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NOTES

HOW MUCH REGULATION CAN WE SWALLOW?

THE BAN ON EPHEDRA AND HOW IT MAY AFFECT YOUR ACCESS TO DIETARY SUPPLEMENTS

Reilley Michelle Dunne*

I. INTRODUCTION

Steve Bechler, a pitcher for the Baltimore Orioles, was young, healthy, and active, and on February 17, 2003, while running sprints, he suddenly collapsed.¹ The paramedics attending the team’s practice session examined Bechler, and after his condition did not improve, they took him to the hospital in an ambulance, giving Bechler oxygen and fluids the entire way.² He died the next day.³

After Bechler collapsed, a member of the team staff took a bottle out of Bechler’s locker and threw it in the trash.⁴ The bottle was a dietary supplement containing ephedrine, a stimulant designed to minimize fatigue, control weight, and enhance athletic performance.⁵ The doctors concluded that Bechler died from multiple organ failure caused by heatstroke and that ephedrine contributed to his death, making Bechler the second player in baseball history to have died as a direct result of on-field activity.⁶

Bechler is not the first professional athlete whose death was linked to ephedrine. In August 2001, Minnesota Vikings offensive lineman Korey Stringer died from complications of heat stroke, and several bottles of supplements containing ephedrine were found in his locker.⁷ In addition, eleven football players at various levels died in training in 2001, including Northwestern University defensive back Rashidi Wheeler and Florida State University’s DeVaughn Darling.⁸ Many other consumers who were

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². Id.
⁴. Durkin, supra note 1.
⁵. Id.
⁶. The other player in organized baseball who died as a direct result of on-field activity was Cleveland Indians shortstop Ray Chapman, who was hit in the head by a pitch from the New York Yankees’ Carl Mays during a game in 1920. Peter Schmuck, Ephedrine Banned by NFL, not MLB, CHI. TRIB., Feb. 18, 2003, at 4.
⁷. Durkin, supra note 1, at C1.
⁸. Id.
not high caliber athletes have also died after taking supplements containing ephedrine. For example, Anne Marie Capati, a 37-year-old mother of two children, took several supplements recommended by her "trainer-nutritionist" and died from intracranial bleeding due to elevated blood pressure. These incidents were serious enough that the National Football League ("NFL"), various high school federations, and other athletic organizations reviewed their drug policies, and several enacted bans against using any supplements containing ephedrine. Baseball was slow to react, however, and did not ban the use of ephedra; Steve Bechler suffered as a result.

Despite the fact that the Federal Drug Administration ("FDA") has reported nearly 150 deaths and has received almost 16,000 adverse event reports due to the use of ephedra, its use was not banned until the FDA and the Department of Health and Human Services ("HHS") issued a consumer alert notifying all manufacturers that the sale of products containing ephedrine alkaloids would be banned. Although the action to ban ephedra was long overdue, the consequences of this ban are not yet realized.

A potential consequence is that, because the FDA and HHS banned the sale of products containing ephedra, the agencies will also ban the sale of other dietary supplements. Although banning ephedra is an appropriate step that the FDA is justified in taking in order to protect consumers from the dangers that ephedra poses, the government should not overstep its boundaries by banning other less harmful dietary supplements. The ban on ephedra should be a special case, limited only to products containing ephedra or ephedrine-alkaloids, and should not extend to other dietary supplements.

This Note examines the FDA's ban on ephedra and the potential effects that the ban may have on the dietary supplement industry and on consumers. Part II discusses the history of the FDA's authority to regulate food and drug products in the United States and the current law regulating dietary supplements. Part III explains the special dangers that ephedra presents and shows the strong reaction that federal and state governments, as well as consumers generally, have had to the harsh effects of ephedra. Finally, in Part IV, the Note examines other dietary supplements available on the market and concludes that, while the FDA was justified in banning ephedra, the FDA should not ban other dietary supplements simply because they may pose some threats to consumer health. The Note suggests that, although the current law regulating the dietary supplement industry is adequate, the FDA needs more funds to fully enforce the law. Furthermore, the FDA must make increased efforts to educate consumers about the benefits and dangers of using dietary supplements.


