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AND THEIR ADVERSE AFFECT ON YOUNG
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Andrew Bernard Jaffe



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Andrew B. Jaffe

Introduction

Sport supplements are a form of dietary supplements that are consumed by numerous young adults and the popularity of these products continues to grow each day. Since 2011, the supplement industry has grown to be worth more than 27 billion dollars.¹ Supplements can be characterized as energy supplements; protein supplements/weight gainers, vitamin supplements, mineral supplements, and other supplements.² Dietary supplements can fall into one of three major categories: (1) substances with established nutritional function such as vitamins and minerals; (2) Botanical products and their concentrates/extracts; and (3) other substances with wide varieties of origins and physiological roles.³ Dietary supplements can be marketed in forms such as tablets, capsules, soft-gels, and gel-caps.⁴ This Note examines how the Dietary Supplement Health and Education Act of 1994 (DSHEA) was detrimental to the FDA's ability to regulate dietary supplements in a strict manner and how this can be directly related to issues arising in the health of young adults and other individuals.

Any individual that purchases a dietary supplement is purchasing it for a specific reason. Young adults, as well as any member of the public, expect dietary supplements that are bought over the counter to produce positive results. What most people are not aware of is there can be harmful side-effects from taking dietary supplements.⁵ There are numerous functions that dietary supplements, including sport supplements can be used for by any individual depending on the results they are seeking to obtain. An individual could use a dietary supplement to aid them in

weight loss, increase energy production, promote muscle growth, and even as a simple meal replacement. It should be noted that unlike drugs, the U.S. Food and Drug Administration (FDA) has held that dietary supplements are not intended to treat, diagnose, prevent, or cure diseases.⁶

Congress responded to increased pressure from the dietary supplement industry to restrict FDA regulation by enacting the Dietary Supplement Health and Education Act of 1994 (DSHEA).⁷ This Act took a great of power away from the FDA's ability to regulate dietary supplements.⁸ Part I of this note provides an overview of DSHEA's meaning of a dietary supplement, the flaws in the Act, and what power is given to the FDA to regulate dietary supplements. Part II presents an analysis of how the flaws of DSHEA are negatively impacting young adults and other individuals by providing modern examples of supporting evidence and cases. Finally, Part III suggests proposed changes and if adopted, could better help the FDA regulate dietary supplements more efficiently to protect young adults and other individuals from health risks. This Note concludes that DSHEA has had a damaging impact on young adults and others and the adoption of new regulations giving the FDA broader power to regulate dietary supplements is a valid solution.

I. Flaws in the Dietary Supplement Health & Education Act

A. DSHEA Definition of a Dietary Supplement Leads To Absence of Pre-market Approval

The Dietary Supplement Health and Education Act of 1994 established a new approach to the method the FDA regulated dietary supplements.⁹ The DSHEA provided a new definition for the term "dietary supplement" to mean; (1) a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet increasing the total dietary intake; or (F) a concentrate,

metabolite, constituent, extract, or combination of any ingredient described previously.¹⁰ A major aspect of the new definition of dietary supplement is the form of the supplement that is described.¹¹ A dietary supplement must be intended for ingestion.¹² As a result of the changes that were made to DSHEA, dietary supplements are still considered to be foods under the act.¹³ Exceptions exist under the Act, and due to these exceptions, dietary supplements can be regulated more leniently than food or drugs.¹⁴ Food additives and drugs are subject to pre-market approval by the FDA, but dietary supplements are not required to have pre-market approval.¹⁵

In order for the FDA to be able to remove dietary supplements from the market, they must determine them to be “adulterated.”¹⁶ A dietary supplement may be classified as adulterated if there is an unreasonable risk of illness or injury, if there is inadequate information about this new ingredient, or the Secretary declares the ingredient to pose an imminent hazard to public safety.¹⁷ It is unclear what the actual meaning of an “unreasonable risk of injury” entails. An example of an unreasonable risk would be a dietary supplement containing a very harmful ingredient to human health. As a result, a much higher burden of proof is placed on the FDA to deem a dietary supplement adulterated because it would have to be shown that the supplement presented a “significant or unreasonable risk of illness or injury.” Unlike the burden of proof for dietary supplements, the FDA has a much lighter burden of proof to satisfy to deem food adulterated.¹⁸ In order to find food adulterated, the FDA must prove that the food contained “any” poisonous substance which could render it injurious to health.¹⁹ Comparing the burden of proof between a dietary supplement, where the risk must be “significant” compared to the burden of proof of food where the risk could be classified as “any” risk, it is apparent the FDA has broad authority in the subject area of foods but limited authority in the subject area of dietary supplements. Something serious would have to occur supported by valid, thorough evidence in

order for the FDA to remove a dietary supplement from the market. Due to this increased burden of proof the FDA must meet, there can be a greater chance of a dietary supplement severely hurting an individual and even killing them before action can be taken. As a result of the increased burden on the FDA, consumers of dietary supplements must rely on self-regulation within the supplement industry for assurance of product safety and quality.²⁰

