Dietary Supplement and Health Education Act 1994:

This is No Fairy Story and No Joke

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I. Introduction:

"This is no fairy story and no joke," (Sinclair, 1906, pg. 131). There was a time in American history, when poisoned rats were ground up with breakfast sausage and the miracles of chemistry masked the stench of spoiled meat. Sly-tongued salesmen were able to bamboozle unsuspecting consumers into buying dangerous products. This story was *The Jungle*. Upton Sinclair's novel illuminated the horrors of the meatpacking industry in the United States at the turn of the twentieth century, as part of the broader discussions about consumer protection from unscrupulous manufacturing practices and claims. Shortly after the release of his novel, the passage of the Pure Food and Drug Act of 1906 marked the beginning of the Food and Drug Administration (FDA) and the regulation of two major industries in the name of consumer safety (Patel and Rushefsky, 2005, pg. 233).

The powers and responsibilities of the FDA progressed alongside the twentieth century. Eventually, the FDA began regulating, "everything from the most common food ingredients to the complex medical and surgical devices, lifesaving drugs, and radiation emitting consumer and medical products," (Patel, 2005, pg. 31). By 1990, the regulation of food labeling was the primary legislative pursuit pertaining to consumer protection on Congress's agenda. Although the proper labeling of food may seem straightforward, the experience proved otherwise. Vested interests in the dietary supplement industry, politicians, and consumers, who were resolute in their adherence to homeopathic tradition, cried foul. They believed that dietary supplements were not food, nor were they drugs. Rather, they were part of a long-standing practice of herbal remedy, a category that ought to be exempt from expensive testing and restrictive regulation (Hilts, 2003, pg. 283).

The lobbying efforts to exempt dietary supplements from regulation was swift and powerful, ultimately leading to the Dietary Supplement and Health Education Act of 1994 (DSHEA). In brief, under DSHEA companies do not need to go under FDA review of their product before marketing their supplements. Even more, the advertised claims about the benefits of supplements are not tested or verified by the federal government. The power of the FDA to regulate dietary supplements is reactive because it relies on post-market observation and action.

For nearly its entire existence, the FDA has been tasked through legislative acts to protect the interests and health of consumers. Many question whether DSHEA has followed the tradition of robust consumer protection and has been an effective policy in protecting the interests of the American people. Testing that very question, this research indicates that DSHEA has not sufficiently protected consumers. As evidence will show, DSHEA is a failed policy, which does very little to protect consumers. It was an act driven by the desire to prevent sound regulatory measures meant to protect consumers, from being implemented, in the name of maintaining an unregulated billion-dollar market. Based on two high profile case studies of the FDA's response to dangerous supplements under DSHEA and an analysis of federal databases, it is clear that the Dietary Supplement and Health Education Act of 1994 betrays the spirit of consumer protectionism, which is engrained in the legislative history of the United States. Returning to Upton Sinclair, the story about to be told is "no fairy story and no joke." It is a story desperately in need of rewriting.

II. The Legislative Story:

To fully comprehend the passage and effectiveness of the Dietary Supplement and Health Education Act of 1994, one must first understand the development of the FDA's institutional

responsibilities through previous legislative acts. These legislative acts are manifestations of the American desire for consumer protection.

Pure Food and Drug Act 1906

When revelations of horrid food and drug manufacturing practices came to light in the early-1900s, like those vividly described in *The Jungle*, Congress was compelled to act in order to alleviate the disgust and safety concerns of the nation. The Pure Food and Drug Act of 1906, "established federal penalties for adulterating or misbranding medicines [and food]" (Carpenter, 2010, pg. 75). This act placed the powers of regulating manufacturing practices into the hands of the U.S. Department of Agriculture Bureau of Chemistry, which eventually evolved into the FDA.

Over the course of the 20 years following the implementation of the Pure Food and Drug Act, policy makers and bureaucrats slowly began to realize that the act might not be doing enough to protect consumers. The chief problem was that there was no strong mechanism of authority to enforce purity standards by being able to permanently recall adulterated products and shutdown companies in violation of the law (Carpenter, 2010, pg. 76). Nonetheless, this was the first of many acts to come, which held the protection of American consumers as a top priority.

Food, Drug, and Cosmetic Act of 1938

Until 1937, there was no concrete evidence that indicated the 1906 Pure Food and Drug act needed to be updated, just hypothesizing by those working in the FDA. However, "the FDA began to hear reports of several deaths in Tulsa, Oklahoma, associated with a proprietary drug called 'Elixir Sulfanilamide,'" (2010, pg. 85). Ultimately, nearly 100 people died from illness associated with consumption of this early pharmaceutical. Yet, at the end of the tragic events, the

FDA concluded, “Technically nothing in the elixir sulfanilamide disaster implied that the company had broken a single law,” under the 1906 standards (2010, pg. 92). Understandably, this focusing event pressured Congress to update the 1906 law to ensure that there would be no repeat event of the sulfanilamide tragedy.

In 1938, Congress passed the Food, Drug, and Cosmetic Act (FDCA), which brought sweeping reforms to the regulatory power of the FDA. For the first time in American history, the FDA was given authority, “to reject the ex ante marketability of any new pharmaceutical product,” (Carpenter, pg. 73). In other words, the FDA was given the power to review and test drug claims *before* they reached the consumer, to ensure safety and quality. Even more, the measure, “corrected abuses in food packaging and quality, and it mandated legally enforceable food standards,” (Food and Drug Administration, 2017, part II). This regulation of safe manufacturing standards carried into cosmetics as well. Ultimately, the Food, Drug, and Cosmetic Act of 1938 gave teeth to the FDA as a regulatory agency and transformed the agency into an effective champion of American consumer health.

The Development of the Dietary Supplement Gray Zone

As the twentieth century entered its latter half, amendments to the Food, Drug, and Cosmetic Act of 1938 would shape the very foundation of the dietary supplement industry and eventually the Dietary Supplement and Health Education Act of 1994.

Under the FDCA, ingestible products fell into two categories: drugs and food. “Yet, an important and popular set of commodities existed and profited in the legal and conceptual space between drugs and foods,” (Carpenter, 2010, pg. 387). These were dietary supplements. As Carpenter highlights, “‘new drugs’ [which] encompassed a vast array of compounds, implements, and synthesized substances” were heavily regulated by the FDCA (2010, pg. 387).

However, dietary supplements did not fall into this category because they were natural, herbal, ingredients more akin to food.

In the 1950's, the government began enacting tighter control over the food industry, which at the time included dietary supplements. In 1954 they regulated pesticides, in 1958 food additives, and in 1960 color additives (FDA, 2017a). The purpose of these amendments was to give the FDA power to pre-approve ingredients used in the above categories to ensure tighter food standards to protect consumers. However, "dietary supplements were usually not considered food additives because they fell under the category of 'generally recognized as safe'" (Carpenter, 387). Effectively, as court rulings did not classify supplements as additives, they were considered fundamentally food and not subject to FDA regulation or pre-market approval.

Then comes the question, are dietary supplements actually food? The court classifications emerging from the 1960's said yes, however, the spirit of the industry tells a different story. Dietary supplements were, "purported to be natural while they also offered promises of 'health,' carefully avoiding claims about activity against a particular disease," (Carpenter, 2010, pg. 387). In other words, the purpose of the supplement was not to be consumed just for sustenance, rather it was to provide pseudo-medical benefits similar to drugs, but not actually meant to treat specific diseases like drugs, thus creating the gray area. That is to say, supplements are not drugs and functionally not food either.

