

**Optimistic Perception, Dangerous Reality:
Dietary Supplement Regulation and Young-Adult Athlete Supplement Use**

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ABSTRACT

In 1994, Congress enacted the *Dietary Supplement Health and Education Act (DSHEA)*, which dramatically expanded the definition of a dietary supplement and established regulations for the marketing and manufacture of supplement products. The policy was intended to balance consumer access to supplements with consumer safety. However, *DSHEA* currently permits significant use of dietary supplements by uneducated young-adult athletes that were commonly provided or recommended a dietary supplement by an authority figure as a method to maximize their athletic potential. In order to understand the consumption habits of young-adult athletes, I utilized a mixed-methods approach, which included a survey of the University of Chicago Football team, which received eighty responses. Additionally, I conducted extensive interviews with four head coaches (two collegiate head football coaches, one collegiate head basketball coach, and one high school head football coach) and eight University of Chicago Football players. Following an aggregation of the quantitative survey data and an analysis of the qualitative interview findings, a common theme arose. There is currently a substantial disconnect between young-adult athletes' knowledge of dietary supplement regulation in comparison to these athletes significant and diverse supplement consumption habits. As a result, I recommend a number of policy revisions, first at the federal level and, additionally, I recommend the creation of mandatory supplement education programs by the NCAA and high school athletic associations.

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TABLE OF CONTENTS

INTRODUCTION.....	1
LITERATURE REVIEW.....	4
METHODOLOGY.....	13
DATA AND ANALYSIS.....	17
DISCUSSION.....	51
POLICY RECOMMENDATIONS.....	54
CONCLUSION.....	58
APPENDICES.....	59

INTRODUCTION

I was first introduced to supplements by my high school strength and conditioning coach. He recommended I buy whey protein, which is a dietary supplement that promotes muscle growth and improved strength. Later that week, I purchased a massive canister of Muscle Milk at my local Costco and began to regularly consume protein shakes in the summer months before my sophomore year of high school. My coach emphasized that with the incredible benefits of supplement consumption, I could become - bigger, faster, stronger, more agile, less prone to injury, and even recover faster. What competitive athlete does not want to maximize their athletic potential? As a standout on the junior varsity team with dreams of playing at the collegiate level, I was captivated by the idea that supplements could further boost my athletic prowess. I distinctly remember overhearing an older varsity player excitedly announcing he had put on the ten pounds of muscle in a single month, with the help of a supplement called creatine. Soon after, I purchased my own canister of creatine with the encouragement of my coach and the full support of my athletically-oriented father.

The results were close to 'as advertised'. Within two months, I put on fifteen pounds and was shattering my previous personal records on both squat and bench press. I was bigger than ever and, as a result of the creatine, my body recovered more rapidly, alleviating soreness faster, which allowed me to get back in the gym sooner. My teammates and friends began to consume similar supplements during this same period. Midway through the season, however, I realized all these benefits came with some rarely discussed drawbacks. Players cramped non-stop during games, practice, and even in class due to the dehydration that creatine can cause to its user.

Weightroom injuries skyrocketed, as players pushed for heavier weights that exceeded their body's natural capacity. By the end of my sophomore year I stopped consuming creatine, but continued to drink whey protein shakes.

I had seen the athletic benefits possible with the aid of supplements and once I became a collegiate athlete, I expanded my dietary supplement consumption to include pre-workout, post-workout, branched-chain amino acids (BCAA's), and experimented between casein and whey protein. Pre-workout got me to the gym, with a caffeine content equivalent to three cups of coffee in a single scoop. During my workouts, I drank BCAA's, which were advertised to enhance muscular performance and hasten muscle recovery. After the gym, I always drank a protein shake, which I staunchly believed was necessary for my continued strength gain. I experimented between whey and casein proteins to ascertain which type of protein could provide the best results. I even consumed a post-workout that supposedly further stimulated muscle growth and recovery. I researched what supplements NFL players and Olympic athletes consumed to better inform my purchases and I regularly browsed Bodybuilding.com's supplement marketplace for the newest products from my favorite brands. I continued to consume supplements in this fashion for my first three years of college and, all the while, I hardly knew the contents of what I was putting into my body. It wasn't just me though. My supplement use was in no way out of the norm nor was it extreme in comparison to my friends and teammates. If anything, I knew many teammates whose' use of supplements greatly outpaced my own. My teammates all took similar supplement products and our coaches never condemned our consumption habits.

