effects - products of dubious quality can stay in the market without consequence.”⁴⁶

It took until 2007 for a response when Congress finally passed the Dietary Supplement and Non-prescription Drug Consumer Protections Act (DSNDCP).⁴⁷ The law amended the Federal Food, Drug, and Cosmetic Act (FDCA) to require manufacturers of dietary supplements to report serious adverse events to the FDA. Prior to this law being passed, the FDA were under no obligation to collect adverse health occurrences from the manufactures; the only information they had access to respond to, was any complaints the public had put forward directly to the FDA. However, the passing of the DSNDCP went further. As Senator Richard Durbin said at the time, “[w]ith this bill, the FDA will have the tools to monitor

⁴² HEALTH.GOV, *supra* note 35 (“The new legislation defines dietary supplements, places the responsibility for ensuring their safety on manufactures, identifies how literature may be used in connection with sales, specifies types of statements of nutritional support that may be made on labels, specifies certain labelling requirements, and provides for the establishment of regulations for good manufacturing practices.”)

⁴³ Ahar H. Bimal, *The Dietary Supplement Health and Education Act: Time for a Reassessment. Comment on “Acute Selenium Toxicity Associated with Dietary Supplement,”* JAMA NETWORK <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/415585> (Feb. 8, 2010).

⁴⁴ *New Dietary ingredients in Dietary Supplements – Background for Industry*, FDA <http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcesses/ucm109764.htm> (last visited Oct. 4, 2019).

⁴⁵ Jaap Venema, et al., *Dietary Supplements Quality Analysis Tools from the United States Pharmacopeia*, DRUG TEST ANALYSIS <https://onlinelibrary.wiley.com/doi/full/10.1002/dta.1940> (last visited Mar. 2016).

⁴⁶ *Id.*

⁴⁷ Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469.

supplements that cause dangerous health problems like heart attacks, strokes, seizures, and liver failure.”⁴⁸

In the same year, the FDA released regulations establishing standards for Current Good Manufacturing Practices (CGMPs) for dietary supplements. At the time, the current FDA Commissioner Andrew C. Von Eschenbach stated that the regulations would “help to ensure the quality of dietary supplements so that consumers could be confident that the products they purchase contained what is on the label.”⁴⁹

In 2011 the FDA released draft guidance that clarified what constituted a new dietary ingredient requiring additional assurances of safety and streamlined the necessary reporting structure. The agency’s press release called for “preventive control to ensure that consumers are not exposed to unnecessary public health risks from new ingredients with unknown safety profiles.”⁵⁰ A worrying statistic to note is that despite the FDA’s new requirement to register new ingredients, even with the increase of 86,000 supplements on the market since 1994 when the DSHEA was passed, only 170 notifications of new ingredients were received.⁵¹ A majority of the market value is covered by only about 100 ingredients (e.g. fish oil, calcium, glucosamine/chondroitin, CoQ10, and ginkgo), and major product categories (e.g. multivitamins, sports nutrition, and probiotics).⁵²

III. THE METHOD’S ALREADY IN PLACE

In an ideal world, all manufacturers would follow the guidance, legislation, and rules that has accumulated over the years. The responsibility is in the hands of the manufacturer when it comes to the supplements themselves.⁵³ Even with the CGMPs and DSHEA, there are still three main areas left untouched; “(1) they do not limit consumers’ access to dietary supplements; (2) they do not address the safety of the supplements’ ingredients; and (3) they do not address the

⁴⁸ R. Durbin, *U.S. Senate Committee on Environment & Public Works: Durbin Dedicates Dietary Supplements Legislation* (2006), <https://www.epw.senate.gov/fact.cfm?party=rep&id=267066>.

⁴⁹ Press Release, *FDA Issues Dietary Supplements Final Rule*, (Jun. 22, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108938>.

⁵⁰ U.S. Food and Drug Administration, *Press Release: FDA Issues Anti-Smuggling Strategy and Draft Guidance on New Dietary Ingredients* (Jul. 5, 2011), <https://www.prnewswire.com/news-releases/fda-issues-anti-smuggling-strategy-and-draft-guidance-on-new-dietary-ingredients-125011839.html>.

⁵¹ See generally Pieter A. Cohen, et al., *Presence of Banned Drugs in Dietary Supplements Following FDA Recalls*, JAMA NETWORK (Oct. 22, 2014), <https://jamanetwork.com/journals/jama/fullarticle/1917421>.

⁵² Zickl, *supra* note 28.

⁵³ Editorial Content Team, *Manufacturing Guidelines for Dietary Supplements*, U.S. CANCER SOCIETY (Mar. 31, 2015), <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/manufacturing-guidelines.html> (“Many manufacturers have always followed careful consistent standards and sell only high-quality, correctly labeled supplements. But there are manufacturers out there who are less careful and end up making supplements that contain little or none of the products listed on the label. It is important to keep in mind that despite the continuous accumulation of regulation many supplements are still found to be tainted with real drugs or dangerous substances as not all manufactures follow the rules.”)

supplements' effects on the body as long as good manufacturing processes are used."⁵⁴ The danger with these three areas left open, especially (2), is that criminal manufacturers still have the potential to get their product onto the market as only after it is on the market will the FDA have the power to remove it.

Honest manufacturers and those who pride themselves on standardized quality do have options to show the consumers that they are doing all they can to remain an integral part of the industry. Manufacturers can register with the United States Pharmacopeial Convention (USP) - an independent, non-profit, scientific-based organization, which has worked with volunteer experts from a wide cross-section of stakeholders to develop and continuously revise and update science-based quality standards for medicines, including their test methods and other tools that help protect public health.⁵⁵ Since 1992, USP has developed the science-based quality standards for nutritional and dietary supplements following an open and transparent public consultation process, whereby input from manufacturers, regulators, suppliers, and any other interested party is considered and evaluated by volunteer experts organized in expert committees. The USP admission evaluation process involves consideration of safety information from multiple sources, including adverse event reports from FDA MedWatch.⁵⁶ The relevance for consumers is that they can go into any store that the USP website lists as having safe products with the awareness those products have been tested and have gone through an assessment.⁵⁷

The assessment is conducted for the sole purpose of determining whether or not to develop a compendial monograph that is admitted in the United States Pharmacopeia-National Formulary (USP-NF), however this is not intended as a determination of the intrinsic safety or efficacy of the dietary supplement ingredient or product under review. The USP-NF collaboration is recognised as official compendia of the United States.⁵⁸ The USP-NF contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. Over the counter drugs are required to be in compliance with these standards - whereas,

⁵⁴ *Id.*

⁵⁵ U.S. Pharmacopeia, *Dietary Supplements Compendium*, USP <http://www.usp.org/products/dietary-supplements-compendium> (last visited Oct. 9, 2019); *see also* U.S. Pharmacopeia, *Dietary Supplements Verification Program*, USP <http://www.usp.org/verification-services/dietary-supplements-verification-program> (last visited Oct. 9, 2019) (Dietary Supplement Verification Program Participants include the following top manufacturers: Church & Dwight Co., Inc., Cyanotech Corporation, MeriCal Inc., and Nutrawise Corporation).

⁵⁶ USP, *Guideline for the Admission of Dietary Supplement Ingredients to the USP-NF Monograph Development Process* (Feb. 5, 2017), <https://www.usp.org/sites/default/files/usp/document/get-involved/submission-guidelines/guideline-for-the-admission-of-dietary-supplement-ingredients.pdf>.

⁵⁷ U.S. Pharmacopeia, *USP Dietary Supplement Verified*, QUALITY SUPPLEMENTS, <https://www.quality-supplements.org/verified-products/verified-retailers> (last visited Oct. 9, 2019) (Retailers that carry USP verified products include BJ's Wholesale Club, Costco Wholesale Club, HEB, K-Mart, Kroger, Meijer, Sam's Club, Target, Walgreens and Walmart.)

⁵⁸ Federal Food, Drug, Cosmetic Act, 21 U.S.C.S. § 321(j) (LexisNexis 2019).

dietary supplements have the option.⁵⁹ It is unsurprising that many diet supplement manufacturers typically avoid going through the USP-NF process to avoid any risk of not meeting the compliance.

The importance of this process is that under the DSHEA, if a dietary supplement manufacturer has gone through the USP-NF protocol and has gone on to brand their product as doing one thing, but in fact it does not, then that dietary supplement may be deemed misbranded because it has failed to comply with an official compendium.⁶⁰ In essence, despite the good intentions from the DSHEA in misbranding products that do not conform to the standards that they claim to have under the USP-NF, they are just disincentivising manufacturers from going through this process due to the risk of being misbranded. It is safer for them to brand their product in getting as many purchasers as possible and waiting for them to bring the product to the attention of the FDA.

