S.O.S. FROM THE FDA: A CRY FOR HELP IN THE WORLD OF UNREGULATED DIETARY SUPPLEMENTS

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I. INTRODUCTION

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.¹

The above-quoted mission statement of the Food and Drug Administration (“FDA”) highlights several duties that the Agency must juggle. First, it must protect the nation’s health. Second, it must do its part to advance the public health by helping to make medicine and food more effective, safe, and affordable for the public. In 1994, Congress muddied the waters by forcing the FDA to refrain from interfering with the public’s access to dietary supplements.² In a perfect world, there would never be a conflict between these duties. Unfortunately, since this perfect world does not exist, what is the FDA to do when faced with the growing reality of dangerous dietary supplements being marketed when it has its hands tied by legislative action requiring it to allow largely unencumbered access to these products?

While the possibility of health problems is clearly the most important issue discussed in this comment, there also exists an

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² See infra Part II.
interesting, and extremely relevant, side issue. “Somebody has to be accountable for this. . . . [I]f somebody’s doing something illegal with supplements sold over the counter, they need to be accountable for their actions and be penalized. . . . [W]e have to do the right thing so the youth don’t go to stores and buy dirty supplements.”3 This statement, made by J.C. Romero, the Philadelphia Phillies pitcher who was suspended for fifty games after testing positive for the banned substance Androstenedione, highlights an important issue in the sports world—both professional and amateur—as well as in the general public. Not only are Americans being persuaded by dietary supplement manufacturers to purchase potentially harmful products, but professional and collegiate athletes are also taking supposedly legal products, only to later discover that the product was either adulterated or misbranded. In certain cases, as with J.C. Romero, this mistake or carelessness could lead to suspension, loss of pay, or loss of athletic eligibility.4 In other cases, the results can be much more serious.

In a 2006 study, researchers discovered that seventy-three percent of adults over the age of eighteen had used dietary supplements within the past year.5 These numbers are a fairly significant increase from the Congressional findings in 1994 which concluded that “almost 50 percent of the 260,000,000 Americans

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6 As of September 12, 2010, the United States population was estimated to be 310,399,180. U.S. & WORLD POPULATION CLOCKS, U.S. CENSUS BUREAU (Oct. 3, 2010),
regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition, and the increase in use does not appear to be stopping anytime soon. While United States legislators were hopeful that decreasing the amount of regulation surrounding dietary supplements would “improv[e] the health status of the United States,” there exist a number of negative effects that were not considered to be significant when this deregulation of dietary supplements was quickly pushed through Congress. In response to a growing concern for greater regulation of the dietary supplement industry, Congress should pass new legislation, such as the proposed Dietary Supplement Safety Act of 2010, which would repeal the Dietary Supplement Health and Education Act. Further, it should adopt a new system that mimics that of the European Union’s Food Supplements Directive and Canada’s Natural Health Products Regulations. This would thereby require pre-market approval of all dietary supplements in order to protect consumers from potentially hazardous side effects, reduce supplement-related litigation, and instill confidence in the dietary supplements industry once again.

Part I of this comment will examine the numerous American statutes and regulatory framework surrounding the dietary supplement industry. Part II will examine the FDA’s Adverse Event Reporting System, giving statistics of injuries allegedly caused by dietary supplements as reported by manufacturers as well as by the American public. Part IV will analyze foreign systems of dietary supplement regulation. Part V will outline the roles played by the FDA as well as the Drug Enforcement Agency (“DEA”) in these matters. Part VI will discuss a report created by the United States Government Accountability Office that calls for several changes to the current regulatory system. Lastly, Part VII will examine why there is a need for new legislation and solutions, and identify the drawbacks to such an approach.


8 Id. § 2(1).
9 See Barbara A. Noah, Foreword: Dietary Supplement Regulation in Flux, 31 Am. J.L & MED. 147, 147 (2005) (“Congress apparently acted in response to anxious lobbying from the dietary supplement industry.”).
10 See infra notes 68–75 and accompanying text.
II. THE HISTORY OF DIETARY SUPPLEMENT REGULATION

Over the past one hundred years, the food, cosmetic, drug, and dietary supplement industries have seen countless laws and regulations come and go, and have dealt with numerous legislative acts and amendments. In 1938, Congress passed the Food, Drug and Cosmetic Act ("FDCA") which gave the FDA the power to not only remove dangerous products from the market, but also to require pre-market approval from the FDA before certain products were placed on the market. Under the FDCA, dietary supplements were classified as drugs. The FDCA makes it illegal to introduce "into interstate commerce . . . any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." Under the FDCA, "a food shall be deemed to be adulterated . . . [i]f it is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling." Notably, during the reign of the FDCA, regardless of whether a supplement was classified as a drug or a food additive, the manufacturer was required to have the product pre-approved, and if "experts did not regard the product as safe . . . the manufacturer was then assigned the burden of proving the safety of the product."
While § 342 of the FDCA deals with adulterated food, § 343 describes misbranded foods. The statute states that “[a] food shall be deemed to be misbranded . . . [i]f . . . its labeling is false or misleading in any [manner].”\(^\text{18}\) Included in this section are regulations for the labeling of dietary supplements.\(^\text{19}\) Additionally, a food will be considered misbranded if the product is a dietary supplement and “the label or labeling of the supplement fails to list the name of each ingredient of the supplement that is described in [the dietary supplement section] of this title.”\(^\text{20}\) Furthermore, “representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.”\(^\text{21}\) Section 343 goes on to state that “nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established.”\(^\text{22}\) However, “a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation.”\(^\text{23}\)

The next major step for the dietary supplement industry came in 1962 with the Kefauver-Harris Amendments.\(^\text{24}\) These changes to the FDCA required manufacturers to “prove effectiveness for the products’ intended use, and not simply product safety.”\(^\text{25}\) Around the same time, the FDA attempted to pass new regulations\(^\text{26}\) “aimed at loosening the restrictions on safer supplements provided in small dosages, while at the same time retaining and strengthening its authority to regulate other supplements as drugs.”\(^\text{27}\) The final regulations were published in 1973.\(^\text{28}\) Unfortunately for the FDA, after spending nearly eleven years finalizing these regulations, notwithstanding over a million objections,\(^\text{29}\) subsequent federal

\(^{20}\) Id.
\(^{21}\) 21 C.F.R. § 101.18(a) (2010).
\(^{23}\) Id.
\(^{25}\) Schindler, supra note 14, at 264.
\(^{29}\) Id. at 257.
court decisions hindered major parts of the new regulations. The next in a long line of significant blows to the FDA came with the passage of the Vitamin-Mineral Amendments of 1976, better known as the Proxmire Amendments. Lastly, new attempts by the FDA to change the 1973 regulations were rebuffed, but this time due to improper procedure on the part of the FDA.

The dietary supplements regulatory scene was relatively quiet until the profound changes that occurred in the 1990s. First, the Nutrition Labeling and Education Act of 1990 ("NLEA") was passed in order to "clarify and to strengthen the [FDA's] legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." Furthermore, under NLEA, "[t]he Secretary shall promulgate regulations authorizing claims of the type described in [this Act] only if the Secretary determines . . . that there is significant scientific agreement . . . that the claim is supported by such evidence." While this appears to be a plus for the FDA, a massive lobbying effort once again took hold and opposed the FDA's authority in "implementing any regulations regarding health claims appearing on the labels of dietary supplements."

These lobbying efforts led to the passage of the Dietary Supplement Act of 1992 ("DSA"). Congress found that "prompt

\[\text{\textsuperscript{30}} \text{Id. (citing Nat'l Nutritional Foods Ass'n v. Food & Drug Admin., 504 F.2d 761 (2d Cir. 1974); Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325 (2d Cir. 1977)).}\]

\[\text{\textsuperscript{31}} \text{Vitamin-Mineral Amendments of 1976, Pub. L. No. 94-278, 90 Stat. 410 (1976) (codified at 21 U.S.C. § 350 (2006)). For example, "the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful." 21 U.S.C. § 350(a)(1)(B). These amendments, therefore, "show a long swing of the pendulum towards laissez faire regulation of the dietary supplement industry." Kassel, supra note 28, at 238.}\]

\[\text{\textsuperscript{32}} \text{See Nat'l Nutritional Foods Ass'n v. Kennedy, 572 F.2d 377 (2d Cir. 1978). As pointed out by Kassel, the court very wisely noted that this dispute is "probably not the last chapter in the bitter battle between the FDA and manufacturers and vendors of pills and liquids containing vitamins and minerals." Kassel, supra note 28, at 259 (quoting Kennedy, 572 F.2d at 379).}\]


\[\text{\textsuperscript{34}} \text{H.R. REP. NO. 101-538, at 7 (1990). Additionally, this Act "allowed claims of disease prevention by food only when the nutrient and disease relationship was supported by significant scientific agreement based upon publicly available scientific literature." Schindler, supra note 14, at 270 (discussing 21 U.S.C. § 343(c)(3)(C)(ii) (2006)).}\]

\[\text{\textsuperscript{35}} \text{In this note, "Secretary" refers to the Secretary for Health and Human Services ("HHS"), the department that houses the FDA. 21 U.S.C. § 321(d) (2006).}\]


\[\text{\textsuperscript{37}} \text{Kassel, supra note 28, at 261.}\]

approval of safe and effective new drugs is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease. This prompted the belief that the “DSA seems to have had a single purpose, namely to prohibit regulation of the dietary supplement industry through bureaucratic delay.” If the Congressional finding was not enough to usurp authority from the FDA, the DSA continues by stating that “the Secretary of Health and Human Services may not implement [NLEA] . . . or any amendment made by such Act, earlier than December 15, 1993, with respect to dietary supplements . . . or other similar nutritional substances.”