B. DSHEA and Loose Labeling of Dietary Supplements

Dietary supplement manufacturers also benefit from a less restrictive labeling requirement compared to the requirements that food producers must adhere to. Dietary supplement labels must include nutritional information only for ingredients that are “present in the product in a significant amount and for which a recommendation for daily consumption has been established.”²¹ There is not label requirement for ingredients that is “not present in a significant amount.”²² The problem with not requiring dietary supplement manufacturers to disclose ingredients that are not in significant amounts is some of these ingredients can still possess harmful traits to the person taking them. A main issue that can be clearly inferred from this labeling requirement is the inconsistencies that can exist between dietary supplement manufacturers in electing which ingredients they will list in deciding what is and isn’t a significant amount.

Another main problem with labeling requirements is manufacturers listing “proprietary blends” instead of listing each individual ingredient in the dietary supplement. A manufacturer may list a proprietary blend on the dietary supplement for one of two reasons: (1) to stop their competition from knowing exactly what ingredients are in their product and the amount of each; or (2) to hide the fact the formula contains very little of the active ingredient listed on the bottle in a false representation to consumers.²³ Unfortunately the second reason is more common than

the first; companies list countless ingredients which may seem impressive, but none which are in amounts that are proven to aid in what the product claims.²⁴ In regards to a research and clinical safety perspective, it is extremely hard to determine the safety and efficacy of products when formulas are not fully disclosed.²⁵ In order to combat this struggle, proprietary blends of supplements should be further regulated to require manufacturers to provide all the ingredients in their product unless they can show a valid reason for not disclosing them. The manufacturer should still be required to disclose all the ingredients in their product to the FDA.

C. Result of Dietary Supplements Being Classified As Foods

One of the biggest problems with the DSHEA classifying dietary supplements as foods is the fact that structure/function claims can be made about the product that are usually only intended to be used by actual drugs.²⁶ Drug approval is very time consuming and one of the goals of the DSHEA was to allow for the sale of dietary supplements that might have some drug like effects, but did not have the extensive evidence required to support the health claim.²⁷ As a result, dietary supplement manufacturers can make certain claims, including structure/function claims, without proof of safety or efficacy.²⁸ Structure/function claims describe the role of dietary supplements and the way they are intended to effect the function of the body.²⁹ An example of a structure/function claim may be, “maintains a healthy immune system”³⁰ or a sport supplement manufacturer claiming, “helps promote extreme muscle growth.” The only thing the manufacturer is required to do when making a claim about the benefits of the dietary supplement is the label must contain the phrase, “these statements have not been evaluated by the Food and Drug Administration and this product is not intended to diagnose, treat, cure, or prevent any disease.”³¹ Implications have been made that the FDA simply does not have the resources to adequately monitor dietary supplement manufacturers and their advertising claims.³² Due to this

loosely regulated area floodgates may be opened to false advertising by manufacturers of numerous brands of dietary supplements trying to get someone to buy their product over another competitor. Manufacturers have the opportunity to make statements about their products that might not even be supported by valid research and all they have to do is place the warning on the product that the statements have not been evaluated by the FDA.