IV. WHY REFORM IS NEEDED

A. *Unsafe Until Proven Safe vs. Safe Until Proven Unsafe*

Today there is a disproportionate standard being applied to prescription/over-the-counter drugs and dietary supplements. Two out of the three have the obligation to go through clinical processes, be certified by the official United States Compendia, and to go through extensive testing to prove that what it says on the label is in fact what the product contains/does. The combination of the processes that prescription and OTC drugs have to go through ensure that what the consumer is administering has in fact been proven to be safe for their health. The outlier here is the lack-lustre regulation of dietary supplements. Since 1962, the FDA has required that prescription drugs demonstrate safety and efficacy through standard means of evaluation before they can be used by the public.⁶¹ Sixty years on and the FDA still does not require dietary supplements to go through the same extensive testing as prescription or OTC drugs. Dietary supplements are still labelled as a food despite being taken to have more of the same effect as drugs rather than food.⁶² Considering a supplement unsafe until proven safe is a standard that should have been cemented into the industry a long time ago.⁶³

⁵⁹ U.S. Pharmacopeia, *Dietary Supplements & Herbal Medicines*, USP <http://www.usp.org/dietary-supplements-herbal-medicines> (last visited Oct. 9, 2019) (To protect and improve their health, many people purchase dietary supplements and herbal medicines over the counter – often assuming they’re regulated like drugs. While the law requires pharmaceuticals to meet specific quality standards set by USP, the same requirements don’t apply to supplements.)

⁶⁰ Zickl, *supra* note 28.

⁶¹ *Kefauver-Harris Amendments Revolutionized Drug Development*, FDA (last modified Oct. 10, 2012), <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm322856.htm>.

⁶² Editorial Content Team, *Drugs are Considered Unsafe Until Proven Safe*, U.S. CANCER SOCIETY (Mar. 31, 2015), <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/fda-regulations.html> (“[B]ecause supplements aren’t considered drugs, they aren’t put through the same strict safety and effectiveness requirements that drugs are. So all the drugs you can buy, even without a prescription, must be proven safe and effective – but dietary supplements do not.”)

⁶³ *Id.*, (This will all begin with the FDA changing their classification from food. This paper is not to say that the classification should explicitly fall within the drug category,

As more people reach for the easiest option when it comes staying healthy, the Government and the FDA need to realise that categorizing dietary supplements as food is neither suitable nor effective. This issue needs to be attacked with aggression and force to protect the public. A stronger relationship with the FDA is needed to establish a screening process that dietary supplement manufacturers need to go through in order to get their ingredients tested and their products labelled correctly in a similar way that drugs are.⁶⁴ This paper is not setting forth a requirement that dietary supplements go through the exact same protocols and testing as drugs due to time and money/resource restraints. What this paper is proposing is a happy medium – so consumers are aware of the side effects and the FDA can continue to follow up on new products to see how they are performing on the market.⁶⁵

B. Current Drug FDA Regulation vs. Dietary Supplement Regulation

The time it takes for a new drug to get onto the market can be years. The weight on the FDA's shoulder's is immense because the public are putting their faith in the agency in making sure that what they are buying from the store or what they are being prescribed by their doctor is safe and reliable to be taken in accordance with their illness. The journey of a drug reaching the market "follows a cyclical path of proposal, modification, and re-proposal until, finally, they reach a decision on the product and create regulations."⁶⁶

The major difference between drugs and dietary supplements as, already demonstrated, is that "the FDA only approves drugs if they are deemed both safe and effective for their intended purpose."⁶⁷ Once a drug has been approved, the FDA is "then responsible for regulating the drug which includes ensuring that the

but dietary supplements need to escape from the bubble that encompasses the same regulations as food.)

⁶⁴ Editorial Content Team, *FDA Regulation of Drugs Versus Dietary Supplements, Drugs are considered unsafe until proven safe*, U.S. CANCER SOC'Y (Mar. 31, 2015), <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/fda-regulations.html> (One the FDA approves the drug, it must be manufactured under carefully monitored conditions and packaged with complete information on the best dose, route, and schedule. The package information must also include: conditions the drug has been proven to treat, known side effects, contraindications (special conditions under which using the drug should not be used because it would cause too much risk), and unsafe interactions with other drugs.)

⁶⁵ *Id.*, (Once the general public is using a new drug, the FDA follows up on any ill effects patients and their doctors report. The drug company is required to file information they get about side effects as well. This data helps ensure that any side effects not seen in the clinical trials will eventually be found and tracked for the safety of other people.)

⁶⁶ Michael Moneheit, *How the FDA Regulates Drugs*, THE DOCTOR WEIGHS IN, <https://thedoctorweighsin.com/how-the-fda-regulates-drugs/> (last modified Aug. 26, 2016) (Before the FDA gets involved, scientists must develop and test a drug on animals, after which point a drug company becomes involved to design a prototype of the drug. The same drug company must then file an Investigational New Drug application with the FDA. This is permission to hold clinical trials using humans. After completion of these human trials, the research and all information gleaned from the clinical trials is submitted to the FDA for final approval. If approved, the drug is then allowed to be marketed to the general public.)

⁶⁷ *Id.*

drug is labelled appropriately and isn't causing adverse reactions with consumers."⁶⁸ FDA regulation does not stop at approval; "there is also a multi-tiered activity level in place to provide continuous safety."⁶⁹

Dietary supplements are regulated – it is not a free for all market where manufacturers can do what they please. The FDA is in charge of regulating dietary supplements in many different ways. They do the following: (1) The FDA monitors the marketing claims made by dietary supplement companies; making sure that those companies do not claim that their products prevent, reduce the symptoms of, or cure diseases.⁷⁰ (2) The FDA reviews and approves the introduction of new ingredients to the market by affirming generally recognized as safe (GRAS) status, or as new dietary ingredients (NDI).⁷¹ (3) If the evidence indicates an ingredient is harmful, the FDA establishes supplement label warning requirements and – if necessary – mandates removal of an ingredient from the market place.⁷² (4) The FDA inspects manufacturing facilities to make sure that they follow Current Good Manufacturing Practices (CGMPs).⁷³ (5) The FDA's CGMPs cover everything from raw material verification to finished product testing and accurate labelling.⁷⁴ CGMPs are the most efficient and effective way in which the FDA manages to control supplements.⁷⁵ CGMPs do impose higher standards and look to increase the likelihood that supplements are produced in a quality manner and are accurately labelled.⁷⁶

⁶⁸ *Id.*

⁶⁹ *Id.*; See also Susan Thual and Agata Dabrowska, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, CONGRESSIONAL RESEARCH SERVICE (2018) <https://fas.org/sgp/crs/misc/R41983.pdf> (The FDA regulates new drugs through a multi-tiered activity record that takes into account: product integrity, labeling, reporting, surveillance, drug studies, risk management, information dissemination, off-label use, and direct-to-consumer advertising. From changes to the way the drug is marketed to label changes or warnings to a drug being pulled from the market entirely, the actions of the FDA control the fate of medications across the country.)

⁷⁰ *The FDA and Dietary Supplements: How Supplements are Regulated*, Now <https://www.nowfoods.com/now/knowledge/fda-and-dietary-supplements-how-supplements-are-regulated> (last visited Oct. 9, 2019).

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*, ("[W]hile the FDA expects manufacturers of dietary supplements to comply with CGMPs, the FDA does not certify companies to be in compliance. Instead when the FDA inspects a manufacturing facility, it will issue "observations," identifying deficiencies. The manufacturers then need to correct these deficiencies.")