FDA Attempts Dietary Regulation – 1970's

For the next 30 years, FDA officials would grapple with the contradiction of the dietary supplement gray area. In 1973, the FDA, "imposed minimum and maximum standards for the contents of vitamin and mineral products, where the upper and lower bounds were tied to the National Academy of Science' recommended daily allowance criteria," which was an

administrative attempt to regulate dietary supplements (Carpenter, pg. 389). As this paper will later explore further, attempting to regulate the supplement industry is a painful and often unsuccessful process. Public pressure and lobbying efforts lead Congress to roll back the regulatory measures through a Congressional mandate in 1976, effectively ending regulatory authority over supplements (FDA, 2017a). This tension in America over dietary supplements, manifested by the events in the 70's, effectively set the stage for a showdown in the 90's, concluding with the passage of DSHEA.

Passing DSHEA: Business or Public Health?

After decades of lying low in the gray zone, dietary supplements again became the focus of debate. Congress passed the Nutrition Labeling and Education Act of 1990, which was a policy directed toward making "it easier for the consumer to compare products by standardizing nutritional terms, serving sizes and other wording" (Margulis, 1991). This policy was not only a question about labeling, but accuracy and accountability. Food was also to be subject to, "a general standard that required testing for any claims made on labels," (Hilts, 2003, pg. 282). All things considered, the food labeling measure considered and ratified by Congress in 1990, significantly expanded the powers of the FDA and was geared toward consumer protection and manufacturer accountability.

Again, since dietary supplements were legally considered food, they would be subject to this testing regulation. General health claims are still the lifeblood of the dietary supplement industry today, and this new 1990 food policy endangered the industry's ability to make broad sweeping health claims at that time. For example, claiming that a supplement can "encourage hair growth" or "promote sexual arousal and performance" would need to be verified (FDA, 2017b).

The fear of becoming over-regulated by an expanded FDA, spurred to life massive lobbying effort by politicians, citizens, and industry leaders to exempt dietary supplements from the 1990 food-labeling act. Senator Orrin Hatch (R-Utah), an ardent supporter of the supplement industry, claimed, "there was $700 million worth of supplement companies," in his district alone and the expanded powers of the FDA would put those companies at risk (Hilts, 2003, pg. 284). The fear was rooted in the notion that the FDA would start eventually evaluating supplements like drugs, due to the claim-testing requirement of the food-labeling act, and remove them from the market. This, in turn, would take away the option for consumers to resort to homeopathic medicine and the ability to take their health into their own hands.

A new lobbying group latched on to the fear of supplement removal by the FDA. The Nutritional Health Alliance, began a massive marketing campaign accusing the FDA of intending to use "police powers," to "put health food stores under threat of siege" (Hilts, 2003 pg. 285). At that time, however, there was nothing tangible to justify those fears.

Not until May 1992. "Armed agents of the United States Food and Drug Administration burst into [a] Tahoma Clinic, where practitioners of alternative medicine used injections of vitamins, minerals and amino acids to treat a variety of ailments" (Williams, 1992). To the public, it appeared as though the FDA was aggressively going after vitamins and supplements.

Eventually, thousands of citizens wrote to Congress and a political fervor enveloped the nation. To best illustrate the vehement atmosphere surrounding dietary supplements and the FDA, "a sixty-second commercial featuring actor Mel Gibson, showing a SWAT team with guns drawn raiding his house to get his vitamin C in the bathroom cabinet," was released (Hilts, 2003,

pg. 288). For the first time in its existence, many Americans perceived the Food and Drug Administration as a public enemy of choice instead of a public champion of health.

The true nature of the FDA under the food-labeling act, however, was less dramatic and malicious. The intention of the FDA was to ensure the quality and accuracy of the claims made by supplements. For example, testing around the time of the food-labeling act revealed that the supplement St. John's-wort had dangerous side-effects, and counter to the label claim, did nothing to help depression (Hilts, 2003, pg. 284). The founding spirit of the FDA was to protect consumers, and testing health claims aligns with that spirit to ensure dangerous products are kept away from consumers and the public is given accurate information.

Nonetheless, public pressure fueled by supporters of the supplement industry forced Congress to act. The feud between the FDA and dietary supplement industry, public health and business interests, ultimately ended with the passage of the Dietary Supplement and Health Education Act of 1994. This research will make clear the winners of DSHEA by analyzing its policy feedback. Policy feedback is the story of who benefits from DSHEA and the relationship between the policy and public health. Has experience proven that businesses, consumers, or both have benefited from DSHEA? Has the government protected or neglected the health of the American people under DSHEA guidelines? This story of policy feedback is told by analyzing new interest groups, case studies, and the extensive public health datasets provided by the federal government.

III. Dietary Supplement and Health Education Act: Summary

The Dietary Supplement and Health Education Act passed in 1994, as a result of the heated battle between the FDA and dietary supplement industry, not only created new definitions

for dietary supplements, but also demarcated FDA and manufacturer regulatory responsibilities, which were different from those of food or drugs.

Dietary Supplements: Not a Drug, Not a Food, A Food Substance

As has been noted, prior to DSHEA, supplements existed in the dietary gray zone between food and drugs without a true classification or definition as to what a supplement was. So, what are dietary supplements? According to the new regulations, supplements are:

> "Vitamins, minerals, herbs or other botanicals; amino acids; 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 of these ingredients." (Israelsen, 1995)

Broadly speaking, these specific ingredients fall under the name "Food Substances." What is not a supplement? According to the act, any substance that used to be sold as a drug cannot be sold as a supplement (1995). Moreover, any substance used in clinical trials seeking approval to become a drug, cannot be classified as a supplement. These are the parameters the FDA works with to identify supplements under DSHEA.

Self-Reported Ingredients: Old v. New

Before selling a dietary supplement, companies must follow certain procedures depending on the ingredients in their product. If all of the ingredients in the supplement were marketed any time before October 15, 1994, the product can be sold immediately (Israelsen, 1995). If the product contains an ingredient never before sold, but the ingredient "has been in the food supply as a food in a form in which the food has not been chemically altered," the product can be sold immediately (1995). However, if an ingredient has never been in the food supply and has been chemically altered, the manufacturer must notify the Health and Human Services

Secretary (the FDA is subordinate to the Department of Health and Human Services) and wait for 75-days before selling their product. As part of the notification, research must be provided indicating the safety of the ingredient. After the initial waiting period, a 90-day period of confidentiality begins before the information is released to the public (1995).

As can be easily seen, the entire process of reporting ingredients to the federal government is entirely self-regulated. It is incumbent on the manufacturers to provide accurate and honest information.

Safe Manufacturing Standards: Self-Regulation

Under the authority of the Health and Human Services Secretary, the FDA can establish safe manufacturing practices and guidelines for companies to follow (Israelson, 1995). Similar to ingredient reporting, it is the responsibility of manufacturers to self-regulate. If at anytime, evidence is submitted to the FDA that a manufacturer is not following safe manufacturing procedures, the FDA will classify the dietary supplement as "adulterated" (1995). Adulterated products are subject to removal from the market, following procedures outlined in DSHEA, which will soon be touched upon.