The final blow to what little power the FDA still had over the dietary supplements industry came with the passage of the Dietary Supplement Health and Education Act of 1994 (“DSHEA”). This time, Congress made sure to leave nothing to chance in its statements by making it clear that the Act’s main purpose was to facilitate greater access to dietary supplements in order for Americans to lead healthier lives. As for the actual content of DSHEA, it disallows classifying dietary supplements as food additives, and defines a dietary supplement as “a product . . . intended to supplement the diet” that may contain a vitamin, mineral, herb, amino acid, or other “dietary substance for use by man to supplement the diet by increasing the total dietary intake.”

In an instant, DSHEA successfully recategorized supplements under the framework of food. Since supplements can be classified

39 Id.
40 Kassel, supra note 28, at 261–62.
41 Dietary Supplement Act § 202(a)(1).
43 DSHEA states that “although the Federal Government should take swift action against products that are unsafe or adulterated, [it] should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of products and accurate information to consumers.” Id. § 2(13).
44 Id. § 3(b). See also Stephen H. McNamara, Food and Drug Administration Regulation of Dietary Supplements, in REGULATION OF FUNCTIONAL FOODS AND NUTRACEUTICALS 89, 92 (Clare M. Hasler ed., 2005) (“One of the most important provisions of DSHEA from the perspective of manufacturers and consumers of dietary supplement products is the explicit amendment of the [FDCA] to be clear that the term food additive does not apply to a dietary ingredient in, or intended for use in, a dietary supplement.”).
45 Dietary Supplement Health and Education Act § 3(a)(ff).
46 Wais, supra note 13, at 854. Dietary supplement manufacturers, “through labeling and advertising representations, can determine the [product’s] use and thus influence the [product’s] respective classification by the FDA.” Compare Edgar R. Cataxinos, Note, Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform,
as food and not as drugs, manufacturers are allowed to make structure and function claims on product labels.\textsuperscript{47} DSHEA’s attempt at justification comes in the form of provisions that require all statements to contain the warning: “This statement has not been evaluated by the [FDA]. This product is not intended to diagnose, treat, cure, or prevent any disease.”\textsuperscript{48} This raises the obvious problem of having a product on the market that claims particular effects, but has the potential for being completely erroneous, yet will still fall completely within the bounds of DSHEA.

After the passage of DSHEA, the only significant manner in which the FDA can determine that a supplement is adulterated is if it is “a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.”\textsuperscript{49} Furthermore, DSHEA shifted the burden of proof, stating “the United States shall bear the burden of proof on each element to

\textsuperscript{47} A dietary supplement may contain a statement of nutritional support if the statement “describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, [or] characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.” Dietary Supplement Health and Education Act of 1994 § 6 (codified as amended at 21 U.S.C. § 343(r)(6)(A) (2006)).

\textsuperscript{48} Id. (codified as amended at 21 U.S.C. § 343(r)(6)(C)). If a manufacturer wishes to make such a claim on its product, it “shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.” Id. Additionally, DSHEA requires that the manufacturer, in labeling, “present a balanced view of the available scientific information on a dietary supplement.” Id. § 5 (codified as amended at 21 U.S.C. § 343-2). Professor Peter J. Cohen feels that, although this statement is intended to inform consumers that the products are not intended to “diagnose, cure, mitigate, or treat disease . . . , it is likely that many customers will not truly assimilate this information and will use supplements to treat disease.” Peter J. Cohen, Science, Politics, and the Regulation of Dietary Supplements: It’s Time to Repeal DSHEA, 31 AM. J.L. & MED. 175, 183 (2005); see also Stephanie Kauflin, Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme, 33 SETON HALL L. REV. 411, 423 (2003) (“[T]his system allows manufacturers of dietary supplements to hint that a product will help a disease without actually saying so.”) (quoting Laura A. W. Khatcherian, Regulation of Dietary Supplements: Five Years of DSHEA, 54 FOOD & DRUG L.J. 623, 637–38 (1999)).

\textsuperscript{49} Dietary Supplement Health and Education Act § 4 (codified as amended at 21 U.S.C. § 342(f)(1)(B)).
show that a dietary supplement is adulterated.”\(^{50}\) As long as a manufacturer creates a product that contains dietary ingredients as listed in DSHEA, “it would not need to be confirmed by the FDA as safe or go through the food additives approval procedures.”\(^{51}\)

With the passage of DSHEA, removing authority from the FDA to pre-approve dietary supplements has clear drawbacks regarding possible public health concerns. However, some view DSHEA as also providing a number of benefits to the FDA, a certain “quid pro quo”\(^{52}\) for the FDA. For example, as mentioned above, DSHEA now provides a section that considers a supplement to be adulterated if it “presents a significant or unreasonable risk of illness or injury.”\(^{53}\) Additionally, a dietary supplement containing a new dietary ingredient will be considered adulterated, and therefore a violation of DSHEA. Unfortunately, in this situation the manufacturer can simply show that there is “evidence of safety establishing that the dietary ingredient . . . will reasonably be expected to be safe,” and must provide the FDA with this evidence “75 days before being introduced or delivered for introduction into interstate commerce.”\(^{54}\) Furthermore, this seventy-five day “mechanism is only minimally effective at protecting consumers because so few ingredients are subject to this requirement.”\(^{55}\)

DSHEA defines a new dietary ingredient as a substance that, at the time DSHEA was passed, was not “present in the food supply as an article of food in a form in which the food has not been chemically altered.”\(^{56}\) Another alleged luxury provided to the FDA under DSHEA was a provision allowing the Secretary to ‘declare a dietary supplement ‘to pose an imminent hazard to public health or safety,’ in which case it immediately

\(^{50}\) Id. (codified as amended at § 342(f)(1)(D) (2006)).

\(^{51}\) Lewis-Eng, supra note 46, at *2. Under DSHEA, “manufacturers hold the responsibility to determine the safety of their ingredients. If the manufacturer [determines] that the ingredients are safe for their intended use, the products can go to market without prior FDA approval or review.” Id.

\(^{52}\) McNamara, supra note 44, at 93.

\(^{53}\) Dietary Supplement Health and Education Act § 8 (codified at 21 U.S.C. § 350b(a)(2) (2006)). McNamara makes sure to note that this seemingly promising provision is counteracted by the provision that shifts the burden of proof in this matter to the government. McNamara, supra note 44, at 92; see also id. § 8 (codified at 21 U.S.C. § 342(f)(1)(D)).

\(^{54}\) Id. (codified at 21 U.S.C. § 350b(a)(2)).

\(^{55}\) INSPECTOR GENERAL REPORT, supra note 5, at 5. Since 1994, the “FDA has received 97 premarket notifications, covering 114 ingredients, 102 of which were new dietary ingredients (the remaining products/ingredients were found to be drugs or biologics).” Id.

\(^{56}\) Dietary Supplement Health and Education Act § 8 (codified as amended at 21 U.S.C. § 350b(a)(1)).
becomes illegal to market the product.”

The number of potentially harmful side effects to this regulatory framework seems endless: (1) a manufacturer does not inform the FDA that they are marketing a product with a new dietary ingredient and it goes straight to market; (2) a product contains a harmful combination—knowingly or not—of approved products under DSHEA's definition of a dietary supplement and it is legally for sale; and (3) the manufacturer gives the FDA the requisite seventy-five day notice period in which to approve the sale of a supplement with a new dietary ingredient, but the FDA, being severely overburdened already, is not able to adequately evaluate the claims made by the manufacturer to meet the deadline before it goes to market. With all of these holes, why was DSHEA passed in the first place?

DSHEA was passed with the aid of successful lobbying from dietary supplement manufacturers:

[T]he health-food industry and its allies urged Congress to “preserve the consumer’s freedom to choose dietary supplements.” To whip up their troops, industry leaders warned retailers that they would be put out of business. Consumers were told that unless they took action, the FDA would take away their right to buy vitamins. These claims, although bogus, generated an avalanche of communications to Congress. The end result was [the] passage of DSHEA, which defined “dietary supplements” as a separate regulatory category and liberalized what information could be distributed by their sellers . . . . [DSHEA] also expanded the types of products that could be marketed as “supplements.”