II. Modern Examples of How Young Adults Are Affected by the Struggle to Regulate Sport/Dietary Supplements

The struggle to regulate dietary supplements is not something the FDA has recently been forced to deal with. This issue has been present for decades and this article will examine current examples of how young adults are easily susceptible to harm by the current regulation. The first example examined is a case where a dietary supplement ingredient was being linked to deaths and the ongoing challenge the FDA was faced with to try to remove the ingredient from the market.³³ Second, a class action lawsuit is studied that was filed against the “Kardashians” because they were endorsing a product which was proven to be unsafe and misleading to consumers.³⁴ Finally, Monster Energy drinks advertising their products directly towards young adults & children, and how America’s youth are currently being severely harmed or dying as a result of drinking the product.³⁵

A. DMAA: A Dietary Supplement Ingredient Proving the Absence of Pre-Market Approval as a Serious Risk

Most individuals who strive to be active are continuously faced with the challenges of finding the motivation to bring themselves to the gym after a stressful day. Many individuals as well as young adults take supplements known as “pre-workouts” to boost their energy and ability to obtain a successful workout. Pre-workout supplements contain ingredients, which most individuals cannot even pronounce and many health professionals are concerned about the

harmful effects pre-workouts can have on people.³⁶ Many of these supplements contain the same ingredients, however, one of the most controversial ingredients in some is known as 1-3 dimethylamylamine or DMAA.³⁷ Many different pre-workout supplements contain DMAA, but USP Labs, a manufacturer of sport supplements posed the biggest issue in the ban of DMAA.³⁸ As of April 11, the FDA has received 86 adverse reports which were believed to be linked to DMAA, some symptoms included; depression, anxiety, vomiting, loss of consciousness, chest pain, and even death in some cases.³⁹ At this point, it was clear that there was something wrong with this dietary supplement; yet, the product was still being allowed to exist on the market. Dr. Daniel Fabricant, director of the division of dietary supplements program at the FDA was asked why these products were still being sold and responded, “we don’t evaluate dietary supplement products for safety prior to them making it to the market and it would be difficult banning them.”⁴⁰ In 2012, the FDA did raise concerns with the use of DMAA and sent warning letters to 11 manufacturers questioning the safety of the ingredient; all of those manufacturers except one withdrew DMAA from the market.⁴¹ USP Labs, objecting to the FDA’s contention, claimed the product to be safe and it was a natural substance.⁴² It should be noted that the struggle to ban DMAA from being used as an ingredient in dietary supplements was ongoing in year 2013.

On February 13, 2013, the parents of Michael Sparling, a soldier who died after taking Jackd 3d, filed a wrongful death lawsuit in San Diego Superior Court targeting the controversial ingredient DMAA and naming USPLabs as a defendant.⁴³ In the Complaint, the plaintiffs alleged that DMAA-containing dietary supplement “Jack3d” is marketed as a safe supplement and fails to warn consumers about the potential health risks.⁴⁴ Michael Sparling was one of two soldiers who unexpectedly died during a routine training exercise in 2011, both soldiers had DMAA in their system.⁴⁵ In response to this problem, in 2012, the Department of Defense banned the sale

of DMAA-containing supplements on military bases even though DMAA had not been banned by the FDA.⁴⁶ Despite the ban of supplements containing DMAA on military bases by the Department of Defense in 2012, in February, 2013 it was determined that there were over 200 supplements containing DMAA on the shelves of supplement stores.⁴⁷ Even though the Department of Defense banned DMAA in 2012 it is clear that as a result of the heavy burden the FDA must meet to remove a product from the market, DMAA containing supplements continued to exist for over a year.

Besides the ban of DMAA by the Department of Defense, other crucial bans took place in 2012 which should have given the FDA enough notice that DMAA is a dangerous ingredient and should be banned immediately. On August 8, 2012 the Australian Government through the Therapeutic Goods Administration (TGA) banned the use of DMAA .⁴⁸ The TGA stressed to its citizens to not obtain, supply, or use DMAA and that the ingredient is a toxic substance with dangerous side effects.⁴⁹ According to the TGA risks associated with the use of DMAA were increased high blood pressure, psychiatric disorders, bleeding in the brain, and stroke.⁵⁰ After increased efforts, the TGA made a final decision to include DMAA in Appendix C of the Poison Standard.⁵¹ The fact that Australia banned DMAA and listed it as a "poison" should have been a red flag to the FDA to take DMAA off the market.

It was not until April 11, 2013 that the FDA issued a statement saying they were using all of their available tools to ensure that DMAA was no longer distributed and available for consumers in the marketplace.⁵² The FDA further stated that, "FDA has warned companies known to be using DMAA in dietary supplements that those products containing this ingredient are illegal."⁵³ The health risks associated with DMAA as well as actual deaths occurring throughout America and in other countries were apparent many years before the FDA banned

DMAA. The amount of time it took the FDA to ban DMAA from the market clearly establishes that supplements not being subjected to pre-market approval can seriously impact young adults and even lead to death.