My skepticism of dietary supplements began when I observed my teammates' creatine-related incidents in high school. It was during my fourth year of college, however, as I researched the next protein powder to buy, that I stumbled upon an article discussing supplement manufacturers use of the term “proprietary blend” on their products. A proprietary blend refers to certain ingredients contained within a supplement product, however, the manufacturer is not required to specify the exact amount of each ingredient within the “blend”. I glanced over the nutritional facts on my supplements and, to my dismay, they all contained “proprietary blends”. I felt cheated, I thought I had thoroughly researched my supplements to ensure the safety of their contents, but I was wrong. Soon after, my disenchantment with supplements began and I gradually stopped consuming all of my supplements, except for the pre-workout that I may have been genuinely addicted to.

My disdain for the lack of transparency and honesty of dietary supplement marketing led to my selection of supplement regulation as the topic for my BA thesis and my preliminary research vindicated my view that this was not a problem limited to me as an individual, but rather a systemic issue that arose from the federal government's current regulatory framework. While I initially viewed the supplement manufacturers as unaware of the dangers they were creating for consumers, the story of one industry whistleblower confirmed that these companies are fully aware of the risks consumers face.

In 2015, a Harvard Professor published the results of a laboratory analysis of 21 supplements, 11 of which were found to contain β -Methylphenethylamine or BMPEA, an illegal amphetamine-like drug.¹ The supplement manufacturer, Hi-Tech Pharmaceuticals, which

produced six of the eleven illegal products, sued Cohen for \$200 million claiming defamation.² Although the FDA ordered these illicit manufacturers to recall their products, all six of Hi-Tech Pharmaceuticals, remained on the market after minor modifications were made to the products' formulas.³ A year after the initial publication, Cohen re-tested these products and still found traces of BMPEA within the products.⁴ Clearly, the FDA's recall order did little to deter Hi-Tech Pharmaceuticals from capitalizing on the continued illicit production and sale of their harmful supplements.

This example exemplifies the current lack of effective supplement regulation, which stems from an outdated policy passed in the mid-1990's. The *Dietary Supplement Health and Education Act of 1994 (DSHEA)* broadly defined what a dietary supplement is and enacted various rules about the marketing and manufacturing practices permitted for dietary supplements. The issues with this obsolete policy are quite evident to the modern viewer. For instance, the FDA is responsible for taking action against any adulterated or misbranded dietary supplement product only **after** it reaches the market. Additionally, the FDA has no responsibility for regulatory action or regulation until an actual issue arises or a breaking of DSHEA guidelines becomes apparent. Rather than active oversight of the dietary supplement market, the FDA must passively wait until an issue arises, instead of being a proactive regulatory force.

At the time of *DSHEA*'s enactment, policymakers intended to expedite the dissemination of information and research associated with dietary supplements that had the potential to aid human lives. While theoretically admirable, *DSHEA* actually exposed American consumers to far greater risks by severely limiting the preliminary and active oversight of the FDA, the only

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federal agency that regulates the dietary supplement marketplace. Obviously, there is an inherent tension between the goal of *DSHEA* and a more consumer-safety oriented regulatory policy. Currently, *DSHEA* streamlines the process that regulates the production and marketing of dietary supplements. This current iteration of dietary supplement regulation permits a greater dissemination of information and allows consumers to more quickly access supplements that might otherwise be bogged down by a more stringent regulatory process framework similar to that of over the counter and prescription drugs. Unfortunately, *DSHEA*'s emphasis on consumer access enables dietary supplement manufacturers to rapidly push untested products to the public marketplace, that may contain mislabeled and untested chemicals, which poses a threat to consumers' health.

I will investigate and analyze the unforeseen implications of the *Dietary Supplement Health and Education Act of 1994 (DSHEA)* on the dietary supplement marketplace, with an emphasis on the policy's effect on young-adult athlete supplement use. Additionally, I plan to educate consumers about the risks they may unknowingly be subjecting themselves to. Through an aggregation of the quantitative survey data and an analysis of the qualitative interview findings, a common theme arose. There is currently a substantial disconnect between young-adult athletes' knowledge of dietary supplement regulation in comparison to these athletes significant and diverse supplement consumption habits. As a result, I recommend a number of policy revisions, first at the federal level and, additionally, I recommend the creation of mandatory supplement education programs by the NCAA and high school athletic associations.