In a report detailing the need for less regulation by the FDA, the Senate Committee on Labor and Human Resources stated that “in

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58 See infra note 102.
59 Cohen, supra note 48, at 180 (quoting STEPHEN BARRETT & VICTOR HERBERT, THE VITAMIN PUSHERS: HOW THE "HEALTH FOOD" INDUSTRY IS SELLING AMERICA A BILL OF GOODS (1994)); see also Noah, supra note 9, at 147 ("Congress apparently acted in response to anxious lobbying from the dietary supplement industry."); Jennifer Akre Hill, Creating Balance: Problems Within DSHEA and Suggestions for Reform, 2 J. FOOD & L. POLICY 361, 364 (2006) ("[T]he lobbying power of the dietary supplement industry caused DSHEA to be a political compromise that promised law in a hurry without giving due care to its repercussions."); McNamara, supra note 44, at 89 ("Many members of the [House] and Senate stated that they were receiving more mail, more phone calls, and generally more constituent pressure on this subject than on . . . health care reform, abortion, or the deficit.").
fact, FDA has been distorting the law in its actions to try to prevent the marketing of safe dietary supplement substances.\footnote{McNamara, supra note 44, at 89. Additionally, the FDA’s “history of suppressing marketing . . . probably explains why the agency has not been given comprehensive preclearance authority.” Id. at 98. McNamara continues by explaining other examples of alleged improper actions taken by the FDA under the FDCA. For example, the Agency considered any addition of black currant oil to be a food additive, thereby requiring approval from the FDA. Id. at 90. A Senate Report places cost-estimates for this approval process at approximately $2 million, and with a timeframe of two to six years. Id. (citing S. REP. 103-410, at 21 (1994)).} Prior to the passage of DSHEA, two district courts and two courts of appeals had struck down attempts by the FDA to classify products as food additives.\footnote{See United States v. Oakmont Inv. Co., 987 F.2d 33 (1st Cir. 1993); United States v. Viponte Ltd. Black Currant Oil, 984 F.2d 814 (7th Cir. 1993).} With federal courts willing to penalize the FDA for these supposedly erroneous classifications, why was the passage of DSHEA necessary? Author Stephen McNamara, recognizing this issue, stated that “Congress concluded that unless it stepped in and passed DSHEA, the facts showed that FDA would continue to try to prohibit marketing of safe and proper dietary supplements by using its own interpretation of the then-existing ‘food-additive’ law.”\footnote{McNamara, supra note 44, at 90. Congressional records further explain their reasoning: Although a fair reading of the current statute . . ., as most recently interpreted by two United States courts of appeal, should make . . . amendment [of the FDC Act by DSHEA] unnecessary, the committee has heard testimony that the FDA has rejected these . . . holdings. The committee is therefore concerned that the FDA will persist in such litigation and thereby continue to subject small manufacturers to the choice of abandoning production and sale of lawful products, or accepting the significant financial burden of defending themselves against baseless lawsuits. Id. at 91 (quoting S. REP. 103-410, at 21).} As McNamara points out, Congress’ concerns—namely that the FDA would abuse its authority—were as much of a deciding factor to pass DSHEA as were the extensive lobbying efforts by dietary supplement manufacturers.\footnote{Senator George Mitchell explains his experiences during the time of DSHEA’s passage: [I]n 1994 Congress passed and the President signed into law [DSHEA]. It was approved unanimously by the Senate, without objection. I was the Majority Leader of the Senate when DSHEA was approved. It was one of thousands of measures that the Senate considered during my tenure. Today, thirteen years later, I have only a vague recollection of the Senate’s consideration of the Act. However, with the benefit of hindsight, knowing what I now know, I regret that I did not speak out against the manner of regulating supplements that resulted from enactment of that law. SENATOR GEORGE J. MITCHELL, REPORT TO THE COMMISSIONER OF BASEBALL OF AN INDEPENDENT INVESTIGATION INTO THE ILLEGAL USE OF STEROIDS AND OTHER PERFORMANCE ENHANCING SUBSTANCES BY PLAYERS IN MAJOR LEAGUE BASEBALL 60 (2007), available at http://files.mlb.com/mitchrpt.pdf.}

For the moment, if we are to take these allegations as true, why did Congress feel as though the American public would agree more with a laissez faire approach than with a policy that still gave
consumers access to the products, but simply made them wait for a safety screening prior to marketing? As stated at the time by FDA Commissioner Dr. David Kessler, “[t]his is not about health and this is not about well-being; this is about money and jumping on a bandwagon.” It is not an unreasonable preliminary assumption that in 1994, Congress was more concerned with keeping supplement manufacturers happy than complying with the overall goal of the FDA: to protect the health of the American public. In the words of Georgetown Law School Professor Peter J. Cohen, “[i]f we accept the rationale for strong regulation of pharmaceuticals, it is difficult to reject the thesis that the same standards should be applied to dietary supplements which are similar to drugs in everything but statutorily-assigned name.”

While it is nice to think of the ideal scenario for controlling and policing the dietary supplement industry, what would be the result if such a bill were brought before the legislature? Since this would be pure speculation, it would be helpful to examine a past attempt at passing this type of legislation. In 2003, Senator Richard Durbin, joined by Senators Hillary Clinton, Dianne Feinstein, John McCain, and Charles Schumer, sponsored Senate Bill 722: Dietary Supplement Safety Act of 2003. A few months later, Representative Susan Davis, joined by ten co-sponsors, sponsored H.R. 3377: Dietary Supplement Access and Awareness Act. Both of these acts died before any vote took place. While neither of these

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64 Perhaps Congress was not worried about public health at all. Instead, maybe references to “improving the health status of United States citizens” and “the importance of nutrition and the benefits of dietary supplements to health promotion” were peppered in to mask the mention of: (1) how dietary supplements can reduce “health care expenditures [which] is of paramount importance to the future of the country and the economic well-being of the country”; (2) how “the nutritional supplement industry is an integral part of the economy of the United States”; and (3) “the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000.” Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2, 108 Stat. 4325, 4325–26 (codified as amended at 21 U.S.C. § 321 (2006)).


66 See Richard E. Nowak, DSHEA’s Failure: Why a Proactive Approach to Dietary Supplement Regulation is Needed to Effectively Protect Consumers, 2010 U. ILL. L. REV. 1045, 1074–76 (2010) (“It is more likely, however, that Congress believed that the dietary supplement industry, which has significant lobbying power, should not be hampered by unnecessary legislation and prohibitions.”).

67 Cohen, supra note 48, at 210.


bills directly addressed pre-market approval, they both asked for stricter regulation of supplements. Both of these attempts recognized the problems with the current regulatory framework and attempted to come up with a compromise that would not upset the lobbyists for the supplement manufacturers.

In a more recent attempt, on February 3, 2010, Senator John McCain introduced the Dietary Supplement Safety Act of 2010 (“DSSA”). In announcing this new legislation, Senator McCain stressed its importance:

All Americans should know the exact ingredients of any dietary supplement they use and the FDA must have the tools necessary to ensure the safety of dietary supplements. This legislation would require dietary supplement manufacturers to register with the FDA and fully disclose the ingredients contained in the supplement. Surveys have found that a majority of dietary supplement users believe the FDA approves the safety of dietary supplements prior to market introduction. However, that is not the case.

If passed, this bill would require all dietary supplement manufacturers to “file with the secretary a list of all dietary supplements manufactured, packaged, held, distributed, labeled, or licensed by [its] facility. . . . [This list] shall be accompanied by a full list of the ingredients contained in each dietary supplement.” The “registration” shall be updated at least annually.

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70 Senate Bill 722 was an attempt to pass a law similar to the Nonprescription Drug Consumer Protection Act that not only would have required manufacturers to report serious adverse events, but also required them to submit an annual report of all non-serious adverse events. See infra note 79 and accompanying text. Additionally, the manufacturer may be ordered to “conduct postmarket surveillance for the dietary supplement if [it is determined] that there is a reasonable possibility that a use or expected use of the dietary supplement by a significant number of consumers may result in serious adverse experiences.” S. 722, 108th Cong. § 416(c)(1) (2003). House Bill 3377 sought much of the same in the way of serious and non-serious adverse event reporting. However, this bill went further in that twice a year, the manufacturer of dietary supplements would be required to provide the FDA with (1) a list of each supplement that the company manufactures; (2) the label for each of those products; (3) lists of the major ingredients in each supplement; and (4) the reason for the discontinuance of the manufacturing of any supplement. H.R. 3377, 108th Cong. § 416(b)(1)–(4) (2003). Lastly, this bill went one step further by giving the Secretary of HHS the authority to order a demonstration of safety if it is believed that a product “may be adulterated under section 402(f)(1).” Id. § 416(e)(1).


73 Dietary Supplement Safety Act § 2.

74 Id.
DSSA provides two additional safeguards for the American public. First, it requires manufacturers to not only report all serious adverse events, but they must also report any adverse event—serious or not. Second, if “there is a reasonable probability that a dietary supplement . . . would cause serious, adverse health consequences or death,” DSSA gives the FDA authority to force a manufacturer to “cease distribution of such dietary supplement or a product marketed or sold as a dietary supplement.” What seemed like a ray of hope for consumer protection quickly turned sinister on March 4, 2010 when Senator Orrin Hatch graciously thanked McCain for withdrawing his support for the bill. Instead, McCain will “work with [Hatch] on solutions that will truly help dietary supplement consumers without injuring this important industry.”

Based strictly on how past attempts played out, the proactive approach that is advocated in this comment seems unlikely to pass. The support of Senator McCain was, at first, a testament to the importance of this issue. Yet, the pressure put forth by the supplements champion, Orrin Hatch, suppressed any hope of this bill being passed to create stringent restrictions on dietary supplement manufacturers. However, simply because a piece of legislation is unlikely to pass—in this case most likely due to extensive lobbying from supplement manufacturers—does not correlate to the belief that the proposed legislation is poorly reasoned.