10. Schmuck, supra note 6, at 4.

11. Consumers who wish to file complaints about food products, including dietary supplements, can complete a form and submit it to the FDA. Forms are available at http://www.fda.gov/medwatch/report/consumer/consumer.htm. See also discussion infra Part II.B.

II. THE DEREGULATION OF THE DIETARY SUPPLEMENT MARKET

According to HHS, approximately 60% of Americans take some form of dietary supplement, including vitamins, minerals, and other herbal remedies, daily without any adverse effects. Yet dietary supplements, also known as herbal supplements or herbal remedies, may be extremely dangerous when taken with other substances or alone in excessive amounts, and therefore they must be regulated just as other drug and food products are regulated. However, unlike other food and drug products, the FDA is not the main regulatory body that oversees the production, advertising, and manufacturing of dietary supplements. The removal of the FDA from the forefront of regulating dietary supplements has been the subject of most of the controversy surrounding the current regulatory scheme of dietary supplements. Although the law currently regulating dietary supplements has several downfalls, dietary supplements continue to be necessary and desired by consumers. Therefore, the law should not be drastically amended simply because one dietary supplement, ephedra, has been found to present unreasonable risks to consumers.

A. Progression to the Current Deregulatory Scheme

Until 1994, the FDA was largely responsible for controlling dietary supplements in the United States. The FDA regulated herbal supplements under the Federal Food, Drug, and Cosmetic Act ("FDCA"), under which the FDA could classify dietary supplements as drugs or food additives. For example, under the FDCA, the FDA could classify a dietary supplement as a drug based on the manufacturer's intended use for the supplement. Under either classification, the supplement had to receive FDA approval prior to any marketing of the supplement.

However, supplements were most commonly classified as food additives, and, under the 1958 Food Additive Amendment to the FDCA, the FDA received authority to regulate dietary supplements as food additives. This meant that the FDA could evaluate the safety of all new ingredients, which ensured that the supplements available to the public were safe and labeled accurately. As a result of this amendment, the FDA directed more attention to studying the dangers of dietary supplements, and in the 1960s, the FDA spent more money trying to regulate this industry than any other area. In the 1970s, the FDA focused its regulation of herbal supplements by prohibiting

14. See discussion infra Part II.B.
18. Id.
20. Kaiser, supra note 17, at 1252–53.
21. Id.
22. Id. at 1252.
“irrational combinations” and dosages of vitamins and minerals, which the Second Circuit validated as falling within the FDA’s regulatory authority.

In response to outraged consumers and herbal supplement manufacturers, Congress revoked this power by enacting the Proxmire Amendment, which retracted the FDA’s authority to regulate dietary supplements based on irrational combinations or levels of potency. Furthermore, in *National Nutritional Foods Association v. Mathews*, the Second Circuit held that the FDA must justify its classification of a nutrient contained in a dietary supplement as a drug by analyzing the public’s use of and need for the supplement, which strengthened the effect of the Proxmire Amendment and effectively stripped the FDA of its regulatory power over herbal supplements.

As a result of the Proxmire Amendment, the FDA scaled back its efforts to regulate dietary supplements, and the market for herbal supplements expanded by the 1990s. However, in the summer and fall of 1989, the amino acid supplement L-tryptophan was linked to 1,500 adverse effects, including thirty-eight deaths, and the FDA renewed its efforts to protect the public from dietary supplements with increased aggressiveness.

For example, when Congress enacted the Nutrition Labeling and Education Act of 1990, which requires labeling of foods and prohibits manufacturers from making unsupported health claims about their products, the FDA required that the same standards apply to dietary supplements. Congress reacted by enacting the Dietary Supplement Act of 1992, which stopped the FDA from applying these standards to herbal supplements. However, the FDA continued its efforts to limit the availability of dietary supplements to consumers.

The FDA’s renewed proactive course for regulating dietary supplements prompted dietary supplement manufacturers to organize a “National Blackout Day” in which dietary supplement retailers draped black cloths over the supplement bottles that would potentially be affected by the FDA’s increased regulation in an effort to convince

23. Irrational combinations are those “provid[ing] quantitative combinations or nutrients for which no human individual need could possibly exist, if the products are used only as dietary supplements.” Definitions and Standards of Identity for Food and Special Dietary Uses, 38 Fed. Reg. 20,730, 20,738 (Aug. 2, 1973).