Labeling Products: Don't Be Too Specific

As had been the case under old FDA regulations, dietary supplements cannot claim to treat specific diseases. Rather, they can only make broad claims about health benefits. A simple example that follows the guidelines provided by the FDA: a supplement can say, "Calcium pills encourage healthy bone structure," it cannot say, "Calcium pills reverse bone deterioration" (FDA, 2017b). Furthermore, the package of the supplement must include specifications of the products, like ingredients and nutritional measures similar to food. The FDA reviews the labeling, along with the other self-reported materials submitted to the FDA. Finally, the package

must have the statement, “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" (2017b).

The Responsibilities of the FDA?

The responsibilities of the FDA under DSHEA generally fall into post-market review of dietary supplements. The agency maintains a database of complaints and reports regarding potentially dangerous supplements, now known as the CAERS Adverse Event Reporting System, which will be critical to later analysis in this paper. After further investigation, if the FDA believes that a supplement is adulterated or dangerous, the FDA must build a case and present evidence to a U.S. attorney to open a civil lawsuit (Hilts, 2003, pg. 288). If the courts agree with the findings of the FDA, only a court order can remove the product from the shelves.

However, there is a built-in provision for emergencies, like the previously mentioned case of Elixir Sulfanilamide. “The Secretary of Health and Human Services may declare a dietary supplement to pose an imminent hazard to public health or safety and suspend sale of the product” (Israelsen, 1995). Altogether, the ability of the FDA to regulate dietary supplements is very much a reactionary process, which requires meeting burdens of proof over the course of a lengthy administrative process.

In summation, DSHEA is a policy driven via self-regulation by manufacturers of dietary supplements. The duty of the FDA is to assemble evidence, analyze reports from harmed parties, and undergo extensive investigation to root out dangerous ingredients and products. This is entirely dissimilar to the FDA’s regulatory measures of both drugs and food, which both undergo measures of pre-market approval (Carpenter, 2010, pg. 388).

IV. Post-DSHEA Policy History and Feedback

The passage and structure of the Dietary Supplement and Health Education Act of 1994 had far reaching consequences. Stakeholders concerned about public health became entrenched in opposing views about the consequences of the act and supplements in general. An expanded supplement industry, physician groups, users, non-users, and sub-groups within those categories viewed DSHEA with split opinions. The viewpoints of supplements by everyday Americans would shift. Finally, decades after its passage, the policy is still being reviewed for its successes and failures.

Polarization of Stakeholders

After the passage of DSHEA, the dietary supplement industry significantly expanded. According to David Carpenter, the size of the dietary supplement industry in the United States is now the largest and least regulated in the world (2010, pg. 390). It seems that every city and every shopping mall has some sort of health-food store that sells all manners of dietary supplements.

With an expanded market, comes expanded power. In his article, Dr. Stephen Pray highlights that, "Pandora's Box is open, and those supporting unproven therapies and medications have sufficient funds to mount advertising campaigns that will surely defeat any attempt to halt their sales" (Pray, 2012, pg. 562). In short, as a result of DSHEA, the dietary supplement industry has become a more powerful and entrenched stakeholder than ever before.

On the contrary, Dr. Pray's comment is indicative of the consternation within another group of stakeholders: physicians. Their outspoken concern is, "people grasp at straws who instead should seek help from trained physicians instead of [placing] misguided faith in websites promising [herbal] relief from serious medical conditions," (Pray, 2012, pg. 562). For physicians,

dietary supplements, more often than not, have no scientific backing indicating the benefits of use.

Even more concerning for physicians is dietary supplement use can impede medical treatment. It is has been found that patients often do not report supplement use to physicians and communication about supplement use in the medical professional is limited (Rawson, 2005). As a result, potentially dangerous interactions with prescribed medications can occur because of the lack of communication and information about supplement use by patients.

Overall, many physicians have become stakeholders who believe DSHEA has had negative effects. The biggest concern is the lack of scientific evidence backing the claims of many dietary supplements, even though many patients still seek "quackery medicine" that has little to no actual medical benefits (Pray, 2012, pg. 561).

The users of dietary supplements, however, tend to disagree with physicians. A simple search on Google about the benefits of dietary supplements yields millions of articles, blogs, and discussion forums advocating the benefits of supplement use. Some users' beliefs are supported in research, while others' claims are refuted.

For example, a study conducted on the benefits of supplement use during pregnancy, an important subgroup of users, indicates that supplements can be critical factors in helping women meet their elevated nutritional needs during and after pregnancy (Gomez et al., 2015, pg. 507). Even more, a study conducted found the use of the supplement folic acid, can play a role in reducing the risk of autism in children (Wang et al., 2017, pg. 3). Overall, there are studies that reinforce the claims of many users and highlight the benefits of supplement use.

However, other studies indicate that claims made by subgroups are entirely wrong. Many claim that daily supplement use can lead to a longer and fuller life. However, according to a

study released in the *American Journal of Public Health*, there is no evidence to support the claim that vitamin and mineral supplements increase the length of a person's life (Kim et al., 1993, pg. 550). Furthermore, many in the athletic community encourage regular use of supplements to bolster athletic performance. However, a study published in the *Journal of Sports Sciences*, cautioned against "indiscriminate use of supplements" to bolster performance (Maughan, Depiesse, and Geyer, 2007, pg. 550). Rather, supplements ought to be used based on careful consideration of individual health profiles because people respond differently to supplements and exhibit different dietary needs. Ultimately, athletes can be put at risk of over-dosing on supplements if they do not carefully consider their own dietary profile.

As a result of the passage of DSHEA, a grey cloud of uncertainty seems to have been cast over the benefits and risks of supplement use. Some supplements have studies that reinforce claimed benefits; yet, other studies exemplify the risks of certain dietary supplements. As the concerns of physicians have highlighted, some studies have no research at all. In the end, it is up to consumers to perform their due diligence by researching on their own in order to weed through the claims of a diverse group of stakeholders.

America's Views on Dietary Supplements Post-DSHEA

The United States has a unique relationship with homeopathic and herbal medicine. When discussing the passage of DSHEA, Senator Hatch argued supplements "have been safely used for centuries," (Hilts, 2010, pg. 284). As will become clear, Senator Hatch's statement is indicative of a larger American perception that supplements are rooted in a tradition of an extensive and proven history.

A study published by the American Medical Association in 2001, found that approximately 48% of surveyed Americans used some type of dietary supplement (Blendon et

al., 2001, pg. 806). Of those regular users, over 85% indicated that supplements were beneficial to long-term health, while only 48% of non-users believed the same (2001, pg. 807). In terms of regulation under DSHEA, only 37% of all surveyed Americans believed that supplements are adequately tested to verify safety and claims, which translated into over 80% of surveyed Americans believing that the FDA should be given more power to further regulate supplements in some way (2001, pg. 809). In terms of supplement safety, 47% of the respondents believed that supplements are sometimes harmful, while 44% believed that supplements are rarely or never harmful.

Of the many findings of the 2001 study, the most compelling is the notion that most Americans, users and non-users alike, seem to believe that supplements ought to be further regulated and tested by the FDA and those who use supplements genuinely believe in their profound effectiveness on overall health and wellbeing.