B. Celebrities Endorsing Supplements with False Promises

It is widely observed that numerous dietary products on the market contain a picture of a celebrity or athlete claiming success as a direct result of the product. Almost any magazine could be opened, displaying an advertisement with a celebrity claiming that a particular supplement aided them in achieving their fitness goals. Most individuals that watch television would also agree that it's common for a dietary supplement commercial to reveal a celebrity presenting the product with personal guaranteed success. The majority of members in our society, including young adults, or those of elderly age are subjected to dietary supplement advertisements through the broad spectrum of modern day media. An individual's final choice in deciding which dietary supplement to take may fall on their belief that a celebrity using a certain product must mean the product is worth purchasing. What the average supplement purchaser does not realize is celebrity endorsed products are just as poorly regulated as other supplements sold if not more.⁵⁴ Supplements sold on the market endorsed by celebrities can still consist of ingredients which are unsafe, and most advertisements continuously follow misleading claims.⁵⁵ A disclaimer on a supplement is insufficient to address this problem because celebrities can market a product that can actually consist of harmful ingredients. Celebrities should not be able to hide behind disclaimers giving them the opportunity to make false claims.

A class action lawsuit brought against the "Kardashians" endorsing the supplement "QuickTrim" is an accurate example of consumers of a dietary supplement being negatively impacted by the products misleading claims.⁵⁶ The Complaint alleges that the defendant's

marketed and promoted the product QuickTrim based on numerous unsubstantiated and misleading claims regarding the product's safety and efficacy.⁵⁷ In January 2010, Kim Kardashian informed "Ok Magazine" that she used numerous QuickTrim products and lost 15 pounds and some of her curviness in just a few weeks.⁵⁸ The class action lawsuit filed against Kim, Kourtney, and Chloe Kardashian consisted of damages estimating 5 million dollars raised on behalf of four consumers who claim that QuickTrim did not produce results the product guaranteed.⁵⁹ QuickTrim products are designed to "detoxify and clean" the body by removing excess water weight and bloating, in large part because of the laxatives they include.⁶⁰ The products are available for purchase nationwide at more than 25,000 stores.⁶¹ Besides the allegations in the Complaint previously mentioned it was also alleged that there was no competent and reliable scientific evidence supporting any of QuickTrim's weight-loss claims.⁶²

In 2010, Kim Kardashian was the highest paid "reality star" on television, earning around \$6 million dollars for her product endorsements.⁶³ The Kardashian sisters are considered to be the principle endorsers of QuickTrim.⁶⁴ Their images consume QuickTrim's labels and packing.⁶⁵ They appear in almost every advertisement for the product.⁶⁶ Their surname is even incorporated into one of the primary web addresses selling the product.⁶⁷ Ms. Cowan, one of the parties to the class action suit, claimed to have seen the Kardashian sisters on television, in magazines, and even on the label of QuickTrim making positive claims regarding the product and decided to try it.⁶⁸ She purchased QuickTrim in reliance on the claims that it was a safe and effective "sustained weight loss formula" that would "help burn calories" and "help support a healthy metabolism."⁶⁹ Ms. Cowan stated in the Complaint that she would not have bought QuickTrim if she knew that the product and its ingredients were not safe and effective treatments for weight-loss, and that the representations concerning the benefits of the product were

unsubstantiated.⁷⁰ A study published in the *Journal of Family Practice* in 2011 analyzed 20 case studies reported over the past 10 years, and discovered that colon cleanses cause symptoms from mild cramping to kidney failure.⁷¹

Federal law allows for structure/function claims by supplement manufacturers which are statements of nutritional support referring to representations about dietary supplement's effect on the structure or function of the body in regards to good health without FDA authorization.⁷² Structure/function claims are only permitted if the manufacturer has substantiated that the claim is truthful and not misleading.⁷³ The DSHEA disclaimer must also be displayed on the product stating that the statement has not been evaluated by the FDA and is not meant to treat, cure, prevent, etc. any disease.⁷⁴ A few claims that QuickTrim makes is that the product can be used for weight control, appetite suppression, and to burn stored fats and decrease the appearance of cellulite.⁷⁵ None of the claims mentioned by the product have been authorized by the FDA or any scientific body.⁷⁶ The claims that QuickTrim makes cannot be structure/function claims because the product does not possess substantiation that the statements are truthful and not misleading.⁷⁷ As a result, people are purchasing Quick Trim assuming the product provides proven results when in reality, they were falsely misled by celebrities to purchase a product that does not yield guaranteed results and can consist of unsafe ingredients. This is just one of many examples of how consumers may buy a dietary supplement as a result of being subjected to false advertisements through celebrity endorsements. Until more strict regulations are passed limiting the claims celebrities can make in regards to supplements they take, individuals as well as young adults will continue to buy dietary supplements that will produce insignificant results and can potentially harm them.