24. Nat’l Nutrition Foods Ass’n v. FDA, 504 F.2d 761, 774, 786 (2d Cir. 1974) (expressing the court’s favorable impression of the FDA’s effort to more strictly regulate dietary supplements, but disallowing the FDA to completely block the sale of any dietary supplement whose nutritional value is unclear).


26. *Id.*

27. 557 F.2d 325 (2d Cir. 1977)

28. *Id.* at 337–38.


30. *Id.* at 676.


35. See generally Beckstead, *supra* note 33, at 111.
consumers that the FDA was trying to destroy consumer access to supplements. The movement worked. As a response to significant pressure from the public and dietary supplement manufacturers, Congress passed the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), which created an entirely new regulatory scheme for dietary supplements.

B. Congress’s Current Legislation: The DSHEA

The DSHEA represents Congress's attempt to balance consumer access to dietary supplements and the regulation necessary to ensure product safety. Congress intended the DSHEA to benefit consumers who wanted access to herbal supplements that could remedy their ailments as alternatives to prescription drugs. Congress realized that consumers believed that dietary supplements could improve their health, and so it passed the DSHEA to empower consumers "to make choices about preventative health care programs based on data from scientific studies of health benefits related to particular dietary supplements." Congress further found that "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies" and that "dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare." Therefore, Congress determined that "legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness . . . ."

The DSHEA has changed the regulation of dietary supplements in several significant ways. Prior to the DSHEA, the term "dietary supplement" was defined as a vitamin or mineral, but the DSHEA redefined dietary supplement as "a product [for ingestion] intended to supplement the diet." Any product that meets the definition outlined in the DSHEA is now classified as a dietary supplement and is exempt from classification as a food additive. This classification prevents the FDA from requiring dietary supplement manufacturers, unlike food additive manufacturers, to meet premarket approval standards for safety. Therefore, if a manufacturer introduces a product into the market and classifies it as a dietary supplement, the product does not need to meet any additional safety requirements. The DSHEA does not require scientific evidence showing that the product is reasonably safe for public consumption.

36. Kaiser, supra note 17, at 1258.
40. See Beckstead, supra note 33, at 112; see also Sloane, supra note 39, at 332-33.
41. Dietary Supplement Health and Education Act § 2(8).
42. Id. § 2(14).
43. Id. § 2(15)(A).
44. Beckstead, supra note 33, at 109.
45. Dietary Supplement Health and Education Act § 3 (codified in 21 U.S.C.A. § 321(ff)).
46. Id. § 3(b) (codified in 21 U.S.C.A. § 321(s)(6)).
but instead presumes that the dietary supplement is safe. Manufacturers are not required to submit safety and efficacy reports to the FDA for prior approval, and dietary supplements may enter the market without standardized dosages or strengths.

Although the United States is one of the few industrialized nations that does not require premarket approval of dietary supplements, the DSHEA does include some premarket safety provisions. First, under the DSHEA, if a manufacturer proposes to make a claim that the supplement can mitigate, treat, cure, or prevent a disease, the manufacturer must notify the FDA that the supplement's label contains such a claim within thirty days after first marketing the supplement. Second, the DSHEA extends the FDA's rule on current good manufacturing practices ("cGMP"), which previously only applied to food products, to apply to dietary supplements as well. Although the FDA has not finalized the publication of a dietary supplement cGMP rule, which was initially proposed on March 13, 2003, the rule will likely create standards for how dietary supplements are prepared, packaged, and stored, and is intended to help prevent the inclusion of wrong ingredients in dietary supplements and of contaminants in the supplement bottles. Third, the DSHEA provides specific requirements for premarket notification to the FDA of any new dietary ingredients, which are defined as ingredients that were sold on the market in the United States after October 15, 1994. The manufacturer must show evidence that the new dietary ingredient can "reasonably be expected to be safe," and the FDA may prohibit any marketing of the product if the FDA finds the evidence unsatisfactory. In addition, the FDA may take action and conclude that the supplement presents a risk to public safety if the dietary supplement or an ingredient in the supplement is adulterated, which means that the dietary supplement or ingredient "presents a significant or unreasonable risk of illness or injury" under conditions of use recommended in the labeling or under ordinary conditions of use.