⁷⁶ *Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling, or Holding Operations for Dietary Supplements*, FED. DRUG ADMIN. (2010). <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm238182.htm> ("[T]he DS CGMP rule requires persons who manufacturer, package, label, or hold a dietary supplement to establish and follow current good manufacturing practice to ensure the quality of the dietary supplement and to ensure that the dietary supplement is packaged and labelled as specified in the master

All of these regulatory techniques in place are great on paper, but they are retrospective and only attack the problem once the problem is too large to tackle. The FDA's regulation of drugs attack the problem before the problem is there and that is the difference. As it is explicitly stated on the FDA website, the 'FDA is not authorized to review dietary supplement products for safety and effectiveness before they are marketed.'⁷⁷ The manufacturers and distributors of dietary supplements are responsible for making sure their products are safe before they go to market. It is only if a serious problem associated with a dietary supplement were to occur, must then manufacturers report it to the FDA as an adverse event. The FDA can only take dietary supplements off the market if they are found to be unsafe or if the claims on the products are false and misleading.⁷⁸

C. Marketing Techniques: Drugs vs. Dietary Supplements

A comparison of the drugs and dietary supplements marketing efforts shows the need to increase and heighten the current regulation in place before a supplement will reach the market. In 2015, one recent analysis estimated that manufacturers spent approximately \$60 billion per year on such marketing, including over \$4 billion directed at consumers.⁷⁹

For years, the FDA has been restricting manufacturers' promotion of prescription drugs in several important ways, including preventing manufacturers from promoting their products to treat conditions for which the FDA has not determined adequate efficacy or safety (off-label uses).⁸⁰ However, despite the requirement for dietary supplements to follow CGMPs, there are still loopholes that manufacturers may wiggle their way through if they wish to get their product into the market. The following case excerpt is a worrying example of how a manufacturer is able to manipulate the loopholes in the supplement market.

1. Amarin Pharma, Inc v. FDA

The facts of the case are pretty simple (especially given it is a drug regulation dispute). In 2012, the pharmaceutical manufacturer Amarin received FDA approval for a new drug, Vascepa, as an adjunct to diet to reduce triglyceride levels in adult patient with severe hypertriglyceridemia.⁸¹ Following the approval,

manufacturing record. Dietary supplements containing contaminants or those not containing the dietary ingredient represented on the label would be considered adulterated or misbranded by the FDA.”)

⁷⁷ *Dietary Supplements: What You Need to Know*, FDA (Nov. 2011), <https://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm109760.htm>.

⁷⁸ *Id.*

⁷⁹ Lexchin, *The cost of pushing pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, PLOS MED. 5(1): E1. (2008) <https://doi.org/10.1371/journal.pmed.0050001>.

⁸⁰ Aaron Kesselheim, et al., *Mandatory Disclaimers on Dietary Supplements Do Not Reliably Communicate The Intended Issues*, 34 HEALTH AFF. (Mar. 2015). https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0515?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed.

⁸¹ *Amarin Pharms. Ir, Ltd. v. FDA*, No. 15-5214, 2015 U.S. App. LEXIS 21333 (D.C. Cir. Dec. 9, 2015).

Amarin designed and then discussed an additional two trials to see if Vascepa effected triglyceride levels among statin-treated patients with persistently high triglycerides and if it actually reduced major cardiac events. The latter trial was denied by the FDA and they rescinded its prior agreement to allow Amarin to market the drug as doing so. The FDA notified Amarin that any effort to market Vascepa for this unapproved use could constitute misbranding under the FDCA. Amarin took the FDA to court, seeking a preliminary injunction preventing the agency from taking any action against the company for truthful, non-misleading promotion of Vascepa to health care professionals for patients with persistently high triglycerides and it won. The FDA's concern is with off-label promotion by pharmaceutical companies, and it has taken the position that such promotion violates the FDCA, even though there is no such proscription in the Act itself. It does so by reasoning that off-label promotion amounts to misbranding the drug.

Without getting into the merits of the case, what really needs to be taken from this decision was what the FDA stated in their argument. Counsel for the FDA said that, if Amarin repackaged Vascepa as a dietary supplement – Vascepa is essentially fish oil – the FDA would not object to including the coronary heart disease claim, on certain conditions. What the FDA were saying was that Amarin could not promote it to doctors by making truthful coronary heart disease claims, but selling it directly to consumers on that basis would be just fine. The Court agreed that if Amarin were to label their dietary supplement with a coronary heart disease claim, then they would not expose themselves to liability for misbranding under the pharmaceutical protocol. As long as Amarin would place a disclaimer on the dietary supplement label, then they would be in the clear.

This case shows the purely illogical rationale behind the FDA and the regulations in place for dietary supplements when compared to the exact same ingredients and products under the pharmaceutical umbrella. Amarin portrays a huge loophole in the system and a clear indication as to why so many manufacturers can get their product into the market – potentially harming a huge amount of people.

In response, this paper calls for dietary supplements to go through a multi-tiered screening and testing process (similar to prescription drugs), meaning gaps like the one shown in Amarin can be avoided. This paper calls for a two-step process that addresses how dietary supplements reach the shelves. The public can be re-assured of the safety and efficacy of what they are taking on a day to day basis.

D. Product Labelling Claims

Despite not being taken as a replacement for prescription drugs; dietary supplements are used to boost general health, and to ward off illnesses.⁸² However, several meta-analyses of rigorous efficacy studies report that dietary supplements are not effective in either treating or preventing disease.⁸³ Although certain supplements can prevent or treat specific ailments – for example, calcium plus vitamin D has been approved to treat osteoporosis – it is unclear whether many other supplements offer real health benefits to those without nutrient

⁸² *Reasons of U.S. Consumers to Take Vitamins, Minerals and Nutritional supplements as of 2012*, STATISTA <http://www.statista.com/statistics/308645/reasons-us-consumers-use-vitamin-mineral-nutritional-supplements/> (last modified Dec. 1, 2012).

⁸³ Swartzberg, *Dietary Supplements Your Complete Guide to Making the Best Choices*, BERKLEY SCH. OF PUB. HEALTH (2016).

deficiencies.⁸⁴ Unsubstantiated product-benefit claims in the advertising of supplements are driving the market in to the ground, while the pharmaceutical market is able to stay afloat due to the stringent regulations supporting it.⁸⁵

E. Claims Being Made

Typically, supplement manufacturers will make two types of benefit claims in advertising their product for the public.

Firstly, they state health claims. Health claims describe an established scientific relationship between supplement ingredients and a reduction in the risk of a disease or health-related condition.⁸⁶ These health claims have a substantiation standard applied, meaning competent and reliable scientific evidence has to be proven.⁸⁷ Eventually the health claim has to be evaluated and authorized by the FDA prior to marketing.⁸⁸

Dietary Supplements are then allowed structure-function claims - regulated by 21 U.S.C. § 3434(a)(1) and 21 U.S.C. § 3434(r)(6)(13). Structure-function claims describe the intended benefit of the supplement on the structure or function of the body.⁸⁹ These claims are the ones that are driving the dietary supplement market into the ground because they do not bear the same high evidentiary burden and do not require FDA approval prior to marketing.⁹⁰ The FDA lacks the authority to review or approve these claims before the products enter the market. A manufacturer must notify the FDA when it uses structure-function claims, and a product label must include a disclaimer stating that FDA has not reviewed the claim and that the product is not intended to diagnose, treat, cure, or prevent any disease.⁹¹

However, if a public survey were to be taken to see whether they actually took this disclaimer into consideration, then the majority would answer no.⁹² The reason being is that they see the bottle or the tub of pills/powder on the shelves of well-established stores and automatically think that because the store is selling the product, then the entirety of the product must have gone through some

⁸⁴ Rosemary Avery, et al., *An Examination of Structure-Function Claims in Dietary Supplement Advertising in the U.S.: 2003-2009*, 97 PREVENTIVE MED. 86 (2017) <http://dx.doi.org/10.1016/j.jpmed.2017.01.008>.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*; see also Guallar, et al., *Enough is enough: Stop Wasting Money on Vitamin and Mineral Supplements*, 159 ANN. INTERN. MED. 850 (2013).

⁹¹ OFFICE OF INSPECTOR GENERAL, DIETARY SUPPLEMENTS: STRUCTURE/FUNCTION CLAIMS FAIL TO MEET FEDERAL REQUIREMENTS (2012).

⁹² (This survey has not been taken yet but it would be extremely interesting to carry out to see how ineffective the disclaimer really is on the labels of dietary supplements.)

testing/regulation. The plethora of information about dietary supplements at point of purchase and in the media is also often unclear, unreliable, and conflicting.⁹³

F. Availability of Dietary Supplements

The place of purchase is another aspect to take into consideration because of the freedom they have in selling such products. Stores such as GNC and The Vitamin Shoppe are everywhere and provide instant access to thousands of products that are safe, but at the same time the opportunity is there for unsafe products with misleading claims to find their way onto the shelves.⁹⁴ Although GNC started in 1935 and The Vitamin Shoppe opened its doors in 1977, it has not been until the last few decades that they have both seen a real surge in customers.