C. Monster Energy Drinks Marketed Towards Children and Other Individuals: Generating a Heightened Concern

Monster Energy is an energy drink beverage line that was launched by Monster Corporation in 2002.⁷⁸ Currently, there are 34 different kinds of Monster Energy drinks that an individual can choose from.⁷⁹ The caffeine content of most Monster Energy drinks is approximately 160mg for a 16 ounce can.⁸⁰ In one case, San Francisco City Attorney Dennis Herrera sued Monster beverage in May 2013 alleging that Monster marketed its energy drinks to children and that the products pose severe health risks.⁸¹ Monster Beverage stood by the safety of its drinks and noted that their drinks possess on the label that the drink is not intended to be consumed by children.⁸² Mr. Herrera claims that despite Monster's own warning label, they aggressively market their products towards young children.⁸³ Mr. Herrera cited the company's "Monster Army" website, which uses children as young as six years old to promote its brand, as well as Monster's sponsoring youth athletic tournaments.⁸⁴ The lawsuit aims to restrict the way the company markets its drinks and is also seeks civil penalties.⁸⁵ Monster Beverage has also defended claiming that the level of caffeine in their product is often lower than the level of caffeine sold in a cup of Starbucks coffee.⁸⁶ Mr. Herrera and other officials are concerned with Monster directing its product on the market to be sold to young teenagers, which is a group more sensitive to caffeine's effects than adults.⁸⁷ It was also pointed out that Monster Beverage was marketing programs titled "Monster Energy Drink Player of the Game," which displayed photographs of high school athletes holding the beverage.⁸⁸

A 14-year-old girl, residing in Maryland, died in December 2011 after drinking two Monster energy drinks in a 24-hour period.⁸⁹ After she drank two of the energy drinks, when combined, contained 480 milligrams of caffeine she went into cardiac arrest a day later and died from cardiac arrhythmia due to caffeine toxicity.⁹⁰ A recent study was conducted by the journal Pediatrics that showed that anywhere from 30 percent to 50 percent of teens and young adults

consume energy drinks.⁹¹ Nearly fifty percent of the 5,448 reported caffeine overdoses in 2007 were in people younger than 19.⁹² In October of 2013, the parents of the 14-year-old girl who died in December 2011 sued the Monster Energy Drink, claiming caffeine in the product contributed to their daughter's death.⁹³ Monster's lawyer, Daniel Callahan said the company hired a team of physicians and determined her death was a result of natural causes due to a pre-existing heart condition and that no blood test was performed to prove she died of caffeine toxicity⁹⁴ The attorney representing the parents of the deceased child claimed that because their daughter went into cardiac arrest just a few hours after consuming the energy drink there was enough evidence that she died from caffeine toxicity for a jury to rule on.⁹⁵ Monster claimed their product is marketed towards individuals ranging from 18 to 34 years of age, but that its drinks are still safe for children⁹⁶

Another lawsuit was brought by the mother of a teenager in 2013, which died of arrhythmia in 2012 blaming her son's death on Monster Beverage by regularly drinking the company's energy drinks.⁹⁷ Alex Morris, 19, went into cardiac arrest on the morning of July 1, 2012 and was taken to the hospital where he was pronounced dead.⁹⁸ The lawsuit filed alleges that Alex Morris would have never died if he did not drink 2 Monster energy drinks a day for 3 years, including the day of his death.⁹⁹ The autopsy and toxicity reports found no illegal drugs or alcohol in his system.¹⁰⁰ Following Alex's death, the Coroner determined that his cause of death was cardiac arrhythmia and cardiomyopathy.¹⁰¹ A cardiac arrhythmia is an electrical problem with a person's heartbeat meaning it can beat too slow or too fast and when this occurs, the heart may not pump enough blood to the brain and other organs, which could lead to death.¹⁰² Monster did not immediately respond to this accusation but maintains safety of its drinks, which it says

contain 240 milligrams of caffeine for a 24-ounce can, compared with 330 milligrams in a 16-ounce cup of Starbucks coffee.¹⁰³