Despite these provisions, the FDA faces many challenges in being able to implement the protective provisions contained within the DSHEA. Most dietary supplements are not subject to any premarket approval and may appear on the shelves, available to consumers, without FDA approval. Furthermore, the DSHEA shifts the burden of ensuring the safety of the product from the dietary supplement manufacturer to the FDA to show that the product is unsafe. To do this, the FDA primarily relies on

48. See Beckstead, supra note 33, at 109.
51. Dietary Supplement Health and Education Act § 6 (codified in 21 U.S.C.A. § 343(q)(5)(F)).
52. Id. § 9 (codified in 21 U.S.C.A. § 342(g)(1)).
54. Dietary Supplement Health and Education Act § 8 (codified in 21 U.S.C.A. § 350b(a)).
55. Id. (codified in 21 U.S.C.A. § 350b(a)(2)).
56. Id. § 4 (codified in 21 U.S.C.A. § 342(f)).
58. Id.
59. Id. (stating "the United States shall bear the burden of proof on each element to show that a dietary
The Ban on Ephedra and Access to Dietary Supplements

The Adverse Event Reporting System developed by the FDA's Center for Food Safety Applied Nutrition ("CFSAN"), under which consumers can notify the FDA that they have experienced a harmful effect or illness from consuming a dietary supplement. However, because the reporting of adverse events is not mandatory, the system in its current form is ineffective at alerting the FDA to the dangers of some dietary supplements, such as ephedra, as the FDA is slow to respond to the reports it receives. Furthermore, the reporting only occurs after consumers have experienced adverse reactions to the dietary supplement, which does nothing to alleviate the pain of those consumers who experienced the reactions.

The FDA must build a strong case in order to remove the product from the market, which often takes years and requires the development of strong scientific evidence and a large collection of adverse event reports showing that the product is dangerous to consumers. Consequently, the FDA will commonly issue public warnings rather than attempt to declare that a dietary supplement is adulterated. However, these warnings usually do not result in the removal of the product from the retail market, and consumers may still have access to the unsafe dietary supplements, such as ephedra.

III. Ephedra: A Dangerous Dietary Supplement That Presents a Special Case for the FDA and HHS

Many dietary supplements sold in drug stores, pharmacies, and supermarkets contain ephedrine and related alkaloids as their primary ingredients. Because ephedra is a dietary supplement, it is regulated under the DSHEA. As the most controversial dietary supplement on the market, ephedra arrived at the forefront of the debate surrounding the pitfalls of the DSHEA. However, because it has received such national attention and led to numerous deaths of young, healthy people, it is a unique dietary supplement, and the FDA and HHS should treat it as such. We must examine the special qualities and circumstances involving ephedra in order to understand what makes ephedra different from other dietary supplements and determine why it should therefore be banned while others should not.

supplement is adulterated").


62. See id. ("If you think that you have suffered a serious harmful side effect or illness from a dietary supplement, your health care provider can report this by [using the Adverse Event Reporting System].").

63. Int'l Ass'n of Def. Counsel, supra note 38, at 520.

64. Id.

65. Id.

66. Id. at 517.

67. See discussion infra Part I.
A. Characteristics, Functions, and Uses of Ephedra

Ephedra is a chemical compound naturally occurring in the Chinese herb *ma huang*, which was originally used as a decongestant for colds, asthma, and hay fever. Ephedrine, which is the active ingredient in ephedra, is a compound that boosts metabolism and consequently burns calories. Ephedrine also acts as adrenaline in the human body. It excites the nervous system, opens the blood vessels, and then stimulates the heart.

Dietary supplement manufacturers have capitalized on this function of the herb by including it in many weight loss dietary supplements, claiming that ephedrine will burn fat while maintaining muscle tissue. Many athletes—from the high school to the professional levels—have used ephedra to improve their appearance or athletic performance, hoping that it will help them reduce their fat weight relative to their muscle weight.

