



# The Impact on Athletes of the Current Regulatory Scheme for Dietary Supplements

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The Impact on Athletes of the Current Regulatory Scheme for  
Dietary Supplements

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## Abstract

This paper uses the popularity of dietary supplements among athletes and the possibility that such athletes may unknowingly fail drug tests because of said supplements as a lens for examining some of the weaknesses caused by the FDA's current limited authority over the supplement industry. After providing an outline of both the current state of the law with respect to dietary supplements and the regulations and liability to which athletes are subject, I emphasize the impact and potential consequences of widespread use and endorsement of dietary supplements by athletes. I then specifically address the possibility of surprise liability for supplement use and what this possibility reveals about the supplement industry, as a whole. Ultimately, I conclude that the FDA should regulate more tightly the supplement industry. Although the possibility of treating dietary supplements as drugs seems promising in many ways, I propose that, at least in the short term, the FD&C Act be amended to treat dietary supplements strictly as foods – without the exceptions brought about by DSHEA – in order to solve some of the current problems (and specifically the problem of surprise liability among athletes) caused by the loose regulation of the supplement industry.

## Introduction

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the regulatory authority of the Food and Drug Administration (FDA) over the dietary supplement industry in the United States (US) was significantly reduced in many ways. This limited regulation – which involves, for example, looser labeling requirements,<sup>1</sup> exemption from pre-market approval,<sup>2</sup> and authorization for manufacturers to make structure/function claims<sup>3</sup> – presents a host of issues for consumers. Because so many of these supplements are marketed as healthy dietary additions for people with active lifestyles, athletically-inclined people are perhaps even more likely than the average person to purchase and use these substances.<sup>4</sup> In an era where athletes in nearly all sports at nearly all levels – from high school and younger through the highest-paid professional athletes – are subject to league and public scrutiny over the substances put into their bodies, the use of certain dietary supplements can land an individual in quite a quandary.

Because of the common use of a strict liability-style regime<sup>5</sup> in the discipline of athletes who test positive for banned substances, questions arise concerning the adequacy of the current regulation of dietary supplements. Does the current regulatory scheme provide consumers, and specifically athletes, with sufficient information to make informed choices about what they are putting in their bodies? If not, is the potential of

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<sup>1</sup> Federal Food, Drug, and Cosmetic Act (FD&C Act) §403(q)(5)(F).

<sup>2</sup> FD&C Act §201(s)(6).

<sup>3</sup> FD&C Act §201(g)(1)(D).

<sup>4</sup> According to the European Specialist Sports Nutrition Alliance (ESSNA), 90% of the 11,000 athletes competing in the Beijing Olympic games used dietary supplements. (“Dietary Supplements Win Olympic Gold,” <http://www.foodnavigator-usa.com/Financial-Industry/Dietary-supplements-win-Olympic-gold>.) The portion of Americans, in general, who use dietary supplements regularly is about 48%, while about 68% of Americans report using dietary supplements at all. (“Consumer Confidence in Dietary Supplements Remains Steady, Annual Survey Results Show,” [http://www.crnusa.org/CRNPR08\\_Survey102208.html](http://www.crnusa.org/CRNPR08_Survey102208.html).)

<sup>5</sup> Athletes in all types of competitions from NCAA athletics to the Olympics to American professional sports leagues are subject to immediate discipline (such as temporary or permanent suspension) upon testing positive for a banned substance, regardless of any explanation they can offer.

surprise liability for athletes who unknowingly consume a banned substance an issue that should concern the federal government? Considering the high stakes for both professional and amateur athletes, should Congress grant the FDA the authority to tighten the regulation of the dietary supplement industry? Although providing definitive answers to these questions is a complicated task, this paper will endeavor to examine these and other issues that arise for athletes who use dietary supplements.

### The Current Regulatory Regime that Governs the Manufacturing and Marketing of Dietary Supplements

The definition of the term “dietary supplement” includes “products intended to supplement the diet” that contain one or more of “a vitamin, a mineral, an herb or other botanical, an amino acid,” that “are not represented for use as a conventional food or as a sole item of a meal or the diet,” and that are “labeled as dietary supplement[s].”<sup>6</sup> This broad definition, which was first adopted by Congress under DSHEA,<sup>7</sup> includes a wide array of products that are “intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form.”<sup>8</sup> Pursuant to changes made to the Federal Food, Drug, & Cosmetic Act (FD&C Act) under DSHEA, dietary supplements are “deemed to be a food” within the meaning of the Act,<sup>9</sup> but important exceptions exist to that general rule; these exceptions carve out a position for dietary supplements that subjects them to less scrutiny than either food or drugs.

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<sup>6</sup> FD&C Act §201(ff)(1-2).

<sup>7</sup> Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, “Food and Drug Law: Cases and Materials.” 3d edition. New York: Foundation Press, 2007. p. 261

<sup>8</sup> FD&C Act §411(c)(1)(B)(i).

<sup>9</sup> FD&C Act §201(ff).

Unlike both food additives and drugs, dietary supplements are not subject to pre-market approval.<sup>10</sup> Instead, the burden shifts to the FDA to identify and remove any dietary supplements that it considers “adulterated.” The definition of adulteration, though, is also different with respect to dietary supplements than it is with respect to food. A dietary supplement can be deemed adulterated if it:

- (A) presents a significant or unreasonable risk of illness or injury under --
  - (i) conditions of use recommended or suggested in labeling, or
  - (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
- (B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;
- (C) the Secretary declares to pose an imminent hazard to public safety, except that the authority to make such a declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding ... to affirm or withdraw the declaration; or
- (D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.<sup>11</sup>

The repeated emphasis on a “significant or unreasonable risk of illness or injury” sets a much higher hurdle for the FDA to overcome when seeking to remove a dietary supplement from the market. By contrast, the FDA can deem a food adulterated if it contains “any poisonous or deleterious substance which may render it injurious to health.”<sup>12</sup> The distinction between a “significant” or “unreasonable” risk and any risk of injury at all is clear – the FDA has much broader authority with respect to most foods but, with dietary supplements, must wait until there is actual evidence of serious illness or injury before removing a product from the market.

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<sup>10</sup> Section 201(s)(6) of the FD&C Act explicitly distinguishes dietary supplements from food additives (which are subject to pre-market approval). In practice, Congress’ addition of this subsection exempts dietary supplements from pre-market approval.

<sup>11</sup> FD&C Act §402(f)(1).

<sup>12</sup> FD&C Act §402(a)(1).

Because of this heightened burden on the FDA, a supplement may cause many injuries, and even deaths, before the FDA is able to remove it from the market. One good example of this possibility is the FDA's struggle to remove ephedra from the market. Because claims that ephedra enhanced athletic performance were shown false, the FDA was able to remove forms of ephedra making those claims from the market in 2000. Since it took much longer to establish a case for "unreasonable risk of illness or injury," though, dangerous doses of ephedra remained on the market in other forms (namely, as diet aids) for about four more years.<sup>13</sup> In the meanwhile, over 155 people died from the use of ephedra.<sup>14</sup> The FDA came under attack from critics and from the public for their delay in banning ephedra,<sup>15</sup> but one must ask whether the FDA was limited because of the scope of its regulatory power – had it not needed to prove the higher adulteration standard necessary for dietary supplements, ephedra very well could have been removed from the market faster.

Manufacturers of dietary supplements also benefit from looser labeling requirements than other food manufacturers must follow. Dietary supplement labels must include nutrition information for ingredients "that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary" but need not list an ingredient that is "not present in a significant amount."<sup>16</sup> As this paper will discuss later, though, consumption of even trace amounts of certain ingredients can have an effect on the outcome of tests for banned

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<sup>13</sup> "FDA Issues Regulation Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids and Reiterates Its Advice That Consumers Stop Using These Products," 6 February 2006. (<http://www.cfsan.fda.gov/~lrd/fpephed6.html>.)

<sup>14</sup> "FDA Moves to Ban Ephedra: Too Little, Too Late, Say Critics," *Consumer Affairs*, 30 December 2003. ([http://www.consumeraffairs.com/news03/ephedra\\_ban.html](http://www.consumeraffairs.com/news03/ephedra_ban.html))

<sup>15</sup> *Ibid.*

<sup>16</sup> FD&C Act §403(q)(5)(F)(i).

substances. In addition, the FDA has no regulatory authority over other publications (such as articles or pamphlets) that are written about dietary supplements, even if the literature is written by people with an economic interest in the sale of the supplement and even if the literature is available in the same store that is selling the supplement.<sup>17</sup> Therefore, manufacturers and marketers of dietary supplements have another available avenue to make claims about the benefits of their products.

One final key change that the DSHEA made to the advantage of the dietary supplement industry is that such supplements, because of their classification as foods, can make the types of structure/function claims that are usually reserved for drugs. Although these assertions, which claim that a certain substance has a certain affect on the human body, usually gives the FDA authority to regulate a substance as a drug, Congress gave the dietary supplement industry an explicit exception to this rule.<sup>18</sup> This carve-out for the dietary supplement industry is perhaps especially strange when compared to the rules that regulate the cosmetic industry – cosmetics, which are applied to the exterior of the body – cannot make structure/function claims without becoming classified as drugs, but dietary supplements (and other foods), which are ingested into the body, can make such claims. The FDA can, as seen in the ephedra case, remove from the market dietary supplements that make unsubstantiated structure/function claims; also, because dietary supplements are not subject to pre-market approval, all labels that make these claims must include the disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”<sup>19</sup>

Nevertheless, the ability of dietary supplement manufacturers to make structure/function

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<sup>17</sup> FD&C Act §403B(a).

<sup>18</sup> FD&C Act §201(g)(1)(D).

<sup>19</sup> Paula Kurtzweil, “An FDA Guide to Dietary Supplements,” *FDA Consumer*, September-October 1998.

claims is perhaps one of their most effective marketing tools and is also one of the primary ways that athletes and other consumers are drawn to try to improve their overall health and performance through supplement use.

### An Overview of Athlete Liability that Arises from Testing Positive for Banned Substances

After reviewing the regulatory regime that governs the manufacturing and marketing of dietary supplements, this paper will now examine the liability that athletes face when testing positive for banned substances, in order to provide a context for the later analysis of supplement use among athletes. Both the lists of banned substances and the testing policies vary, depending on sport, level, and league. Since this paper addresses the FDA regulation of dietary supplements, it will focus primarily on drug tests to which American athletes may be subject.

American amateur athletes who compete in the Olympics are subject to testing both from the International Olympic Committee (IOC) and the United State Olympic Committee (USOC). The IOC established the World Anti-Doping Agency (WADA) about a decade ago to combat the use of banned performance-enhancing substances.<sup>20</sup> The consequences of failing a WADA drug test can range from disqualification from the current competition to suspension from any number of future competitions.<sup>21</sup> Considering how infrequently Olympic competitions occur, an athlete's career can be substantially harmed by testing positive for a banned substance, even just once. The USOC also fully complies with WADA by testing athletes and suspending them when

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<sup>20</sup> "WADA History," <http://www.wada-ama.org/en/dynamic.ch2?pageCategory.id=253>

<sup>21</sup> Ryan Connolly, "Balancing the Justices in Anti-Doping Law: The Need to Ensure Fair Athletic Competition Through Effective Anti-Doping Programs vs. the Protection of Rights of Accused Athletes," 5 Va. Sports & Ent. L.J. 161, 178 (Spring 2006).

appropriate.<sup>22</sup> Moreover, WADA explicitly states that its testing program involves a strict liability regime:

For purposes of anti-doping violations involving the presence of a Prohibited Substance (or its Metabolites or Markers), the Code adopts the rule of strict liability which is found in the [Olympic Movement Anti-Doping Code, predecessor to the WADC] and the vast majority of existing anti-doping rules. Under the strict liability principle, an anti-doping rule violation occurs whenever a Prohibited Substance is found in an Athlete's bodily Specimen. The violation occurs whether or not the Athlete intentionally or unintentionally used a Prohibited Substance or was negligent or otherwise at fault.<sup>23</sup>

When athletes are held strictly liable for any positive tests, the stakes of potential surprise liability are, of course, much higher.

The National Collegiate Athletic Association (NCAA) is another very important governing body for American amateur athletes. The NCAA tests college athletes in all sports during post-season activities both on a random basis and on the basis of “position of finish, playing time, or position.”<sup>24</sup> The testing policy also requires athletes to submit to any tests required by the NCAA member school for which they play.<sup>25</sup> The NCAA has some of the strictest consequences for use of banned substances – “Student athletes caught using banned substances are suspended from the regular-season and postseason competition for one calendar year” and those who are caught a second time become “ineligible for any remaining seasons of eligibility in all sports.”<sup>26</sup> The NCAA’s list of banned substances is very extensive and includes many substances, such as guarana

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<sup>22</sup> United States Anti-Doping Association FAQs, <http://www.usada.org/resources/faqs.aspx>

<sup>23</sup> Article 2.1.1 of the World Anti-Doping Code, qtd. in 5 Va. Sports & Ent. L.J. at 179

<sup>24</sup> Darryl C. Wilson, “ ‘Let Them Do Drugs’ -A Commentary on Random Efforts at Shot Blocking in the Sports Drug Game,” 8 Fl. Coastal L. Rev. 53, 90 (Fall 2006).

<sup>25</sup> *Ibid.*

<sup>26</sup> Carl I. Fertman, *Student-Athlete Success*. Boston: Jones & Bartlett Publishers, 2008. p. 125

(natural caffeine),<sup>27</sup> that are legal and easily available at many stores. Therefore, an athlete who does not monitor strictly what he consumes, or who does not make himself aware of all of the ingredients in what he consumes, may find himself facing surprise liability with great consequences to his athletic career.

In addition to this drug testing on amateur athletes, all four of the major professional sports leagues in the United States<sup>28</sup> have lists of banned substances and procedures for testing athletes. The National Football League (NFL) has a list of banned substances, which includes the brand names of the substances (mostly anabolic steroids and hormones) that are forbidden by the league and also provides players with a hotline they can call if they have questions about supplements.<sup>29</sup> All players in the league are tested at least once a year for these banned substances.<sup>30</sup> The penalties are not as strict as they are for amateur athletes, since players are first offered rehabilitation for any type of positive tests (including both legal and illegal drugs); those who do not adhere to treatment programs, though, can face high fines and suspension without pay.<sup>31</sup> In baseball, too, athletes are given one chance at rehabilitation before they are subject to a series of pre-set escalating fines and suspensions for each additional offense.<sup>32</sup> The other

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<sup>27</sup> NCAA Banned-Drug Classes, 2008-09 (accessed at <http://www.ncaa.org/wps/wcm/connect/resources/file/ebb83308f4d9141/banned%20drugs%202008-09%2006-20-08.pdf?MOD=AJPERES&attachment=true>)

<sup>28</sup> This paper will address the National Football League (NFL), Major League Baseball (MLB), National Hockey League (NHL), and National Basketball Association (NBA), which are widely recognized as the four most popular sports leagues in the United States.

<sup>29</sup> "List of Prohibited Substances" (Accessed at <http://www.nflplayers.com/user/template.aspx?fmid=181&lmid=334&pid=0&type=n>)

<sup>30</sup> "Pro Sports' Dilemma," <http://online.wsj.com/public/resources/documents/info-mlbsteroids0504.html>

<sup>31</sup> Allan H. "Bud" Selig, "Symposium: Sports and the Law: The Regulation of Nutritional Supplements in Professional Sports," 15. *Stan. L. & Pol'y Rev.* 35, 55-56 (2004).

<sup>32</sup> 15. *Stan. L. & Pol'y Rev.* at 53.

major league sports have similar, albeit sometimes even looser, regulations concerning banned substances.<sup>33</sup>

Like amateur athletes, professional athletes are also held strictly liable for positive tests (in other words, explanations are not an acceptable way to escape the consequences of a positive test), but the stakes are a bit lower since professional athletes have a treatment-based option before they are fined or suspended. Nevertheless, the potential of surprise liability for professional athletes is still a very real issue that can lead to serious consequences. First, players are subject to media scrutiny and reputation damage when the results of drug tests become public. As the recent controversy surrounding Alex Rodriguez of the New York Yankees shows, these results can reach the public, even when they are intended to be confidential.<sup>34</sup> In addition, over the last decade, the leagues have continued to push for stricter regulation of player use of banned substances;<sup>35</sup> as a result, the potential of surprise liability could, in the future, lead to very strict consequences for professional athletes as well.

#### Dietary Supplement Use and Endorsement among Athletes

Athletes' use of dietary supplements is very extensive. As of 2006, the sports nutrition products industry (which includes bars, drinks, and other supplements) had more than \$22 million in sales per year.<sup>36</sup> Furthermore, 61% of NCAA athletes report using dietary supplements, with 23% of those taking supplements at least five times a

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<sup>33</sup> 15. Stan. L. & Pol'y Rev. at 55.

<sup>34</sup> Michael S. Schmidt, "Union Official Says He Did Not Tip Off Rodriguez," *New York Times*. 9 February 2009.

<sup>35</sup> 15. Stan. L. & Pol'y Rev. at 35-36.

<sup>36</sup> Heather Hedrick Fink, Lisa A. Burgoon, Alan E Mikesky, *Practical Applications in Sports Nutrition*. Boston: Jones & Barlett Publishers, 2008. p. 257

week.<sup>37</sup> Among Olympic athletes the use of dietary supplements is even more extensive – 90% of the competitors in the Beijing Olympic Games reported using such substances.<sup>38</sup> Although exact statistics about dietary supplement use among professional athletes are hard to come by, the high-profile deaths of athletes such as NFL player Korey Stringer (who was taking a dietary supplement containing ephedra that allegedly may have contributed to his heat stroke<sup>39</sup>) and MLB Player Steve Belcher (who died at age 23 after taking a dietary supplement with ephedra<sup>40</sup>) have shown the prominence of dietary supplements in sports.<sup>41</sup>

Not only do athletes tend to use these supplements, but many prominent athletes endorse dietary supplements. This endorsement, in turn, continues to cultivate new generations of young athletes who also consume dietary supplements.<sup>42</sup> Perhaps one of the most prominently advertised dietary supplements currently marketed to athletes is 5-Hour Energy™ (“5-Hour Energy”). NFL players Braylon Edwards and Osi Umenyiora appear in television and online ads for this product, as does racer Rusty Wallace, whose entire car now serves as an advertisement for this dietary supplement.<sup>43</sup> In addition to containing 2000% the recommended daily allowance (RDA) of Vitamin B6, 150% the RDA of Niacin, and 8333% the RDA of Vitamin B12, 5-Hour Energy contains an “energy blend” of taurine, glucuro lactone, malic acid, n-acetyl l-tyrosine, l-

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<sup>37</sup> *Ibid.*

<sup>38</sup> “Consumer Confidence in Dietary Supplements.”

<sup>39</sup> Chris Williams, “Vikings Raise Ephedra as ‘Causal Link’ to Stringer’s Fatal Heatstroke,” *USA Today*. 25 February 2003. (Accessed at [http://www.usatoday.com/sports/football/nfl/vikings/2003-02-25-stringer-ephedra\\_x.htm](http://www.usatoday.com/sports/football/nfl/vikings/2003-02-25-stringer-ephedra_x.htm))

<sup>40</sup> Elisabeth A. Cawthon, *Medicine on Trial*. Santa Barbara, CA: ABC-CLIO, 2004. p. 194.

<sup>41</sup> 15. *Stan. L. & Pol’y Rev.* at 35.

<sup>42</sup> Jeffrey A. Crossman, “Comment: ‘Sparing Cain: Executive Clemency in Capital Cases’: Mark McGwire Does It, So Why Can’t I? High School Student Use of Dietary Substances and the Failure of DSHEA,” 28 *Cap. U.L. Rev.* 617, 622 (2000).

<sup>43</sup> <http://www.5hourenergy.com>

phenylalanine, caffeine, and citicoline.<sup>44</sup> This blend of stimulants could potentially be in violation of the NCAA policy concerning banned substances and, at the very least, schools cannot provide this product to athletes because it contains amino acids.<sup>45</sup>

Large dietary supplement producers such as Nutrilite™ (“Nutrilite”), which claims to be the world’s leading brand of vitamin, mineral, and dietary supplements as of 2006,<sup>46</sup> rely on the endorsement of prominent athletes in order to market their products. The company’s website prominently boasts, “Nutrilite is the proud sponsor of the fastest athletes in the world,” and its “team” of athletes includes two-time FIFA World Player of the Year Ronaldinho as well as Sanya Richards, Olympian and U.S. record-holder in the 400 meter track event.<sup>47</sup> In this case, Nutrilite exploits the athletic abilities of its athlete-endorsers by using them to make a back-door structure/function claim, whereas their advertising campaign insinuates that the use of Nutrilite in some way contributes to the speed of the athletes.

A famous case of prominent dietary supplement endorsement occurred in 1998, when a Colorado-based producer of dietary supplements called Experimental & Applied Sciences (“EAS”) enlisted several athlete-spokespersons from the Denver Broncos (including quarterback John Elway) to wear EAS apparel during the week surrounding their competing in the Super Bowl.<sup>48</sup> The NFL declared that this endorsement violated league policy, but EAS gained valuable endorsement by the Broncos’ announcement that about 75% of the team used EAS supplements (many of which contained creatine).<sup>49</sup>

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<sup>44</sup> Supplement Facts for 5-Hour Energy, available at <http://www.5hourenergy.com/ingredients.asp>

<sup>45</sup> “The NCAA’s Advertising and Promotional Standards,” <http://www.ncaa.org/wps/ncaa?ContentID=635>

<sup>46</sup> <http://www.nutrilite.com/en-us/TeamNutrilite/Athletes/ronaldinho-pressrelease.aspx>

<sup>47</sup> <http://www.nutrilite.com/en-us/teamnutrilite/athletes/overview.aspx>

<sup>48</sup> Mike Freeman, “PRO FOOTBALL: NOTEBOOK; N.F.L. Is Uneasy about Diet Supplements’ Use,” *New York Times*. 24 May 1998.

<sup>49</sup> *Ibid.*

This incident illustrates a few key issues surrounding athletes' use of dietary supplements – first, in order for a majority of a team to use to same company's supplements, professional athletes must talk about supplements with one another and likely encourage others to use a product that they find particularly useful; second, using the 1998 Broncos as an example, we can probably infer that dietary supplement use among professional athletes is quite high (although exact data on this topic are very hard to come by); and third, supplement manufacturers likely see significant returns from investments in athlete endorsements, if a company such as EAS is willing to spend resources on Super Bowl week advertising.

Prominent athletes need not even be paid spokespersons of dietary supplements to encourage increased use among younger athletes; rather, for some young athletes, merely knowing that professionals use these substances motivates them to emulate that consumption. A classic example of this phenomenon occurred during and following Mark McGwire's 1998 homerun race with Sammy Sosa, during which McGwire admitted to using both Androstendione and Creatine, both of which were available in the form of over-the-counter dietary supplements.<sup>50</sup> Immediately following that admission, sales of those two products to teenaged consumers increased drastically.<sup>51</sup> Creatine, in particular, was especially popular during this timeframe – with annual sales in excess of \$100 million<sup>52</sup> -- despite both evidence that the supplement may cause liver and kidney damage and also a 1997 incident in which three college wrestlers died while using Creatine.<sup>53</sup>

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<sup>50</sup> 28 Cap. U.L. Rev. at 622.

<sup>51</sup> *Ibid.*

<sup>52</sup> 28 Cap. U.L. Rev. at 632.

<sup>53</sup> 28 Cap. U.L. Rev. at 633.

Overall, a survey of dietary supplement use indicates that such substances are exceptionally popular among athletes at all levels of competition. Moreover, the endorsement of these products by well-known athletes, as well as the media attention when an athlete announces his use of a certain supplement, perpetuates the popularity of athletes' dietary supplement use in at least two major ways. First, such publicity encourages young athletes (often even high school students) to use the same dietary supplements as their role models in order to achieve their dreams of athletic greatness, and, second, it encourages other amateur and professional athletes who are already at high levels of competition to use supplements in order to gain an edge that they feel is necessary to ultimate success.

#### Potential of Surprise Liability

Considering the widespread use of supplements among sports players, the strict liability to which they are subject, and the potential that DSHEA changes to the FD&C Act allow supplement manufacturers to omit some ingredients, the possibility of surprise liability for positive drug tests seems far from remote. And, in fact, the use of dietary supplements does lead to many documented cases of positive drug tests that affect athletes. In the NCAA, for example, a lead researcher reports that, as of 2001, 90% of the positive drug tests among collegiate athletes were a result of the use of dietary substances.<sup>54</sup> Not all of these tests results are necessarily “surprises” to the athletes, but studies indicate that some of them very well could be. Because of this possibility, the NCAA officially cautions student-athletes:

Many nutritional/dietary supplements contain NCAA banned substances. In addition, the U.S. Food and Drug Administration (FDA) does not

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<sup>54</sup> “Truth or Scare,” ESPN’s *Outside the Lines*, Show 54 (Aired April 8, 2001).

strictly regulate the supplement industry; therefore purity and safety of nutritional dietary supplements cannot be guaranteed. Impure supplements may lead to a positive NCAA drug test. The use of supplements is at the student-athlete's own risk. Student-athletes should contact their institution's team physician or athletic trainer for further information.<sup>55</sup>

Although this admonishment certainly raises student-athletes' awareness of potential problems in the dietary supplement industry, it leaves athletes with little guidance other than to avoid supplements altogether or to risk possible liability.

The FDA itself notes that "the growing market for supplements in a less restrictive regulatory environment creates the potential for supplements to be prone to quality-control problems," and the agency has "identified several problems where some manufacturers were buying herbs, plants and other ingredients without first adequately testing them to determine whether the product they ordered was actually what they received or whether the ingredients were free from contaminants."<sup>56</sup> These additional contaminants and ingredients can, in some cases, even be steroids. A study conducted in IOC-accredited laboratories in Europe found that as much as 25% of available dietary supplements contain low levels of unlisted steroids.<sup>57</sup> Furthermore, an eighteen-month study conducted by Dr. Don H. Catlin, M.D., a long-time faculty member at the University of California at Los Angeles (UCLA), and his researchers found that many over-the-counter dietary supplements "were mislabeled or contained precursors such as androstenedione, which are converted by the body into steroids."<sup>58</sup>

In recent years, several athletes have asserted that their positive drug tests were the results of trace amounts of banned substances in dietary supplements. During the

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<sup>55</sup> NCAA Banned-Drug Classes, 2008-09

<sup>56</sup> Kurtzweil, "An FDA Guide."

<sup>57</sup> Ronald J. Maughan and Louise Burke, *Sports Nutrition*. Hoboken, NJ: Wiley-Blackwell, 2002. p. 139

<sup>58</sup> "Truth or Scare."

Sydney Olympics, an American shot-putter raised attention to this possibility of surprise liability; many critics questioned his claim because of the high amount of banned substance in his test,<sup>59</sup> but since then, many athletes' claims have seemed more credible. This year, for example, J.C. Romero, a Philadelphia Phillies relief pitcher, began the season with a 50-day suspension for testing positive for androstenedione after taking a dietary supplement purchased at a General Nutrition Center (GNC) in New Jersey.<sup>60</sup> The dietary supplement did not list any banned substances.<sup>61</sup> In 2004, several tennis players tested positive for a steroid that was believed to have come from a contaminated dietary supplement.<sup>62</sup> Leading up to the 2008 Beijing Olympic Games, most of the Greek weight-lifting team was suspended for testing positive for banned substances, which they claimed they ingested from contaminated dietary supplements.<sup>63</sup>

Some of these assertions are, of course, difficult to verify, but with all of the research indicating contamination in dietary supplements, odds are that at least some claims of surprise liability are legitimate. If dietary supplements were more strictly regulated, athletes (and other consumers) would benefit from greater certainty in what they were ingesting, and governing bodies in athletics would also be better able to evaluate the claims of athletes who do test positive. Some critics of athletes' complaints about surprise liability suggest that athletes simply avoid all dietary supplements, but many athletes assert that this "just say no" approach is unreasonable, considering the integral role that supplements play in their training regiment.<sup>64</sup> Moreover, the widespread

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<sup>59</sup> *Ibid.*

<sup>60</sup> "Dietary Supplements a Way of Life in Professional Sports," [http://www.lehighvalleylive.com/today/index.ssf/2009/01/brian\\_westbrook.html](http://www.lehighvalleylive.com/today/index.ssf/2009/01/brian_westbrook.html)

<sup>61</sup> *Ibid.*

<sup>62</sup> Elliott Almond, "Tennis plagued by positive drug tests," *Knight-Ridder Newspapers*. 23 February 2004.

<sup>63</sup>

<sup>64</sup> 5 Va. Sports & Ent. L.J. at 172.

use of dietary supplements seems to indicate that the strategy of just telling athletes and other consumers not to use these products would not be a very effective one.

Would Additional FDA Regulation Be an Effective Way to Protect Athletes and Other Members of the Public?

Because of the FDA's limited resources and the complications involved in federal government bureaucracy, some opponents of greater FDA oversight of the dietary supplement industry claim that, even if FDA had the legislatively-mandated authority, its oversight would be insufficient to protect athletes (and other consumers). One such critic points to the ephedrine (ephedra) case study as an illustration of the proposition that "the time and costs associated with government intervention will not likely be efficient."<sup>65</sup> The article, which focuses specifically on the NFL, further claims that extended FDA regulation over the supplement industry would result in taxpayers' paying for regulation that private sports leagues could implement on their own.<sup>66</sup> Although these points have some validity, such critiques perhaps miss the bigger picture. First, some of the current perceived inefficiencies in the FDA's regulation of supplements could be a result of the limitations that Congress placed on the agency through DSHEA. As mentioned earlier in the paper, the ephedra case serves as an example of the challenges the FDA faces in removing a supplement from the market. Had ephedra products been treated as drugs, for instance, the FDA would have known the possible risks before this product ever hit the market.

The proposal that private sports leagues set their own regulations concerning dietary supplements is intriguing, but arguably even more inefficient than government

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<sup>65</sup> Scott B. Shapiro, "Who Decides: Institutional Choice in Determining a Performance-Enhancing Drug Policy for the NFL," 7 Wyo. L. Rev. 183, 217 (2007).

<sup>66</sup> *Ibid.*

regulation. Unless all sports leagues were to ban all dietary supplements, individual leagues would be left to test supplements to find which ones contained banned substances and which ones did not. Moreover, unless leagues were compelled to disclose the results from their dietary supplement studies, young athletes and other consumers would have no benefit from this regulatory oversight of the supplement industry.

Granting greater regulatory authority to the FDA, on the other hand, would centralize the regulation of the dietary supplement industry and would protect athletes at all levels, as well as non-athlete consumers. Without creating an entirely new set of statutes and regulations, the two main possibilities for greater FDA regulation of dietary supplements are (1) to eliminate the current carve-outs under DSHEA and treat supplements strictly as food under the FD&C Act or (2) to treat dietary supplements as drugs under the FD&C Act. Both possibilities have pros and cons, some of which this paper will now address.

Since dietary supplements are already technically classified as foods, simply eliminating the DSHEA special exceptions for supplements is, legislatively speaking, probably the simpler of the two options. Further, the regulation of food is far less costly than the regulation of drugs. Under this scheme, new supplement ingredients could undergo pre-market approval as “food additives,” but the FDA would not have to expend resources testing each supplement on the market. While this possible solution would certainly be an improvement, it would not provide complete protection for athletes and consumers. Even substances classified as food rather than dietary supplements, though, can be a part of the lack of clarity athletes experience with respect to banned substances. A recent example of this phenomenon is the NCAA controversy involving Vitamin

Water® (“Vitamin Water”). Vitamin Water is a part of Coca-Cola Co.’s Glaceau division, and Coca-Cola selected this year’s NCAA Men’s Basketball Tournament (known as “March Madness”) to advertise the product aggressively because of the company’s desire to market it as “a drink for active lifestyles.”<sup>67</sup> In fact, all beverages visible on camera during this year’s NCAA tournament must be in Vitamin Water-labeled cups, and Coke chose to have Vitamin Water logos replace Dasani (its bottled water brand) on all jugs and water coolers, as well.<sup>68</sup> Perhaps the most peculiar aspect of this sponsorship, however, is that the NCAA announced earlier this year that six different flavors<sup>69</sup> of Vitamin Water contain substances that are banned under NCAA regulations<sup>70</sup>; therefore, drinking products from one of their league’s top sponsors could result in rules violations for NCAA student-athletes.

Although this situation could arguably lead to cases of surprise liability if NCAA athletes were suspended for consuming products from a top sponsor, at least the FDA labeling enables athletes who are sufficiently diligent to make informed decisions. NCAA athletes (and the general public, for that matter) can access the list of banned substances easily online,<sup>71</sup> and the FDA-mandated Nutritional Label and/or the Ingredients lists on bottles of Vitamin Water indicate that they contain these substances.

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<sup>67</sup> Joe Guy Collier, “During the NCAA tournament, Coca-Cola is a major player.” *Atlanta-Journal Constitution*, 21 March 2009. (accessed at <http://www.ajc.com/services/content/printedition/2009/03/21/cokemadness0321.html>)

<sup>68</sup> “NCAA saturated by Vitamin Water.” *Arizona Wildcat*. (accessed at <http://phoenix.fanster.com/2009/03/21/ncaa-saturated-by-vitaminwater/>)

<sup>69</sup> The banned flavors (and the substances they contain) are Power-C (taurine, L-theanine, ECGC), Energy (excessive amount of a banned caffeine substance, guarana), B-relaxed (taurine, L-theanine, ECGC), Rescue (excessive amount of a banned caffeine substance, taurine, L-theanine, ECGC), Vital-T (roiboos tea extracts, and Balance (glucosamine)

<sup>70</sup> Mitra Anoushiravani, “Some Vitaminwater flavors contain banned substances.” *The Brown Daily Herald*, 6 February 2009. (accessed at <http://media.www.browndailyherald.com/media/storage/paper472/news/2009/02/06/CampusNews/Some-Vitaminwater.Flavors.Contain.Banned.Substances-3616813.shtml>)

<sup>71</sup> NCAA Banned-Drug Classes, 2008-09

Moreover, the Vitamin Water website elaborates on the key ingredients in each flavor variety of this product.<sup>72</sup>

The NCAA/Vitamin Water case illustrates a couple important factors. First, FDA regulations of foods can play an important role in informing athletes about the contents of what they are consuming – if Coca-Cola chose to market Vitamin Water as a dietary supplement instead of as a food product,<sup>73</sup> it would not have to disclose the precise contents of its different flavors. On the other hand, though, it also shows the limitations of current FDA regulation and the onus placed on athletes to monitor closely the substances they are putting in their bodies. A lay person might think that substances banned for college and/or professional athletes would not be readily available in popular products in grocery stores, but the FDA does not ban many of these substances and does not currently have an efficient way of giving athletes a clear warning of problem substances. Nevertheless, the information that FDA regulation of food products can provide to athletes is far superior to the alternative of loosely-regulated supplements.

If treating dietary supplements as foods for FDA regulatory purposes nevertheless seems insufficient, the other possible solution to current under-regulation would be to classify dietary supplements as drugs. Section 505 of the FD&C Act requires that all drugs receive pre-market approval from the FDA. Although this process can be costly and time-consuming, the advantages of subjecting dietary supplements to this rigor would be reduced risks to consumers and decreased ability of supplement manufacturers to

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<sup>72</sup> Vitamin Water website, <http://www.glaceau.com>

<sup>73</sup> Marketing a Vitamin Water-like product as a supplement is certainly possible. Function:™ (“Function”), one of Vitamin Water’s competitors, classifies itself as a dietary supplement and therefore avoids stricter labeling requirements. (See <http://www.functiondrinks.com> for information on this product and for Supplement Label images of all of Function’s flavors.) Based on some of the structure/function claims made by Function, it may be in violation of FDA regulations, but it nevertheless continues to label its drinks in this manner.

make bogus structure/function claims. Substances such as ephedra and creatine would be tested before they were ever available to consumers, and the potential side effects would be known and disclosed. Athletes and other consumers would know not only the exact contents of what they were ingesting, but also the possible risks involved. Although this access to information is ideal, the process of revising regulations and procedures to treat dietary supplements as drugs would be so costly and time-consuming that revising the current legislation to treat supplements strictly as foods (without the DSHEA special exceptions) is likely a superior solution, at least in the short term.

### Conclusion

Perhaps with adequate resources and more time, the FDA could eventually have the infrastructure to evaluate supplements as they do drugs. For the time being, though, eliminating the DSHEA exceptions would have many desirable effects and would offer a strong solution to the problem of surprise liability in drug testing for athletes. Dietary supplement manufacturers would have to seek approval for new additives, which would benefit public health and also reveal the effects of these ingredients. In addition, with more precise labeling requirements and greater regulation of the manufacturing of supplements, the likelihood of an athlete's unknowing ingestion of a banned substance would decrease.

Because of dietary supplements' prominence in the diets of consumers, especially athletes, and the apparent increasing popularity of such substances, the government has reasons to tighten regulations that are even more important than protecting American athletes from surprise liability. The examination of athletes and supplement use in this paper reveals many of the problems for sports players and other consumers, highlights the

extent of problems in the manufacturing and marketing and the supplement industry, and suggests greater regulation of this very popular and lucrative industry. Stricter regulation of the supplement industry by the FDA would benefit the American public, and policy-makers should seriously weigh these extensive benefits against the interests of the dietary supplement industry's lobby; if such an honest assessment were made, it should be apparent that the current regulatory scheme is highly inadequate.