A similar study was conducted ten years later in the *Journal of Health and Communication* in 2011. When testing the knowledge about how the government regulates supplements, the study found "people lack knowledge regarding most aspects of the DSHEA despite that it has been in place for more than 15 years" (Dodge, Litt, and Kaufman, 2011, pg. 241). This was concerning because their study found that about 70% of respondents used dietary supplements within a year (2011, pg. 239). Even more importantly, the study indicates that increased knowledge about DSHEA, led to more skeptical beliefs about the effectiveness and safety of dietary supplements (2011, pg. 242).

When combining the findings of both the 2001 and 2011 study, it becomes clear that a significant portion of Americans take supplements and the number has grown over the course of a decade. These American's are convinced of their efficacy in improving the health. However,

there is prevailing belief that the federal government is not doing enough to ensure safety standards. Yet, if a person is more knowledgeable about the current policies regulating supplements, there appears to be an increased skepticism about the dietary supplement industry, especially the benefits and safety of using supplements.

Has the Dietary Supplement and Health Act of 1994 Been Viewed as a Success?

The development of new stakeholders, a cloud of uncertainty over the risks/benefits of supplements, and the views of the people indicating the FDA does not do enough to regulate supplements all beg the question: has the Dietary Supplement and Health Education Act been a success or failure? To begin framing an answer, one must look toward how other scholars view DSHEA.

In an Albany Law Review article entitled, "S.O.S. From the FDA: A Cry for Help in the World of Unregulated Dietary Supplements," the author takes a very critical role of DSHEA. "[The] legislation exposed millions of dietary supplement users to potentially harmful substances, all in the name of aiding [the supplement] industry" (Dier, 2011, pg. 417). The school of thought manifested by this article is that DSHEA reneges on the promises of protecting consumers by impeding the FDA's ability to keep them safe. The FDA is forced to be reactionary, rather than proactive, under the legislative guidelines, and people must be hurt before anything can be done (2011, pg. 403).

Another criticism, published in *The Journal of Nutrition*, highlights under the current standards, the FDA is slow in responding to crisis. "For example, it took years for the FDA to assemble scientific data to first prove harm and then effectively remove both ephedra and DMAA from the market (Wallace, 2015, pg. 1684). Again, this is attributed to the post-market

process established by DSHEA, which is entirely unique to dietary supplements. These are case studies that will be further analyzed in this paper.

As has been said, but worth repeating, some believe DSHEA does not do enough to prevent unfounded claims, rather, it enables quackery. “We need laws to force all pseudo-medical healers (eg, naturopaths, herbalists, acupuncturists, iridologists, reflexologists, and shamans) to submit their treatments to the light of science, or to fold up their house of cards and head home” (Pray, 2012, pg. 562). This returns to the issue of labeling restrictions, or the lack thereof. Courts have ruled that labels are protected under the First Amendment, and the FDA must prove that disclaimers would not be enough to rectify a misleading label, which is a high standard to meet (Wallace, 2015, pg. 1685). Essentially, labels can claim pretty much anything, with very little evidence to support their claims. For all of these reasons, many people believe that DSHEA is a failed law that must be replaced.

This is not the only position to take. Others believe that DSHEA is a reasonably effective law that does what it needs to do to protect consumers, whilst protecting consumer choice. They say the notion that the industry is unregulated is a myth because, “The FDA and the Federal Trade Commission (FTC) cooperate under a long-standing agreement governing the division of responsibilities between the two agencies,” (Wollschalger, 2003, pg. 389). In short, the two agencies work hand in hand to keep consumers safe. It is the FDA’s job to take harmful products off of the shelves, which it appears to have proven as being capable of doing. The FDA has issued warnings and recalls for about 1% of the dietary supplement sales from 2001 to 2010, which is in line with other industries like food, drug, and medical devices (Soller, Bayne, and Shaheen, 2012).

The Federal Trade Commission (FTC) deals with misrepresented labeling and claims. The FTC has filed more than 80 law enforcement actions over the past decade [1993-2003] challenging false or un-substantiated claims about the efficacy or safety of a wide variety of supplements (Wollschlaeger, 2003, pg. 389) In other words, it is the purview of the FTC to apply regulations to all products sold in the United States to ensure proper marketing and advertising standards, not the FDA.

Finally, the FDA collaborates with other government agencies like the DEA, CDC, and Customs and Border Protection, as well as non-government research institutions, to assist with data collection and evidence gathering to identify harmful supplements in the $27 billion supplement industry (Soller, Bayne, and Shaheen, 2012). Ultimately, those who view DSHEA as a sufficient policy measure believe the complex web of federal agencies is enough to prevent tragic disasters and root out the minority of manufactures who engage in unsafe practices.

V. Research Design

Armed with the extensive history of the Dietary Health and Supplement Education Act of 1994, we return to the question: has the act been a success or failure? The first task of this research is to define what constitutes a policy success and what constitutes a policy failure. Remembering the policy history of the FDA through the 1906 Pure Food and Drug Act, the 1938 Food Drug and Cosmetic Act, the 1990 Nutrition Labeling and Education Act, and the subsequent amendments leading up to DSHEA, the spirit of the FDA's legislative history is one of consumer protection from unsafe food and drug products. When evaluating DSHEA, the spirit of the FDA's legislative history is critical when shaping the broad research question of this study: Does the Dietary Supplement and Health Education Act of 1994 sufficiently protect consumers?

Based on the DSHEA framework, the concerns of new stakeholders, surveys of the American people, and arguments for and against the act's success, the driving theory of this research is that DSHEA woefully undermines the ability of the FDA to protect American consumers because it forces the FDA to rely on slow and cumbersome post-market monitoring practices, while manufacturers are allowed free reign through self-regulation, which is against the very spirit of consumer protection identified throughout legislative history. To test this claim, a historical case study of the FDA's response of two major cases and an analysis of various dietary supplement databases will be undertaken to gather a full picture of the FDA's ability to protect consumers.

Case Study Selection

The cases selected for this study are the Ephedra poisonings and dimethylamylamine (DMAA) poisonings. Both of these cases were high profile events for the FDA that tested their ability to respond to tainted supplements. No other comparable cases exist where dietary supplements have presented a visible and well-known danger to the American consumer, requiring an urgent and effective response from the FDA, as the Ephedra and DMAA poisonings. Analyzing how the FDA gathered information, responded, and the final outcomes tell the story of how effective the agency is operating under DSHEA guidelines. When reviewing these case studies, particular attention will be paid to how long it took for the FDA to implement a mandate that took the products off of the shelves and how many people were injured by the tainted products.

Data collection:

There are three databases that this study uses to gauge the ability of the FDA to protect consumers: the CAERS Adverse Event Reports database, the supplemental label database, and the tainted products database. All of these databases are managed by the FDA and its affiliates.

The CAERS database contains information on every adverse events reported to the FDA since 2004. Adverse events are medical incidents that lead to outcomes such as hospitalizations, serious injury, disabilities, and death (CAERS, 2017). These events are self-reported, reported by healthcare providers, and/or manufacturers. It is important to note, that this database includes products that are merely suspected to have been a cause of a medical emergency, however, there is no way to verify the relationship with 100% certainty.

The dietary supplement database contains every new supplement marketed by manufacturers, since 2011 (Office of Dietary Supplements (ODS) and National Library of Medicine (NLM), 2017). The name of the manufacturer, ingredients list, and the current market status are relevant sets of information provided by this database.