Unfortunately, serious problems arise when the product is taken in incorrect dosages, which is not uncommon and extremely dangerous. Ephedrine has several side effects, none of which are life-threatening on their own: "nervousness, headaches, insomnia, dizziness, palpitations, skin flushing, tingling, and vomiting." However, if the consumer takes too much ephedrine—exceeding the amount suggested on the label—the herb can cause serious injuries and even death. Also, ephedrine takes six to ten hours to metabolize in the body, and therefore, if the consumer repeatedly takes the supplement, the substance can build to toxic levels in the body. Furthermore, the combination of ephedrine with caffeine-containing products, such as coffee, chocolate, or over-the-counter pain relievers, can amplify ephedra’s effects and can further increase the risks associated with the herb.

Manufacturers of dietary supplements containing ephedra have experienced the backlash that can result from consumption of supplements containing ephedra. For example, Metabolife International, Inc. ("Metabolife"), a manufacturer of dietary supplements and nutritional herbs, markets its products as aids for weight management, wellness, and health maintenance. One of Metabolife’s products, Metabolife 356, contains ephedrine alkaloids, and after several individuals suffered adverse reactions

68. Zuk, supra note 47, at 43.
69. Id.
71. Id. at 634.
72. Id.; see discussion infra.
73. Crossman, supra note 70, at 634.
74. Id.
76. Id.
77. Sardina, supra note 49, at 118.
78. Id. at 118–19.
80. Id. at 4–5.
after taking Metabolife 356, Metabolife found itself defending several lawsuits. Class action lawsuits asserted strict products liability claims against Metabolife for marketing unsafe products, as well as claims of false advertising and consumer fraud. The pending litigation has added to the media attention, spurring a debate concerning the safety of ephedra, ephedrine alkaloids, and dietary supplements in general.

### B. The Fight Against Ephedra

Despite the political power of dietary supplement manufacturers, those supporting the ban on ephedra have created a national debate surrounding the substance. Ephedra has received most of the attention from those challenging the effectiveness of the DSHEA, most likely due to the deaths of high profile athletes such as Bechler, Stringer, Wheeler, and Darling, and the fact that the FDA ultimately banned the supplement.

1. Federal Action against Ephedra

The FDA's early recognition of the dangers of ephedra and ephedrine-containing dietary supplements led to the FDA's long-term efforts to discourage consumers from purchasing and using the supplement. Beginning as early as September 1994, the year that the DSHEA was passed, the FDA issued a "Medical Bulletin," alerting consumers that it had received many adverse event reports associated with ephedrine-containing dietary supplements for weight loss, energy, performance-enhancing, and body-building purposes. The FDA continued this fight against ephedra in 1997 by holding several hearings to discuss the substance, and subsequently proposed several regulations for labeling ephedrine alkaloids, such as advising against using more than eight milligrams "per serving" or twenty-four milligrams daily of ephedrine, and warning against use during pregnancy or in the presence of other health conditions.

The FDA modified this proposed rule in 2000, and on February 28, 2003, HHS and the FDA issued a press release, announcing a series of actions designed to protect Americans from the potentially serious risks of ephedra. The announcement followed

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83. In Kemp, the District Court in Louisiana granted summary judgment motions in favor of Metabolife, stating that the plaintiffs failed to prove through medical testimony that Metabolife is the "actual cause" of the injuries the plaintiffs suffered. Kemp v. Metabolife Int'l, Inc., No. 00-3513, 2004 WL 2095618, at *4, *6 (E.D. La. Sept. 13, 2004). This ruling shows the challenges that plaintiffs asserting claims against dietary supplement manufacturers will face, as proving causation for injuries sustained from taking dietary supplements is difficult.

84. See discussion supra Part I.

85. See Int'l Ass'n of Def. Counsel, supra note 38, at 520.

86. Id.

87. Rheingold, supra note 9, at 43.

88. Press Release, FDA Announces Plans to Prohibit Sales, supra note 12.

the release of numerous studies that found that ephedra may be associated with important health risks while showing only limited health benefits. This announcement included publishing a Federal Register notice reopening a comment period so that consumers could voice their own opinions on the FDA’s proposed regulation from 1997 and 2000.