III. THE ADVERSE EVENT REPORTING SYSTEM

In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (“NDCPA”) which required that any “manufacturer, packer, or distributor of a dietary supplement whose name . . . appears on the label of a dietary supplement marketed in the United States . . . shall submit to the Secretary any report received of a serious adverse event associated

55 Id.
56 Id. § 418.
57 Letter from Senator Orrin G. Hatch to Senator John McCain (Mar. 4, 2010), available at http://fdcalerts.typepad.com/files/100308_hatch_mccain_s3002_letter.pdf (“I want to thank you for agreeing to withdraw your support for the provisions of [DSSA] that I believe would do great harm to the dietary supplement industry . . .”).
58 Id. It is perhaps not surprising that Hatch, the author of DSHEA, was the individual who persuaded McCain. As previously discussed, Hatch helped to push DSHEA through Congress in a swift manner, motivated at least in part by his interest in pleasing his home state of Utah—the state which houses a number of dietary supplement manufacturers. See infra note 181 and accompanying text.
with such dietary supplement when used in the United States." 79

Before this Act, a manufacturer could withhold this type of information from the FDA. Additionally, in 2003 the FDA created the Adverse Event Reporting System ("AERS")—"a computerized information database designed to support the FDA’s post-marketing safety surveillance program for all approved drug and therapeutic biologic products"—which tracks the total number of reports received by professionals, "such as physicians, pharmacists, nurses and others," as well as from consumers, "such as patients, family members, lawyers and others." 80 According to AERS, the total number of reports has increased every year since 2002. 81

An adverse event is statutorily defined as "any health-related event associated with the use of a dietary supplement that is adverse," while a serious adverse event is defined as an adverse event that results in "(i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) congenital anomaly or birth defect; or . . . requires, based on reasonable medical judgment, a medical or surgical intervention." 82

While AERS appears on its face to be a good system for the FDA to seek out harmful dietary supplements, reports have indicated otherwise. A study by the Department of Health and Human Services that evaluated "how well FDA’s adverse event reporting system for dietary supplements functions as a consumer protection tool," stated that the FDA "receives . . . less than 1 percent of all the


81 Id. Over the past ten years, the number of total adverse reports entered has risen from 266,866 in the year 2000 to 526,527 in 2008. In 2009, there were 490,835 adverse reports entered, which is yet another increase from the previous year. Through the first quarter of 2010, there were 136,235 adverse reports entered. While it could be argued that this increase is due to the increased number of individuals utilizing dietary supplements, in no way would numbers this high be considered encouraging for proponents of the current system.

82 Dietary Supplement and Non-Prescription Drug Consumer Protection Act § 761.
adverse events associated with dietary supplements.” 83 Interestingly, the study found that, due to a lack of information generated by AERS, “it is not surprising that FDA rarely reaches the point of knowing whether an action is needed in order to protect consumers,” 84 which leads to a relatively small number of safety actions taken by the FDA. In conclusion, the report found that “the potential of [AERS] to serve as a consumer safeguard is inherently limited,” and it “simply cannot serve as an adequate safety valve until other measures are taken that will allow FDA to generate and confirm signals of possible public health concerns.” 85

The 2010 proposed legislation by Senator McCain sought to solve one of the crucial issues with AERS. The legislation would have stricken the word “serious” from the statutory text, thereby requiring manufacturers to report “all non-serious adverse events” resulting from the use of supplements that they manufacture or sell. 86

### IV. FOREIGN REGULATORY SCHEMES

In 2002, the European Union (“EU”) passed the Food Supplements Directive (“Directive”) “[in] order to ensure a high level of protection for consumers and facilitate their choice, [and to ensure that] the products that will be put on the market must be safe and bear adequate and appropriate labelling.” 87 This solution to the problem “establish[es] a positive list” of “[o]nly vitamins and minerals normally found in, and consumed as part of, the diet.” 88 If a manufacturer wishes to sell a dietary supplement in the EU, that supplement may only contain substances that are on the positive list. If a manufacturer used a substance that is not on the positive list at the time the Directive was passed, the substance “should be

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83 Inspector General Report, supra note 5, at 9. The study goes on to state that the reason why this phenomenon may occur is because many consumers: (1) “presume supplements to be safe”; (2) “use these products without the supervision of a health care professional”; and (3) “may be unaware that FDA regulates them.” Id. at ii.

84 Id. at 16 (“After a careful review, we did document 32 safety actions taken between January 1994 and June 2000 . . . . But, it is quite clear that at a time when more than 100 million people were taking dietary supplements, the number of FDA safety actions was strikingly low.”).

85 Id. at iv.


88 Id. at (9). This positive list contains over one hundred substances.
submitted to the European Food Safety Authority for urgent evaluation.”

There are some clear drawbacks to the Directive. In 2004, it was estimated that “campaigning” for an ingredient to be added to the positive list would cost somewhere between “EUR100,000 and EUR400,000 [between $140,000 and $570,000], which only large companies can afford.” Furthermore, this process of “demonstrating the safety of a vitamin, mineral, or other dietary ingredient generally takes two to three years to complete. These time and cost restraints would likely impair all but large, established dietary supplement manufacturers.” The public outrage that resulted from the passage of the Food Supplements Directive culminated in litigation. Unfortunately for the European citizens opposed to the regulations, the European Court of Justice upheld the legality of the Directive.

Even though the regulations put in place by the EU are considered highly favorable for consumers, and highly unfavorable for supplement manufacturers, there are some holes in the Directive that show that it does not go far enough in protecting consumers. While some authors have interpreted the Directive to imply that pre-approval of a manufacturer’s supplements is required, there is nothing specific in the text of the Directive that requires all manufacturers to submit their products for approval if they claim to contain only those substances that are on the positive list. The inherent problem in this system is that it could

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89 Id. at (10).
93 See Nowak, supra note 66, at 1075 (“The Food Supplements Directive . . . requires manufacturers to have each dietary supplement they seek to market evaluated and approved by the Scientific Committee on Food.”); LeCong, supra note 91, at 117 (“Because the Food Supplements Directive requires pre-market approval, food supplements must be safe for human health before being sold in the Community.”).
94 Manufacturers that had products on the shelves when the Directive was passed are required to submit the product for approval within a three-year time period if it contains substances not listed on the positive list. The product will not be contrary to the Directive if “the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance . . . on the basis of a dossier supporting use of the substance in question.
encourage manufacturers to falsify their labels in order to avoid this approval process.

On the other hand, our neighbors to the north went even further than the EU and passed the Natural Health Products Regulations (“NHPR”) in 2004. Under NHPR, “no person shall sell a natural health product unless a product license is issued in respect of the natural health product.” Once the license application is submitted, a product license will be issued permitting the sale of the product if (a) the application is submitted properly under NHPR; (b) the applicant submitted any additional information that was requested; (c) the application does not contain any false or misleading statements regarding the products; and (d) if the license is issued, the product is not likely to “result in injury to the health of a purchaser or consumer.”

This proactive approach is one from which the United States supplement industry could benefit. The current state of regulation calls for a reactive approach by federal agencies; allowing for harm to come to the public before any sort of enforcement or remediation is done. This is because DSHEA does not require pre-approval of dietary supplements prior to marketing, and also relies almost exclusively on AERS reports to find violators and potential health risks. On the other hand, with a regulatory framework such as NHPR, the United States could preempt most health risks by approving the product prior to consumption by over one hundred million Americans. While this is a much more proactive approach than what is present in the United States, there is still a drawback that rings all too familiar: “soon after [NHPR] came into force, to be submitted to the Commission by the Member States not later than 12 July 2005.” Food Supplements Directive, art. 4, § (6)(b).

In Canada, “dietary supplements” are referred to as “natural health products” or NHPs. LeCong, supra note 91, at 118.


Id. § 7(a)–(d). If a license application is denied, the applicant may appeal the decision within thirty days. Id. § 9(2).

Noah, supra note 9, at 150 (“Because premarket approval is not required for dietary supplements, the FDA’s safety authority over these products appears more reactive than proactive.”).

The approval process could be the same as Canada’s, which would include: “a qualitative list of the non-medicinal ingredients that are proposed for the [NHP], the recommended conditions of use for the [NHP],” the proper name, quantity, potency, and description of each medicinal ingredient, “information that supports the safety and efficacy of the [NHP],” and the “text of each label that is proposed to be used in conjunction with the [NHP].” Natural Health Products Regulations, SOR/2003-196 § 5.
Health Canada indicated through a policy document that although all unlicensed natural health products were against the law, enforcement action would be focused only on those products that were considered to pose the greatest threat to health.\(^{101}\) While it is unfortunate that a violator may go unpunished even under such a proactive regulatory framework, it would be a pipe dream to expect an overburdened federal agency, such as the FDA,\(^{102}\) to be able to enforce every violation, major or minor.