The tainted product database (CDER) is another database managed by the FDA. This dataset identifies all products where the agency has identified enough evidence to classify the product as adulterated because of hidden ingredients in the supplement not reported on the label (FDA, 2017c). This list goes back to 2007. It lists the product name, manufacturer, hidden ingredients, and product categories. An important disclaimer by the FDA about the database indicates it only contains a "small fraction of the potentially hazardous products with hidden ingredients marketed to consumers on the internet and in retail establishments" (FDA, 2017c). This is because, again, the FDA is not able to test every product on the market for hidden ingredients.

Data Analysis Design:

This research created summary tables to identify trends and patterns within each of the three datasets. For the CAERS database, two tables were compiled. The first table is a year-by-year summary of the number and type of adverse events attributed to dietary supplements for a 10-year period between 2006 -2016. Note, there are instances in the database where one person reported multiple products as part of their report, causing duplicate reports within the dataset for a single individual. These duplicates where removed, in order to get an accurate measure of the number of people experiencing an adverse reaction, instead of the number of drugs suspected to be the cause. The expectation is that this summary would allow inferences to be made about the number of adverse events being reported each year. If a negative pattern occurs, it could be said that the FDA is effectively dealing with dangerous products. If a positive pattern occurs, the FDA may not be effectively regulating the supplement industry.

The second data table for the CAERS database is a categorical summary that identifies which categories in the dataset have the most adverse events. Again, foodstuffs and cosmetics are included along with dietary supplements. This study expects that food will have a higher percentage of reported adverse events because more people ingest everyday food products than they do supplements. Furthermore, there are significantly more food products than dietary supplements.

The supplemental label database was used to also create a yearly snapshot of how many dietary supplements are released in a given year. This can be compared to the yearly summary generated by the adverse events to see if there is a relationship. Furthermore, the supplemental label database was divided into two categories: on market and off market, which shows how many products released in a given year are still on the market today. Please note, products are

removed for various reasons, such as the manufacture pulling the product due to a lack of sales or it could be FDA encouraged removal. There is no way to differentiate this distinction using the given data. This is a way to gauge just how fast the market expands. If more products are taken off the market than left on, the market is shrinking. If less products are removed, then the market and industry is expanding. If it is relatively equal, this may be an indicate a fairly stable market.

Finally, similar to the adverse reports database, the tainted supplement database was summarized into a yearly snapshot and category type. This indicates how many products a year are pulled from the shelf, but more importantly what sector of the supplement industry is the biggest culprit of producing dangerous products. It is expected that everyday vitamins will not be a culprit, rather, the complex mixes found in weight loss pills and sports vitamins, like those containing ephedra and DMMA, are likely the principal perpetrators of adverse events. All of the above expectations are based on the concerns echoed by the consumer surveys, physicians groups, and the following case studies.

VI. Case Studies

Ephedra

The first true test of the FDA after the passage of the Dietary Supplement and Health Education Act, reached a critical period in 2003, when the FDA banned the supplement ingredient known as Ephedra, commonly found in weight-loss products, by following the procedure outlined in DSEHA (Dier, 2011, pg. 404) However, the story began ten years earlier, when the FDA first began receiving reports about adverse events. From 1992 – 2004, "[the] FDA received 2,777 reports of adverse events associated with dietary supplements containing ephedra," (GAO, 2003, pg. 7). The sum of these reports outpaced any other dietary supplement

in the database during that period. Other non-government organizations, like the Poison Control Center and Metabolife 365 also received a significant volume of self-reports about possible dangers concerning ephedra (2003).

According to the Government Accountability Office analysis of the Metabolife records, there were close to 100 reports of individuals suffering heart attacks or strokes, culminating in five deaths (2003, pg. 10). Note, these numbers don't include the reports made to the FDA and other third-party research institutions. Ultimately, over the course of 10 years, patients suffered significant medical emergencies and the commonality was the regular use of dietary supplements containing ephedra. It is important to realize that the actual numbers are likely higher because the reports depend upon self-reporting. Since, as previous studies in this paper indicate, a general lack of communication exists between patients and physicians concerning the use of dietary supplements, which means there are likely ephedra cases that went unreported.

As a result of growing evidence between the FDA and third-party sources, the FDA issued a warning to consumers in 1997 cautioning of the dangers of dietary products containing Ephedra (Dier, 2011, pg. 404). The most striking aspect of the Ephedra case is the fact that the FDA warned the public nearly seven years prior to taking the product off the shelves.

The fact that a dangerous ingredient in dietary supplements was on the radar of the federal government for nearly 10 years before action was taken is indicative of a slow reactionary process. In 2002, "the number of calls to poison centers related to ephedra poisonings peaked at 10,326," until settling at 130 in 2013 (Zell-Kanter, Quigley, and Leikin, 2015). This indicates that the ban was eventually successful in removing ephedra from the market.

However, this occurred after many people died, hundreds suffered major medical emergencies, and thousands endured mild to moderate health events (2015). As perfectly described by a Reuter's news report:

> "[the FDA's] ability to act quickly and to ban other dangerous products has been severely crimped by the 1994 Dietary Supplement Health and Education Act. This awful law classifies herbal products as dietary supplements and prevents the FDA from banning them without proof that they have caused deaths and/or serious injuries. That's backwards." (Emery, 2015)

Ultimately, this case study emphasizes the fact that the FDA's powers to regulate dangerous drugs under the Dietary Supplement and Health Education Act is slow and untimely. While the FDA works to compile evidence to identify dangerous supplements and to build a case that meets the burden of proof standards for the courts, a process that can take years, consumers suffer tragic consequences and remain unprotected while supplement companies continue to make a profit. The outcome of the Ephedra case study runs contrary to the long tradition of effective consumer protection in the United States.

DMAA

Another high profile case, which tested the ability of the FDA to protect consumers, was the response to dimethylamylamine (DMAA), an ingredient found in sports supplements. In May 2011, a member of the United States military serving in Afghanistan was admitted to the military hospital after suffering a severe hemorrhagic stroke (Young, et al., 2012, pg. 1450). Based upon further investigation, it was believed that a supplement known as Jack3d, which contained DMAA, may have caused his stroke (2012, pg.1452).

In June of the same year, another United States military service member, otherwise healthy, died after suffering a massive heart attack; the autopsy suspected the DMAA in his blood as the likely cause of death (Palmer, 2014, pg. 311). These were not isolated cases, rather, they were part of a larger problem. Between 2007 and 2013, the FDA received more than 10,000 reports of serious outcomes related to the use of products containing DMAA: "115 deaths, 2,100 hospitalizations, 1,000 serious injuries, 900 emergency room visits, and over 4,000 other medical events" (2014, pg. 311).

To understand the FDA's response, one must first appreciate a few minor policy amendments to the Diet Supplement and Health Education act of 1994. In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which requires manufacturers, packers, or distributors of dietary supplements to report any adverse events they are made aware of (2014, pg. 318). Like the other provisions in DSHEA, this is rooted heavily in self-regulation and the honor system of manufactures.