In conjunction with the FDA’s efforts to make consumers more aware of the dangers of ephedra, certain members of Congress focused their attention on the dangers of ephedra, particularly following the death of Steve Bechler. Senators John McCain (R-AZ) and Fritz Hollings (D-SC) were primarily responsible for spurring this movement in Congress to ban, or at least increase the regulation of, ephedra.

In March 2003, the Senate Committee on Commerce, Science, and Transportation, of which Sen. McCain is Chairman and Sen. Hollings is Ranking Member, wrote to the Secretary of HHS, Tommy G. Thompson, encouraging him to expand his agency’s review of ephedra and other “potentially-dangerous dietary supplements.” The Committee further stated that HHS’s “ongoing effort to assess the potential health risks of ephedra and to help educate the American public about the product is clearly necessary and overdue.” This committee was primarily responsible for the government’s push to ban ephedra until the FDA and HHS took action against the dietary supplement in December 2003.

2. States and Private Organizations React Against the Use of Ephedra

Several states initially took a more proactive approach than the federal government toward achieving increased regulation and a ban against ephedrine-containing products. In May 2003, Illinois Governor Rod R. Blagojevich signed legislation that made Illinois the first state in the country to ban the sale of ephedra. In signing the bill, Blagojevich stated, “With enough commitment, this ban can sweep through state legislatures across America and sweep this product right off the shelf.”

Several states followed Illinois’s lead in banning or restricting consumer access to products containing ephedrine alkaloids. New York banned the sale of dietary supplements containing ephedra by amending the state’s general business law in August
In California, the sale or distribution of any dietary supplement product containing ephedrine alkaloids is now prohibited unless the product label clearly and conspicuously contains a statement warning consumers that the product has a specified amount of ephedrine alkaloid. Florida also makes it unlawful to distribute weight-loss pills that contain ephedra or ephedrine alkaloids to any person less than eighteen years of age.

Private organizations have also banned the use of ephedra because of the serious health risks associated with it. For example, the National Collegiate Athletic Association ("NCAA") and the International Olympic Committee ("IOC") have banned products containing ephedra or ephedrine alkaloids. In September 2001, following the death of Korey Stringer, the NFL banned ephedra, becoming the first professional sports organization to do so. Under the NFL ban, players are prohibited from taking, distributing, having, and even endorsing ephedra and companies that manufacture products containing ephedrine alkaloids.

C. FDA and HHS Announce Ban of Ephedra

On December 30, 2003, the FDA and HHS announced the agencies' intent to ban the sale of these dietary supplements. On February 11, 2004, the FDA issued its final regulation prohibiting the sale of dietary supplements containing ephedrine alkaloids, effective April 12, 2004, declaring "dietary supplements containing ephedrine alkaloids are adulterated under the [FDCA] because they present an unreasonable risk of illness or injury . . ." Sixty-two companies received the letter from the FDA announcing the intended ban on their products.

This ban on ephedra was the FDA's first ban on any dietary supplement. FDA Commissioner Mark B. McClellan stated that the purpose of their action was to "notify Americans about the unreasonable risk of ephedra as currently marketed in dietary supplements" and was based on "diligent and thorough work by the agency . . . [to] review all the available evidence about the risks and benefits of ephedra, including its

97. 2003 N.Y. LAW 385.
100. Int'l Ass'n of Def. Counsel, supra note 38, at 518.
101. See discussion supra Part I.
102. Id.
103. Int'l Ass'n of Def. Counsel, supra note 38, at 518.
104. Press Release, FDA Announces Plans to Prohibit Sales, supra note 12.
106. To view a list of all the companies that were notified of this ban, see U.S. FDA, Companies Marketing Ephedra Dietary Supplements that Received FDA's Letter Dec. 30, 2003, at http://www.fda.gov/oc/initiatives/ephedra/december2003/letterslist.html (last visited Mar. 15, 2005).
pharmacology, studies of ephedra’s safety and effectiveness, adverse event reports, and reviews by independent experts.”