V. ENFORCEMENT ROLES OF THE FDA AND DEA

While most of this comment thus far has consisted of various attacks on the weak regulatory system that controls the dietary supplement market, we must look at what authority certain federal agencies possess in order to protect the public’s health and allow for access to these products. As opposed to the manner in which drugs must be pre-approved prior to sale,\(^{103}\) the FDA has no authority to pre-approve a dietary supplement under the DSHEA regime. So what is left for the FDA to do? Aside from the relatively small number of cases in which a manufacturer seeks to introduce a new dietary ingredient into interstate commerce,\(^{104}\) the “FDA may take action only after a supplement has been marketed and then been shown to constitute an imminent threat to the public welfare.”\(^{105}\)

The best known example of the FDA taking control of a dangerous situation after a product has been marketed is the Ephedra ban. In 2003, the FDA announced a ban of all marketing of Ephedra, marking an end to a six-and-a-half-year period after which the Agency had “first proposed a mandatory warning statement on


\(^{102}\) In the words of Senator Orrin Hatch, “[t]he FDA is overburdened . . . I blame Congress for a lot of these things. We don’t give you enough support.” Teri Thompson & Nathaniel Vinton, Senate Seeks Tighter Supplement Regulation from USADA, N.Y. DAILY NEWS, Sept. 29, 2009, http://www.nydailynews.com/sports/2009/09/29/2009-09-29_senate_seeks_tighter_supplement_regulation.html. The FDA, not surprisingly, agrees with Senator Hatch’s determination: “FDA has limited resources to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness.” Overview of Dietary Supplements, U.S. Food & Drug Admin. (Oct. 14, 2009), http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm.

\(^{103}\) “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.” Federal Food, Drug and Cosmetic Act § 306 (codified at 21 U.S.C. § 355(a) (2006)).

\(^{104}\) See INSPECTOR GENERAL REPORT, supra note 5.

\(^{105}\) Cohen, supra note 48, at 182–83.
dietary supplements containing [E]phedra.”106 If the FDA knew that there were potentially harmful side effects to the use of Ephedra, why wait so long? Although the FDA “investigation ha[d] been underway for almost seven years and ephedra-based supplements have long been the subject of criticism, under the limiting standards of DSHEA, the FDA ha[d] not been able to accumulate enough data to issue this ban until [2003].”107 This ban marked “the first time that the standards in the DSHEA, now [over fifteen] years old, have been used to impose major restrictions on the sale of a dietary supplement.”108

While this ban marked a major victory for the FDA, it also further highlighted the need for legislative reform. While the FDA’s concerns about Ephedra were only made public in 1997, it is safe to assume that the Agency did not put the mandatory warning statement on the products on a whim. Therefore, erring on the safe side of estimation, Ephedra-based products were on the market for a minimum of seven years after the FDA first reported concerns over this potentially harmful product.109 In this situation, DSHEA certainly reached its goal of allowing greater access to dietary supplements, whether safe or not. If there was any doubt that the FDA was overburdened and incapable of adequately protecting the public’s health under DSHEA, a seven-year period in which dangerous products were knowingly being sold should be enough of an encouragement for change.110

The next well-publicized product enforcement action came almost immediately after the Ephedra crisis. This time the culprit was

106 Id. at 190; see Amy M. Ling, FDA to Ban Sales of Dietary Supplements Containing Ephedra, 32 J.L. MED. & ETHICS 184 (2004).
107 Id., supra note 106, at 184. Each year before the ban, “[t]welve to seventeen million Americans use[d] [E]phedra each year and last year’s sales of [E]phedra totaled about $1.4 billion.” Id.
108 Id.
109 According to the HHS, Ephedra had caused: “dangerous effects on the heart,” raised blood pressure, and was known to stress the circulatory system; such “effects . . . have been conclusively linked to significant and substantial adverse health effects like heart problems and strokes.” FDA Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra, U.S. DEPT. OF HEALTH & HUM. SERVS. (Dec. 30, 2003), http://archive.hhs.gov/news/press/2003pres/20031230.html
110 As is common with issues related to dietary supplement regulation, not all agree with this point. Reilley Dunne states that even though “ephedra poses serious threats to public health and safety, the FDA and HHS should not embark on a crusade to ban more dietary supplements. . . . The FDA and HHS took appropriate measures to ban ephedra, but the ban should stop there.” Reilley Michelle Dunne, How Much Regulation Can We Swallow? The Ban on Ephedra and How It May Affect Your Access to Dietary Supplements, 31 J. LEGIS. 351, 363 (2005).
Androstenedione ("Andro"),\textsuperscript{111} the ingredient famously used by former baseball star Mark McGwire.\textsuperscript{112} Unfortunately, as was the case with Ephedra, the FDA did not take notice of McGwire’s use of a product that was already banned in other leagues.\textsuperscript{113} After McGwire’s admission, “sales of Andro exploded. Reports say that Andro sales increased 1,000 percent to $50 million in 1999. Supplement companies like SportsOne and MuscleTech couldn’t make enough of the stuff.”\textsuperscript{114} As part of this initiative, the FDA sent twenty-three warning letters to companies “asking them to cease distributing [Andro] and warning them that they could face enforcement actions if they do not take appropriate actions.”\textsuperscript{115} Furthermore, the Anabolic Steroid Control Act of 2004\textsuperscript{116} ("ASCA") “removed most over-the-counter steroid precursors (including androstenedione[]) from the grocery and vitamin stores.”\textsuperscript{117} This oversight by the FDA, like Ephedra, is simply another example of a harmful substance being kept on the market for consumers to purchase.

The FDA is the only agency charged with enforcing provisions of DSHEA. However, the DEA does have some limited influence in these matters.\textsuperscript{118} As stated by Joseph T. Rannazzisi, Deputy

\begin{footnotesize}
\footnotesize{\textsuperscript{111} HHS Launches Crackdown on Products Containing Andro: FDA Warns Manufacturers to Stop Distributing Such Products, DEPT. OF HEALTH & HUM. SERVS. (Mar. 11, 2004), http://www.fda.gov/newsevents/newsroom/pressannouncements/2004/ucm108262.htm [hereinafter HHS Launches Crackdown] ("Androstenedione is produced naturally in humans . . . [and] is considered an anabolic steroid precursor because it can be converted in the body to testosterone. Scientific evidence shows that when [Andro] is taken over time in sufficient quantities, it may increase the risk of serious and life-threatening diseases.").

Subsequent to a reporter’s discovery of the product in McGwire’s locker in 1998, the slugger admitted to having used it for over a year. Darren Rovell, McGwire’s Andro Cover Was Very Profitable, CNBC.COM (Jan 12, 2010), http://www.cnbc.com/id/34822812.

Shayna M. Sigman, Are We All Dopes? A Behavioral Law & Economics Approach to Legal Regulation of Doping in Sports, 19 MARQ. SPORTS L.J. 125, 145 (2008) ("Andro was legal in the United States at the time, and not prohibited by [Major League Baseball]."); Joseph M. Saka, Back to the Game: How Congress Can Help Sports Leagues Shift the Focus from Steroids to Sports, 23 J. CONTEMP. HEALTH L. & POL’Y 341, 350 (2007) (“Although andro was neither illegal nor restricted by the rules of baseball at the time, andro had already been banned by the [NFL], the [NCAA], and the IOC.").

Rovell, supra note 112.

HHS Launches Crackdown, supra note 111.


Jacobs, supra note 3, at 1403.

Body Building Products and Hidden Steroids: Enforcement Barriers: Before the Subcomm. on Crime and Drugs of the S. Comm. on the Judiciary, 111th Cong. 2 (2009)}
\end{footnotesize}
Assistant Administrator of the DEA, there are dietary supplements currently on the market that contain small amounts of the steroids banned under the Anabolic Steroid Control Act of 1990,119 the presence of which “was not listed on the label of specific products and the consumer was not aware that the substance that he or she had purchased from the local nutrition shop contained a controlled anabolic steroid.”120 While the DEA does not have the same sort of clout under DSHEA as the FDA, the Agency is an integral part of the system as it is charged with preventing the consumption of illegal anabolic steroids in dietary supplements. Once the DEA discovers that a supplement contains such a banned substance, they initiate “a scientific review and analysis followed by any appropriate administrative scheduling process.”121 Therefore, two agencies are working concurrently to bring an end to dirty dietary supplements. Yet, problems still abound due to the fact that once again, all of the actions taken by the FDA and DEA must be reactive—waiting for a violation of the public’s health to occur, then taking years attempting to solve it.

Once it identifies a safety concern, the FDA has many options. Advisory actions range from holding a meeting with the company or manufacturer to issuing a warning, consumer alerts, or an advisory to the entire dietary supplement industry.122 On the other hand, if the FDA wishes to take a product off the market, its options range from working together with the company or manufacturer to conduct a product recall, refuse to import the products, pursue legal action, or ban an ingredient altogether.123

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120 Rannazzisi Statement, supra note 118, at 4 (“An analysis of more than 600 dietary supplements revealed that approximately 15% contained anabolic steroids. Two-hundred and forty of these supplements were from the United States with 18.8% containing undeclared anabolic steroids.”). Id.
121 Id. at 5. “Scheduling,” in this context, refers to the process allowing “DEA to administratively classify additional steroids as schedule III anabolic steroids.” Id. at 3.
122 GAO REPORT, supra note 79, at 20.
123 Id.
VI. GOVERNMENT ACCOUNTABILITY OFFICE REPORT OF 2009

A report from the United States Government Accountability Office, entitled Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding (“GAO Report”), described the concerns that exist in the present state of supplement regulation.\(^\text{124}\) Says Senator Dick Durbin:

The problem is that some supplements contain concentrated extracts of herbs and botanicals mixed with other ingredients that can be harmful. Our experience with [E]phedra should convince everyone that the FDA should have the regulatory authority it needs to protect the American consumer. I will continue [to] work with my colleagues in Congress and with the administration to make sure we do everything we can to protect the public health.\(^\text{125}\)