Dietary supplements were once only associated with bodybuilders, strongmen, and professional athletes. The average Joe felt no inclination to take them. It was seen as if they were only necessary if you were about to step on the stage at the Mr. Olympia. However, as the years have passed and social media has developed, people have now started to take supplements upon waking, during work, with their food, and before bed – 2019 is a time where the tables have turned. It is seen as a rarity if you are not taking at least one form of dietary supplementation. Stores such as GNC and The Vitamin Shoppe have taken advantage of the ‘less-informed’ consumers by not only selling uncertified products in their store, but also failing to advise those consumers of the adverse effects what may arise upon extended use.⁹⁵

1. Hubert v. Gen. Nutrition Corp.

In 2017, a class action lawsuit was brought against GNC alleging that they knowingly sold products containing unlawful synthetic chemicals to consumers.⁹⁶ In Hubert, Plaintiffs alleged that GNC marketed and sold supplements manufactured by third party vendors which allegedly contained Picamilon, BMPFA or acacia rigidula, despite having known that these substances are not dietary ingredients.⁹⁷ The supplements at issue in Hubert, are primarily weight-loss and sports nutrition supplements available as powders and liquids. Plaintiffs averred that federal and state law place primary responsibility for the safety of

⁹³ Sharon Akabas, et. al, *Quality Certification Programs for Dietary Supplements*, 116 J. OF THE ACAD. OF NUTRITION AND DIETETICS 1370, 1372-1379 (2016).

⁹⁴ *Company Overview*, GNC, <https://www.gnc.com/company-overview.html> (last visited Oct. 9, 2019) (GNC has more than 4,800 retail locations throughout the United States – including more than 1,000 franchise and 1,200 Rite Aid store-within-a-store locations and franchise operations in 46 international markets); *See also About the Vitamin Shoppe*, THE VITAMIN SHOPPE, <http://investors.vitaminshoppe.com/corporate-profile> (What began as a single store in 1977 has evolved into more than 700 locations in 42 states, the District of Columbia and Puerto Rico and an easy to shop web site.)

⁹⁵ (Blame is not imputed to GNC and Vitamin Shoppe but the reason that they are allowed to sell such products is because they have not been succumbed to the same testing as is required for drugs. It can be dangerous with the public spending hundreds of dollars at a time on such products and them not getting the instant results that they always require.)

⁹⁶ *Hubert v. General Nutrition Corp.*, No. 15-CV-1391, 2017 U.S. Dist. LEXIS 145506 (W.D. Pa. Sept. 8, 2017).

⁹⁷ *Id.* at *4.

dietary supplements, as well as truthful labelling and advertising, on supplement manufacturers and distributors such as GNC. According to Plaintiffs, GNC sold products with false and misleading labelling, and further failed to disclose material facts about the dangers of ingesting Picamilon, BMPEA, and acacia rigidula to consumers. Plaintiffs claimed that they were “hoodwinked” into purchasing supplements containing these substances and would not have done so if GNC had disclosed that they contained mislabelled ingredients which purportedly pose serious health risks and are not marketable as dietary supplements.⁹⁸ The lack of FDA regulation is pivotal to the case - both for the Plaintiffs and the Defendant. In 2015, Dr. Cara Welch of the FDA issued a declaration stating that “Picamilon does not qualify as a dietary ingredient under the FDA act.”⁹⁹ Part of Plaintiffs claim is that they alleged GNC continued to sell dietary supplements containing Picamilon until September 21, 2015; despite having known since 2007 that it was not a dietary ingredient.

In terms of acacia rigidula and BMPEA, Plaintiffs further claimed that GNC had been aware since the 2013 that some dietary supplements labelled as containing acacia rigidula actually contained BMPEA. The significance of this is that FDA researchers conducted a study which revealed that many dietary supplements purportedly containing acacia rigidula actually contained BMPEA, despite no testing to show that BMPEA was safe for humans.¹⁰⁰

Plaintiffs averred that despite GNC’s alleged knowledge regarding Picamilon, BMPEA, and acacia rigidula, GNC sold products containing those substances which were supplied by third-party vendors. Plaintiffs claimed that GNC exercised significant control over the third-party products it sold by reviewing and pre-approving labels, warnings, packaging and advertising. By controlling the product labels of third party vendors, Plaintiffs alleged that GNC misrepresented that supplements containing Picamilon, BMPEA, and acacia rigidula were safe for consumers and legal to sell.¹⁰¹ As a result, Plaintiffs asserted that they purchased supplements they otherwise would not have purchased, paid more for supplements than they otherwise would have paid and have been subjected to unreasonable safety risks.¹⁰²

The significance of this case reiterates the FDA’s lack of control from the moment a dietary supplement is manufactured right through until it is sitting on the shelves of an international store.¹⁰³ Despite the case being dismissed, it shows

⁹⁸ *Id.*

⁹⁹ *Id.* at *5.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.* at *8.

¹⁰³ Sheryl Allenson, *Failure to allege economic injur-in-facts tanks class ction against GNC*, HEALTH LAW DAILY (Sept. 11, 2017), http://www.dailyreportingsuite.com/health/news/failure_to_allege_economic_injury_in_fact_tanks_class_action_against_gnc (The court eventually dismissed the action because of a lack of injury-in fact. The court found several arguments from the Plaintiffs’ to be lacking. Noticeably the court rejected the argument that GNC sold products with false and misleading labels and did not disclose material facts. The court stated that “the complaint did not allege what those material facts allegedly were or even whether GNC had an obligation to so disclose. The complaint also did not allege that the consumers were induced to purchase the dietary supplements based on any specific

a gap in the industry that needs to be altered in a way to stop companies like GNC from taking advantage of the consumer.

According to the FDA, Picamilon is a substance that does not meet the statutory definition of a dietary ingredient. Picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. Picamilon is absorbed into the body, crosses the blood-brain barrier and accumulates in the brain as a separate chemical entity. Because Picamilon does not fit any of the categories of dietary ingredients under the Act, any products marketed as dietary supplements that declare Picamilon as a dietary ingredient are misbranded.¹⁰⁴

Acacia rigidula is different to Picamilon because it is a new dietary ingredient. Acacia rigidula is labelled as a dietary ingredient in some products marketed as dietary supplements. However, the FDA is unaware of any information that it was lawfully marketed as a dietary ingredient in the United States before October 15, 1994. Due to the fact there is no history of use or other evidence of establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product labelling, will be safe for consumers, the product is deemed to be adulterated.¹⁰⁵

Finally, BMPEA is also a substance that does not meet the statutory definition of a dietary ingredient. While it was listed as a dietary ingredient on the product labels (within GNC), BMPEA does not meet the statutory definition of a dietary ingredient.¹⁰⁶

The significance of this class action lawsuit being filed is that under existing law, including the DSHEA passed by Congress in 1994, the FDA can take action to remove products from the market, but they must first establish that such products are adulterated or misbranded.¹⁰⁷ The publicity that this lawsuit has subsequently caused should prove to be the ignition that is needed to get such dangerous products off of the shelves which are so easy for consumers to buy.

The FDA is not the sole regulator and that is the issue in the Hubert case. Given the size and diversity of the products and ingredients, the rapid pace with which new dietary supplements are introduced into the market, and the fact that FDA approval is not required before products are introduced to the market, manufactures can get around the obstacles far too easily.

misrepresentation. Nor did it allege that GNC identified its product as superior or identify comparable less expensive products to support an argument that an economic injury existed in the form of premium prices paid for the GNC supplements.”).

¹⁰⁴ *Picamilon in Dietary Supplements*, FDA (Nov. 29, 2017), <https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm472881.htm>.

¹⁰⁵ *Acacia rigidula in Dietary Supplements*, FDA (Nov. 29, 2017), <https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm489921.htm>.

¹⁰⁶ *BMPEA in Dietary Supplements*, FDA (Nov. 29, 2017), <https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm443790.htm>.

¹⁰⁷ *Id.*

G. Third-Party Certification Programs

As noted, there are independent third-party certification programs that offer quality assurance for dietary supplements in the market place.¹⁰⁸ However, third-party certification/verification programs are not universally used by the dietary supplement industry; they are fee-based programs and participation is voluntary.¹⁰⁹

ConsumerLab.com, NSF International, and US Pharmacopeial Convention are three of the largest and most notable third-party organizations who test dietary supplements as finished products - pills, powders, liquids, drinks, and sport and energy products.¹¹⁰ Quality certification by these companies ensure that these supplements do not contain harmful levels of toxic botanical species, or greater or lesser amounts of active or marker compounds than indicated on the product specification and label. NF-USP was discussed earlier in this paper which leads to the importance of ConsumerLab.com.