At the time, the FDA’s evaluation of ephedra reflected the available studies, reviewed by the RAND Corporation, which “found little effectiveness other than for short-term weight loss” of ephedra, yet also suggested serious safety risks. As mentioned previously, those risks include increased blood pressure and other stresses to the circulatory system, which have been “conclusively linked to significant and substantial adverse health effects like heart problems and strokes.”

Despite the studies and evidence supporting the FDA’s ruling that ephedra presented an unreasonable risk to consumer safety, on April 13, 2005, a federal district court in Utah found that the FDA violated the DSHEA when it issued the ban on ephedra. In Neutraceutical Corp. v. Crawford, several manufacturers of dietary supplements containing low-doses of ephedrine-alkaloid challenged the validity of the FDA’s ban on ephedra, arguing that the rule violates the DSHEA. Specifically, the plaintiffs argued that the FDA did not establish that ephedra was adulterated because it presented a “significant or unreasonable risk of illness or injury” as required under the DSHEA. The court granted the plaintiffs’ motion for summary judgment, finding that the FDA improperly applied a risk-benefit analysis in determining that ephedrine-alkaloids are adulterated. The court held that, in enacting the DSHEA, Congress did not intend for dietary supplements to be required to demonstrate a benefit to health, and thus the FDA should not have weighed the benefits of ephedra against the risks associated with the dietary supplement. Furthermore, the court found that the evidence upon which the FDA based its ban was insufficient to show that the low-dose of ephedrine-alkaloids in this case presented an unreasonable risk to consumers. The court remanded the decision to the FDA and enjoined the FDA from enforcing the ban on the sale of dietary supplements containing ten milligrams or less of ephedrine-alkaloids per daily dose.

This district court ruling raises questions as to whether the FDA’s ban on ephedra will remain intact. To date, the FDA has not responded to the decision, and so the consequences of this ruling are yet unknown. Despite this new development, ephedra has presented significant—and devastating—risks to consumer health, and therefore the ban was appropriate.

109. The RAND Corporation is a nonprofit organization that conducts research in areas such as business, education health law, and science. See http://www.rand.org/about/ (last visited Mar. 15, 2005).
111. Id.
113. The recommended dose of the dietary supplements in this case yielded less than ten milligrams of ephedrine-alkaloids per day, which is considered a low-dose. Id. at *1.
114. Id. at *5.
115. Id. at *3, 5; see also 21 U.S.C. § 342(f).
116. Id. at *8.
117. Id. at *8.
119. Id. at *10.
120. See discussion supra Parts I, III.A; see also discussion infra Part.IV.
IV. THE BAN ON EPHEDRA SHOULD NOT LEAD TO A CRUSADE TO BAN OTHER DIETARY SUPPLEMENTS

While the FDA's and HHS's response to the dangers that ephedra presented to public safety was necessary and long overdue, the agencies should not use this action as a springboard for banning other dietary supplements. Ephedra was a special case; it was a unique dietary supplement that led consumers to question the effectiveness of dietary supplements in general. According to a study published in 2003 in the *Annals of Internal Medicine*, ephedra is associated with greater risks for adverse effects than other commonly used herbal products.121 Although products containing ephedra make up less than 1% of all dietary supplement sales, these products account for 64% of adverse events associated with dietary supplements.122 Furthermore, the study found that relative risks for adverse effects from ephedra were 100 times greater than from Kava and as much as 700 times greater than from Ginko Biloba, two other common herbal remedies.123 Although ephedra had negative consequences, a multitude of other dietary supplements are not harmful and should not be banned.

Simply because ephedra poses serious threats to public health and safety, the FDA and HHS should not embark on a crusade to ban more dietary supplements. Ephedra received extensive media coverage, which is evident by the fact that the NFL, NCAA, and IOC banned the substance, and the U.S. Senate created a special committee to address concerns regarding the supplement. Aside from the 2004 controversy surrounding androstenedione,124 no other dietary supplement has received as much attention and public outcry as ephedra. In fact, not one state has attempted to ban other herbs, such as Echinacea or St. John’s wort, even though some consumers have experienced adverse reactions to both.125 The FDA and HHS took appropriate measures to ban ephedra, but the ban should stop there. Dietary supplements provide valuable benefits to the public, and the FDA should not interfere with consumers' rights to access these affordable remedies.