The GAO Report outlines two main concerns: (1) several factors limit the FDA’s ability to identify and act on safety concerns; and (2) the FDA has taken limited steps to educate consumers about dietary supplements.\(^\text{126}\)

A. Failure to Identify and Act on Safety Concerns

The first concern in this area is that the FDA is hindered by a lack of information.\(^\text{127}\) Consumers are supposedly protected by AERS,\(^\text{128}\) but the lack of information that this system provides inhibits the FDA’s efforts to take dangerous supplements off the market or inform consumers of the dangers.\(^\text{129}\) This is exacerbated by the fact that the FDA estimates that there are, in fact, over 50,000 adverse events every year, but only 948 were reported in the first ten months of 2008.\(^\text{130}\) This underreporting certainly does not further the FDA’s efforts to spot products that are causing harmful

\(^{124}\) Id.
\(^{126}\) See GAO REPORT, supra note 79, at 4.
\(^{127}\) Id. at 22.
\(^{128}\) See supra Part III.
\(^{129}\) The “FDA has limited information on the companies and products it is required to regulate, and more complete information could help FDA analyze adverse event reports.” As one solution to this problem, “FDA officials have noted that receiving adverse event reports for moderate and mild events could improve the agency’s ability to assess safety-related signals from adverse event data.” GAO REPORT, supra note 79, at 6.
\(^{130}\) Id. at 15.
side effects. Examples of actions taken by the FDA include monitoring adverse events and consumer complaints, screening imported products, conducting inspections, and monitoring the Internet “to identify products that purport to be dietary supplements but may be fraudulently promoted for treating diseases.”\footnote{Id. at 18. While researching this comment, the author took it upon himself to find substances online available for purchase that contain banned substances. Simply by searching “purchase ephedra,” the author was brought to numerous websites offering the opportunity to purchase Ephedra-based products. \textit{See Diet Pills with Ephedra}, \url{http://www.dietpills-with-ephedra.com} (last visited Nov. 15, 2010). Next, the author performed a search for “purchase androstenedione” and was once again quickly directed to a website where an individual could purchase the banned substance. \textit{See Herbs Proven Universally}, \url{http://www.herbspro.com/shop/productdetail.asp?ptid=65042&utm_source=Googlebase&utm_medium=Feed} (last visited Nov. 15, 2010).}

Along with a lack of data on adverse events, the GAO Report stated that there is a lack of information on: (1) the identity and location of dietary supplement manufacturers; and (2) a general lack of knowledge regarding the products on the market and the ingredients used.\footnote{Id. at 23 (explaining that roughly one percent of funds for the FDA’s Office of Regulatory Affairs are used for dietary supplement programs).} These problems are exacerbated by the fact that the “FDA dedicates relatively few resources to dietary supplement oversight activities.”\footnote{Id. at 25.} Most notably, the GAO Report notes that the FDA lacks the authority to remove dangerous supplements from the market.\footnote{Id. at 25.} The report explains that “recall authority would . . . ensure the prompt and complete removal of unsafe products from distribution channels in cases where a firm was unwilling to cooperate voluntarily.”\footnote{Id.} One cannot help but compare this issue to the Ephedra problem where the product was kept on the market for several years after the adverse effects became known.\footnote{See supra note 108 and accompanying text.}

\textit{B. Failure to Educate Consumers}

Aside from the fact that the FDA is allowing consumers access to harmful supplements, the Agency is doing little to “educate consumers about . . . dietary supplements, and studies and experts indicate that consumer understanding . . . is lacking.”\footnote{GAO REPORT, \textit{supra} note 79, at 7.} The GAO Report states that the problem in this area exists because the FDA’s
limited efforts at consumer education reach an extremely small percentage of the adults that use dietary supplements (roughly half of the U.S. population), and there is little hope that these efforts will expand.\textsuperscript{138}

Further, the GAO Report recognizes that the majority of dietary supplement users do not understand the effects, safety, and labeling of dietary supplements.\textsuperscript{139} Specifically, most individuals are not able to identify the extent of government regulation of supplements, the requirement of warnings on labels, and most consumers believe the “myths” about the safety of supplements.\textsuperscript{140}

\textbf{C. GAO Report Recommendations}

The GAO Report’s recommendations are not entirely surprising, but their simplicity indicates that this need not be a subject that politicians frown upon. First, the FDA should require companies to: (1) “identify themselves as a dietary supplement company . . . and update this information annually”; (2) “provide a list of all dietary supplement products they sell and a copy of the labels and update this information annually”; and (3) “report all adverse events related to dietary supplements [and not just serious events].”\textsuperscript{141} Further, the FDA should “issue guidance to clarify when an ingredient is considered a new dietary ingredient, the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing ingredient identity.”\textsuperscript{142} The Agency should also issue guidance clarifying when a substance should be marketed as a food, and, of course, should increase consumer understanding about supplements.\textsuperscript{143}

The proposed DSSA, introduced by John McCain in 2010,\textsuperscript{144} is similar to the GAO Report’s recommendations in many respects. For instance, DSSA would have required the reporting of all adverse events (not just serious events), the filing of a list of all dietary supplements produced by a manufacturer as well as a list of all ingredients used, and the bill would have also given the FDA the authority to recall harmful products, thereby avoiding other

\textsuperscript{138} \textit{Id.} at 30–32 (explaining that the FDA has done little to improve consumer education in the past ten years).
\textsuperscript{139} \textit{Id.} at 32.
\textsuperscript{140} \textit{Id.} at 32–33.
\textsuperscript{141} \textit{Id.} at 34.
\textsuperscript{142} \textit{Id.} at 34–35.
\textsuperscript{143} \textit{Id.} at 35.
\textsuperscript{144} See supra note 71 and accompanying text.
Ephedra-like situations.\textsuperscript{145} Not only is DSSA similar to the GAO Report’s recommendations, it is also very similar to Canada’s regulatory system that requires the licensing of products, accompanied by identifying information regarding the manufacturer to allow for greater enforcement, the power to recall a product, and the requirement that all adverse events be reported.\textsuperscript{146} Even with such a comprehensive report outlining the significant risks to the nation’s health and welfare, lawmakers seem to defeat any proposal to improve this situation in an effort to appease the supplement industry.

\textbf{VII. THE SOLUTION: LEGISLATIVE REFORM}

Enacting new legislation, especially on an issue as surprisingly contested as this, is admittedly a difficult task. However, regulations passed by the FDA alone will not suffice because DSHEA would expressly forbid any regulations that attempt to restrict the free marketing of dietary supplements. An agency can only use regulations to enforce the legislation passed by Congress; they cannot simply disregard the law and issue regulations that conflict with the legislation:

When a court reviews an agency’s construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter . . . [and] the agency[] must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, . . . the question . . . is whether the agency’s answer is based on a permissible construction of the statute.\textsuperscript{147}

While it would likely be a quicker process to get the FDA to pass new regulations that require pre-market approval of supplements, it is simply an illegal notion. Under the \textit{Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.} standard, the congressional intent in passing DSHEA is clear: the American public should have greater access to dietary supplements and, barring certain circumstances such as when there are “new dietary ingredients,”

\textsuperscript{145} See supra notes 71–76 and accompanying text.
\textsuperscript{146} See supra notes 95–97 and accompanying text.
the supplements do not need to be analyzed or approved prior to marketing. Therefore, legislative reform is necessary to change the entire regulatory scheme and return power to the FDA.

There are critics who argue that the system in place right now—where the FDA does not have to pre-approve dietary supplements—works as enough of a deterrent so that change is not needed. This is the perspective of Richard Kingham, an attorney at Covington & Burling LLP, who testified on this very issue before the Senate Subcommittee on Crime and Drugs. He stated that because “courts are willing to interpret the provisions of the FDCA liberally to protect the public against unlawful products[,] a warning from FDA, backed up with a credible threat to take formal enforcement action, is usually sufficient to achieve compliance.” Mr. Kingham seems to be stuck on the fact that the FDA and DEA can take measures to prevent the problems in the supplement market. Unfortunately, not only does it appear as though these measures are not taken very often, the measures do not seem to be very effective, and it takes too long to remove harmful products from the shelves.

Kingham is not alone on this issue. Also testifying before the Senate Subcommittee, Daniel Fabricant, Ph.D., Interim Executive Director & CEO of Natural Products Association (a producer of dietary supplements), identifies the FDA’s main problem as a lack of funding. Additionally, Mr. Fabricant notes that even when the FDA and DEA do recognize a problem, their method of sending “warning letters”—an effective deterrent in the eyes of Mr.

148 See supra note 49 and accompanying text.
150 Id. at 2; McNamara, supra note 44, at 98 (“Although controversy will surely continue over how pervasively and how aggressively dietary supplements should be regulated by the FDA, it is clear that the agency does possess substantial regulatory authority at present.”).
151 See supra note 109 and accompanying text.
152 Body Building Products and Hidden Steroids: Enforcement Barriers: Before the Subcomm. On Crime and Drugs of the S. Comm. on the Judiciary, 111th Cong. (2009) (statement of Daniel Fabricant, Interim Exec. Dir. & CEO, Natural Prods. Ass’n), available at http://judiciary.senate.gov/pdf/09-09-20%20Fabricant%20Testimony.pdf  [hereinafter Fabricant Statement] (explaining that, for many years, the resources necessary to enforce the applicable laws had been lacking); see also GAO REPORT, supra note 79, at 23 (On the other hand, “FDA dedicates relatively few resources to dietary supplement oversight activities, including conducting inspections and developing guidance for industry on key safety-related aspects of DSHEA.”). This may suggest that the FDA does have the necessary funds, but is simply utilizing them in an inefficient manner.
Kingham—or proposing to list only “three additional compounds” in five years, is insufficient.\(^{153}\) What deters a manufacturer from marketing a supplement illegally and then, upon receiving a warning letter, deciding to take measures to legalize their product?\(^{154}\) While it is true that courts are generally willing to side in favor of the government on this issue,\(^{155}\) the FDA and DEA are not ambitious enough, or perhaps simply lack the resources necessary to pursue these claims.