Starting in 1999, the ConsumerLab.com Quality Certification Program was the first national third-party verification program for dietary supplements.¹¹¹ A difference of the ConsumerLab.com is that it does not accept products directly from the manufacturer; instead it purchases products from the marketplace and the products must comply with FDA labelling requirements, must disclose necessary information about each ingredient (such as the correct plant name and plant part in botanical products), and can only display allowed product claims. Although the results of these tests (pass or fail) are proprietary and confidential to the manufacturer; if the product meets test standards, manufacturers can license the use of the ConsumerLab.com seal of approval to use on their product labels, packaging, advertising, and marketing. However, in order to continue to carry the CL Seal directly on product labelling, the product must pass retesting every twelve months.¹¹² One thing extraordinary about ConsumerLab.com is that it indicates when the recommended serving size for a nutrient exceeds the Tolerable Upper Intake Level established by the Institute of Medicine of the National Academies.

The alternate to ConsumerLabs.com is NSF International. According to the website, manufacturers, regulators and consumers look to NSF International for the development of public health standards and certification programs that help protect the world's food, water, consumer products and environment.¹¹³ Like a CL Seal, NSF International has a mark on products that have been tested and subsequently passed the procedure. The NSF mark is the assurance that the product has been tested by one of the most respected independent certification organizations in the world. It means that the product contains the ingredients listed on the label in the declared potency and amounts; it does not contain harmful levels of specified contaminants, including >200 athletic banned substances for

¹⁰⁸ U.S. Pharmacopeia, *supra* note 57.

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *The NSF Mark*, THE PUB. HEALTH AND SAFETY ORG. <http://www.nsf.org/about-nsf/nsf-mark> (last visited Oct. 9, 2019).

Certified for Sport products, and it has been manufactured according to FDA's current CGMPs.¹¹⁴

These third-party certification programs are not mandatory for manufacturers of dietary supplements to follow.¹¹⁵ It is therefore no wonder that cases such as Hubert are being brought forward against large stores such as GNC. It is all too easy for manufacturers to mislabel their products, as the chances of them being caught by consumers is low. People generally do not go into a store searching for ingredients that they know are banned. They merely see what they want on the TV or on the Internet, and then proceed to their local supplement store. On the other side of the spectrum is the blind eye that these stores show towards the array of supplements that come through their doors. As illustrated by the Hubert case, GNC do not have a protocol in place to wire out any misbranded supplements. Assuming that The Vitamin Shoppe have similar standards in place, that means that every general American wishing for that quick fix will generally have no inclination that they may end up buying a product that could be detrimental to their health. The employees are at no duty to warn customers of the effects, because they too have no idea whether an ingredient is banned or whether a dietary supplement has conformed with the FDA's regulation protocol.

V. THE PROPOSAL

A new form of regulation; one that takes the pressure away from the FDA needs to be established. The public is at the risk of continuous danger as the market continues to grow. A multi-tiered regulating system is needed to ensure that the public - who are currently being preyed on by manufacturers - can be confident that what they are putting into their body has been tested, tested, and tested again before they ingest.

Currently, consumers like the freedom in being able to 'one-click purchase' vitamins, powders, and pills from an array of websites. A majority of the public believe that the government do not, and should not decide what can and cannot be on the market, and that consumers should have some say in the process.¹¹⁶ Many believe (especially individuals who take supplements day in and day out), that if a supplement were to be really harmful, then the market will eventually speak and there will be no demand for it.¹¹⁷ The counter-argument on the other side of the spectrum is that if there were to be no regulation what so ever, then consumers may be harmed by the ingestion of harmful supplements.¹¹⁸ This follows on from the idea that they need to be regulated in a way that is very similar to prescription and OTC drugs.

Imagine living in a world where manufacturers such as Pfizer Consumer Products (a major pharmaceutical company), had the option of getting pills such as 'Advil' or 'Viagra' onto the market through a lack-lustre testing regime that had no implications what so ever. Would the public still feel inclined to reach for their dose of Advil to help combat an inflammation? Or would they be so willing to reach for a 'Viagra'? The answer to these two example questions are

¹¹⁴ U.S. Pharmacopeia, *supra* note 57.

¹¹⁵ *Id.*

¹¹⁶ Sax, *supra* note 14 at 379.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

undoubtedly no. But if you were to switch the variables around and replace ‘Advil’ and ‘Viagra’ with ‘Pre-Workout Powder’ and ‘Weight Loss Pills’ then because of the freedom that consumers have on the market, they will be more willing to try the product despite them not going through the same testing process as the NSAID’s and sexual enhancers. Just as the FDA is charged with securing a safe food and drug supply, the FDA should have the same ability to ensure a safe dietary supplement supply.¹¹⁹ A somewhat distant analogy can further be made with cigarettes. Consumers want the autonomy and freedom to purchase as many cigarettes as they want, all in the face of the data that demonstrates the life-threatening health risks that they pose. Cigarettes go through extensive regulation, yet consumers still enjoy the autonomy. Dietary supplements on the other hand go through about half of that regulation, yet consumers still want and are able to enjoy the same autonomy and freedom.

A. *The Classification Phase*

Currently, the FDA’s definition of Dietary Supplements includes a wide array of products that many people may feel to be overwhelming.¹²⁰ For example, a supplementary Vitamin C tablet has far less ingredients than a ‘pre-workout’ supplement.¹²¹ Until recently, Jack3d was a popular pre-workout among body-builders and college gym goers who wanted that crazy boost of energy.¹²² With no relative comparison, it is crazy to think that these two should go through the same testing/regulation process. This is an example of why in the future, although the term “Dietary Supplement” as used by the FDA is the catch all phrase, those within that category, need to be split up into separate divisions so that they can be regulated accordingly. The disparity in the repercussions of ingesting ascorbic

¹¹⁹ *Id.*

¹²⁰ *Dietary Supplement Products & Ingredients*, FDA (Nov. 20, 2018), <https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/default.htm> (The Federal Food, Drug, and Cosmetic Act “defines a dietary ingredient as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances.”)

¹²¹ Chad Bjorklund, *Ingredients of Vitamin C Tablets*, LIVESTRONG, <https://www.livestrong.com/article/285497-ingredients-of-vitamin-c-tablets/> (“[W]hile particular formulations of vitamin C tablets may differ slightly among competing manufacturers’, the primary ingredient should be raw ascorbic acid. Vitamin C tablet makers utilize raw ascorbic acid that is either extracted from plants like corn, or chemically synthesized. Those Vitamin C tablets that do not have ascorbic acid as the primary ingredient are marketed as special vitamins or multi-vitamins. However, consumers should be aware of the filler ingredients. Filler ingredients may include but are not limited to: vegetable or magnesium stearate, methylcellulose, glycerol and silica. These agents are considered non-active ingredients because they are not expected to have any negative or positive impact on your health.”)

¹²² *Jack3d Ingredients*, JACK3D <http://www.jack3d.org/ingredients> (The famous ‘lethal’ pre-workout ingredients were: arginine Alpha-Ketoglutarate, Creatine Monohydrate, Beta Alanine, Caffeine, 1,3-Dimethylamylamine HCL, Schisandra Chinensis Extract, Citric Acid, Silicon dioxide, Acesulfame Potassium, Sucralose, Vegetable Stearate, and Beta Carotene.)

acid¹²³ as compared to dimethylamine is worrying.¹²⁴ This incongruence calls for vitamins and minerals etc., to go through alternate testing regimes. Whereas supplements which have the potential to have the same effect as amphetamines should obviously go through more rigorous testing to ensure that the standards being met are of the highest degree. The difference in testing is for two reasons: (1) consumer safety and (2) consumer awareness. Ascorbic acid can be tested relatively quickly and efficiently. Dimethylamine on the other hand would require a larger subject group because of the detrimental effects that it may induce.

This paper recommends that there be five tiers within this first ‘classification’ phase. Tier one being the lowest form of testing and tier five having to go through a laborious period which could delay the product from reaching the shelves for months and even years. Manufacturers must submit what they feel their product is before any testing is done. Once manufactures have submitted their preferred tier, those in charge of testing at the designated organization shall look to the current side effects of each ingredient within the proposed supplement and determine based on the severity of such side effects, whether that tier is applicable.

When submitting their preferred tier, a manufacturer must provide testing methodology to support their position. Alternatively, if they fail to provide such evidence, then their product will automatically be placed into tier five for the sake of protecting the public.