In 2011, President Obama signed the Food Safety Modernization Act (FSMA). This is "the first major legislative expansion of the FDA's ability to govern and oversee the safety of the food supply," since 1990 (Palmer, 2014, pg. 218). For dietary supplements, the act gives the FDA power to temporarily embargo suspected adulterated supplements for 30 days, thus giving the FDA time to take further legal action. In short, this provision does not lower the burden of proof the FDA has in the court process, but it gives the agency a window of time to compile evidence and determine how to handle dangerous supplements.

In 2012, the FDA sent warning letters to 11 companies warning them of the dangers of DMAA, stating that they were in violation of federal law by selling the dangerous ingredient, and asking them to remove products containing the substance from the market (2014, pg. 321).

However, one company USPlabs refused to do so. After an intense correspondence dispute, the FDA enacted their powers under the 2011 Food Modernization Act and ordered the company to stop producing their products, in anticipation of pursuing legal action under DSHEA.

This was enough to stop USPlabs from producing their products containing DMAA (Palmer, 2014, pg. 323). However, they refused to take current inventory off of the shelves and continued to sell off the rest of their inventory, thus resolving the DMAA episode.

When reviewing the events of the DMAA episode as it relates to DSHEA, one cannot help but make comparisons to the Ephedra case. The FDA took approximately five years to effectively respond to the DMAA poisonings, and nearly a decade to eliminate ephedra. Nonetheless, the FDA's response time is still a matter of years, years in which consumers are at risk and unprotected.

Additionally, the ability for the FDA to embargo the products for 30 days under the 2011 legislative update to DSHEA was a powerful political tool for the agency to use while they negotiated with the drug company that refused to take the side of consumer protection. The failure of this story is that the company sold the rest of its tainted product to make a profit, and there was nothing the FDA could do in a timely manner to remove the product from the shelves entirely.

Overall, the two biggest cases of dangerous dietary supplements highlight the blatant weaknesses of the Dietary Supplement and Health Education Act and its inability to effectively protect consumers. Under the post-market review structure of DSHEA, the FDA was required to spend years gathering data to even indicate that there was a serious problem with certain dietary supplements. Afterwards, under the original guidelines, the FDA had to build an extensive legal case, a lengthy process, to secure a court order to remove the supplement from the shelves and

stop its production. For DMAA, it was the new powers under the Food Modernization Act of 2011 that allowed the FDA to leverage political power to force the companies to stop production of their products. However, a simple Google search reveals that DMAA is still being sold. Why? Because the FDA never litigated a court case, like Ephedra, to effectively make the substance illegal to produce. Instead, they rely on the consistent use of warning letters to encourage manufactures not to use DMAA in their products. In the end, the threat of litigation is enough to keep manufacturers in compliance, if only for a brief period of time.

As a reminder, under the 1938 Food and Drug Act, its subsequent amendments, and the 1990 Nutritional Labeling Act, foods and drugs are required to undergo pre-market approval of their products. Under this standard, the FDA maintains a list of tested food and drug ingredients, and has the power to deny a company from selling a product to consumers if it contains an unapproved product. Again, this is not the same standard set for supplements. This comparison reinforces further that DSHEA does not adequately protect consumers, especially when dietary products still can be manufactured with DMAA and sold for brief periods of time.

VII. Data Results

Select case studies can be interesting and provide compelling evidence, however, there are thousands of ingredients and supplements on the market, so attempting to analyze the entire industry using data collected by the FDA provides interesting findings. These findings further reinforce DSHEA's failures as a policy because it contradicts the historical legislative spirit of consumer protection.

[Insert Appendix A]

The first data table constructed was a snapshot of the Adverse Event Database maintained by the FDA. Over a ten-year period, 24,168 adverse events have been reported to the FDA.

Approximately 18% of these events required hospitalization, 10% E.R. visits, and about 336 people died due to suspected complications with a supplement or mix of supplements. Again, there is no way to definitively confirm the relationship between dietary supplements and medical events suspected by healthcare providers.

Looking at the graph in Appendix A, there is an interesting trend identified by this data, a steady positive increase in the number of adverse events being reported each year for supplements. There is a reduction of events between 2013 and 2015, which could be a result of the FDA's intervention with DMAA, however, the events are again on the rise in 2016. Ultimately, this study suggests the positive trend of adverse events is an indicator that DSHEA is a policy ineffective in protecting consumers. If the guidelines of DSHEA were effective, less of a steady positive increase would likely be visible. For example, the graph for food is far less of a steady increase; rather, there are periods of spikes and periods of decline. The spikes may indicate a dangerous food hitting the market and the decline may indicate a public health response. The graph for cosmetics tells a similar story of low and steady levels of adverse events, with a spike of potential dangerous products in 2015, the outcome of which yet to be determined. This may indicate that the FDA is more effective at identifying dangerous foods/cosmetics and can quickly intervene. Yet, when it comes to supplements, the steady increase may indicate a lack of quick responsiveness.

[Insert Appendix B]

Of the entire adverse events database, just over 53% of all adverse events are attributed to dietary supplements. Cosmetics make up about 13%, which means that food makes up approximately 34% of all adverse reports. It goes without saying that the entire food industry is much larger than the dietary supplement industry. Everybody eats food, but not everybody takes

supplements. Yet, the percentage of adverse events attributed to dietary supplements far outweighs the percentage of events attributed to food. This may indicate that the regulations for food are much more effective than the DSHEA regulations for dietary supplements, thus exemplifying its failure as a policy meant to protect the public.

[Insert Appendix C]

The market of dietary supplements continues to expand, based off the data gathered from the supplemental label database. On average, over 8,000 new dietary products are released each year that remain on the market. This data is limited by the fact that it analyzes only a period of five years. However, the expanding market indicates that the FDA has to work harder and harder every year to keep up with the post-market analysis of new dietary supplements and potential sources of dangerous ingredients.

[Insert Appendix D]

In terms of removing products from the market, the table in Appendix D identifies 842 products containing hidden ingredients that the FDA has issued warnings for. This does not necessarily mean they have been removed from the market; however, the DMAA case sets the precedent that most companies will remove their products if requested to do so by the FDA. Graph 2 in appendix D identifies a very non-linear and inconsistent trend of warnings between 2007-2017. When considering the steady increase in adverse events attributed to supplements and an expanding market, this inconsistency may indicate that the FDA may not be able to consistently apply the procedures of DSHEA to respond to trends.

The major benefit of the table in Appendix D is it highlights the dietary supplement categories that seem to be the biggest culprits in producing dangerous supplements: sexual enhancement, weight loss, and muscle building products. This information is telling because

simple products, like Mel Gibson's vitamin C, are not the major concern of the FDA. Rather, they focus on the complex mixtures found in sports supplements, weight loss ingredients, and sexual enhancement products, which should be a consideration of any future policy update.

Overall, the data analyzed by this research tells a disturbing story. Not only is the dietary supplement market expanding, the numbers of adverse events have seen a steady, positive increase. The irregular number of warnings issued by the FDA in this environment indicates that post-market analysis may be an inconsistent method for protecting consumers. The key comparison is with the food industry, whose pre-market regulatory measures appear to effectively respond to spikes in adverse events and its ability to keep adverse events lower than that of dietary supplement industry. The smaller dietary supplement market should not bring more harm to people, as indicated by the percentage of adverse events in the entire FDA dataset, than the larger food market. These facts all indicate that as a policy, DSHEA has failed as a measure implemented to protect consumers.