The next inquiry is why pre-market approval is the answer over other enforcement action or regulatory tools. The answer is that pre-market approval is the only solution to this growing problem. At present, the only way the FDA can assure the public that a dietary supplement is safe is in the rare case when a manufacturer decides to inform the Agency that it contains a new dietary ingredient and it needs to be pre-approved.\(^{156}\) Even in this situation, the manufacturer need only submit a report demonstrating its safety.\(^{157}\) In this safety report, manufacturers are only obligated to show “evidence of safety to the FDA and are not responsible for proving that a new ingredient is indeed safe.”\(^{158}\)

Supplement manufacturers must meet a minimal burden in order to market a new dietary ingredient, which, by definition, is unregulated and untested by the FDA, and therefore has the

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\(^{153}\) Fabricant Statement, supra note 152, at 2 (“[T]he FDA sent 28 warning letters to firms that were illegally marketing products containing steroids. Warning letters are a good start, but how many of those were followed by court action, which is well within the authority of the FDA to pursue? Likewise, to our knowledge, the DEA has only proposed the listing of three additional compounds under the Anabolic Steroid Control Act of 2004—just three compounds in five years. These limited enforcement activities are not an effective deterrent and make it far too easy for criminals to stay one step ahead of the law.”).

\(^{154}\) In 2007, the FDA discovered that an iced tea product contained an herb “that has not been approved as a food additive” due to the possibility of significant health concerns. After a warning letter was sent to the company manufacturing the product, it simply “changed the product label to classify that product as a dietary supplement rather than a food so that it could continue to add [the herb] to its product.” GAO REPORT, supra note 79, at 7.

\(^{155}\) See Hi-Tech Pharm., Inc. v. Crawford, 544 F.3d 1187 (11th Cir. 2008); Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033 (10th Cir. 2006); United States v. Turcotte, 405 F.3d 515 (7th Cir. 2005).

\(^{156}\) Due to the relatively small number of times this has occurred, this does not appear to be an impressive enforcement tool. See supra note 57 and accompanying text.

\(^{157}\) Nowak, supra note 66, at 1075 (“[T]he manufacturer need only submit a report demonstrating a ‘history of use or other evidence of safety establishing that the dietary ingredient when used . . . will reasonably be expected to be safe.’”) (quoting Dietary Supplement Health and Education Act of 1994 § 8 (codified at 21 U.S.C. § 350b(a)(2) (2006)).

\(^{158}\) SHAWN M. TALBOTT, A GUIDE TO UNDERSTANDING DIETARY SUPPLEMENTS 10 (2002) (“As long as it makes the requisite demonstration, the manufacturer is free to market the dietary supplement once the seventy-five day submission period concludes.”). See also Nowak, supra note 66, at 1059.
potential to be dangerous. Enormous benefits would therefore emerge if new legislation was enacted, following the lead of the EU Directive or Canadian NHPR, in which new dietary ingredients must undergo pre-market approval. Following the pre-market approval approach, as opposed to the current state of regulation and enforcement, is likely the most acceptable option for creating a safe dietary supplement market.

Second only to the need to protect the public from potentially harmful dietary supplements, new legislation is necessary to once again instill confidence in this enormous market so that the public will feel safe making a supplement purchase. A 2004 Consumer Reports survey found that “[m]ore than nine out of [ten] consumers want dietary supplements to be proven safe and effective before they are marketed[.]”159 Other studies simply reiterate the contention that Americans desire pre-market approval, and feel unsafe with the notion that for the last sixteen years, there has been little to no regulation over substances that millions of Americans ingest daily.160

In July 2009, the FDA published a Public Health Advisory recommending that “consumers should not use body building products marketed as containing steroids or steroid-like substances.”161 The FDA reasons that the products mentioned in the Advisory “are NOT [sic] dietary supplements because they contain synthetic steroid or steroid-like active ingredients. [Instead,] [t]hese products are unapproved new drugs because they are not generally recognized as safe and effective.”162 The FDA took

159 9 of 10 Consumers Want Dietary Supplements to be Proven Safe Before Put on Store Shelves: National Survey Shows Most Believe Supplements Are Poorly Regulated; CU Testifies at Senate Hearing Tuesday on Weak Supplement Law, CONSUMERSUNION.ORG (June 7, 2004), http://www.consumersunion.org/pub/core_product_safety/001171.html. The report states that “the law governing supplements is so weak, it took 10 years to finally remove Ephedra from the market, despite numerous reports of disabling injuries and deaths. Ephedra is the poster child for failed policy, and Congress needs to act to make sure we don’t repeat this tragedy.” Id.


162 Warning on Body Building Products Marketed as Containing Steroids or Steroid-Like
further action by executing a search warrant for these products.\(^{163}\) However, while this appears to be a significant proactive measure taken by the FDA, before this Advisory, the FDA had not issued a single other warning regarding dietary supplements.\(^{164}\)

For the sake of argument, assume that AERS is a sufficient way to identify safety concerns in the dietary supplement industry. Unfortunately, this system is of no use if the FDA does not have the ability, once it receives such information, to effectively take a product out of the stream of commerce because it lacks the authority to order a mandatory recall.\(^{165}\) This once again highlights the problem with forcing the Agency to “establish adulteration under the significant or unreasonable risk standard.”\(^{166}\) As mentioned above, the passage of DSHEA gave the FDA the difficult task of “balancing its mandate to protect the public’s health, which often requires more restricted access to products, with the spirit of DSHEA, which promotes increased consumer access to dietary supplements.”\(^{167}\)

This power struggle is evidenced by statements made once again before the Senate Subcommittee on September 29, 2009. Michael Levy, the Division Director of the Office of Compliance in the Center for Drug Evaluation and Research at the FDA, describes the arduous process of bringing a violator to justice:

The marketing of unsafe or otherwise violative products as dietary supplements places FDA in a position where it must identify the products and the firms that market them after

\(^{163}\) Id.

\(^{164}\) See id.

\(^{165}\) GAO REPORT, supra note 79, at 6. (“FDA’s ability to ban an unsafe ingredient has proven difficult because the [FDCA] requires that the agency demonstrate a significant or unreasonable risk or that the dietary supplement is otherwise adulterated.”). This goes back, once again, to the unnecessarily high burden on the FDA to prove that a dietary supplement is not safe as opposed to the logical standard that would leave the burden of proof on the manufacturer seeking to sell the product.

\(^{166}\) Id. at 25. This standard led to the ten-year delay between the time Ephedra’s dangers were first noticed and the time it was officially considered a banned substance. The GAO Report points out how other countries have banned products, yet the United States has either taken no action or is in another one of its ten-year battles. For example, the ingredient Aristolochic acid, banned in numerous European nations as well as Japan, Venezuela, and Egypt, is known to potentially cause kidney damage, cancer, or death. Id. at 26. Comparatively, in 2000 and 2001 the FDA “listed aristolochic acid as a ‘Botanical Ingredient of Concern’ and issued letters to industry and health care professionals. In 2001, FDA issued an ‘Import Alert’ for products containing the ingredient and issued a consumer advisory. FDA has also taken some enforcement or advisory actions against individual products.” Id.

\(^{167}\) Cassandra A. Soltis, Between a Rock and a Hard Place: FDA’s Regulation of Dietary Ingredients in Dietary Supplements, 2 J. FOOD L. & POL’Y 11, 11 (2005).
the products have already been introduced into the marketplace. FDA scours online and retail marketplaces in search of illegal supplement products, conducts scientific and legal analyses of the ingredients, discovers the manufacturers’ locations, and, when appropriate, takes action. Because of the complexity of this process, it often takes the Agency many months to complete an investigation and take an action against a violative firm.168

Intuitively, most litigation concerning dietary supplements is a result of post-market analysis. Because the FDA has very little authority in pre-approving a supplement before it goes to market, litigation typically occurs after a supplement is sold to the public. Therefore, the proposal advocated in this comment, which would require pre-approval of a dietary supplement before it is sold to the American public, would reduce the reactive litigation by the FDA. However, since this shifts the burden to the manufacturer to prove the product’s safety, would this not also give them the right to bring suit for a poor ruling by the FDA (in the same manner that the FDA would bring suit if the manufacturer was not in compliance)? What seems promising about this seemingly negative aspect of this comment’s proposal, is that the new legislation could order an administrative hearing to challenge a ruling by the FDA, which would be more cost-effective than bringing a suit in federal court.