Any products which have already shown a significant relationship with death, abnormalities in child birth etc., will automatically be banned from ever being administered into phase one. Again, this is purely for the safety of the consumer, as for too many years they have been the scapegoat for many companies. The FDA has been making blind choices; for example, when they see ingredients such as dimethylamine on a tub of pre-workout that is labelled as “the best pump guaranteed,” they quickly disengage the doubt and adhere to whatever the label says.

B. Post-Classification Tier for Testing

Once manufactures have been placed into the tier for their product to be tested, they must then decide and further prove what category of dietary supplements they wish to be defined as. Categories include but are not limited to: bodybuilding supplements, energy drinks, energy food products, nutritional supplement companies, relaxation drinks, sports nutrition and body supplements, and vitamins and minerals.¹²⁵ If a manufacturer does not fit into one of these categories, they must then establish the category that they wish to defined under – again supported by scientific data.¹²⁶

¹²³ *Vitamin C*, OFFICE OF DIETARY SUPPLEMENTS
<https://ods.od.nih.gov/factsheets/VitaminC-HealthProfessional/> (last visited Oct. 9, 2019)
(Vitamin C, also known as ascorbic acid, is a water-soluble nutrient found in some foods. In the body, it acts as an antioxidant, helping to protect cells from the damage caused by free radicals. Free radicals are compounds formed when our bodies convert the food we eat into energy.)

¹²⁴ Avery, *supra* note 84 (For example, multiple deaths have been associated with a workout booster called “Jack3d,” which contains dimethylamine, described by the medical literature as a synthetic stimulant similar to amphetamines.)

¹²⁵ *Dietary Supplements*, WIKIPEDIA
https://en.wikipedia.org/wiki/Category:Dietary_supplements (last visited Oct. 9, 2019).

¹²⁶ *Id.*; see also *Dietary Supplements for Weight Loss*, NAT’L INSTITUTE OF HEALTH
<https://ods.od.nih.gov/factsheets/WeightLoss-HealthProfessional/> (last visited Oct. 9,

The reason for this classification is the transparency that such would bring to the consumers. On the labelling for each product would indicate which tier that the product is in. If a pre-workout supplement is in Tier four within the first phase and under “bodybuilding supplement” in the second phase, then that is exactly what is to be shown to those who will be buying such a product.

C. Labelling Requirement

The ingredients and the effects of the supplement on the body are only a portion of why someone ends up buying it. The other half is the marketing and how such a supplement has been branded to the public. The government’s right to restrict off-label promotion has been the subject of criticism in the past.¹²⁷ This was amplified in *US. v. Caronia*, a Federal Circuit Court of Appeals case.¹²⁸ Under the DSHEA that was passed in 1994, there is somewhat of a combative measure against frivolous claims because health-related statements made for dietary supplements must be accompanied by a standard disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”¹²⁹

Not only will this statement be no longer needed with this reform, but any statement that has not been evaluated by the governing body will not be sold under the umbrella that is dietary supplements. All statements must be evaluated and proven by the determined organization and the manufacturer respectively.

D. The Federal Trade Commission’s Role

Currently the FTC regulates dietary supplement advertising; it has the primary responsibility for monitoring claims in advertising, including print and broadcast advertisement, infomercials, the Internet, catalogues, and similar direct marketing materials.¹³⁰ Because the FTC and FDA have shared jurisdiction for advertising claims, they often work together on enforcement activities. This should not be a requirement. This reform recommends a deviation from all of the different

2019) (For example, “if a manufacturer were to list their supplement in the ‘Weight-Loss’ category, they must be able to prove that active weight loss ingredients such as: African mango (*irvingia gabonensis*), beta-glucans, bitter orange, caffeine, calcium, capsaicin, carnitine, chitosan, chromium, coelus forskohlii, conjugated linoleic acid, fucosanthin, garcinia cambogia, glucomannan, green coffee bean extract, green tea, guar gum, hoodia, probiotics, pyruvate, ketones, vitamin D, *Phaseolus vulgaris* and yohimbe are not combined with other active ingredients that mask the effects such as benzodiazepines and anti-depressants which mask the side effects of those listed stimulants within the same pill.”)

¹²⁷ Kesselheim, *FDA Regulation of Off-Label Drug Promotion Under Attack*, 309 JAMA 445 (2013) <https://www.ncbi.nlm.nih.gov/pubmed/23385267>.

¹²⁸ *U.S. v. Caronia*, 703 F.3d 149 (2nd Cir. 2012) (the Court held that the First Amendment of the US Constitution protects off-label promotion by manufacturers and their sales representatives as a form of commercial speech, as long as the marketing is not overtly false or misleading.)

¹²⁹ *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 65 Fed. Reg. 1000, 1001 (Jan. 6, 2000) (to be codified at 21 C.F.R. pt. 101).

¹³⁰ FEDERAL TRADE COMMISSION, *DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR THE INDUSTRY* (2001).

organisations with the sole responsibility embedded into one. By requiring manufacturers to support that their label does what it says to a high percentage of certainty will give the FDA and the FTC some breathing space. Requiring proof to be submitted before the product goes on sale will lower the amount of frivolous claims being made by individuals who often moan about the 10lbs not being lost in 10 days. Such claims will not be made as often because such assertions will not be authorised to be on a bottle of weight loss pills unless a reliable study has shown that such an effect is highly probable.

The current situation of the market allows for the companies to make advertisements and statements pointing to certain side effects. This is because in 1998, the Federal Trade Commission published a guidance document that contained nonbinding recommendations that advertisements need not meet any preapproval standard.¹³¹ The difficulty in there being no “black letter law” for regulators or the industry to follow is that when dealing with a claim, courts have so much discretion in deciding whether an advertisement claim is misleading or not. What courts have to decide between is the First Amendment rights of a company versus the “potential”, “weak, non-individualized injury suffered by the plaintiff.” It is of no surprise that in recent years, courts have shifted from a position of protecting the consumer to now favoring the supplement manufacturer and marketer.¹³² What is remarkable is that courts often find the First Amendment to prevail in such situations because they feel that inconclusive, unsupported health claims are not enough to meet the ‘misleading’ threshold. If a company places a disclaimer, then they are to be protected by commercial free speech despite the disclaimer being used in support of an unsupported claim.¹³³

E. Disclaimer Requirement

As demonstrated, manufacturers currently have a duty to place a disclaimer on their product to ensure that they are not “misleading” the consumer. However, this is somewhat of an oxymoron because the disclaimer is being used as a safety net for the statement that is misleading in general. They do it in such a way to cover their tracks and to relinquish any liability if someone were to be negatively affected by taking their supplements. How often have you seen the statement on a tub of protein or a container of vitamins that says, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” An example of an untested product using such a claim would be on any weight loss pill. If the statement on the front said – “this product promotes healthy weight loss,” then this is suitable under current regulations. However, because it has not been tested it cannot say that “this product will lose you pounds.” The manufacturer would only have to add that disclaimer to the bottle and now the supplement industry has won in being

¹³¹ *Id.*; see also Vilafranco, *Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission*, J. OF FOOD DRUG LAW (2007), <https://www.ncbi.nlm.nih.gov/pubmed/18557227>.

¹³² Nguyen, *Potential FTC restrictions on diet advertising*, J. OF FOOD DRUG LAW (2008); See also J. Zigler, *A Free Market for Dietary Supplements: Issues Surrounding DSHEA's Exceptions to the Labelling Exemption for Third-Party Literature*, J. OF FOOD DRUG LAW (2007), <https://www.ncbi.nlm.nih.gov/pubmed/17444029>.

¹³³ Marlys J. Mason et al., *The Impact of Warnings, Disclaimers, and Product Experience on Consumers' Perceptions of Dietary Supplements*, J. CONSUM. AFF. (2007), <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1745-6606.2006.00069.x>.

able to state that an untested product promotes health weight loss merely because it contains a disclaimer. People are unaware that the disclaimer used means that these products are not in fact drugs, and do not carry the same level of regulation by the FDA, nor likely the same weight of scientific evidence.¹³⁴ A disclaimer signals to the consumers that it is up to them whether they want to take that supplement and up to them whether they believe the product will benefit their health and is safe for them to take.¹³⁵ A disclaimer provides that the government – specifically the FDA – does not vouch for its effects, but it is not saying that the supplement does not work at all.