Not only are lawsuits being filed against Monster Energy for wrongful deaths occurring due to their caffeine content but a class action law suit was filed against Monster alleging a dangerous ingredient being present in the beverage.¹⁰⁴ A class action lawsuit was filed against Monster Energy in 2012 claiming that its Monster Rehab Green Tea + Energy drink contained unknown amounts of epigallocatechin-3-gallate (ECGC), which is considered to be an extremely dangerous ingredient.¹⁰⁵ The Complaint also alleges that Monster failed to warn consumers that the unknown amounts of this ingredient could cause hepatotoxic side effects, or chemical driven liver damage.¹⁰⁶ Jennifer Woodling, the lead Plaintiff in the case, alleged that medical research has proven that ECGC has been associated with liver injuries and could cause harmful side effects, including without limitation, death, acute liver failure, hepatitis, and other liver injuries.¹⁰⁷ Even though research proving potential side effects from this ingredient, Monster continued to market and sell this energy drink to millions of consumers without any warning.¹⁰⁸ ECGC may contain antioxidant properties in small doses, but the class action lawsuit presents 20 year old research that shows ECGC yielding toxic liver effects when used in doses present in dietary supplements.¹⁰⁹ Despite the continued lawsuits filed against Monster Energy Co. for the deaths of multiple individuals, some even under the age of 15; Monster Energy drinks continue to exist in almost every convenient store and supermarket. Monster has not made any effort to attempt to decrease consumption by young individuals and continues to market its product towards them.

Not only has Monster Energy failed to market its product away from young adults, it has threaten to sue individuals who claim that its product kills children.¹¹⁰ In 2013, Monster Energy

threatened to sue a Connecticut pediatric nutritionist, Deborah Kennedy, who claimed that children have died from drinking their beverages.¹¹¹ In the early month of March 2013, Monster demanded a removal of her statement and that she must publish statements in a nationally circulated newsletter that she defamed Monster and then threatened her with a lawsuit.¹¹² At a press conference, Ms. Kennedy noted that she did not mention Monster specifically and she was alleging that the level of caffeine in energy drinks was too high for children in general.¹¹³ Senator Blumenthal claimed that Ms. Kennedy was wrongly threatened by Monster in an effort to silence her through intimidation and that Monster owes her an apology, plus an explanation to the American people as to why they appear to be marketing to adolescents.¹¹⁴ Monster Energy claimed they did not intend to threaten her but continue to object to her claims that energy drinks kill children.¹¹⁵

Monster Energy drinks, in addition to countless others, have been on the market for decades and continue to exist regardless of countless claims linking their consumption to the death of numerous people. The average person knows that drinking too much caffeine can be detrimental to their health. If a person chooses to ingest a dangerously high amount of caffeine the manufacturer should not have to suffer the burden of the consumer's decision. There have been numerous cases discussed expressing the reality behind Monster Energy drinks being linked to the deaths of young adults even as low as 14 years old. As time progresses, more teenagers and other individuals will be subdued by energy drinks if the current regulation continues to exist.

Part III. Proposed Methods for the FDA to Further Regulate Dietary Supplements

An abundant amount of proposals can be made which can lead to dietary supplement manufacturers being subjected to more strict regulations. Proposals have been made in the past

through the introduction of Supplement Bills and have repeatedly been struck down.¹¹⁶ In 2011, Senator Durbin introduced the Dietary Supplement Labeling Act which was a bill that threatened the supplement industry by granting the FDA more power to regulate supplements as if they were drugs.¹¹⁷ The bill required supplement manufacturers to provide a list of ingredients in proprietary blends used in their products which could cause serious and negative reactions.¹¹⁸ Senator Durbin's bill had little support and his amendment was struck down.¹¹⁹ Multiple arguments can be made as to why this proposed bill was shut down. One reason may be that supplement manufacturers lobbied the passing of this bill because if it was passed it would severely impact the supplement industry. This proposed bill is just one example of many made in the past to grant the FDA more power to further regulate dietary supplements.