LITERATURE REVIEW

Scholarly literature regarding the regulation of dietary supplements expanded dramatically following the *Dietary Supplement Health and Education Act of 1994 (DSHEA)*, which significantly expanded the definition of a dietary supplement and curtailed various regulations that had previously restricted aspects of the marketing and manufacture of dietary supplements. A significant number of deaths and hospitalizations associated with the consumption of dietary supplements like ephedra, tryptophan, and hydroxycut indicated a severe need for scholarly research on the subject of supplement regulation. As a result, there is now a sizeable body of literature that emphasizes the astonishing surge in supplement production, which coincided with an increasingly dangerous and under-regulated consumer market that developed as a result of the eased regulation after the passage of *DSHEA* in 1994.

A Brief History of Dietary Supplement Regulation

Before elaborating on contemporary scholarly research regarding dietary supplements, I offer a brief summary of key essays and legislative journals detailing the history of dietary supplement regulation in the United States, which is necessary for understanding today's regulatory practices.

The *Food, Drug, Cosmetic Act of 1938 (FDCA)* was the federal government's first indirect attempt at supplement regulation, as under the Act, vitamins and minerals were

categorized as food and regulated as such.⁵ The Act required that a drug must be shown as safe prior to any marketing.⁶ In 1958, Congress passed the *Food Additives Amendment*, which classified dietary supplement as food additives and required manufacturers to present sufficient evidence of a supplement product's safety **before** it could be marketed.⁷ It was not until 1962, that the *Kefauver-Harris Amendment* mandated that the efficacy of a drug must be demonstrated prior to its introduction to interstate commerce.⁸

By the early 1990's, Congress was considering two proposals to significantly increase the federal government's regulation of dietary supplements. One proposal would have bolstered the FDA's enforcement abilities and increased the penalties for violating the *FDCA*.⁹ The other proposal would have tightened controls on the marketing of supplements, prohibiting manufacturers from advertising therapeutic claims on the labels of dietary supplements.¹⁰ In response, the health-food industry initiated an aggressive lobbying campaign that focused on retaining consumers' freedom to choose dietary supplements.¹¹ Although these lobbying tactics often contained unsubstantiated claims including assertions that the FDA was attempting to take away consumers' rights to buy vitamins, the lobbying efforts proved to be extremely effective.¹²

The health-food industries lobbying efforts culminated with the passage of *Dietary Supplement Health and Education Act of 1994 (DSHEA)*, which redefined a dietary supplement in its own regulatory category. *DSHEA*'s expanded definition permitted a greater number of

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products to be marketed as supplements and, additionally, made it possible to reclassify all such substances as “food”.¹³ While Congress claimed the policy was intended to balance consumer access to supplements with consumer safety, a substantial number of substances that were similar to pharmaceuticals could now be more easily purchased by consumers, with significantly less regulatory oversight. For example, *DSHEA* allowed dietary supplements to enter the market without requiring manufacturers to submit safety and efficacy information to the FDA,¹⁴ which essentially meant that there was no longer any premarket approval process for dietary supplements. Additionally, following the passage of *DSHEA*, the FDA could only take action **after** a supplement was marketed and shown to pose a threat to public welfare.¹⁵ As a result, *DSHEA* unequivocally placed the burden of proof on the FDA, a government agency that has historically been understaffed and underfunded.¹⁶

In 2006, Congress passed the *Dietary Supplement and Nonprescription Drug Consumer Protection Act*, which primarily added the requirement that a “responsible person” must submit all reports of adverse effects associated with a dietary supplement product to the FDA.¹⁷ While this legislation provided an additional level of oversight, through an expedited identification of problematic supplement products, it is highly limited in its potential, since a consumer must report the adverse effect directly to the manufacturer before the manufacturer is legally required to report the incident to the FDA. Similar to *DSHEA*, this policy placed the burden of proof primarily on the consumer and the FDA, rather than the dietary supplement manufacturer.

¹³ Pg 180 of repeal dshea pdf

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¹⁵ Pg 183 of repeal dshea pdf

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¹⁷ *DSHEA's Failure: Why A Proactive Approach to Dietary Supplement Regulation is Needed*

Since the passage of *DSHEA* in 1994, the number of dietary supplement products has skyrocketed from 4000 to more than 85,000.¹⁸ Relatedly, the dietary supplement industry grew from \$15.6 billion in sales in 1994 to attaining a market revenue of over \$50 billion in 2016.¹⁹ The dietary supplement market was valued at \$133.1 billion in 2016 and has been projected to continue its steady growth.²⁰ Clearly, *DSHEA* has led to a massive expansion of the lucrative supplement marketplace, but at what cost?