In a study conducted by the Associate Professor of Medicine at Harvard Medical School, a survey was propounded upon the public to get their take and beliefs on what a disclaimer on dietary supplements really does – or what they believed it to do. Three example questions were very consistent with the points that have already been made in this paper. (1) Question: Do supplement users have differing perceptions of safety, efficacy, and regulatory oversight of dietary supplements than nonusers? (1) Answer: Despite the presence of a disclaimer, approximately 50% of respondents believed the FDA approves dietary supplements for safety and efficacy. Younger respondents, minorities, and less educated respondents were more likely to misunderstand the FDA's role in regulating dietary supplements.¹³⁶ (2) Question: What are consumers' comprehensions of dietary supplement label information? (2) Answer: Consumers misunderstood the disclaimer language, with 40% believing the disclaimer meant that insufficient research had been done to prove the claimed benefits. Consumers also misunderstood the FDA's role in regulating dietary supplements, with 33% believing the disclaimer meant that the product was not approved or regulated by the FDA. In addition, 18% believed that the DSHEA disclaimer protected the FDA from legal action.¹³⁷ (3) Question: How do consumers interpret information on dietary supplement materials? (3) Answer: Despite nearly universal awareness of the FD disclaimer, many participants believed that supplements' claims were FDA-reviewed and distrusted the FDA's ability to effectively regulate health products. Health risks of supplements were generally ignored. The disclaimer did not change the FDA's role in approving dietary supplements.¹³⁸

¹³⁴ Why “this Statement” Isn’t Evaluated by the Food and Drug Administration, ELYSIUM HEALTH (Oct. 2017), <https://endpoints.elysiumhealth.com/fda-disclaimer-explained-5738f7aba0d5>.

¹³⁵ *Id.*, (The Officer of Inspector General, in a report on effective labelling, notes that such a strong, clear disclaimer on supplement labels is meant to balance out any marketing claims made by supplement brands. But in effect, experts like Nestle say, the disclaimer is a signal from the FDA that it is up to consumers to decide whether a supplement will benefit their health and is safe for them to take. “The disclaimer is the FDA’s way of showing its lack of responsibility,” Nestle says.)

¹³⁶ Pillitteri, *supra* note 18.

¹³⁷ Carla Miller & Tony Russell, *Knowledge of Dietary Supplement Label Information Among Female Supplement Users*, PATIENT EDUC. COUNS. (2004), <https://www.ncbi.nlm.nih.gov/pubmed/14998599>.

¹³⁸ Marlys J. Mason, *Unintended Consequences of Health Supplement Information Regulations: The Importance of Recognizing Consumer Motivations*, J CONSUM. AFF. (2011), https://www.researchgate.net/publication/230459231_Unintended_Consequences_of_He

When taken in context of what has already been discussed, it seems that disclaimers in the dietary supplement world are not only irrelevant for warning consumers, but they also seem to mislead consumers into thinking that the manufacturer has complied with “any and all” regulations that are currently in place for their product to be on the shelves. In support of these answers from the surveys taken, it is explicitly clear that the disclaimer currently required is not needed on dietary supplements. This is correct because all dietary supplements will be going through a rigorous classification/regulating period so that all products have in fact been tested by an organizational body. An alternate statement on dietary supplements should be required to inform the buyer that the product has gone through testing and regulation.

Dietary supplements should follow the recent decision by the FDA to enhance the medical information on prescription drugs.¹³⁹ Currently, prescription medications do not have disclaimers because they are tested rigorously by the FDA. However, there are many requirements for those manufactures to meet if they decide that they want to advertise their product on the television, radio, or internet.

According to the FDA, different advertisements require different amounts of benefit and risk information.¹⁴⁰ For example reminder ads do not have to include any risk information because they cannot include any claims or pictures about what a drug does or how it works. Reminder ads are only for drugs without certain specified serious risks. (Ibuprofen could be used in a reminder ad if the ad did not describe or name the condition that ibuprofen treats or make dosage recommendations.)¹⁴¹ The next classification is print product claim ads – these may make statements about a drug’s benefit(s). They must present the drug’s most important risks in the main part of the ad (fair balance). These ads generally must include every risk, but can present the less important risks in the detailed information known as the brief summary.¹⁴² Print product claim ads and reminder ads must include a disclaimer just like dietary supplements are required to. However, the difference in the context of the disclaimer is worrying for dietary supplement users. Print product claim and reminder ads must include the following statement: “You are encouraged to report negative side effects of

alth_Supplement_Information_Regulations_The_Importance_of_Recognizing_Consumer_Motivations.

¹³⁹ *The FDA Announces New Prescription Drug Information Format*, FDA (Dec. 4, 2015),

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm188665.htm> (In January 2006, the FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert. To manage the risks of medication use and to reduce medical errors, the newly designed package insert will provide the most up-to-date information in an easy-to-read format that draws physician and patient attention to the most important pieces of drug information before a product is prescribed. The new format also will make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.)

¹⁴⁰ *Basic of Drugs Ads*, FDA (Jul. 2015),

<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm>.

¹⁴¹ *Id.*

¹⁴² *Id.*

prescription to the FDA. Visit MedWatch or call 1-800-FDA01988.” The FDA wants to know about side effects, they retain some sort of responsibility with their product. They want to ensure that the public are in the safest hands possible when it comes down to prescription medication ingestion. Whereas when compared to the disclaimer listed on dietary supplements – the FDA is relinquishing any responsibility by unequivocally stating that this “product has not been tested.”

New regulation would be advantageous because it would put that lost responsibility back into the regulator and/or the organization in charge of the testing methods. The public and the consumers would now have an easy avenue to proceed down if they were to experience any irrational side effects. Currently, those disclaimers placed on prescription drugs have caused the U.S. Government to investigate illegal off-label marketing efforts by manufacturers and subsequently they have dished out approximately \$15 billion worth of civil and criminal fines.¹⁴³ The dietary supplement industry does not have the capacity to order such fines because there is no background to support the allegations. Manufacturers therefore look for gaps in the market, pounce upon that gap, and subsequently take advantage of the consumer as they know that it is unlikely that they will be reported – and if they were to be reported, the odds of a fine/penalty in the same pedigree as prescription drugs is unimaginable. Dietary supplement companies and manufacturers currently have a two-strike rule. It is not until the second offense that they are to be punished.¹⁴⁴

F. *The Marketable Product*

Currently, dietary supplement manufacturers can claim anything not seriously misleading on their product. However, there are three main categories of claims that are defined by statute and/or FDA regulations: health claims, the nutritional content, and structure/function claims.¹⁴⁵

Health claims describe a relationship between a food substance (dietary supplement ingredient), and a reduced risk or a disease or a health-related condition. A health claim lacking these two requirements does not meet the regulatory definition of a health claim.¹⁴⁶ Health claims are currently regulated by the FDA because of the potential effect that they can have on the consumer buying the product. There are currently three ways in which the FDA exercises its oversight in determining which health claims may or may not be used on dietary supplements.¹⁴⁷

(1) The 1990 Nutrition Labelling and Education Act provides for the FDA to issue regulations authorizing health claims for foods and dietary supplements after reviewing and evaluating the scientific evidence, either in response to a health

¹⁴³ Sammy Almashat & Sidney Wolfe, *Pharmaceutical Industry Civil and Criminal Penalties*, CITIZEN (Sept. 2012), <http://www.citizen.org/documents/2073.pdf>.

¹⁴⁴ Josh Long, *FDA warns marketers of supplements and other products to stop making cancer claims*, NATURAL PRODUCT INSIDER (Apr. 2017), <https://www.naturalproductsinsider.com/regulatory/fda-warns-marketers-supplements-and-other-productsstop-making-cancer-claims>.

¹⁴⁵ *Label Claims for Conventional Foods and Dietary Supplements*, FDA (Jun. 2018), <https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements>.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

claim petition or based on its own initiative.¹⁴⁸ The FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant scientific agreement standard to determine whether the substance/disease relationship is well established.¹⁴⁹

(2) The 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government with responsibility for public health protection or nutrition research; such claims may be used 120 days after a health claim notification has been submitted to FDA, unless the agency has informed the notified that the notification does not include all the required information.¹⁵⁰ However, this method cannot be used for dietary supplements at this time.¹⁵¹

(3) As described in FDA's guidance entitled Interim Procedures for Qualified Health Claims in the Labelling of conventional Human Food and Human Dietary Supplements, the agency reviews petitions for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation.¹⁵² This is used when there is emerging evidence of a relationship between a food substance and reduced risk of disease or health-related condition, but the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. The qualified health claims petition process provides a mechanism to request that FDA review the scientific evidence and exercise enforcement discretion to permit the use of the qualified claim in food labelling.¹⁵³

Not only do dietary supplements contain health claims but they also contain nutrient content claims. The nutrient content claim describes the level of a nutrient in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*,

¹⁴⁸ *Id.*, See also *Authorized Health Claims That Meet the Significant Scientific Agreement (SSA) Standard*, FDA (Jan. 2018), <https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard>.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*; See also *Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labelling*, FDA (Jan. 2007), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-dear-manufacturer-letter-regarding-food-labeling>.