A current bill has been submitted by the Senate in 2013 to ban the purchase of sports supplements by individuals under the age of 18.¹²⁰ Furthermore, the bill will also require that consumers receive a copy of a warning label when they purchase certain products; the warning label will tell whether the product contains banned ingredients determined by certain regulatory agencies.¹²¹ The purpose of the bill is to protect those who are underage from the dangerous side effects of sport supplements currently sold on the market.¹²² Due to loopholes in federal law, consumers are not able to evaluate what they are putting into their body and what is actually in sport supplements.¹²³ This bill was introduced in direct response to the detrimental side effects that supplements consisting of DMAA produced in young adults and how the process for the FDA to ban the ingredient from the market was overly extensive.¹²⁴ The bill does not specifically address the proprietary blend issue. This proposal is an example of one excellent way to combat the hostile effects that the current regulation of dietary supplements can have on our Nation's

youth. Despite this single proposal that is currently being made, there are other significant measures that can be taken to give the FDA broader authority to protect young adults.

A. Dietary Supplements Subjected to Pre-Market Approval

Currently food additives and drugs are subject to pre-market approval by the FDA, but dietary supplements are not required to have pre-market approval.¹²⁵ A dietary supplement can only be removed from the market once it is deemed to be unsafe.¹²⁶ Countless examples have been presented displaying young adults being severely injured and even dying as a result of dietary supplements existing on the market without pre-approval. In order to ensure the safety of young adults and other individuals purchasing dietary supplements, every dietary supplement being introduced on the market should be subjected to pre-market approval. One might argue that there is an overly excessive burden placed on the FDA and also supplement manufacturers in abiding by this proposal. A vast amount of supplement manufacturers exist with profits exceeding millions. As a result, supplement manufacturers should bear the burden of incurring the cost for the FDA to approve their product lines. It is likely that these supplement manufacturers would rather settle with the families and individuals that are harmed by their products on a case-by-case basis to lower their costs. This type of approach should be forbidden when the lives of countless individuals can be saved by forcing dietary supplements to adhere to pre-market approval. Requiring pre-market approval of every dietary supplement sold would not only ensure the safety of people purchasing these products but would eliminate the ambiguity of the FDA's authority to remove products once they are deemed to be unsafe.

B. Advertising Limitations Place Upon Supplement Manufacturers

One of the issues previously mentioned discussing dietary supplements being classified as foods is that structure/function claims can be made by manufacturers without proof of safety

or efficacy.¹²⁷ Many products exist on the market with manufacturers making claims on their product that are outlandish. Supplement manufacturers should be prohibited from making any claim on their product which could falsely mislead a person to purchase their product just because of the claims stated on it. In order to ensure that manufacturers follow this proposal, fines should be imposed on manufacturers who do not obey the new regulation.

Celebrities and athletes should also be limited in regards to the successful claims they can make in reference to dietary supplements. Many individuals may purchase a supplement just because they saw a celebrity on television or saw an athlete in a magazine claiming a certain supplement gave them amazing results. Celebrities endorsing supplements can affect countless young adults looking for results from supplements, thus, their claims should be restricted.

Celebrities and athletes may get paid millions of dollars to claim that they take a supplement and that it worked for them. These false claims can induce many individuals to purchase the product and it may never provide any results the product claimed and the supplement could even consist of unsafe ingredients. There should be mandatory restrictions placed on celebrities and athletes making claims about dietary supplements. Heavy fines would be a good method to deter celebrities and athletes away from making successful claims about supplements which scientific evidence proves to be of little accuracy.

C. Further Age Restrictions On The Purchase of Supplements

A proposed bill introduced in 2013 by the Senate has already suggested that sport supplements should not be sold to individuals under the age of 18.¹²⁸ Many young adults have died over the past few years from taking supplements which were easily made available to them. Almost any student in high school could walk into a supplement shop and purchase a product with a label stating it's intended to be used by someone over the age of 18. This proposed bill

would be an exceptional way to reduce the sale of sport supplements to young adults under the age of 18. A problem with the bill is it does not specify how the ban should be carried out. A way to ensure that individuals under 18 do not get their hands on sport supplements would be to ID them at the register before finalizing the purchase. Another decent method to ensure people under the age of 18 do not even get to hold the product is by not having the product readily accessible. Products intended to be used for individuals over the age of 18 should be displayed in a glass case and the actual supplement should be kept behind the register. This would guarantee that someone under the age of 18 could not buy the product without showing ID and would not have the chance to steal it due to the age restriction.