Dietary Supplement Regulatory Failures

Since the passage of *DSHEA*, there has been numerous instances of adverse events and deaths due to the lack of regulation regarding the purity, safety, and efficacy of supplement products. Unknowingly exposed to a vast array of untested supplement products with minimal to no premarket oversight, everyday consumers purchase and consume supplements that might prove to be detrimental to their immediate and long-term health. A few examples clearly illustrate the danger assumed by American consumers following the passage of *DSHEA*. These regulatory incidents highlight some of the regulatory obstacles the FDA faces when attempting to protect consumers under *DSHEA*.

In 1997, the FDA proposed a ban on the stimulant ephedra, but due to the burden of proof assumed by the FDA under *DSHEA*, the agency failed to enact an effective ban.²¹ As a result, ephedra was not successfully stripped from the supplement market until 2007.²² Ephedra was

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¹⁹ *Americans' Views on the Use and Regulation of Dietary Supplements*

²⁰ <https://www.grandviewresearch.com/industry-analysis/dietary-supplements-market>

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marketed to increase energy, stimulate weight loss, and enhance athletic performance, but the stimulant was also linked to heart attacks and strokes.²³ Ephedra caused over 16,000 adverse events and 150 deaths before the FDA finally banned the product from the public marketplace.²⁴ Strangely, a Google search of “ephedra” today will generate numerous supplement products marketed under the same name, with near-identical purported benefits to the ephedra product that was banned in 2007. Most current scholarly work regarding supplements cites Ephedra as one of the most pronounced instances of *DSHEA*’s unfortunate impact on supplement consumers within the United States.

Another instance of regulatory failure was the L-tryptophan incident. In the late 1980’s, the company Showa Denko K. K. began to use genetically engineered bacteria to accelerate and increase the efficiency of the tryptophan production process.²⁵ In 1988, these genetically engineered bacteria were utilized in the commercial production process, but since the FDA did not require any additional testing and Showa Denko had previously safely produced tryptophan with non-genetically engineered bacteria, no alarms were raised.²⁶ The FDA did not require this new tryptophan product to be labeled as genetically engineered and within the first three months of the products release into the public marketplace, 37 people died and 1,500 were permanently banned from using the product.²⁷ It took months to discover the presence of the toxicity within these products, but possibly even more terrifying, is the fact that the highly toxic contaminant comprised less than .1% of the total weight of the product and it still killed people.²⁸ In an

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²⁴ *DSHEA’s Failure: Why A Proactive Approach to*

²⁵ http://www.nemsn.org/Articles/summary_ tryptophan%20Fagan.htm

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²⁷ http://www.nemsn.org/Articles/summary_ tryptophan%20Fagan.htm

²⁸ http://www.nemsn.org/Articles/summary_ tryptophan%20Fagan.htm

under-regulated industry the tryptophan incident illustrates the extreme danger that an untested and misbranded product can pose to American consumers.

The lack of governmental oversight within the industry permitted manufacturers and to expose the public to critical danger, which could hardly be prevented under *DSHEA*, as the FDA's ability to regulate supplement products was largely restrained following the enactment of the 1994 legislation.

Comparison with International Dietary Supplement Policies

Other scholarly works compare *DSHEA* to the dietary supplement regulatory policies of other nations and illustrate the effects of the varied stringency of such regulations on each country's respective supplement industries. The European Union enacted the *Food Supplements Directive* in 2004, which introduced a "positive substance" list of just over a hundred substances, vitamins, and minerals that can be contained within a legal dietary supplement.²⁹ Any substance that is not identified on the list cannot be contained within a legal dietary supplement.³⁰ To obtain a place on the positive list, it is estimated that a supplement manufacturer must spend €100,000- €400,000 in order to conduct the necessary tests to be eligible for addition to the positive list.³¹ The entirety of this process can take two to three years, limiting all but large dietary supplement manufacturers to attempt to add ingredients to the EU's positive list.³² Canada adopted a similar policy in 2004, with the *National Health Products Regulations Act*,

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which also created a positive list of substances and ingredients that can be contained within a legal dietary supplement.³³

Australia's 1989 *Therapeutic Goods Act* provided the framework for the import, export, and manufacture of medicine, which included dietary supplements. Any product with a therapeutic action must be listed on a national register of therapeutic goods, but these products cannot claim to prevent or cure disease.³⁴ Although the 1989 *Therapeutic Goods Act* is similarly lenient to *DSHEA*, the legislation provides an additional level of oversight, as 20% of the newly listed medicines and supplements are subject to random compliance testing.³⁵ This Act received significant public scrutiny following the discovery of numerous assurance breaches by the country's largest manufacturer of vitamins, Pan Pharmaceuticals.³⁶ These regulatory failures exposed Australian consumers to supplement products that contained ingredients which ranged from none to seven times the marketed amount or other issues, including ingredient substitutions.³⁷ Incidents like these, exemplify the international difficulty of creating appropriate dietary supplement regulation policy that can effectively protect the consumer, while simultaneously providing consumers' access to pure, safe, and effective supplement products.

33

³⁴ *The Development of the US and Australian Dietary Supplement Regulations*

³⁵ *Ibid.*

³⁶ https://heinonline.org/HOL/Page?collection=journals&handle=hein.journals/unilllr2010&id=1055&men_tab=srchresults

37

METHODOLOGY

In order to understand the dietary supplement consumption habits of young-adult athletes, I utilized a mixed-methods approach, which included a survey of the University of Chicago Football team, which received eighty responses. Additionally, I conducted extensive interviews with four head coaches (two collegiate head football coaches, one collegiate head basketball coach, and one high school head football coach) and eight University of Chicago Football players. Following an aggregation of the quantitative survey data and an analysis of the qualitative interview findings, a few common themes arose.

UChicago Player Survey Analysis

Since I was already a player on the University of Chicago Football Team, survey participants were recruited via the UChicago Football Team's email listhost, which served as a reliable means of communication. I was already permitted access to email listhost as a member of the football team. Eighty survey responses were collected over the course of two weeks in February 2019. No monetary compensation was provided, as my teammates were previously made aware of my BA topic and had expressed a collective willingness to participate in my survey.

Survey respondents were permitted only one response opportunity in order to reduce the risk of duplicate survey responses. Additionally, the question order of the survey was randomized in order to limit question order effects. Unfortunately, within days of sending out the survey, the FDA issued a series of Warnings Letters to dietary supplement manufacturers that were accused of illegally marketing their supplements. Simultaneously, the FDA vowed to change its dietary supplement regulatory policies. These announcements may have influenced respondents decision-making, as knowledge of the FDA's sudden action may have primed certain survey responses. Lastly, my teammates' prior knowledge that I created and distributed the survey may have influenced survey responses. Although these issues could affect the validity of the survey data, I believe the responses illustrate an accurate and valid depiction of UChicago Football players' dietary supplement use.

Head Coach Interview Analysis

In total, four Head Coaches were interviewed. Three are current Head Coaches at Universities in the Midwest and one is the current Head Coach of a high school football team in Southern California. I recruited these coaches from contacts I developed over the course of my football career. I conducted in-depth, informal phone interviews with two of the four head coaches and interviewed the other two head coaches in person.

The initial intention for interviewing a high school football coach was to attain a broader perspective on young-adult athlete supplement use, which often begins in high school. These interviews utilized the head coaches' empirical experiences at various levels of athletic competition to compare young-adult athlete supplement use across collegiate divisions and high

school levels. Additionally, the head coaches' decades of collective work experience elicited valuable information in relation to their experience with young-adult athlete supplement use variation over their respective coaching careers.

Due to my prior relationships with the coaches interviewed there may have been a selection bias and a social desirability bias, as these coaches felt compelled to carefully answer questions regarding their players' use of dietary supplements and their role in facilitating such use.

UChicago Player Interview Analysis

Following the team survey, a total of eight UChicago Football players were selected to be interviewed based on their survey responses. In order to diversify interviewees, respondents with diverse levels of supplement use were selected to more accurately portray use patterns among young-adult football players at the University of Chicago. Additionally, I intentionally selected two players from each class. As a result I interviewed two freshman, two sophomores, two juniors, and two seniors to hopefully broaden the scope of my findings and reduce bias.

Player interviewees were recruited via text message and then interviewed in an informal, but in-depth manner by myself. Since I already knew every player interviewed, responses may have been subject to some bias. However, such bias should be negligible, as the intention of the player interviews was to identify the reasoning and meaning behind the supplement use, rather than discern the level of supplement use among players, as the survey already collected such information.