¹⁵¹ *Id.*

¹⁵² *Id.*; See also *Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labelling of Conventional Human Food and Human Dietary Supplements*, FDA (Jul. 2003), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-interim-procedures-qualified-health-claims-labeling-conventional-human-food-and>.

¹⁵³ *Id.*

and *light*.¹⁵⁴ An example of this would be when a dietary supplement states, “a good source of Vitamin C,” or “high in antioxidants”.¹⁵⁵

Finally, manufacturers may include structure/function claims. These claims describe the basic benefits of the product on a particular area or function of the body. Examples would be, “helps support lower cholesterol,” or “helps maintain fluid joints.” Structure/function claims must include a disclaimer to state that they have not been evaluated by the FDA.¹⁵⁶

Taking into account that these are the only three claims to be regulated by statute and/or the FDA, it is far too confusing of a protocol to go through for every product out there. It is why there are currently thousands of bottles on the shelves of supplement stores and online that choose not to fall into one of these so that they end up this process. However, with new regulation, all claims, no matter what it says shall be evaluated and checked against the science. With the leeway that manufacturers currently have, they swarm their products onto the public with claims that are sometimes inevitably too good to be true.

From now on the labels on dietary supplements will be far easier to understand. Packaging and labels shall be limited in the amount of information that they can provide. Sales will be based on actual health benefits as opposed to the marketability of a product claiming to be the “number one weight loss pill in the U.S.” By limiting packaging to stating the name of the product, the ingredients, the nutritional values (RDA if available), and a regulated description/statement on what the product does; consumers will be in the driving seat as opposed to the companies. People will be buying based on the information available that has been supported, not on frivolous claims.

Currently, the majority of dietary supplements include the disclaimer that there claim has not been evaluated by the FDA. This statement or “disclaimer” is required by the DSHEA when a manufacturer makes a structure/function claim on a dietary supplement label. The reason that a disclaimer is required is because the manufacturer is the one who is responsible for ensuring the accuracy and truthfulness of these claims. The law of the DSHEA states that if a dietary supplement contains such a claim, it must in a “disclaimer” that FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to “diagnoses, treat, cure or prevent any disease,” because only a drug can legally make such a claim.¹⁵⁷ As a consumer, seeing this can be daunting, scary and confusing. Especially seeing as a portion of the public believes that supplements are regulated like drugs. With this new reform that this paper is proposing, there will be no need to have such a disclaimer on the product. The manufacturers would have gone through scientific testing, similar to how drugs are. Despite the reform not requiring that diet supplements go through the exact same protocol as drugs; supplements will be proven safe before they go onto the market. Thus, no such disclaimer will be required. The only statement from the

¹⁵⁴ *Id.*

¹⁵⁵ *The Science Behind the Supplements*, COUNCIL FOR RESPONSIBLE NUTRITION
<https://www.crnusa.org/industry-regulation/regulation/product-claims>.

¹⁵⁶ *Id.*

¹⁵⁷ *Questions and Answers on Dietary Supplements*, FDA
<https://www.fda.gov/food/dietarysupplements/usingdietarysupplements/ucm480069.htm#wording> (last modified Jul. 22, 2019).

FDA that will be on dietary supplements will be that the product has been tested and has been proven to be safe.

A current regulation in place at the moment that is beneficial and should remain in some shape or form is the capability of the public, or a health care provider, to report a problem or illness caused by a dietary supplement to the FDA.¹⁵⁸ Even though the protocols to file such a claim have already been discussed in this paper, it is important to make it as easy as possible to file. When it comes to reporting adverse events or problems, people are often worried that what they are reporting is not linked to the dietary supplement or it was all part of the side effects that were likely to happen. With the new reform in place, the public should be at ease in reporting as they can now be confident that the product has been tested and therefore any adverse events should be reported.

If a diet supplement gets reported through this new reform, then at least the FDA can say that the product was tried and tested before it reached consumers. They may be more aware of the potential effects, what can be changed with the dietary supplement, and whether or not removing it from the market before the problem is solved is the most feasible idea. Problems should be easy to report, but this new reform shall place barriers in place to prohibit frivolous claims being made. However, frivolous claims are often made when a dietary supplement has not done what it said it is meant to do on the label. This is where the new reform will prove to be beneficial because such claims cannot be made unless they have been proven in the pre-approval stage before being allowed to be sold to the public. The new reform will also continue to publish on a quarterly basis data that was extracted from the agency's adverse event reporting system.¹⁵⁹ These quarterly reports will continue to include the adverse events that were submitted by consumers, medical professionals and the industry for those three months.¹⁶⁰ Having such a platform available to the public will enable them to (1) check out a diet supplement before they purchase it and (2) when they want to report a claim then they can check if someone has reported an adverse event already that is similar to theirs. If someone has, then this should raise a red flag when they report it again to the FDA. If a dietary supplement ends up having a certain amount of reports within a certain time period for the same adverse event or problem, then that supplement shall be immediately removed from the market until the FDA has proven that it is safe for human consumption.

The final important aspect of this reform will be current medical professionals' ability to prescribe dietary supplements for those who are lacking vital nutrients and minerals either in their diet or lifestyle. The reason that this will be attainable is because doctors and physicians will now be prescribing supplements that have been tried, tested, and proven to be safe by the FDA. There will be no liability attached to them for prescribing a supplement that has met the required testing protocols. Currently, doctors can prescribe certain weight loss pills but these pills

¹⁵⁸ *Id.*

¹⁵⁹ Josh Long, *FDA Publishes Adverse Events on Dietary Supplements and Conventional Foods*, NATURAL PRODUCT INSIDER (Dec. 2016), <https://www.naturalproductsinsider.com/regulatory/fda-publishes-adverse-events-dietary-supplements-and-conventional-foods>.

¹⁶⁰ *Id.*

are classified as drugs.¹⁶¹ However, they usually only prescribe them only if your BMI is 30 or higher, or if it's at least 27 and you have a condition that may be related to your weight, like type 2 diabetes or high blood pressure.¹⁶² Common prescription weight loss drugs include: Orlistat, Belviq, Contrave, Saxenda, Phentermine, and Qsymia.¹⁶³ The problem with this, is that people are often scared about approaching a doctor because of either the cost of going to see one (people without insurance) and/or the embarrassment about seeing one about their weight. It is far easier for them to walk into a GNC or a Vitamin Shoppe where there is no embarrassment attached whatsoever in picking up the fanciest looking diet pill tub and paying very little money for something that has not been tried and tested by the FDA.

This paper is calling for the ability to be given to doctors to prescribe diet supplements. They will be cheaper for the consumer, they will be covered by insurance in cases where the patient actually needs them, and the doctor will know that what he/she is prescribing will not adversely affect their liability if such a supplement does not work. Transparency will be higher and medical professionals will know exactly what diet supplements have the highest success and safety rate.

VI. CONCLUSION

The intake of diet supplements has increased astronomically within the past decade and the future looks to be heading in the same direction. The ease in which the public can go to a store or visit a website to buy such supplements is extremely worrying. Given the lack of testing that gets done before they are available to purchase, the FDA along with other agencies of the Government, need to take action and stop with the retrospective attitude to such an important situation.

This paper shows that the current regulations in place are lacking given the ease in which supplements are obtained by the public. If the regulation currently in place were to remain for the next decade, then not only would there be tens of thousands of more products on the market, but the claims which those products would be making would continue to take advantage of the consumer. The less educated percentage of the population are not aware of the implications that may arise from taking such a product that claims to be the best in the market for achieving a certain result. Through a combination of the points that this paper has laid out, a reform will cause consumers to feel safer and more aware of the effects when picking and choosing a supplement which they hope will aid them in their everyday lives.

¹⁶¹ *Prescription Weight Loss Drugs*, WEBMD
<https://www.webmd.com/diet/obesity/weight-loss-prescription-weight-loss-medicine#1>
(last visited Oct. 9, 2019).

¹⁶² *Id.*

¹⁶³ *Id.*