Another way to further protect young adults from harmful side effects of supplements is to restrict the sale of energy drinks. Gas stations, grocery stores, convenient stores, etc. should abide by regulations which do not allow the sale of any energy drink to someone under the age of 18. Young adults are part of a group that is more sensitive to caffeine's effects than adults.¹²⁹ Some energy drinks contain enough caffeine to pose significant health concerns to a minor. Thus, minors should not be allowed to purchase any kind of energy drink if they are not 18. Stores that sell energy drinks to individuals under the age of 18 should be fined a pre-determined amount in order to deter future sales to minors.

D. Further Educating Young Adults About Dietary Supplements

Dietary supplement use has been well-documented in college but has not been adequately documented in young athletes.¹³⁰ The few studies that have investigated high school athletes taking supplements claim that dietary supplement usage is common and increasing due to heightened pressure on athletes to succeed in their sport.¹³¹ The frequency of use of dietary supplements among young adults and young athletes range from 22.3% to 71%.¹³²

Approximately only 10% of adolescent athletes report good or very good knowledge about dietary supplements.¹³³ In order to ensure that young adults are taking supplements in a safe manner they need to be educated about dietary supplements in school within a health and wellness class. Most high school programs offer some sort of physical education or nutrition course. Majority of these courses do not cover any aspect of dietary supplements. If the average high school student was asked to name a few ingredients in supplements that they should avoid they would most likely not have a valid answer. Coaches are said to be the most influential on high school athletes, yet, majority of them have no formal training in nutrition.¹³⁴ In one study, high school athletes were asked if they would take supplements if their coaches said they were said and almost 83% said they strongly agreed or agreed.¹³⁵ Not only should high school students be forced to take an educational course providing them with useful knowledge about dietary supplements, but coaches should have to take these courses as well. Further educating young athletes on high school teams would additionally be a useful method to ensure their awareness in regards to the potential harm of taking dietary supplements. Since young athletes may consume more dietary supplements than the average high school student, a dietician should visit each team on a weekly or monthly basis to discuss supplements each team member is taking. Moreover, young athletes would also benefit by meeting with a dietician to discuss current supplements which may possess harmful side effects. Many young adults including athletes choose to take dietary supplements hoping to achieve a specific result. If individuals begin to take dietary supplements at a young age they may come across a variety of products consisting of harmful ingredients throughout their lives. Overall, young adults need to be educated in school to fully understand the seriousness of taking dietary supplements.

E. Further Regulation On Proprietary Blends

Countless supplement manufacturers use proprietary blends in order to hide the exact amounts and types of ingredients in their products. This method continues to exist, and as previously discussed, can pose a great threat to young adults and other individuals. Supplement manufacturers should not be able to hide their ingredients or the amounts unless they can prove that it is ultimately necessary to protect their product. In most cases it seems supplement manufacturers are not disclosing all the ingredients because they are trying to trick the consumer. There needs to be some form of regulation requiring dietary supplement manufacturers to submit all of their ingredients and amounts therein from each product they sell. If they prove a valid reason to not disclose certain ingredients and amounts, they still should be required to have the FDA approve their supplement before it is introduced on the market. Young adults and other individuals will continue to be misled and possibly severely harmed if proprietary blends are allowed to exist on the market subjected to minimal regulation.

Conclusion

There has been a continued struggle in the FDA's ability to regulate dietary supplements since the passage of Dietary Supplement and Health Education Act in 1994. Modern cases are occurring proving that individuals as well as young teenagers are still being negatively impacted by the FDA's ability to regulate dietary supplements. In the past few years, young adults and other individuals have been injured by an ingredient known as DMAA in sport supplements which the FDA could not remove from the market for numerous years. Consumers have also been injured by the false advertisements made by the "Kardashians" endorsing a supplement called "Quick Trim which consisted of unsafe ingredients. Moreover, young adults continue to be harmed by Monster Energy Co. marketing their products toward them. These are a few of

many factual examples proving the FDA's inability to regulate dietary supplements efficiently. Reform must be carried out to provide the FDA with broader authority to regulate sport and dietary supplements to help prevent unnecessary deaths of young adults. By requiring pre-market approval, limiting advertisements by manufacturers, age restrictions, and educating young adults about the harmful side-effects dietary supplements possess are a few of many proposals which can be made to aid the FDA in this current struggle. Waiting for individuals to become severely injured by a product before looking into that product's safety is not the moral process which should be allowed. Young adults and other individuals will continue to suffer while the current dietary supplement regulations exist.

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