A journal article by Cassandra Burke Robertson raised an interesting view on the role of litigation in the world of dietary supplements.169 Robertson states that “[c]ommentators have viewed litigation as a particularly appropriate regulatory mechanism for social problems that Congress has not addressed,” and reiterated that “[l]itigation in the dietary supplement arena is not unknown, and has had some effect on the dietary supplement industry.”170 However, “[u]ntil such time as the industry seeks regulation and reduces the need for lawsuits . . . litigation still presents an important disconnect between risks and incentives.”171 This

170 Id. at 328–29.
171 Id. at 343. Another interesting aspect of this issue is that when “the costs of litigation
appears to conflict with the theory that Congress passed DSHEA with the notion that litigation—even litigation that thus far sided with industry when faced with erroneous claims by the FDA—would be insufficient to combat improper actions by the Agency.

Not only does DSHEA provide inadequate safeguards, it also misinterprets the safety of dietary supplements in general. For instance, “DSHEA assumes that components of foods cannot cause harm, even when ingested in large amounts, and that therefore supplements should be subject only to regulations dealing with foods rather than with the more stringent regulations applied to drugs.”

Professor Peter Cohen gives numerous examples of how common vitamins can lead to potentially harmful consequences, and points out that even at safe dosage levels, a supplement could interact adversely with a drug the consumer is taking, causing serious harm.

As Cohen suggests, the “vast majority of products sold as dietary supplements by this industry are ‘drugs’ in everything but statute in that they have significant physiologic, pharmacologic, and sometimes even pathologic properties.” If this is the case, what is

have become high enough in other industries, sellers have asked for increased regulation as a way of avoiding the high cost of defending lawsuits.” Id. at 342. In the same article, at footnote 190, the author quotes “the executive vice president of a hog-farming company, who said that he ‘would actually prefer more federal regulation rather than letting judges and juries decide complex scientific issues’ that come up in pollution litigation against the company.” Id. at 342, n.190 (quoting Pamela Sherrid, Lawyers on Trial, U.S. NEWS & WORLD REP., Dec. 9, 2001, http://www.usnews.com/usnews/biztech/articles/011217/archive_019880.htm).

172 See supra note 62 and accompanying text.

173 Cohen, supra note 48, at 176–77. Furthermore, “DSHEA also assumes that since herbs and botanicals are ‘natural,’ they warrant regulation only to the same extent as food components, regardless of their pharmacologic, physiologic, or pathologic attributes, and irrespective of whether they are foods at all.” Id. at 177.

174 Id. at 192 (“An intake of vitamin A greatly in excess of requirement results in a toxic syndrome known as hypervitaminosis A or chronic vitamin A poisoning.” (citing H. George Mandel & William P. Weiss, Fat-Soluble Vitamins, in THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 1684 (Lewis S. Goodman & Alfred Gilman eds., 3d ed. 1965))); id. (“[L]arge doses of vitamin D can produce kidney abnormalities and abnormal calcium metabolism.” (citing Mandel & Weiss, supra, at 1684)); id. (High dosages of vitamin E supplements “may increase [cardiac] mortality and should be avoided.” (citing Edgar R. Miller et al., Meta-Analysis: High Dosage Vitamin E Supplementation May Increase All-Cause Mortality, 142 ANN. INT. MED. 1 (2005))); id. at 191 (“The assumption that supplements are just a statutory extension of ordinary foods is easily extrapolated to a belief that vitamins and amino acids—components of food—can be taken in ‘mega doses’ without any ill effects.”).

175 Cohen, supra note 48, at 195–96. For example, “Ginseng, a popular herbal supplement that proponents tout as a tonic for improved energy and vitality, reduces the effect of the anticoagulant medication warfarin.” Id. at 196 (quoting Chun-Su Yuan et al., Brief Communication, American Ginseng Reduces Warfarin’s Effect in Healthy Patients: A Randomized, Controlled Trial, 141 ANN. INT. MED. 23 (2004).

176 Cohen, supra note 48, at 210.
the justification for not subjecting supplements to identical regulations as drugs? Studies have shown that consumers are not able to adequately identify the differences between the intended functions of drugs versus supplements. For instance, “[s]ome consumers will use supplements to treat benign self-limited conditions . . . , while others will use them in an attempt to manage the symptoms of serious and/or chronic illnesses.”

VIII. CONCLUSION

While change is certainly needed, the FDA should be credited for attempting to comply with conflicting decrees: its duty as a federal agency to protect the health of the American people under the FDA’s mission statement, and its obligation to facilitate greater access to dietary supplements for the public in order to lead healthier lives. Even so, effort alone is insufficient when discussing public policy or the need for substantial change in an agency’s regulatory framework. The passage of DSHEA in 1994—with the aid of substantial lobbying from manufacturers—forced the FDA to shift its focus from protecting health to using funds to search the dietary supplement market for dangerous items and attempt to remove those products from shelves. Therefore, this legislation exposed millions of dietary supplement users to potentially harmful substances, all in the name of aiding this industry.

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177 New York State Task Force on Life & the Law, Dietary Supplements: Balancing Consumer Choice & Safety 27 (2005), available at http://www.health.state.ny.us/regulations/task_force/docs/dietary_supplement_safety.pdf; see also Margaret Gilhooley, Deregulation and the Administrative Role: Looking at Dietary Supplements, 62 Mont. L. Rev. 85, 101–02 (2001) (“[C]laims to ‘help maintain cardiovascular function’ or ‘maintain lung function’ are beyond the consumer’s ability to assess and . . . relate to important physical functions.”); Charles A. Morris & Jerry Avorn, Internet Marketing of Herbal Products, 290 JAMA 1505, 1505 (2003) (Consumers “may be misled by vendors’ claims that herbal products can treat, prevent, diagnose, or cure specific diseases, despite regulations prohibiting such statements.”); Khatcheressian, supra note 48, at 638 (DSHEA “allows manufacturers of dietary supplements to hint that a product will help a disease without actually saying so (e.g., ‘lowers cholesterol’ is reasonably understood by consumers to mean that the product treats the illness of high cholesterol.'); Roseann B. Termini, Pharmanex, Inc. v. Shalala: A Wake up Call for Congress and a Not So Bitter Pill for the FDA, 26 Ohio N.U. L. Rev. 269, 270 n.9 (2000) (DSHEA “created a chaotic and possibly hazardous marketplace built on the assumption that people do not take supplements to prevent or treat diseases; however, that is exactly what consumers do.” (citing Richard Harris, Dietary Supplements and Regulations Pertaining to Them (Nat’l Pub. Radio Mar. 26, 1999))).

178 See supra note 1.

179 See supra note 43 and accompanying text.

180 See supranotes 106–09 and accompanying text (discussing the Ephedra crisis).

181 It does not seem unfair to point out that Senator Orrin Hatch, the man who so
Congress must look at this issue as a rudimentary balancing test. They must weigh the benefits of repealing DSHEA—thereby ensuring the safety of supplements—with the limited benefit that comes with the current regulation, namely unencumbered access to dietary supplements. It is difficult to dispute the notion that DSHEA achieved its goals, but it must be determined whether the public is willing to accept those goals. The response to this inquiry must be an emphatic “no”. The safety of the American public cannot be sacrificed in order to appease certain manufacturers under the guise of allowing greater access to health products.

Under the scheme proposed by this comment, Americans would retain access to dietary supplements, but would simply have to wait for these products to be approved. As discussed above, it is unlikely that legislation requiring pre-approval of all products would pass, even though it is the best available option. Therefore, the best course of action would be to adopt some of the principles set forth in the EU’s Food Supplements Directive, in which only products containing a specific list of substances can be marketed, or Canada’s Natural Health Products Regulations, under which a license must be issued for every product to be sold. Another Ephedra-like crisis should not be tolerated. Legislation must pass in order to protect consumers from potentially hazardous side effects, reduce supplement-related litigation, and instill confidence in the dietary supplements industry once again. There are more important issues facing a nation than aiding the financial wellbeing of supplement manufacturers through the current less stringent regulations. Deferring to President Franklin Roosevelt, who even at a time of war recognized this important fact: “The total defense adamantly fought for DSHEA and convinced John McCain to remove support for the DSSA, see supra note 77, had a significant stake in the dietary supplement industry. David G. Yosifon, The Consumer Interest in Corporate Law, 43 U.C. DAVIS L. REV. 253, 278 n.110 (2009) (“Senator Orrin Hatch . . . who has received hundreds of thousands of dollars in political support from the supplements companies, championed the DSHEA in a willing, free-market Congress.”); Ryan Connolly, Balancing the Justices in Anti-Doping Law: The Need to Ensure Fair Athletic Competition Through Effective Anti-Doping Programs vs. The Protection of Rights of Accused Athletes, 5 VA. SPORTS & ENT. L.J. 161, 171 (2006) (“Senator Hatch receives significant campaign contributions from supplement manufacturers,” many of which are in his home state of Utah.); Adam Benforado et al., Broken Scales: Obesity and Justice in America, 53 EMORY L.J. 1645, 1789 n.519 (2004) (Senator Hatch’s son earned millions of dollars from supplement lobbying firms); Crossman, supra note 27, at 640 n.179 (it is not a surprising revelation “that there are several large manufacturers of dietary supplements currently residing in the state of Utah”).

See supra notes 71–78 and accompanying text.

See supra notes 87–92.

See supra notes 95–101.
which this nation seeks involves a great deal more than building airplanes, ships, guns and bombs. We cannot be a strong nation unless we are a healthy nation.”