VIII. Limitations and Future Research

There are several limitations of the data analysis to be considered. First, these databases come from only a single source: the FDA. Individuals can report adverse events to places like the CDC and American Association of Poison Control. Analyzing those datasets in combination with the ones provided by the FDA would provide stronger results. The second major limitation is that the database of the FDA is not able to definitively discern whether or not a supplement had a cause/effect relationship with the medical events, the reports are usually conjecture. The uncertainty can definitely skew the data and call into question the accuracy of the analysis. However, the adverse reporting system is only the starting point for the FDA to pursue further investigation, which is why it was important to include the case studies to highlight specific

instances where the FDA completed an investigation. Finally, the data does not account for how many people use supplements and why they use them. Are people taking them in accordance with manufacturer recommendations? Are they taking a mix of different supplements? Ultimately, this data cannot account for the responsibility of the users. Irresponsible use may be a contributor to adverse events.

The data analysis does provide interesting avenues for further research. An investigation into the steady increase of adverse events associated with dietary supplements. would be important to determine whether it is an increased dietary supplement market, a specific product, or increased use that has a relationship with the increase. Furthermore, a comparative case study between tainted cosmetics, food, and supplements may provide a clearer analysis to support or refute the findings of this study. Finally, the notion that the U.S. has the most expansive, but least regulated dietary market hints that a cross-national study could indicate how well DSHEA protects consumers compared to the policies of other nations.

IX. Policy Recommendations

The long history of the FDA and DSHEA is a clear example of how bad policy emerges from intense lobbying efforts by large industries. Supplements were close to being regulated like food, but the response of vested interested changed the very direction of how the government treats a certain industry. Supplements undergo no pre-market approval; rather, they are continually monitored post-marketing. When problems occur and it appears people are being harmed, the FDA must undergo a lengthy process before they can even remove the products from the shelves. This is not the case for food products, which according to the data found in this study, the FDA has a potentially better reaction rate to adverse events.

Pre-market approval has, "given the FDA and the US Drug Enforcement Agency the authority to act once a potential public health threat from a drug has been identified or perceived" (Wallace, 2015, pg. 1684). Pre-market approval is the process of compiling a list of "safe" products, safe product meaning "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use" (2015, pg. 1683). Food companies are required to provide a list of ingredients for the FDA to review and as long as the ingredients are on the list of safe products, approval is given. If a new ingredient is submitted by manufacturers, but has not yet been approved, the FDA reviews studies and evidence to qualify the safety of the ingredient.

Instituting a pre-market approval process, similar to food ingredients is a reasonable and likely successful step to take, in order to return the spirit of DSHEA to consumer protection. Simple products like Vitamin A, B, and C, would likely be easily approved. However, the more complex products and mixtures, like those identified in Appendix D, would undergo closer scrutiny.

Finally, the Food and Drug Modernization Act of 2011 showed that giving the power of embargo to the FDA is beneficial in protecting consumers while the agency reviews the dangers of the products. However, as exemplified by the DMAA case study, the manufacturers continued to sell their remaining stock, even after promising to end production.

Giving the FDA the power to legally classify supplements, like food ingredients, would also give them the power to seize supplements containing unclassified and illegal ingredients. This would prevent companies from selling products, even after they agree the ingredients are dangerous, like in the DMAA case.

Ultimately, as exemplified by the data results, the regulation of the food industry seems to have a much better process. Regulating supplements, like food, would better protect the consumer, while still giving them the option of choice over safer products.

X. Conclusion

The history of the FDA is both as complex as it is long. The spirit behind nearly every legislative mandate concerning the FDA manifests one central duty of government: to protect the health and welfare of the people. What are they protecting them against? The few, but dangerous, corporate interests seeking to make a profit at any cost. The 1906 Pure Food and Drug Act was the genesis of consumer protection. The 1938 Food, Drug, and Cosmetic Act expanded the ability of the government to more effectively care for those at risk of unnecessary injury, simply for purchasing a good. The 1990 Nutritional Label and Education Act aimed to give consumers accurate and honest information about goods, so the people could best judge the veracity of product claims for themselves.

Then came the Dietary Supplement and Health Education Act of 1994. As has been clearly established, lobbying interests bound together to protect the supplement industry, in the name of consumer choice. As a result, people became sick, disabled, and died, during certain periods, during which the FDA knew about dangerous supplements, but could not act quickly enough to protect consumers. For those people who have spent thousands of dollars on medical treatment or who have lost loved ones, this policy is no story and no joke. It is a policy that must be revised, in order to realign the spirit of the dietary supplement industry to emphasize consumer protection over profit.

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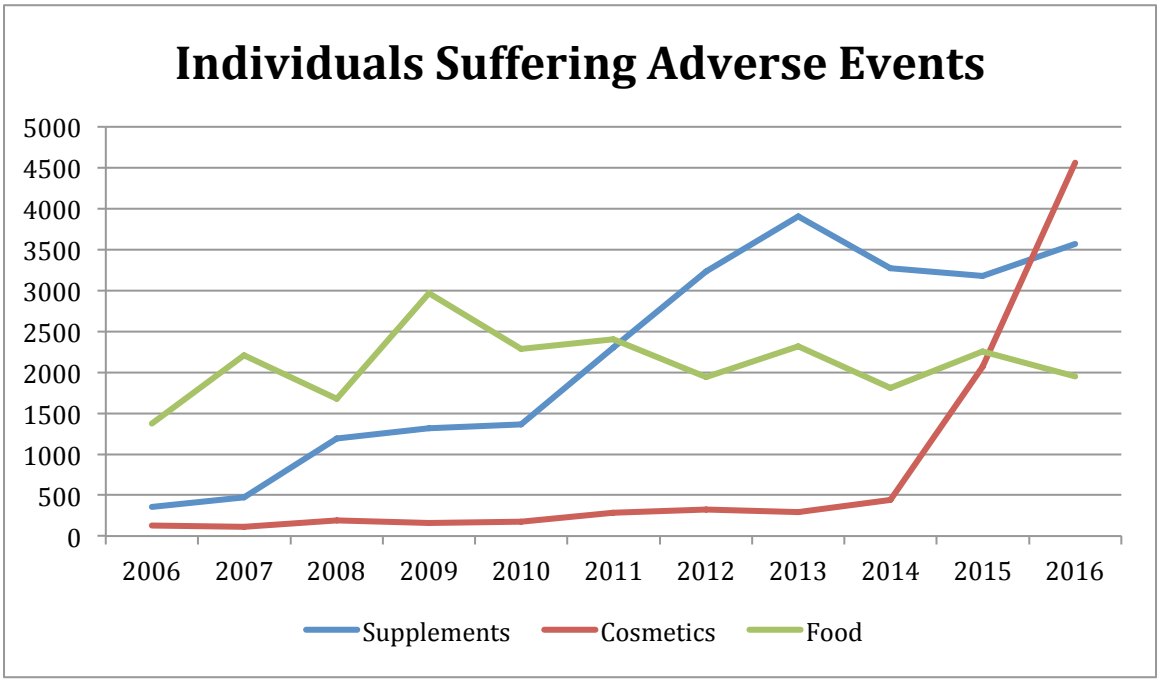
Appendix A:

Table 1:

Adverse Events Database Snapshot													
	Year												
Adverse Event	**'06**	**'07**	**'08**	**'09**	**'10**	**'11**	**'12**	**'13**	**'14**	**'15**	**'16**	**Total**	**%**
Congenital Anomaly		3	1		2	2	1		1		9	19	0.08%
Death	3	8	14	15	12	32	43	88	44	46	61	366	1.51%
Disability	16	18	15	30	37	26	49	69	57	69	86	472	1.95%
Hospitalizations	53	65	146	229	332	380	467	629	565	683	808	4357	18.03%
Life Threatening Events	19	28	36	41	79	95	136	141	151	146	130	1002	4.15%
Non-Serious Injuries	72	74	109	124	96	110	162	132	188	262	246	1575	6.52%
NONE					1	1			1	2	4	9	0.04%
Other Serious Medical Events	66	72	170	232	427	1197	1754	2024	1570	1161	1241	9914	41.02%
Req. Intervention to Prevent Permenant Impairment	6	9	17	13	24	28	83	35	22	11	6	254	1.05%
Serious Injury / Illness	30	57	394	312	34	65	58	42	12	11	1	1016	4.20%
Visited a Healthcare Provider	65	88	142	153	195	196	218	407	356	421	502	2743	11.35%
Visited an ER	26	52	150	165	126	173	264	335	307	368	475	2441	10.10%
Grand Total	356	474	1194	1314	1365	2305	3235	3902	3274	3180	3569	24168	100.00%

Graph 1:



Appendix B:

Table 2:

Percentage of Adverse Events By Category	
Row Labels	**Total**
Alcoholic Beverage	0.0%
Baby Food Prod	1.4%
Bakery Prod/Dough/Mix/Icing	2.8%
Beverage Bases/Conc/Nectar	0.2%
Candy W/O Choc/Special/Chew Gum	0.7%
Cereal Prep/Breakfast Food	1.4%
Cheese/Cheese Prod	0.4%
Choc/Cocoa Prod	0.8%
Coffee/Tea	1.0%
Color Additiv Food/Drug/Cosmetic	0.0%
Cosmetics	12.9%
Dietary Conv Food/Meal Replacements	1.6%
Dressing/Condiment	0.3%
EDIBLE INSECTS AND INSECT-DERIVED FOODS	0.0%
Egg/Egg Prod	0.2%
Filled Milk/Imit Milk Prod	0.2%
Fishery/Seafood Prod	2.6%
Food Additives (Human Use)	0.3%
Food Service/Conveyance	0.0%
Food Sweeteners (Nutritive)	0.3%
Fruit/Fruit Prod	2.5%
Gelatin/Rennet/Pudding Mix/Pie Filling	0.1%
Ice Cream Prod	0.9%
Macaroni/Noodle Prod	0.2%
Meat, Meat Products and Poultry	0.3%
Milk/Butter/Dried Milk Prod	1.7%
Miscellaneous Food Related Items	0.0%
Mult Food Dinner/Grav/Sauce/Special	1.1%
Multiple Food Warehouses	0.0%
Not Available	0.0%
Nuts/Edible Seed	3.7%
Prep Salad Prod	0.2%
Snack Food Item	1.1%
Soft Drink/Water	2.9%
Soup	0.3%
Spices, Flavors And Salts	0.4%

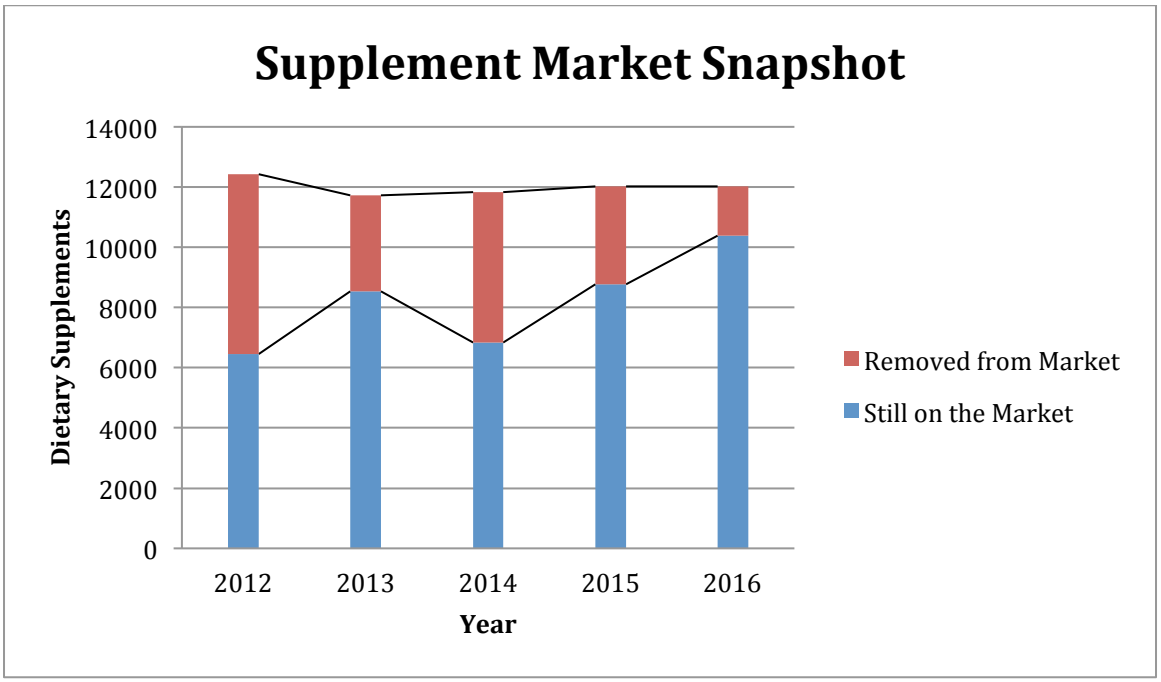
Vegetable Oils	0.1%
Vegetable Protein Prod	0.1%
Vegetables/Vegetable Products	3.4%
Vit/Min/Prot/Unconv Diet (Human/Animal)	**53.4%**
Whole Grain/Milled Grain Prod/Starch	0.4%
Grand Total	**100.0%**

Appendix C:

Table 3:

Dietary Supplements Produced					
	Current Market Status				
Year	On Market	%	Removed From Market*	%	**Grand Total**
2012	6453	52%	5974	48%	**12427**
2013	8534	73%	3181	27%	**11715**
2014	6844	58%	4988	42%	**11832**
2015	8769	73%	3246	27%	**12015**
2016	10386	86%	1639	14%	**12025**
Grand Total	**40986**	**68%**	**19028**	**32%**	**60014**
*Supplements removed by both Manufacturer and/or the FDA at unknown times and for unknown reasons					

Graph 2:



Appendix D:

Table 4:

Supplements Containing Dangerous Ingredients Identified by FDA													
	Years												
Supplement Type	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	**Grand Total**	**Percentage**
Muscle Building			73	16	1		1					91	11%
Other						2	4	7	5			18	2%
Prostate Health					1							1	0%
Sexual Enhancement	14	9	14	73	10	30	50	39	67	49	51	406	48%
Weight Loss	1	70	17	8	27	16	37	52	54	34	10	326	39%
Grand Total	15	79	104	97	39	48	92	98	126	83	61	842	100%

Graph 3: