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# NOTES

## SPREADING THE BLAME: EXAMINING THE RELATIONSHIP BETWEEN DSHEA AND THE BASEBALL STEROID SCANDAL

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### INTRODUCTION

For the sport of baseball, the steroid issue refuses to go away. After a 2008 season without much drama surrounding performance-enhancing drugs, reports of steroid abuse from some of the game's most prominent players periodically

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surfaced throughout 2009.<sup>1</sup> The public outcry about steroid use in baseball goes beyond the physical harm that such substances can do to the human body – it concerns baseball's status as America's pastime.

More than in any other sport, Americans are fascinated with the statistics in baseball. Even casual baseball fans have long been aware of the sport's longstanding home run records, and the nation was captivated as Mark McGwire, Sammy Sosa, and Barry Bonds – all three of whom were later inextricably linked to steroid use – shattered those records.<sup>2</sup> The common notion that legends like Babe Ruth, Hank Aaron, and Roger Maris have been surpassed in the record books by cheaters helps explain why Congress took particular interest in rooting steroids out of the game. In a 2002 congressional hearing about steroid use in baseball, an Illinois Senator cited precisely this concern for the game's history.<sup>3</sup>

But nostalgia was not the only reason that baseball's steroid scandal prompted three congressional hearings over a six-year span.<sup>4</sup> Although the rampant steroid use in professional sports was well-known by 2002, both Congress and the public focused primarily on baseball, whose cherished statistical records had been falling like dominoes over the previous few years. The problem had finally reached the point where members of Congress concluded that Major League Baseball would not impose the appropriate remedies without federal intervention.<sup>5</sup> Congress also recognized that the problem was not limited to professional baseball players, but also impacted

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<sup>1</sup> In spring training 2009, Alex Rodriguez confessed to rumors surrounding his steroid use in prior seasons. *SportsCenter: Peter Gammons Interview with Alex Rodriguez* (ESPN television broadcast Feb. 9, 2009), available at <http://sports.espn.go.com/mlb/news/story?id=3895281>. Manny Ramirez received a fifty-game suspension for failing a drug test in May, and it was revealed in July that both Ramirez and David Ortiz failed a 2003 test for performance-enhancing drugs. Michael S. Schmidt, *One of Baseball's Biggest Stars Is Now Its Latest Drug Culprit*, N.Y. TIMES, May 8, 2009, at A1; Michael S. Schmidt, *Stars of Red Sox Title Years Are Linked to Doping*, N.Y. TIMES, July 31, 2009, at A1.

<sup>2</sup> Jayson Stark, *A-Rod Has Destroyed Game's History*, ESPN.COM, Feb. 8, 2009, [http://sports.espn.go.com/mlb/columns/story?columnist=stark\\_jayson&id=3892788](http://sports.espn.go.com/mlb/columns/story?columnist=stark_jayson&id=3892788).

<sup>3</sup> *Steroid Use in Professional Baseball and Anti-Doping Issues in Amateur Sports: Hearing Before the Subcomm. on Consumer Affairs, Foreign Commerce and Tourism of the S. Comm. on Commerce, Science and Transp.*, 107th Cong. 46 (2002) [hereinafter *Steroid Use in Professional Baseball: Hearing*] (statement of Sen. Peter G. Fitzgerald) (questioning the validity of current baseball statistics).

<sup>4</sup> See *The Regulation of Dietary Supplements: A Review of Consumer Safeguards: Hearing Before the Comm. on Gov't Reform*, 109th Cong. 18 (2006) [hereinafter *The Regulation of Dietary Supplements: Hearing*]; *Restoring Faith in America's Pastime: Evaluating Major League Baseball's Efforts to Eradicate Steroid Use: Hearing Before the H. Comm. on Gov't Reform*, 109th Cong. 9 (2005) [hereinafter, *Restoring Faith, Hearing*]; *Steroid Use in Professional Baseball: Hearing*, *supra* note 3, at 46.

<sup>5</sup> *Restoring Faith: Hearing*, *supra* note 4, at 9 (statement of Rep. Henry A. Waxman, Ranking Member, H. Comm. on Gov't Reform).

American youths striving to perform at the highest level and reach the Major Leagues.<sup>6</sup>

A common phrase heard in the baseball clubhouse is: “If you ain’t cheatin’, you ain’t tryin’.” Throughout baseball’s history, players have searched for something to give them an edge on the competition – be it sharpened spikes, Vaseline, emery boards, sandpaper, a corked bat, or even superballs.<sup>7</sup> Baseball’s post-World War II era saw many players using amphetamines, or “greenies,” to get through the season’s daily grind.<sup>8</sup> In the late 1980s, however, some players began seeking to gain an additional competitive advantage through anabolic steroids.

Congress passed the Dietary Supplement Health & Education Act (“DSHEA”) in 1994, which essentially deregulated the dietary supplement industry.<sup>9</sup> Within two years, a substantial number of professional baseball players were using steroids and other performance-enhancing substances – information which came to light in the ensuing years and turned into a full-fledged scandal by 2002.<sup>10</sup> Baseball’s steroid issues were of particular interest to Congress, not because of any perceived connection between dietary supplement legislation and steroids, but rather because of the health issues posed by abusing steroids and the fact that many young Americans view professional athletes as role models and seek to emulate their behavior.<sup>11</sup>

The resulting congressional hearings, as well as separate internal investigations conducted by Major League Baseball (“MLB”), determined that the sport’s problem with steroid use had been ongoing for nearly two decades.<sup>12</sup> A tangential focus on dietary supplements emerged amidst the steroid debate, as high-ranking baseball officials deflected blame from themselves by pointing out that DSHEA’s deregulatory framework allowed many substances containing steroids to enter the market for legal purchase and

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<sup>6</sup> *Id.* (“Steroids are a drug problem that affects not only elite athletes, but also the neighborhood kids who idolize them. And this issue is challenging not just for baseball, but for our whole society. More than 500,000 teenagers across the country have taken illegal steroids, risking serious and sometimes deadly consequences.”).

<sup>7</sup> In 1974, Graig Nettles of the New York Yankees was called out after superballs flew out of his broken bat. *Biggest Cheaters in Baseball*, ESPN.COM, <http://espn.go.com/page2/s/list/cheaters/ballplayers.html> (last visited Oct. 22, 2009).

<sup>8</sup> Steve Wilstein, *Amphetamines in Baseball: Speed Still the Name of the Game for Some*, ASSOCIATED PRESS, May 22, 2005, available at 2005 WLNR 23363639.

<sup>9</sup> Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified in scattered sections of 21 U.S.C.).

<sup>10</sup> GEORGE J. MITCHELL, REPORT TO THE COMMISSIONER OF BASEBALL OF AN INDEPENDENT INVESTIGATION INTO THE ILLEGAL USE OF STEROIDS AND OTHER PERFORMANCE ENHANCING SUBSTANCES BY PLAYERS IN MAJOR LEAGUE BASEBALL 14-15 (2007) [hereinafter MITCHELL REPORT].

<sup>11</sup> See Joshua Peck, Note, *Last Resort: The Threat of Federal Steroid Legislation – Is the Proposed Legislation Constitutional?*, 75 FORDHAM L. REV. 1777, 1809 (2006).

<sup>12</sup> Bob Hohler, *A Long, Star-Studded Roster*, BOSTON GLOBE, Dec. 14, 2007, at A1.

consumption by ballplayers seeking to improve their performance.<sup>13</sup> This surprising development spurred Congress to hold a hearing on the effectiveness of laws pertaining to dietary supplement regulation in 2006.<sup>14</sup> Despite these hearings and substantial criticism, Congress has not amended DSHEA, reflecting a determination that the statute provides ample protection to the public.

Ongoing steroid use has not been as serious a problem since MLB first instituted a drug-testing program in 2002 – a program that MLB substantially revised and strengthened in both 2005 and 2006.<sup>15</sup> This program has increased the focus on dietary supplements, as many players testing positive for steroids have attributed the results to a contaminated or mislabeled supplement.<sup>16</sup> In admitting to his own use of performance-enhancing drugs, New York Yankees third baseman Alex Rodriguez painted a picture of an atmosphere where many players did not quite know whether products they were using did in fact contain prohibited substances: “There was a lot of gray area . . . . [B]ack then [2001-2003], you could walk [into] GNC and get four or five different products that today would probably trigger a positive test.”<sup>17</sup>

Much has been written about the origins and development of baseball’s steroid scandal. This Note examines a very specific portion of that scandal to determine whether DSHEA may have played any role in facilitating the use of steroids by baseball players. Starting with the origins of dietary supplement regulation, this Note explains the events leading up to the enactment of DSHEA and describes the substance of the legislation. That description is followed by a brief history of the steroid scandal’s evolution, and the Note concludes by evaluating whether Congress and DSHEA bear any responsibility for baseball’s steroid issues.

## I. SUPPLEMENT REGULATION BEFORE DSHEA

### A. *Early Regulatory Legislation*

The Federal Food and Drugs Act of 1906 was the first federal legislation aimed at regulating food, drugs, and other dietary or nutritional products.<sup>18</sup>

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<sup>13</sup> Allan H. “Bud” Selig & Robert D. Manfred, Jr., *The Regulation of Nutritional Supplements in Professional Sports*, 15 STAN. L. & POL’Y REV. 35, 58 (2004).

<sup>14</sup> *The Regulation of Dietary Supplements: Hearing*, *supra* note 4.

<sup>15</sup> MITCHELL REPORT, *supra* note 10, at SR-3 (“The current drug testing program in Major League Baseball . . . appears to have reduced the use of detectable steroids but by itself has not removed the cloud of suspicion over the game.”); *id.* 50-59 (describing the Joint Drug Program under the Basic Agreement).

<sup>16</sup> Howard Jacobs, *Taking Matters into Their Own Hands*, ENT. & SPORTS LAW., Winter 2008, at 1, 35.

<sup>17</sup> *SportsCenter*, *supra* note 1.

<sup>18</sup> Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

Also known as the Wiley Act,<sup>19</sup> the 1906 legislation gave the Bureau of Chemistry – a precursor to the Food & Drug Administration (“FDA” or “Agency”)<sup>20</sup> – power to regulate product labeling and forbid the addition of any ingredients that present a health hazard, constitute unclean substances, or serve as a substitute for food.<sup>21</sup> Through the Wiley Act, Congress banned all misbranded or adulterated foods and drugs from interstate commerce.<sup>22</sup> But the Wiley Act still failed to adequately protect the population from unsafe food and drug products and, as a result, was repealed and replaced in 1938 by the Food, Drug, and Cosmetic Act (“FDCA”).<sup>23</sup>

One of the FDCA’s primary functions was to set out clear definitions for both “food” and “drugs,” the latter being defined as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals.”<sup>24</sup> Unsurprisingly, the FDCA subjected drugs to more stringent regulations than foods,<sup>25</sup> reflecting the notion that strong governmental action was the only way to protect the public.<sup>26</sup>

In 1958, Congress amended the FDCA (the “Food Additive Amendment”) to include a definition for “food additives” as

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component, or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown

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<sup>19</sup> John P. Swann, *Food and Drug Administration*, in A HISTORICAL GUIDE TO THE U.S. GOVERNMENT 248, 250 (George T. Kurian ed., 1998).

<sup>20</sup> Note, *Reforming the Food Safety System: What if Consolidation Isn’t Enough?*, 120 HARV. L. REV. 1345, 1348 (2007).

<sup>21</sup> Swann, *supra* note 19, at 250.

<sup>22</sup> Federal Food and Drugs Act of 1906, *supra* note 18; see also Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 331 (1998). Adulterated foods are currently defined in 21 U.S.C. § 342 (2006). For discussion of adulterated supplements, see *infra* Part III.B.

<sup>23</sup> Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. §§ 301-395); see also Swann, *supra* note 19, at 250-51 (arguing that the public outcry due to shortcomings of the 1906 law reshaped the drug provisions of the new law).

<sup>24</sup> 21 U.S.C. § 321(g)(1)(B-C).

<sup>25</sup> Jennifer J. Spokes, Note, *Confusion in Dietary Supplement Regulation: The Sports Products Irony*, 77 B.U. L. REV. 181, 184 (1997).

<sup>26</sup> Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It’s Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 179 (2005) (explaining Congress’s belief that strict regulation was necessary to “protect individuals from harm that they had no way of combating on their own”).

through scientific procedures . . . to be safe under the conditions of its intended use.<sup>27</sup>

Dietary supplements were not among the substances specifically excluded from the definition of food additives, and therefore were not covered by the amendment.<sup>28</sup> Trying to take advantage of this omission, the FDA eventually attempted to regulate dietary supplements as food additives.<sup>29</sup>

In addition to providing definitions that distinguished various food and drug products, the FDCA required the FDA's premarket approval for all new drugs and also held producers and manufacturers of such products to stricter labeling standards.<sup>30</sup> Furthermore, the FDCA implicitly gave the FDA power to regulate the labeling of dietary supplements by requiring that a producer of food "represented for special dietary uses" provide accurate information concerning its "vitamin, mineral, and other dietary properties."<sup>31</sup> Interpreting this section of the FDCA as a distinct reference to dietary supplements leads to a characterization of such products as foods, rather than drugs, and helps explain their subsequent omission from the Food Additive Amendment.<sup>32</sup> Indeed, a 1976 amendment to the FDCA that defined "special dietary uses" solidified the link between dietary supplements and foods.<sup>33</sup>

Congress increased the FDA's regulatory powers in 1962 by passing the Kefauver-Harris Amendments.<sup>34</sup> This comprehensive legislation required the FDA to determine a drug's efficacy and safety before market entry and also submitted prescription drug advertising and manufacturing practices to FDA regulation.<sup>35</sup> There was not much public outcry when the FDA used its FDCA powers to attack misbranded or adulterated food and drug products, but the public rebelled when the FDA set its sights on dietary supplements.<sup>36</sup> As

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<sup>27</sup> Food Additives Amendment of 1958, Pub. L. No. 86-929, 72 Stat. 1784.

<sup>28</sup> *Id.*

<sup>29</sup> *See, e.g.,* United States v. 29 Cartons of \* \* \* an Article of Food, 987 F.2d 33, 36 (1st Cir. 1993).

<sup>30</sup> Swann, *supra* note 19, at 251.

<sup>31</sup> 21 U.S.C. § 343(j) (2006).

<sup>32</sup> *See* Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 158 (2005) ("When represented solely to supplement the daily diet . . . FDA has always regulated dietary supplements under the [FDCA] as food.").

<sup>33</sup> 21 U.S.C. § 350(c)(3)(B) ("[T]he term 'special dietary use' as applied to food . . . means a particular use for which a food . . . is represented to be used, including . . . [s]upplying a vitamin, mineral, or other ingredient for use by man to *supplement* his diet by increasing the total dietary intake." (emphasis added)); *see also* Hutt, *supra* note 32, at 159.

<sup>34</sup> Pub. L. No. 87-781, 76 Stat. 780 (1962); Swann, *supra* note 19, at 251.

<sup>35</sup> Swann, *supra* note 19, at 251.

<sup>36</sup> *Id.* at 252.

discussed below, Congress soon amended the FDCA to expressly prohibit FDA control over the potency of dietary supplements.<sup>37</sup>

B. *Dietary Supplements: Food or Drugs?*

Dietary supplements first entered the American market in the 1920s as a means to help people compensate for nutrient deficiencies.<sup>38</sup> Accordingly, the FDA and its precursors considered people using dietary supplements for the treatment of any nutritional deficiency to be ingesting those products as food, and not as drugs.<sup>39</sup> The distinction is significant because while drugs are subject to premarket approval, food products are presumed safe unless the FDA can prove a reasonable likelihood that the food will harm a consumer's health.<sup>40</sup> Premarket approval of food products by the FDA is only required for foods that make therapeutic claims or contain food additives that are not "generally recognized as safe."<sup>41</sup> But while dietary supplements have been considered a subset of food historically, proponents of stricter federal regulation support their arguments by pointing to substantive similarities between dietary supplements and many over-the-counter drugs.<sup>42</sup> Recognizing some of the key differences between dietary supplements and conventional food, the FDA tried to exert more substantive power over supplements before DSHEA settled the law on the matter.

II. FDA ATTEMPTS AT REGULATION AND THE DRIVE TO PROTECT DIETARY SUPPLEMENTS

The FDA sought to increase its regulatory power over dietary supplements as they became increasingly popular throughout the United States, but met fierce resistance from the dietary supplement industry.<sup>43</sup> One of the Agency's most common arguments was that dietary supplements are not foods, but rather unapproved food additives, and therefore are subject to premarket oversight and regulation.<sup>44</sup> This argument was plausible because the Food Additive Amendment had not specifically excluded dietary supplements.<sup>45</sup> Most

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<sup>37</sup> *Id.*

<sup>38</sup> Hutt, *supra* note 32, at 158.

<sup>39</sup> Mark A. Kassel, *From a History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 252 (1994).

<sup>40</sup> Jennifer Akre Hill, Comment, *Creating Balance: Problems Within DSHEA and Suggestions for Reform*, 2 J. FOOD L. & POL'Y 361, 367-68 (2006).

<sup>41</sup> See 21 U.S.C. § 321(s) (2006).

<sup>42</sup> Dana Ziker, *What Lies Beneath: An Examination of the Underpinnings of Dietary Supplement Safety Regulation*, 31 AM. J.L. & MED. 269, 282 (2005).

<sup>43</sup> Kassel, *supra* note 39, at 239.

<sup>44</sup> See Stephen H. McNamara, *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 FOOD & DRUG L.J. 341, 343 (1995); see also *United States v. 29 Cartons of \* \* \**, an Article of Food, 987 F.2d 33, 36 (1st Cir. 1993).

<sup>45</sup> See 21 U.S.C. § 321.

notably, the FDA conducted a broad review of its regulatory policies regarding dietary supplements in 1991, after supplements containing the amino acid L-tryptophan were linked to thirty-eight deaths and many more illnesses.<sup>46</sup> This review culminated with a 1993 FDA notice that summarized the Agency's safety concerns regarding various dietary supplements and recommended a more aggressive regulatory scheme.<sup>47</sup>

The FDA's manifestations toward more stringent regulation of dietary supplements incited vehement protests not only from manufacturers, but also from the supplement-consuming public.<sup>48</sup> Those constituencies made clear their beliefs that the FDA was distorting its powers under the FDCA and significantly threatening public access to safe and useful dietary supplements.<sup>49</sup> FDA attempts to categorize dietary supplements as food additives were particularly criticized as being overly prohibitive due to the high costs and lengthy duration (two to six years) of the processes necessary for food additives to secure FDA approval.<sup>50</sup> Even before Congress decided to halt the FDA's perceived over-aggression toward supplements, the First and Seventh Circuits each not only overturned FDA determinations that certain dietary supplements were food additives, but also criticized the Agency for overstepping its bounds.<sup>51</sup>

While these court rulings certainly influenced Congress, their effect pales in comparison to the pressure that dietary supplement manufacturers and the general public placed on the legislature to reign in the FDA: "Many members of the House of Representatives and Senate stated that they had received more mail, phone calls, and constituent pressure on this subject than on anything else

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<sup>46</sup> Selig and Manfred, *supra* note 13, at 39.

<sup>47</sup> Barbara A. Noah, *Foreword: Dietary Supplement Regulation in Flux*, 31 AM. J.L. & MED. 147, 147 (2005).

<sup>48</sup> See McNamara, *supra* note 44, at 341.

<sup>49</sup> Stephen H. McNamara & A. Wes Siegner, Jr., *FDA Has Substantial and Sufficient Authority to Regulate Dietary Supplements*, 57 FOOD & DRUG L.J. 15, 15 (2002).

<sup>50</sup> *Id.* at 16. By comparison, drugs typically do not enter the market until eight years after their initial production, while dietary supplement manufacturers can have their products in stores in as few as two months after a new supplement is first created. David Epstein & George Dohrmann, *What You Don't Know Might Kill You*, SPORTS ILLUSTRATED, May 18, 2009, at 54, available at <http://vault.sportsillustrated.cnn.com/vault/article/magazine/MAG1155395/index.htm>.

<sup>51</sup> *United States v. 29 Cartons of \* \* \* an Article of Food*, 987 F.2d 33, 36 (1st Cir. 1993) ("[T]he FDA's broad definition of a food additive, which would apply to all components, even a substance which comprises the only active ingredient of the whole, subverts congressional purpose. Blurring the distinction between food additives and food in this way would permit the Agency to tilt a delicately balanced statutory scheme that allocates the burden of proving an additive's safety to the processors while leaving the burden of establishing a food's safety with the FDA."); *United States v. Two Plastic Drums*, 984 F.2d 814 (7th Cir. 1993); see also McNamara & Siegner, *supra* note 49, at 16.



– including health care reform, abortion, or the deficit.”<sup>52</sup> This blitz of support for dietary supplements led Congress to conclude that, without the passage of deregulatory legislation, the FDA would prohibit the sale and marketing of safe and useful dietary supplements.<sup>53</sup> Written and sponsored by Utah Senator Orrin Hatch and New Mexico Congressman Bill Richardson,<sup>54</sup> the Dietary Supplement Health and Education Act received unanimous approval in both the Senate and the House of Representatives, and President Clinton signed it into law in October 1994, amending the FDCA.<sup>55</sup>

### III. THE SUBSTANCE OF DSHEA

#### A. *Setting out a Clear Definition for Dietary Supplements*

One of the legislature’s primary objectives in enacting DSHEA was to clearly define the term “dietary supplement,” and prevent the FDA from over-regulating supplements as inherently dangerous and suspect products, like drugs and food additives.<sup>56</sup> DSHEA defined a dietary supplement as:

[A] product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary 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 by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).<sup>57</sup>

The statutory definition of dietary supplement also mandates that such products (1) be intended for ingestion via tablet, capsule, powder, softgel, gelcap, or liquid form; (2) that they not be represented “for use as a conventional food or as a sole item of a meal or the diet;” and (3) that these

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<sup>52</sup> McNamara, *supra* note 44, at 341.

<sup>53</sup> McNamara & Siegner, *supra* note 49, at 17; Noah, *supra* note 47, at 147-48.

<sup>54</sup> Leon Jaroff, *It’s Time to Rethink Ephedra Regulation*, TIME.COM, Mar. 5, 2003, available at <http://www.time.com/time/columnist/jaroff/article/0,9565,429341,00.html>.

<sup>55</sup> Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified in scattered sections of 21 U.S.C. and at 42 U.S.C. § 287c-11 (2006)).

<sup>56</sup> Noah, *supra* note 47, at 148-49 (“Congress accomplished its deregulatory goals by declaring that dietary supplements constitute a subcategory of food . . . [and] explicitly rejected past FDA efforts to treat these products as drugs or food additives under the [FDCA].”).

<sup>57</sup> 21 U.S.C. § 321(ff)(1).

products are actually labeled as dietary supplements.<sup>58</sup> Additionally, the definition includes products that had been approved as new drugs before the passage of DSHEA, but were marketed as dietary supplements before being labeled drugs – so long as they had not been determined unsafe.<sup>59</sup> Products that were *initially* marketed as new drugs, however, may not now be reclassified as dietary supplements under DSHEA.<sup>60</sup> Finally, the statute makes clear that “a dietary supplement shall be deemed to be a food within the meaning of [the FDCA].”<sup>61</sup> Breaking down the statutory language, any product that contains at least one dietary ingredient and is labeled as a dietary supplement may be considered a dietary supplement.<sup>62</sup> This definition provides supplement manufacturers with substantial leeway and flexibility.

Aware of the FDA’s various attempts to regulate dietary supplements as food additives, Congress specifically excluded ingredients found in dietary supplements from the statutory definition of a food additive.<sup>63</sup> By treating dietary supplements as foods, DSHEA entitled all supplements to a presumption of safety, whereas food additives are presumed unsafe without FDA authorization.<sup>64</sup> Thus, the Act exemplifies congressional intent to regulate products *marketed* as dietary supplements as foods and not as drugs or food additives.<sup>65</sup>

DSHEA defines “dietary supplements” broadly, and the term seems to encompass all types of ingredients that are allegedly intended to supplement the diet.<sup>66</sup> As a result, analysis of whether a product is appropriately labeled as a dietary supplement focuses on the ingredients and their effects on the human body, rather than a supplement’s source or method of production.<sup>67</sup>

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<sup>58</sup> *Id.* § 321(ff)(2).

<sup>59</sup> *Id.* § 321(ff)(3).

<sup>60</sup> *See id.*; Scott Bass & Emily Marden, *The New Dietary Ingredient Safety Provision of DSHEA: A Return to Congressional Intent*, 31 AM. J.L. & MED. 285, 289 (2005).

<sup>61</sup> 21 U.S.C. § 321(ff).

<sup>62</sup> Hutt, *supra* note 32, at 159.

<sup>63</sup> 21 U.S.C. § 321(s)(6).

<sup>64</sup> *Id.* § 321(ff); Spokes, *supra* note 25, at 188.

<sup>65</sup> *See* Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1038 (10th Cir. 2006).

<sup>66</sup> Bass & Marden, *supra* note 60, at 295 (describing how the definition incorporates “an almost limitless variety of ingredients, as long as they are ‘intended to supplement the diet’”).

<sup>67</sup> *Id.* at 297, 302 (“Congress clearly intended . . . that the definition of dietary supplements is broad and encompasses dietary ingredients from many different sources and obtained in many distinct ways. . . . [E]valuation of whether a dietary ingredient falls within the dietary supplement definition focuses only on the ingredient itself and not on the source, processing, or synthetic steps involved in creating the ingredient.”).

B. *Safety Standards for Dietary Supplements*

Section 4 of DSHEA lists four sets of circumstances in which a dietary supplement may be deemed adulterated, and therefore subjected to more stringent FDA regulation and market removal:

If it is a dietary supplement or contains a dietary ingredient that –

- (A) presents a significant or unreasonable risk of illness or injury . . . ;
- (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) [poses] an imminent hazard to public health or safety . . . ; or
- (D) is or contains a dietary ingredient that renders it adulterated . . . under the conditions of use recommended or suggested in the labeling of such dietary supplement.<sup>68</sup>

Although Section 4 seems to give the FDA significant power to regulate and ensure that dietary supplements are safe, DSHEA places the burden of proof as to each element of a dietary supplement's adulteration upon the federal agency.<sup>69</sup> Shifting the burden of proving whether a product is safe or adulterated from the manufacturers to the FDA reflects congressional intent to "facilitat[e] the use of dietary supplements by minimizing their regulation."<sup>70</sup> Accordingly, the FDA's approval and assurance of safety is not necessary before a dietary supplement enters the market.<sup>71</sup>

This restriction upon premarket regulation resulted from the congressional decision to classify dietary supplements as a subset of food products, which are presumed safe until the government provides evidence proving that the food is potentially harmful.<sup>72</sup> Likewise, DSHEA only grants the FDA authority to regulate those dietary supplements that are proven to threaten public health, thus facilitating consumer access to supplements in general.<sup>73</sup>

The presumption of safety does not apply, however, to supplements containing "new dietary ingredients."<sup>74</sup> Under DSHEA, supplements without any new dietary ingredients are not even required to be *registered* with the

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<sup>68</sup> 21 U.S.C. § 342(f). Section 342 deals with adulterated foods in general, and DSHEA added subsection (f), which solely addresses the circumstances under which a dietary supplement will be considered adulterated. *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> Cohen, *supra* note 26, at 176; *see also* Josh Zembik, *The FDA's Burden*, SPORTS ILLUSTRATED, May 18, 2009, at 59, 59, *available at* <http://sportsillustrated.cnn.com/vault/article/magazine/MAG1155398/index.htm> (quoting former FDA Commissioner David Kessler: "We've always had a system where if you sell a product, the burden should be on you to show it works . . . DSHEA shifted the burden [to the FDA] to prove it's harmful").

<sup>71</sup> Hill, *supra* note 40, at 368; *see also* Noah, *supra* note 47, at 149.

<sup>72</sup> Ziker, *supra* note 42, at 270.

<sup>73</sup> *Id.* at 269.

<sup>74</sup> 21 U.S.C. § 342(f)(1)(B).

FDA before entering the market.<sup>75</sup> The statute defines new dietary ingredients simply as ingredients that were not marketed in the United States before October 15, 1994.<sup>76</sup> Any supplement containing a new dietary ingredient is considered adulterated unless (1) it “contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered;” or (2) evidence indicates that the new ingredient is reasonably expected to be safe, and the manufacturer provides the Secretary of the United States Department of Health & Human Services with the information supporting that conclusion at least seventy-five days before introducing the supplement to the market.<sup>77</sup>

The new dietary ingredient provision of DSHEA reflected congressional intent to “ensure that there was an opportunity for [the] FDA to review the safety of *new* dietary supplement ingredients that had not previously been on the market while keeping the level of premarket scrutiny below that required for a drug or a food additive.”<sup>78</sup> Interestingly, while DSHEA defines new dietary ingredients by reference to the time when an ingredient first appeared on the market, the statute does not actually provide a definition for the term “dietary ingredient.”<sup>79</sup> Nevertheless, a dietary ingredient is generally considered to be “the substance in a dietary supplement that is highlighted in labeling as having an impact on the structure or function of the body.”<sup>80</sup>

The regulations for supplements containing new dietary ingredients are, however, less stringent than they may initially appear. DSHEA exempts such supplements from classification as adulterated upon the manufacturer’s notification to the FDA of its basis for expecting the new ingredient to be reasonably safe.<sup>81</sup> Thus, upon receiving such notification, the Agency has the burden of demonstrating that the new dietary ingredient is in fact adulterated and not safe in order to prevent it from reaching the market (or to remove it from the market).<sup>82</sup> But making such a determination requires substantial research. The upshot, essentially, is that even supplements containing new dietary ingredients are not subject to premarket approval by the FDA and may enter interstate commerce upon the provision of evidence indicating a reasonable belief as to the new ingredient’s safety.

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<sup>75</sup> Cohen, *supra* note 26, at 184; *see also* McNamara & Siegner, *supra* note 49, at 22.

<sup>76</sup> 21 U.S.C. § 350b(c).

<sup>77</sup> *Id.* § 350b(a).

<sup>78</sup> Bass & Marden, *supra* note 60, at 286.

<sup>79</sup> *Id.* at 291.

<sup>80</sup> *Id.*

<sup>81</sup> Hill, *supra* note 40, at 379-81 (indicating that the obligation to merely provide “some evidence” to the FDA of an ingredient’s anticipated safety is both vague and inadequate).

<sup>82</sup> *Id.*

C. *Labeling and Reporting Standards for Dietary Supplements*

In addition to the rules prohibiting adulteration, DSHEA subjects dietary supplements to labeling standards.<sup>83</sup> Before the Act's passage, the FDA had asserted the right to regulate all products that used publications – including books or articles – claiming to be useful in curing, mitigating, treating, or preventing any illness or disease as drugs.<sup>84</sup> The Agency argued that such promotions constituted “labeling,” and it could accordingly regulate any product making such beneficial health claims.<sup>85</sup>

DSHEA subjects dietary supplement advertising to various conditions, but the FDA cannot interpret such advertising as labeling as long as a manufacturer's publications in connection with the sale of a dietary supplement are not false or misleading.<sup>86</sup> In line with the rest of this statute's requirements, the FDA bears the burden of proof for establishing that a publication in connection with the sale of a dietary supplement is false or misleading.<sup>87</sup> That manufacturers label their supplements accurately is necessary, because otherwise consumers do not know what they are ingesting.<sup>88</sup> The FDA's authority to regulate improperly labeled products is well within its discretion to regulate supplements that pose a threat to public health.<sup>89</sup>

Furthermore, DSHEA specifies the types of statements that supplement manufacturers are allowed to make in connection with their products: manufacturers may describe “the role of a nutrient or dietary ingredient [in the supplement that is] intended to affect the structure or function in humans,” provided that “the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading.”<sup>90</sup> Additionally, all statements concerning a dietary supplement must bear the following disclaimer prominently and in boldface type: “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>91</sup> Effectively, that disclaimer prevents

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<sup>83</sup> See Spokes, *supra* note 25, at 202 (mentioning that dietary supplements are “subject only to specific marketing and adulteration standards”).

<sup>84</sup> McNamara, *supra* note 44, at 345.

<sup>85</sup> See *id.*

<sup>86</sup> See 21 U.S.C. § 343-2(a) (2006).

<sup>87</sup> *Id.* § 343-2(c).

<sup>88</sup> Joseph A. Levitt, *Regulation of Dietary Supplements: FDA's Strategic Plan*, 57 FOOD & DRUG L.J. 1, 4 (2002).

<sup>89</sup> See Bass & Marden, *supra* note 60, at 289.

<sup>90</sup> 21 U.S.C. § 343(r)(6). These are known as “structure or function claims,” which are also included in the sections pertaining to drug labeling. *Id.* § 321(g)(1)(B)-(C).

<sup>91</sup> *Id.* § 343(r)(6)(C).

manufacturers only from promising to cure disease or making egregious misrepresentations in connection with their products.<sup>92</sup>

Statements made by manufacturers in connection with their dietary supplements are as exempt from premarket approval by the FDA as the products themselves. In contrast, drug manufacturers cannot make specific health claims about the drugs they market without FDA approval.<sup>93</sup> Indeed, opponents of DSHEA have lamented that “dietary supplements may be advertised and sold without any evidence that they are safe and effective . . . [and the] FDA may take action only *after* a supplement has been marketed and then been shown to constitute an imminent threat to the public welfare.”<sup>94</sup> The Tenth Circuit confirmed this, noting that “manufacturers of dietary supplements do not need to prove effectiveness prior to taking their product to market.”<sup>95</sup>

DSHEA yields significant power to dietary supplement manufacturers, since products *marketed* as dietary supplements are considered dietary supplements regardless of the products’ prior classifications.<sup>96</sup> For example, products containing potent botanicals that the FDA tried to regulate in the past “are now classified as dietary supplements . . . [and] escape stringent regulation . . . because their manufacturers *disavow intent* to treat disease.”<sup>97</sup> After the passage of DSHEA, some manufacturers soon began taking advantage of such lax labeling requirements to market supplements containing steroids.

#### D. *Debating the Value of DSHEA*

Although the legislation faced few obstacles in Congress, DSHEA has nevertheless been subject to harsh criticism for the deregulation of dietary supplements.<sup>98</sup> Much of this criticism stems from the fact that DSHEA classifies dietary supplements based on the source of their ingredients, rather than the pharmaceutical or physiological properties of those ingredients.<sup>99</sup> DSHEA opponents accuse Congress of endangering the public by stripping the FDA of the ability to prevent the marketing and sale of ineffective or unsafe supplements.<sup>100</sup> Under DSHEA, the FDA may only prevent dietary supplements that contain a new dietary ingredient from initially entering the

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<sup>92</sup> Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. & MED. 215, 220 (2005).

<sup>93</sup> Spokes, *supra* note 25, at 185.

<sup>94</sup> Cohen, *supra* note 26, at 182-83.

<sup>95</sup> Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1039 n.5 (10th Cir. 2006).

<sup>96</sup> Spokes, *supra* note 25, at 191.

<sup>97</sup> Cohen, *supra* note 26, at 194.

<sup>98</sup> See, e.g., *id.* at 176-77.

<sup>99</sup> *Id.* at 176.

<sup>100</sup> *Id.* at 177 (“Congress abrogated its duty to the public welfare when it ended any meaningful FDA oversight of dietary supplements.”).

market.<sup>101</sup> Otherwise, the Agency is powerless unless the supplement is shown to be unsafe *after* it has gone to market. The result is FDA regulatory authority that is more reactive to problems than proactive in preventing such issues from arising in the first place.<sup>102</sup>

Critics of DSHEA also argue that the statute has enough loopholes to prevent the FDA from effectively taking action to ban dietary supplements that pose threats to the public.<sup>103</sup> The problem largely arises from the fact that DSHEA does not require supplement manufacturers to inform the FDA of any adverse reactions reported by consumers.<sup>104</sup> Estimates hold that the FDA learns of less than one percent of actual adverse reactions suffered by consumers due to underreporting by both manufacturers and customers.<sup>105</sup> As a result, manufacturers may continue to market and sell products that pose a legitimate threat to consumer health because the FDA is unaware of the existence or frequency of problems associated with a certain supplement.<sup>106</sup> Without substantial reporting requirements or the funds to launch adequate investigations, the FDA particularly struggles to monitor supplements that either cause harm gradually or are only harmful when combined with other drugs.<sup>107</sup> Furthermore, without a mandatory reporting provision, consumers are likely to be unaware of a particular supplement's adverse effects and continue purchasing the harmful product.<sup>108</sup> Thus, deregulation may prevent consumers from acquiring sufficient knowledge to make fully informed decisions about a supplement's safety.<sup>109</sup> This lack of knowledge is possible under the DSHEA scheme, largely because the law classifies dietary supplements as food rather than drugs.<sup>110</sup>

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<sup>101</sup> 21 U.S.C. § 350b (2006) (deeming supplements containing new dietary ingredients as "adulterated" unless certain requirements are met); *see also* Stephanie Kauflin, Comment, *Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme*, 33 SETON HALL L. REV. 411, 417 (2003).

<sup>102</sup> Noah, *supra* note 47, at 150.

<sup>103</sup> *See* Ziker, *supra* note 42, at 278. For example, some dietary supplement manufacturers respond to accusations of false labeling by marketing those same ingredients as a new and distinct product, requiring the FDA to conduct new rounds of testing. Zembik, *supra* note 70, at 59.

<sup>104</sup> Ziker, *supra* note 42, at 271 ("Dietary supplement manufacturers are encouraged, but not required, to report adverse events to [the] FDA.").

<sup>105</sup> McCann, *supra* note 92, at 251.

<sup>106</sup> *See, e.g., id.* at 253-54 (documenting evidence that ephedra manufacturers "failed to voluntarily report over 15,000 complaints, over ten percent of which involved deaths, heart attacks, [and] stroke," illustrating "manufacture incentive to distort cognitive biases and lower appreciation of product risks").

<sup>107</sup> Zembik, *supra* note 70, at 59.

<sup>108</sup> McCann, *supra* note 92, at 247; *see also* Kassel, *supra* note 39, at 247.

<sup>109</sup> Cohen, *supra* note 26, at 209.

<sup>110</sup> *Id.* at 191; *see also id.* at 196 (arguing that the potency and risk of causing severe illness and death justify regulating supplements in a fashion similar to pharmaceuticals).

There are, however, many who find no problem with DSHEA's regulatory framework, which is partially evidenced by the significant portion of the American population that regularly consumes dietary supplements.<sup>111</sup> Supporters of DSHEA argue that the statute gives the FDA substantial discretion to regulate supplements that do present a risk of illness or injury, while providing the public with access to supplements not yet proven to pose such a threat.<sup>112</sup> This is the access that consumers desired when originally lobbying for DSHEA.<sup>113</sup> DSHEA's supporters consider the attacks on this law to be unwarranted, and argue that "Americans should not be led to believe that dietary supplements are under regulated."<sup>114</sup> Under this theory, the real problem is not that the FDA lacks the necessary regulatory authority to protect the public from harmful supplements, but rather that it "has not used appropriately the ample authority it possesses."<sup>115</sup> However, the recent performance-enhancing drug scandals in the sports world give a contrary indication that steroids are not a particularly rare ingredient in dietary supplements.

#### IV. THE BASEBALL STEROID SCANDAL

##### A. *Early Legislation on Steroids and the Development of a Problem*

Since manufacturers need not obtain premarket approval for dietary supplements, there is a substantial risk that products will enter the market containing harmful or even illegal ingredients. DSHEA characterizes a dietary supplement based on the source of its ingredients,<sup>116</sup> and since the human body naturally produces many steroids,<sup>117</sup> DSHEA left a gaping hole whereby legal dietary supplements could contain illegal steroids.

Anabolic steroids have been classified as Schedule III controlled substances since Congress passed the Anabolic Steroids Control Act of 1990 ("ASCA"),<sup>118</sup> which amended the Controlled Substances Act of 1970.<sup>119</sup> Under federal law, "any drug or hormonal substance, chemically and pharmacologically related to testosterone" is an anabolic steroid.<sup>120</sup> Congress enacted that legislation primarily to prevent athletes from using steroids to

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<sup>111</sup> See Noah, *supra* note 47, at 147.

<sup>112</sup> Hutt, *supra* note 32, at 161.

<sup>113</sup> See McNamara, *supra* note 44, at 341.

<sup>114</sup> *The Regulation of Dietary Supplements: Hearing*, *supra* note 4, at 18 (statement of Rep. Christopher B. Cannon).

<sup>115</sup> McNamara & Siegner, *supra* note 49, at 24.

<sup>116</sup> Cohen, *supra* note 26, at 176.

<sup>117</sup> See, e.g., MITCHELL REPORT, *supra* note 10, at 77.

<sup>118</sup> Pub. L. No. 101-647, § 1902, 104 Stat. 4851 (1990) (codified as amended at 21 U.S.C. § 812(c) (2006)).

<sup>119</sup> Pub. L. No. 91-513, 84 Stat. 1242 (1970).

<sup>120</sup> 21 U.S.C. § 802(41)(A).



enhance their performance.<sup>121</sup> Nevertheless, until recently, athletes testing positive for steroids have not faced criminal liability, but only suspensions or other sanctions from their professional or amateur league of affiliation.<sup>122</sup>

Major League Baseball – in response to the ASCA – first prohibited steroids in 1991, although the sport did not mandate that players subject themselves to steroid testing.<sup>123</sup> When baseball first began testing for steroids in 2001, over-the-counter dietary supplements were not part of the testing regime, despite the fact that some of the most popular supplements among players were known to have anabolic effects.<sup>124</sup> MLB, however, had stalled for many years on the implementation of testing, as baseball insiders suspected a significant and increasing amount of players were using steroids as early as 1992.<sup>125</sup>

In 1996, the first full season after a players' strike had seriously damaged baseball's popularity among the American public, the sport witnessed a dramatic offensive outburst, as bigger and stronger batters began hitting more home runs than ever before.<sup>126</sup> In a 2002 *Sports Illustrated* article, former infielder Ken Caminiti credited steroids for his 1996 National League Most Valuable Player Award and suggested that steroid use was widespread throughout the sport.<sup>127</sup> That article, along with other rumors of rampant steroid abuse, led to congressional hearings shortly thereafter to determine the full extent of baseball's problem.<sup>128</sup>

The increasing speculation of performance-enhancing drug use in baseball exploded into a full scandal in 2003, when federal agents raided the offices of the Bay Area Laboratory Co-Operative ("BALCO"), which had been supplying numerous elite athletes with steroids.<sup>129</sup> Two years later, Jose

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<sup>121</sup> Richard D. Collins, *Of Ballparks and Jail Yards: Pumping Up the War on Steroids*, 30 CHAMPION 22, 24 (2006). In the context of athletic performance-enhancing drugs, "steroids" refers to anabolic androgenic steroids. MITCHELL REPORT, *supra* note 10, at 5.

<sup>122</sup> Collins, *supra* note 121, at 24. It is also worth noting that many baseball players facing criminal liability in connection with their steroid use, such as Barry Bonds, Roger Clemens, and Miguel Tejada, were not targeted for their actual use, but rather for committing perjury before Congress and courts of law. Hohler, *supra* note 12, at 3.

<sup>123</sup> MITCHELL REPORT, *supra* note 10, at 41-43.

<sup>124</sup> *Id.* at 44-45. MLB's first testing policy only covered minor leaguers. *Id.* In 2002, an agreement was reached with the players' union to begin testing major leaguers in the 2003 season. *See id.* at 47.

<sup>125</sup> *Id.* at 69 (quoting Peter Gammons, *They've Met Disappointment*, BOSTON GLOBE, Aug. 16, 1992, at 48).

<sup>126</sup> *Id.* at 71 ("The 1996 season began with an outbreak of hitting so dramatic that Commissioner Selig considered it to be 'startling.' Immediately, speculation turned to the use of steroids by baseball's big hitters . . ." (citation omitted)).

<sup>127</sup> *See* Tom Verducci, *Totally Juiced*, SPORTS ILLUSTRATED, June 3, 2002, at 34, available at <http://vault.sportsillustrated.cnn.com/vault/article/magazine/MAG1025902/index.htm>.

<sup>128</sup> *See generally Steroid Use in Professional Baseball: Hearing*, *supra* note 3.

<sup>129</sup> MITCHELL REPORT, *supra* note 10, at 55-56.

Canseco, another former Most Valuable Player, released a tell-all book that specifically detailed not only his own steroid use, but also that of many other high-profile players.<sup>130</sup> Congress again responded with a hearing – one that received substantial publicity due to the participation of many famous ballplayers and suspected steroid users – and MLB responded to the pressure by significantly strengthening its steroid program.<sup>131</sup> Baseball commissioner Bud Selig also asked former United States Senator George Mitchell to conduct an investigation on behalf of MLB, seeking to determine the full extent of steroid use in the game, including its origins and the identities of specific users.<sup>132</sup>

B. *A Legal Backdoor to Steroids?*

The congressional steroid hearings led to a significant upheaval of MLB's drug-testing program. Baseball's new policy resulted largely from Congress's threats to pass legislation mandating independent drug testing in professional sports.<sup>133</sup> One commentator has credited the hearings with drawing "attention to the seriousness of doping and provid[ing] disincentive not only to pro[fessional] athletes, but to college athletes and athletes younger than that."<sup>134</sup> In a similar vein, Congressman Bobby Rush from Illinois explained that "[r]idding sports of performance-enhancing drugs at the highest levels of competition is . . . about sending a clear message to young people that these dangerous drugs are not the ticket to success."<sup>135</sup>

Yet the congressional hearings focused almost exclusively on anabolic steroids and barely touched on the use of performance-enhancing dietary supplements by ballplayers. Defending MLB's policies, Commissioner Selig pointed out that although "experts have argued that some nutritional supplements have or may have virtually the same deleterious effects as steroids or other government-regulated controlled substances, Congress has permitted these substances to be sold over the counter with virtually no regulatory oversight."<sup>136</sup> In 2002, Robert Manfred, MLB's Executive Vice President of Labor and Human Resources, told Congress that DSHEA's deregulation of

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<sup>130</sup> See generally JOSE CANSECO, JUICED: WILD TIMES, RAMPANT 'ROIDS, SMASH HITS AND HOW BASEBALL GOT BIG (2005).

<sup>131</sup> MITCHELL REPORT, *supra* note 10, at 57-58. See generally *Restoring Faith: Hearing*, *supra* note 4 (featuring testimony from Jose Canseco, Mark McGwire, Rafael Palmeiro, Curt Schilling, Sammy Sosa, and Frank Thomas).

<sup>132</sup> MITCHELL REPORT, *supra* note 10, at 2.

<sup>133</sup> Peck, *supra* note 11, at 1777.

<sup>134</sup> Helene Elliott, *Congressional Hearing on Mitchell Report*, L.A. TIMES, Feb. 14, 2008, at D9.

<sup>135</sup> Brendan McKenna, *Commissioners Meet Before Congress*, DALLAS MORNING NEWS, Feb. 28, 2008, at 13C, available at 2008 WLNR 3922055.

<sup>136</sup> Selig & Manfred, *supra* note 13, at 35-36.

dietary supplements had essentially legalized the sale of some products that bear “all of the properties of an anabolic steroid.”<sup>137</sup>

Indeed, the Mitchell Report recognized that “[f]ollowing the enactment of the DSHEA, supplements claiming anabolic effects that were geared toward bodybuilders and other athletes became more widely available.”<sup>138</sup> Because the 1988 and 1990 amendments to the Controlled Substances Act only covered steroids, dietary supplements considered precursors to steroids were not banned.<sup>139</sup> Athletes generally take supplements for the same reasons that they turn to steroids – to maintain and increase muscle mass, energy, and weight, and to decrease recovery time from injuries or workouts.<sup>140</sup> Since DSHEA encompasses products that are labeled as dietary supplements, sold in powder or pill form, and marketed to enhance athletic performance, some ballplayers naturally opted for this legal alternative to steroids.<sup>141</sup> Such labeling has caused problems, however, because it occasionally hides the fact that supplements are acting as steroids.

### C. *Androstenedione and Ephedra*

The links between dietary supplements and the baseball steroid scandal are best known through the controversies surrounding androstenedione and ephedra. Androstenedione became an overnight sensation in 1998, when an Associated Press story reported that Mark McGwire – the famous slugger then pursuing baseball’s single-season home run record – was using this dietary supplement.<sup>142</sup> At the time, androstenedione was legal under DSHEA, sold over the counter as a dietary supplement, and not subject to strict FDA regulation.<sup>143</sup>

Marketing androstenedione as a “dietary supplement” masked its true nature: it is actually a steroid precursor hormone that the human body naturally produces and later converts into testosterone.<sup>144</sup> Androstenedione may also increase the activity of other hormones in addition to testosterone.<sup>145</sup> Advertising campaigns for the product targeted consumers looking to enhance their athletic performance. One manufacturer promoted androstenedione as “The Product Behind Mark McGwire’s 70 Home Runs . . . . Take your testosterone levels to new heights with this botanically derived extract and see

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<sup>137</sup> *Steroid Use in Professional Baseball: Hearing*, *supra* note 3, at 6 (statement of Robert D. Manfred, Jr.).

<sup>138</sup> MITCHELL REPORT, *supra* note 10, at 21.

<sup>139</sup> *Id.*

<sup>140</sup> Spokes, *supra* note 25, at 194.

<sup>141</sup> *See id.* at 198; *see also* 21 U.S.C. § 321(a)(ff) (2006).

<sup>142</sup> MITCHELL REPORT, *supra* note 10, at 16 (discussing a 1000% rise in androstenedione sales after the public learned of McGwire’s use of the product).

<sup>143</sup> *See id.*

<sup>144</sup> *Id.* at 77.

<sup>145</sup> *Id.* at 82.

why professional baseball player Mark McGwire is continually pounding home runs into the stratosphere.”<sup>146</sup> The emphasis on testosterone effectively told ballplayers that androstenedione was a legal backdoor to steroids.

Without DSHEA, it is unlikely that androstenedione would have been so widely available.<sup>147</sup> Canada, for example, had already classified androstenedione as an anabolic steroid by 1998.<sup>148</sup> Public speculation over the supplement, which had already been banned by other sports, eventually prompted baseball to conduct studies on androstenedione’s physiological effects.<sup>149</sup> Although these studies concluded in 2002 that androstenedione did indeed raise testosterone levels, neither Congress nor baseball changed their stances on the supplement until a 2004 amendment to the ASCA included steroid precursors such as androstenedione in the definition of anabolic steroids.<sup>150</sup> MLB, which has a reactive approach to congressional legislation regarding prohibited substances, automatically banned the use of androstenedione once the ASCA amendment was enacted.<sup>151</sup>

Ephedra posed a more serious health threat than androstenedione. An ingredient once found in more than 200 dietary supplements, ephedra has been linked to 155 deaths and well over 16,000 adverse reactions.<sup>152</sup> Products containing ephedra have been proven to cause seizures, strokes, heart arrhythmia, and heat stroke.<sup>153</sup> Indeed, ephedra was conclusively determined to have played a role in Baltimore Orioles pitcher Steve Bechler’s 2003 death from heat stroke.<sup>154</sup>

As with androstenedione, DSHEA allowed ephedra-containing supplements to reach the market without any prior approval by the FDA. Unfortunately, the FDA was aware of ephedra’s dangers as early as 1997, but was unable to ban or even temporarily halt sales of products that contained the substance until it compiled sufficient evidence to sustain the burden of proof that DSHEA placed on the federal agency.<sup>155</sup> Upon realization that the FDA did not have adequate

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<sup>146</sup> Steve Wilstein, *Andro’s Allure to Young Men Makes It a Hit on Internet*, CHI. TRIB., Jan. 3, 1999, at 14.

<sup>147</sup> *Id.*

<sup>148</sup> MITCHELL REPORT, *supra* note 10, at 77. Interestingly, this means that while most Major Leaguers could use androstenedione in the late 1990s, players on the Montreal Expos and Toronto Blue Jays may have been exposed to criminal liability for such use.

<sup>149</sup> *See id.* at 77-82.

<sup>150</sup> Anabolic Steroid Control Act of 2004, Pub. L. No. 108-358, 118 Stat. 1661 (codified as amended at 21 U.S.C. § 802 (2006)); MITCHELL REPORT, *supra* note 10, at 24, 82-84.

<sup>151</sup> MITCHELL REPORT, *supra* note 10, at 84.

<sup>152</sup> McCann, *supra* note 92, at 252; Scott Danaher, Comment, *Drug Abuse in Major League Baseball: A Look at Drug Testing in the Past, in the Present, and Steps for the Future*, 14 SETON HALL J. SPORTS & ENT. L. 305, 310 (2004).

<sup>153</sup> Len Pasquarelli, *Ephedra Crackdown a Step in the Right Direction*, ESPN.COM, May 22, 2002, [http://assets.espn.go.com/nfl/columns/pasquarelli\\_len/1385554.html](http://assets.espn.go.com/nfl/columns/pasquarelli_len/1385554.html).

<sup>154</sup> Selig & Manfred, *supra* note 13, at 58.

<sup>155</sup> Hill, *supra* note 40, at 381-82; MITCHELL REPORT, *supra* note 10, at 22.

regulatory authority, some states took their own actions to ban supplements containing ephedra.<sup>156</sup>

Less than one year before Bechler's death, Robert Manfred's testimony before Congress had warned of the potential dangers posed by improper dietary supplement regulation, yet no action was taken.<sup>157</sup> It was not until 2004 that the FDA finally collected enough evidence to ban the sale of dietary supplements containing ephedra.<sup>158</sup> Some estimates hold that up to seventeen percent of dietary supplements on the market contained some form of ephedra at the time of the FDA's ban.<sup>159</sup>

Since both androstenedione and ephedra are naturally-occurring substances, DSHEA permitted supplements with these ingredients to enter the market, even though androstenedione is a steroid precursor and ephedra is "an amphetamine-like stimulant."<sup>160</sup> Furthermore, the FDCA regulates ephedrine, the principal ingredient in ephedra, as a drug when made in a synthetic form.<sup>161</sup> These two examples demonstrate one of the primary dangers that critics of DSHEA allege: that "the lack of pre-market regulation has encouraged manufacturers to manipulate their products to fit within the definition of a dietary supplement."<sup>162</sup> Additionally, MLB's unwillingness to prevent players from using legal products has created a reactionary relationship with Congress, where the league will only ban supplements that the legislature has outlawed. Thus, if Congress truly wants baseball to clamp down on the use of illicit substances by players, it must help the league by passing regulatory legislation to keep products containing such substances off the market.

During congressional hearings on the regulation of dietary supplements, Congressman Christopher Cannon of Utah claimed that "just because a steroid – or any other product – is marketed as a dietary supplement doesn't make it one."<sup>163</sup> Nevertheless, DSHEA allows such products to enter the market as dietary supplements by letting manufacturers determine whether their product

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<sup>156</sup> Hill, *supra* note 40, at 382 (observing that three states banned ephedra outright, and over twenty-five took action to limit its sale and use).

<sup>157</sup> *Steroid Use in Professional Baseball: Hearing*, *supra* note 3, at 6 (statement of Robert D. Manfred, Jr., MLB Executive Vice President of Labor & Human Resources).

<sup>158</sup> Press Release, U.S. Food & Drug Admin., FDA Announces Rule Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids Effective April 12 (Apr. 12, 2004), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108281.htm> (last visited Dec. 19, 2009); Carol Rados, *Ephedra Ban: No Shortage of Reasons*, FDA CONSUMER, Mar.-Apr. 2004, at 6, 6, available at [http://web.archive.org/web/20071216000326/www.fda.gov/FDAC/features/2004/204\\_ephedra.html](http://web.archive.org/web/20071216000326/www.fda.gov/FDAC/features/2004/204_ephedra.html) (last visited Nov. 24, 2009).

<sup>159</sup> Cohen, *supra* note 26, at 190.

<sup>160</sup> MITCHELL REPORT, *supra* note 10, at 22.

<sup>161</sup> Rados, *supra* note 158, at 6.

<sup>162</sup> Hill, *supra* note 40, at 378.

<sup>163</sup> *The Regulation of Dietary Supplements: Hearing*, *supra* note 4, at 17 (statement of Rep. Christopher B. Cannon).

falls within the statutory definition of a dietary supplement.<sup>164</sup> The FDA can only take action once a supplement has already been on the market and proven to pose a serious threat to the health of consumers.<sup>165</sup> Ephedra and androstenedione have shown that performance-enhancing dietary supplements are not necessarily safe by virtue of being legal within the DSHEA framework.<sup>166</sup> DSHEA has thus exempted many products from classification as drugs and accordingly prevented any meaningful FDA oversight before these products are sold on the market.<sup>167</sup>

## V. DRUG TESTING AND LINGERING ISSUES

Baseball's steroid testing policies have faced an unexpected – but not surprising – complication that can be linked to the deregulation of dietary supplements by DSHEA: false positives.<sup>168</sup> Testing for prohibited substances is a strict liability regime, so the mere presence of such a substance in an athlete's blood or urine will result in a violation regardless of the athlete's ignorance that a product he was using contained a banned ingredient.<sup>169</sup> This is particularly problematic, considering the report from a 2007 study of fifty-eight dietary supplements that nearly fifteen percent contained steroids or prohormones that were not listed on the product's label.<sup>170</sup>

Dietary supplements are very popular among athletes seeking to improve their performance on the playing field, but under the current regulatory scheme, these consumers cannot be certain that a supplement is free of banned substances.<sup>171</sup> Indeed, since many dietary supplements contain steroid precursors, athletes consuming those supplements may test positive for steroids.<sup>172</sup> Critics of DSHEA have argued that the labeled dosage frequently fails to conform to the actual content of the active ingredient or belies contamination.<sup>173</sup>

Part of baseball's problem in passing initial steroid regulations was that the players' union simply would not permit the prohibition of substances used by

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<sup>164</sup> Cohen, *supra* note 26, at 182-83; *see also* McCann, *supra* note 92, at 243.

<sup>165</sup> Cohen, *supra* note 26, at 182-83.

<sup>166</sup> Danaher, *supra* note 152, at 330.

<sup>167</sup> *Id.* at 306-07.

<sup>168</sup> *See* Jacobs, *supra* note 16, at 36.

<sup>169</sup> *Id.* at 35-36.

<sup>170</sup> MITCHELL REPORT, *supra* note 10, at 24 n.79. Twenty-five percent of those supplements tested contained ingredients that were banned by the World Anti-Doping Agency. Epstein & Dohrmann, *supra* note 50.

<sup>171</sup> Selig & Manfred, *supra* note 13, at 47 (pointing out that the National Collegiate Athletic Association website warns athletes that the purity of dietary substances is unknown due to the lack of regulation before their entrance into commerce); *see also* Nat'l Collegiate Athletic Ass'n Check It Out, <http://www.ncaa.org/checkitout> (last visited Dec. 19, 2009).

<sup>172</sup> Selig & Manfred, *supra* note 13, at 53-54.

<sup>173</sup> Cohen, *supra* note 26, at 196.

so many players. Obtaining approval by the Players Association for testing was an absolute necessity, not only because of collective bargaining rules, but also because of the strength and influence baseball's union.<sup>174</sup> Donald Fehr, the former Executive Director of the MLB Players Association, consistently prevented the league from banning legal, over-the-counter supplements, claiming that only Congress may prohibit these products.<sup>175</sup> MLB could not impose drug testing unilaterally on its players in the first place, and the league secured its current drug-testing program through collective bargaining.<sup>176</sup> Thus, MLB officials believe that if Congress truly wants to cleanse sports of performance-enhancing substances, it must give the FDA greater authority to regulate dietary supplements.<sup>177</sup>

With the current uncertainty surrounding the contents of various supplements, it is not surprising that whenever a baseball player (or any athlete) tests positive for a banned substance, he pleads ignorance and argues that the positive result must have been caused by a contaminated supplement.<sup>178</sup> Because of this apparent loophole and the difficulty of proving that an athlete intended to use steroids, baseball and other sports subject athletes to a strict liability standard regarding substance abuse.<sup>179</sup> On the one hand, this system is arguably unfair to players who buy supplements that are completely legal under DSHEA's framework. On the other hand, ballplayers are aware of the current testing rules and have been warned of the uncertainty that comes with using supplements that have not been approved by the FDA. MLB has also responded to the uncertainty surrounding dietary supplement

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<sup>174</sup> Karen Kaplan & Lance Pugmire, *In Baseball, Union Retains Its Clout*, L.A. TIMES, Sept. 2, 2002, at 3-1 (arguing that the MLB Players Association "retains its clout as one of the nation's most powerful brotherhoods, capable of bringing the . . . national pastime to a halt"). The union orchestrated a strike that cancelled the World Series in 1994 and significantly damaged the sport's popularity; many have suggested that MLB was slow to react to the steroid scandal largely because the game's power surge had fans flocking back to the ballpark. See, e.g., Richard Justice, *Baseball's Image Takes Another Hit*, HOUSTON CHRON., Feb. 9, 2009, at S1 available at 2009 WLNR 2704455 ("Steroids have been great for the business of baseball. They helped get the game back on its feet after the 1994 strike.").

<sup>175</sup> Selig & Manfred, *supra* note 13, at 58.

<sup>176</sup> See MITCHELL REPORT, *supra* note 10, at 12-13 & n.8.

<sup>177</sup> See Selig & Manfred, *supra* note 13, at 36.

<sup>178</sup> Jacobs, *supra* note 16, at 34-35. Recently, upon learning that his name was on a list of players who had tested positive for prohibited substances in 2003, David Ortiz claimed that while he never used steroids, he frequently and carelessly purchased and used legal dietary supplements – attributing any positive test to those purchases. Amalie Benjamin, *Ortiz Denies That He Ever Used Steroids*, BOSTON GLOBE, Aug. 9, 2009, at M1 (describing further concerns about methodology that lead to positive tests).

<sup>179</sup> See Jacobs, *supra* note 16, at 38 ("The anti-doping agencies have made the decision that . . . athletes bear the full responsibility for the contamination problems that became much more frequent with the passage of DSHEA.").

ingredients by instituting a drug hotline for players to call with questions about which drugs or dietary supplements contain ingredients banned by baseball.<sup>180</sup>

## VI. CONGRESSIONAL RESPONSIBILITY FOR BASEBALL'S STEROID PROBLEM?

### A. *DSHEA and the Presence of Steroids in Baseball*

Baseball's steroid scandal interested Congress largely because of the role-model effect that professional athletes have on America's youth and the fear that high school and collegiate players will use unsafe performance-enhancing substances to imitate the professionals.<sup>181</sup> Players striving to reach the highest levels of professional baseball have been tempted to try such substances, not only because of the highly publicized use by Major Leaguers, but also because, as Commissioner Selig told Congress, "there is enough evidence that using performance enhancing drugs gives a player an advantage."<sup>182</sup>

Most critics of the steroid scandal have focused on MLB and Selig himself for ignoring the problem as it developed and then delaying in crafting an adequate solution.<sup>183</sup> Senator Mitchell concluded, after his investigation of the scandal, "Everyone involved in baseball over the past two decades – Commissioners, club officials, the Players Association, and players – shares to some extent in the responsibility for the steroids era."<sup>184</sup> Democratic Congressman Henry Waxman and Republican Congressman Tom Davis echoed these sentiments in a joint statement, saying the Mitchell Report "shows that everyone involved in Major League Baseball bears some responsibility for this scandal."<sup>185</sup> Most notable about the Congressmen's brief statement is that it made no mention of any congressional role in facilitating players' access to performance enhancers.<sup>186</sup>

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<sup>180</sup> Jayson Stark, *Phillies' Romero Out Until June 1*, ESPN.COM, Feb. 14, 2009, <http://sports.espn.go.com/mlb/spring2009/news/story?id=3907318>. Nevertheless, many players are unaware of the hotline's existence or how exactly to access it, and those testing positive for banned substances present in dietary supplements can be suspended for "negligence" by not ascertaining the true nature of relevant supplements. *Id.*

<sup>181</sup> Peck, *supra* note 11, at 1809.

<sup>182</sup> *Mitchell Report on Performance-Enhancing Substances in Major League Baseball: Panel II of a Hearing of the H. Oversight & Gov't Reform Comm.*, 110th Cong. at \*22 (2008) [hereinafter *Mitchell Report: Hearing*] (statement of Bud Selig, Commissioner of MLB) (transcript on file with the Boston University Law Review).

<sup>183</sup> See Gregory D. Hanscom, Comment, *Baseball Juiced Up: Should the Increased Risk Associated with the Use of Performance-Enhancing Substances Create Tort Liability*, 15 VILL. SPORTS & ENT. L.J. 367, 375 (2008).

<sup>184</sup> MITCHELL REPORT, *supra* note 10, at 36.

<sup>185</sup> Hohler, *supra* note 12; Henry A. Waxman & Tom Davis Joint Statement on Mitchell Report (Dec. 13, 2007), available at <http://waxman.house.gov/News/DocumentSingle.aspx?DocumentID=113522>.

<sup>186</sup> Waxman & Davis Joint Statement on Mitchell Report, *supra* note 185.



Some Members of Congress even believe that use of steroids and dietary supplements by baseball players are completely unrelated issues. A Representative from Utah stated at a 2006 hearing, “[W]e don’t have a problem with dietary supplement regulation or safety, rather we have a problem with anabolic steroid enforcement.”<sup>187</sup> But the very same success-driven athletic culture that led to steroid use also established a highly profitable customer base for the dietary supplement industry.<sup>188</sup> Accordingly, it should not be surprising that many ballplayers turned to unregulated dietary supplements as a means of improving their strength, stamina, and performance on the field. Unlike steroids, such supplements are legal and accordingly do not carry the same stigma for users. Despite MLB’s current testing scheme, Commissioner Selig views the wide and largely unregulated availability of dietary supplements as a significant roadblock to cleaning up baseball.<sup>189</sup>

Another way of analyzing the issue could be to view dietary supplements as a gateway to steroids. Of course, steroids first surfaced in baseball in the late 1980s, whereas DSHEA was not enacted until 1994. Nevertheless, steroids were not a serious problem for MLB until after the players’ strike, which began just two months before DSHEA passed into legislation. Selig has argued that “[t]he widespread use of products with drug-like characteristics can be directly tied to Congress’s decision to effectively end the FDA’s regulatory role in this area [dietary supplements] just as the FDA had concluded that closer regulation was necessary to protect the public health.”<sup>190</sup> DSHEA forbids the FDA from regulating supplements until it has gathered conclusive evidence of adverse effects, despite the many supplements that have drug-like effects on the human body.<sup>191</sup> Ballplayers take dietary supplements for the same reason they take steroids – because they believe the ingredients will result in improved performance on the field.<sup>192</sup>

Donald Fehr has echoed Commissioner Selig’s sentiments that DSHEA facilitates an environment where ballplayers will seek and obtain performance-enhancing substances.<sup>193</sup> In a statement to Congress concerning the findings of the Mitchell Report, Fehr suggested that the legislature was sending an inconsistent message by aggressively investigating and seeking to halt the use of steroids by baseball players, while still permitting unregulated dietary

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<sup>187</sup> *The Regulation of Dietary Supplements: Hearing*, *supra* note 4, at 17 (statement of Rep. Christopher B. Cannon).

<sup>188</sup> Pasquarelli, *supra* note 153 (arguing that athletes “catapulted the dietary supplement business into one that generates billions of dollars in revenues”).

<sup>189</sup> Selig & Manfred, *supra* note 13, at 36.

<sup>190</sup> *Id.* at 42.

<sup>191</sup> *Id.* at 41; *see also* Cohen, *supra* note 26, at 213 (“[The] differences between pharmaceuticals and supplements are more semantic and political than scientific . . .”).

<sup>192</sup> *See* Spokes, *supra* note 25, at 201-02.

<sup>193</sup> *Mitchell Report: Hearing*, *supra* note 182, at \*6 (statement of Donald Fehr, Executive Director, MLB Players Association).

supplements on the market.<sup>194</sup> The controversies surrounding ephedra and androstenedione have shown that dietary supplements may be unsafe and carry serious side effects similar to those that are the basis for prohibiting anabolic steroids as controlled substances.<sup>195</sup>

The congressional hearings concerning steroid use in sports, and baseball in particular, have received considerable publicity, and some critics of DSHEA have accused Congress of not demonstrating “the same willingness to address the issue of supplement contamination.”<sup>196</sup> However, this assessment is not entirely accurate. The 2005 hearings on steroid use in baseball inspired a congressional hearing concerning DSHEA and contaminated supplements the following year.<sup>197</sup> But while Congress recognized that there may be a problem when “millionaire athletes with topnotch athletic trainers on staff need to resort to third parties to let them know which supplements are safe to take and which are not because they might unexpectedly . . . contain performance-enhancing drugs,” the 2006 hearing did not result in any changes to the law.<sup>198</sup>

By 2008, the hearing on dietary supplements seemed a distant memory when members of Congress echoed the Mitchell Report in focusing the blame for the steroid scandal upon MLB and all those involved in the sport over the preceding twenty years.<sup>199</sup> Although the Mitchell Report focused primarily on the inner workings of MLB, former Senator Mitchell briefly recognized DSHEA’s contribution to the scandal.<sup>200</sup> Having been the Senate Majority Leader when the legislation was passed, Mitchell retrospectively regretted not speaking out “against the manner of regulating supplements that resulted from enactment of that law.”<sup>201</sup> This regret indicated a belief that baseball’s problem with performance-enhancing substances may not have been as severe without legislation such as DSHEA preventing the FDA from premarket approval of dietary supplements.

DSHEA has provided baseball players with a legal market for purchasing potentially dangerous and harmful performance-enhancing substances.<sup>202</sup> But

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<sup>194</sup> *Id.* at \*31 (testimony of Donald Fehr).

<sup>195</sup> See Danaher, *supra* note 152, at 307 n.16.

<sup>196</sup> Jacobs, *supra* note 16, at 35.

<sup>197</sup> *The Regulation of Dietary Supplements: Hearing, supra* note 4, at 1 (statement of Rep. Tom Davis, Chairman of Comm. on Government Reform) (“Our steroids inquiry also led us in a direction we had not anticipated and that is one reason we find ourselves here today, taking a closer look at the massive and fast-growing dietary supplement industry.”).

<sup>198</sup> *Id.* at 2-3.

<sup>199</sup> Hohler, *supra* note 12 (describing congressional reaction to the Mitchell Report).

<sup>200</sup> MITCHELL REPORT, *supra* note 10, at 60.

<sup>201</sup> *Id.* However, since the Mitchell Report took place thirteen years after DSHEA’s passage, the former Senator had only a “vague recollection of the Senate’s consideration of the Act.” *Id.*

<sup>202</sup> See Selig & Manfred, *supra* note 13, at 58 (“DSHEA has allowed supplement manufacturers to flood the market with dangerous products that put the health of all citizens – not just athletes – at risk.”).

such wide access to dietary supplements is only possible because the law allows manufactures to place products on the market without first establishing that they are safe.<sup>203</sup> Thus, the very deregulation that has permitted the entrance of numerous dietary supplements into the market to help baseball players with their performances has also exposed the players to risks that those products may not only be dangerous, but also contain prohibited substances.

The allure of performance-enhancers proved very difficult to resist for baseball players who faced a competitive disadvantage by not taking any steroids or supplements and risked losing their position and millions of dollars to someone who benefitted from such products.<sup>204</sup> It should therefore not be surprising that players who were uncomfortable with using the syringes necessary for anabolic steroid use would turn to legal supplements to raise testosterone levels and increase muscle mass.<sup>205</sup> For some, that may have been the first step on the path to anabolic steroid use.

#### B. *The Future of DSHEA and Baseball*

While MLB's testing policy has begun weeding steroids out of baseball, the issue of contaminated supplements refuses to go away. As recently as January 2009, J.C. Romero, who helped pitch the Philadelphia Phillies to the 2008 World Series championship, received a fifty-game suspension for violating baseball's steroid policy.<sup>206</sup> The positive test did not result from anabolic steroids, but rather a supplement that Romero had purchased at a GNC store.<sup>207</sup> Unsurprisingly, the supplement's label made no mention of the prohibited ingredient.<sup>208</sup> When questioned about Romero's positive test, Selig once again pointed a finger towards Congress, saying "[T]he government needs to do a lot

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<sup>203</sup> Jacobs, *supra* note 16, at 36-37; *see also* Epstein & Dohrmann, *supra* note 50 (pointing out that many supplement manufacturers have "little or no formal education in science or nutrition").

<sup>204</sup> *See* MITCHELL REPORT, *supra* note 10, at 10 ("[O]ne of the 'biggest complaints' among players was that a 'guy is using steroids and he is taking my spot.'").

<sup>205</sup> *See* Wilstein, *supra* note 146 (commenting on the perceived safety of androstenedione compared to steroids).

<sup>206</sup> Peter Gammons, *Suspended Romero 'Didn't Cheat,'* ESPN.COM, Jan. 6, 2009, <http://sports.espn.go.com/mlb/news/story?id=3812334>. Just four months later, Manny Ramirez became the most prominent player to be suspended for steroid use. Schmidt, *One of Baseball's Biggest Stars is Now its Latest Drug Culpit*, *supra* note 1.

<sup>207</sup> Gammons, *supra* note 206. Romero sued the company that manufactured the supplement that allegedly caused his positive test. The company is run by Patrick Arnold, who both introduced androstenedione to the market and also served prison time for his involvement with BALCO. Mark Fainaru-Wada, *Suspended Phillie Romero Files Suit*, ESPN.COM, Apr. 28, 2009, <http://sports.espn.go.com/mlb/news/story?id=4105353>.

<sup>208</sup> Gammons, *supra* note 206. The supplement, however, did contain a warning that stated, "Use of this product may be banned by some athletic or government associations . . ." Fainaru-Wada, *supra* note 207.

of work . . . . [Trainers] wish the government would do more from the regulation standpoint [about supplements].”<sup>209</sup>

There appear to be two ways of viewing DSHEA’s continued effect on baseball’s quest to rid itself of performance-enhancing substances. One view is that the problem has essentially been solved. MLB has finally instituted a mandatory steroid testing policy that imposes substantial penalties for positive tests and affects not only a player’s reputation, but also his wallet.<sup>210</sup> This should ensure that steroid use will never again be widespread in the sport. Thus, because the congressional hearings on steroid use effectively pressured MLB into action and the game’s current policies are as effective as science allows, Congress does not appear to believe that further action is necessary.<sup>211</sup> Indeed, despite hearings and pleas for reform, Congress has not amended or modified DSHEA in any way.

But adhering to this view reflects a determination that the true nature of baseball’s steroid problem was that MLB turned a blind eye to what its players were doing for years. Now that the appropriate testing procedures and penalties are in place, such a view holds that performance-enhancing drugs will cease to be an issue in baseball. For the most part, this is an accurate assessment of the past and present status of the steroid scandal, as the penalties have led to a dramatic reduction in steroid use by baseball players. Romero was only the twentieth MLB player – and the first since 2007 – to receive a suspension for violating baseball’s steroid policy since the league instituted its more severe testing policy in 2005.<sup>212</sup>

A contrary and possibly more pragmatic view recognizes that the lack of regulatory power over dietary supplements prevents the FDA from guaranteeing the purity and safety of supplements until Congress changes the law. Without such regulatory legislation, players have no assurances that the dietary supplements they legally ingest to improve their performance will not run them afoul of MLB’s regulations. Baseball’s handling of illicit substances has historically been in reaction to congressional legislation,<sup>213</sup> and the Romero suspension has shown that supplements containing forbidden substances will likely continue to be an issue for baseball players and all athletes as long as the current regulatory scheme persists. Indeed, Selig and others in baseball insist that the sport cannot eradicate performance-enhancing drugs as long as

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<sup>209</sup> Jayson Stark, *The Commish Gives His State of the Game*, ESPN.COM, Jan. 23, 2009 [http://sports.espn.go.com/mlb/columns/story?columnist=stark\\_jayson&id=3853027](http://sports.espn.go.com/mlb/columns/story?columnist=stark_jayson&id=3853027).

<sup>210</sup> See MITCHELL REPORT, *supra* note 10, at 13.

<sup>211</sup> For example, human growth hormone, which is not yet detectable by the urine tests administered by MLB, has become increasingly popular. *Id.*

<sup>212</sup> Baseball Almanac, [http://www.baseball-almanac.com/legendary/steroids\\_baseball.shtml](http://www.baseball-almanac.com/legendary/steroids_baseball.shtml) (last visited Oct. 22, 2009) (listing all baseball players who have been suspended for using steroids or stimulants since 2005).

<sup>213</sup> See *supra* notes 151, 175 and accompanying text.

DSHEA remains unaltered.<sup>214</sup> The Commissioner's continuing complaints about dietary supplement regulation are particularly revealing because, unlike his previous attempts to apportion some of the blame for the steroid scandal to DSHEA,<sup>215</sup> MLB is no longer under intense congressional scrutiny to clean itself up.

Dietary supplements will become an increasingly frustrating problem for baseball until the FDA is given stronger regulatory power over them. There are already many indications of this, not only from the most recent interviews with Romero, David Ortiz, and Alex Rodriguez, but also from many of the other steroid suspensions that MLB has doled out for violations of its banned substances policy since 2005.<sup>216</sup> Either players are being penalized for using legal, but tainted, supplements due to the FDA's inability to effectively regulate such products, or some players are continuing to knowingly use performance-enhancing drugs and merely using the "tainted supplement" defense to shield them from public condemnation. Neither scenario is ideal, and as Selig and others recognize, the most effective way to close this loophole and put an end to consumer confusion about the contents of dietary supplements would be for Congress to amend DSHEA and increase the FDA's regulatory authority.

#### CONCLUSION

Since its ratification in 1994, DSHEA has been no stranger to criticism from various fronts. MLB's attempts to deflect some of the blame for its steroid scandal, however, came as a surprise to Congress.<sup>217</sup> A significant number of baseball players take dietary supplements to improve their performance on the field, and DSHEA has permitted many of these supplements to enter the market without prior approval by the FDA.<sup>218</sup>

Congress passed DSHEA as a direct response to public and private fears that the FDA would begin heavily regulating and substantially limiting public access to dietary supplements.<sup>219</sup> But the tradeoff for such wide distribution of dietary supplements is that the FDA cannot ensure the safety or purity of a supplement before it enters the market. Legal supplements became very enticing for ballplayers seeking to gain an edge on the competition, and

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<sup>214</sup> Stark, *supra* note 209.

<sup>215</sup> See generally Selig & Manfred, *supra* note 13.

<sup>216</sup> For example, Mike Cameron proclaimed after his 2007 suspension: "After all of the analysis and testing, I can only conclude that a nutritional supplement I was taking was tainted." *Baseball Suspends Cameron 25 Games for Failed Test*, ESPN.COM, Oct. 31, 2007 <http://sports.espn.go.com/mlb/news/story?id=3088062>.

<sup>217</sup> *The Regulation of Dietary Supplements: Hearing*, *supra* note 4, at 1 (statement of Rep. Tom Davis, Chairman of Comm. on Government Reform).

<sup>218</sup> See Danaher, *supra* note 152, at 306-07.

<sup>219</sup> See Bass & Marden, *supra* note 60, at 287.

athletes in general became prime consumers of many of the dietary supplements that entered the market in the mid-1990s.<sup>220</sup>

The lack of regulation over dietary supplements allowed those with effects similar to anabolic steroids to enter the market – products that were particularly appealing to professional baseball players.<sup>221</sup> Furthermore, since dietary supplements are legal and professional athletes have a role-model effect on America's youth, many amateur baseball players can easily purchase the same supplements used by Major Leaguers.<sup>222</sup> Some of these supplements have turned out to be no different from steroids (androstenedione) or pose serious health risks (ephedra).

Thus, while publicity for the steroid scandal has appropriately focused on the use of steroids by baseball players, the role of dietary supplements and DSHEA should not be ignored. The Mitchell Report recognized that the problem was one of both “widespread illegal use of anabolic steroids and *other performance enhancing substances* by players.”<sup>223</sup> Although use of dietary supplements is legal under DSHEA's framework even when they contain steroids, that Mitchell had such substances in mind should not be doubted. After various internal investigations and congressional hearings, MLB has instituted a drug testing policy that promises to make widespread steroid use by its players a problem of the past.

Referring to the androstenedione controversy, William Harlan, the associate director for disease prevention at the National Institutes of Health, said in 1999: “[U]ntil you get to the point where you actually have the evidence that harm has been done, you won't get a response from Congress. This country's great for responding to a crisis . . . [b]ut we never seem to do the right things to prevent the crisis.”<sup>224</sup> The crisis has now passed, but what should be done about the lingering issue of tainted supplements? Most dietary supplements actually are safe, but DSHEA has limited the FDA's authority to take swift action against contaminated or dangerous supplements.<sup>225</sup> Consumers are often confused about the actual contents of dietary supplements because the industry has become “a Pandora's Box of false claims, untested products and bogus science.”<sup>226</sup> DSHEA's critics have offered various solutions to these

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<sup>220</sup> See Pasquarelli, *supra* note 153.

<sup>221</sup> See MITCHELL REPORT, *supra* note 10, at 21.

<sup>222</sup> See Peck, *supra* note 11, at 1809. One employee of a supplement manufacturer identified the primary consumers of supplements containing steroids as males between the ages of fifteen and twenty-five who do not want to take steroids, but have learned that a particular supplement will nonetheless provide substantial muscle gains. Epstein & Dohrmann, *supra* note 50.

<sup>223</sup> MITCHELL REPORT, *supra* note 10, at 1 (emphasis added).

<sup>224</sup> Wilstein, *supra* note 146.

<sup>225</sup> *The Regulation of Dietary Supplements: Hearing*, *supra* note 4, at 7 (statement of Rep. Henry A. Waxman).

<sup>226</sup> Epstein & Dohrmann, *supra* note 50.

problems, ranging from requiring FDA premarket approval of dietary supplements<sup>227</sup> to mandatory reporting of adverse events by manufacturers,<sup>228</sup> to outright repeal of the legislation.<sup>229</sup> Yet DSHEA's supporters have been equally vocal, claiming that the FDA has sufficient regulatory authority. One congressional supporter went so far as to suggest the problem is not with the law, but rather with the athletes who have abused performance-enhancing substances and accordingly "tainted the dietary supplement industry."<sup>230</sup>

The answer probably lies somewhere in the middle of the dispute between DSHEA's supporters and detractors. Regarding baseball, Bud Selig has specifically targeted DSHEA by arguing that Congress needs to amend or repeal the legislation in order to provide a comprehensive solution to the sport's steroid problem.<sup>231</sup> But the Mitchell Report's attribution of responsibility to everyone involved with MLB over a twenty-year span also should not be ignored;<sup>232</sup> at its core, baseball's problem was with anabolic steroid use. Nevertheless, the role played by DSHEA's deregulation of dietary supplements also was – and still is – significant to the steroid scandal. Whenever a ballplayer tests positive, dietary supplements are now cited as the cause – a trend that is not unique to baseball.<sup>233</sup>

There may be a relatively straightforward solution to the obstacle that DSHEA poses in eradicating performance-enhancing drugs from baseball. Despite the many problems caused by the law's deregulation, the continuing popularity of dietary supplements – along with the general sentiment that led to the DSHEA's enactment in 1994 – make a complete repeal of DSHEA highly unlikely. Increasing the FDA's premarket regulatory powers over dietary supplements, however, could go a long way towards ensuring that supplements do not contain steroids and enhancing public safety as a whole. Even if Congress will not require premarket approval with regard to safety and efficacy, strengthening the labeling standards could help eliminate many problems by increasing public knowledge, without inhibiting public access to supplements. The policy could be implemented by requiring manufacturers to provide the FDA with samples of supplements and their proposed labels before

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<sup>227</sup> Spokes, *supra* note 25, at 206.

<sup>228</sup> Hill, *supra* note 40, at 393 (arguing that the current system prevents the FDA from reacting fast enough).

<sup>229</sup> Cohen, *supra* note 26, at 210.

<sup>230</sup> *The Regulation of Dietary Supplements: Hearing*, *supra* note 4, at 17 (statement of Rep. Christopher B. Cannon).

<sup>231</sup> Selig & Manfred, *supra* note 13, at 58.

<sup>232</sup> Mitchell Report, *supra* note 10, at 36.

<sup>233</sup> Although receiving much less publicity than their baseball counterparts, football and basketball players have both recently attributed positive drug tests to improperly labeled supplements. See *Lewis Suspended 10 Games by NBA*, ESPN.COM, Aug. 7, 2009, <http://sports.espn.go.com/nba/news/story?id=4381822>; *NFL Suspensions of Williamses on Hold*, ESPN.COM, July 9, 2009, <http://sports.espn.go.com/nfl/news/story?id=4316261>.

placing the products on the market. The FDA should also have access to manufacturing plants to observe the manufacturing process and combination of ingredients. The federal agency's premarket regulatory authority would only go to the extent of ensuring that a supplement's label accurately lists *every* ingredient contained in the product.<sup>234</sup> Thus, the only hindrance to market entry would be the time necessary for a manufacturer to produce a complete and accurate label. Giving the FDA power to ensure *accurate* labeling would help prevent tainted supplements from ever reaching the market and allow MLB to create a more comprehensive list of supplements that players should not take.

Regardless of whether such changes take place, DSHEA will hamper baseball's efforts to rid itself of performance-enhancing drugs until Congress takes action to regulate dietary supplements more heavily.

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<sup>234</sup> Of course, the FDA should also have power to prevent supplements containing illegal ingredients from entering the market.