A. The Case of Androstenedione: The FDA's First Action Against the Dietary Supplement Industry Following the Ban on Ephedra

A few months following the ban on ephedra, HHS and the FDA announced a "crackdown" on dietary supplements containing another natural ingredient, androstenedione ("andro").126 Primarily used by athletes to enhance athletic performance, stimulate muscle growth, and increase production of testosterone, andro

122. Id. at 469.
123. Id.
124. See discussion infra Part IV.A.
125. See discussion infra Part IV.B.
acts like a steroid once it is metabolized by the body and therefore can pose health risks similar to those associated with illegal steroids.\textsuperscript{127} Examples of such long-term consequences in men are testicular atrophy, impotence, and the development of female characteristics, such as breast enlargement.\textsuperscript{128} In women, the potential consequences are baldness, deepening of the voice, increased facial hair, abnormal menstrual cycles, and increased risk of breast cancer and endometrial cancer.\textsuperscript{129} Children who use andro are at risk for early onset of puberty and of premature cessation of bone growth.\textsuperscript{130}

Although HHS and the FDA did not completely ban products containing andro, the FDA sent warning letters to twenty-three companies asking them to stop distributing products sold as dietary supplements that contain andro and warning them that they could face “enforcement actions” if the companies do not take “appropriate actions.”\textsuperscript{131}

Although the end-result for products containing andro essentially parallels the end-result for products containing ephedra—both are effectively removed from consumer access—the means that the FDA used to reach the conclusion differs. The FDA banned ephedra following the collection of several years of data and adverse event reports indicating the dangers of ephedra.\textsuperscript{132} The basis for the FDA action against manufacturers of andro, on the other hand, lies in the definition of “dietary ingredient” and the requirement for premarket approval for new dietary ingredients in the DSHEA.\textsuperscript{133} In the warning letter, the FDA stated that it assumed that andro is a dietary ingredient, and therefore, because the FDA believes that andro is also a new dietary ingredient, premarket safety notification is required.\textsuperscript{134} Because no manufacturer or distributor of andro products has submitted such notification, the products are adulterated and therefore cannot be marketed under the FDCA.\textsuperscript{135}

The problem with this analysis is that the FDA has broadened its authority to regulate dietary supplements, overreaching the powers granted to the agency to regulate dietary supplements in the DSHEA. Under this framework, the FDA is able to simply assume that any ingredient in any dietary supplement is a new dietary ingredient, thereby requiring the manufacturers of the product containing the ingredient to submit premarket notifications to the FDA, which may then make it more expensive and difficult for manufacturers to offer dietary supplements to consumers. Although a total ban on andro may be a justifiable action to protect consumers against the harmful effects of andro, the method that the FDA used to achieve this regulation may be troublesome to manufacturers of other safe dietary supplements and to consumers using those supplements.\textsuperscript{136}

\textsuperscript{127} Id.
\textsuperscript{128} Id.
\textsuperscript{129} Id.
\textsuperscript{130} Id.
\textsuperscript{131} Id. The actions that the FDA warned it would take to non-complying manufacturers include “seizing violative product[s] as well as pursuing injunctions or seeking criminal sanction against persons who violate the law.” HHS Launches Crackdown, supra note 126.
\textsuperscript{132} See discussion supra Part III.
\textsuperscript{133} Id.; see also discussion supra Part II.B.
\textsuperscript{134} Press Release, HHS Launches Crackdown, supra note 126.
\textsuperscript{135} Id.
\textsuperscript{136} Congress is currently considering a bill, the Anabolic Steroid Control Act of 2004, which would prohibit the sale of certain steroid hormone precursors, like andro, by adding them to the list of controlled
B. Public Health Benefits of Other Dietary Supplements

Many cultures have used herbal remedies for thousands of years, and consumers should continue to have access to these types of alternative medicines. Consumers prefer using herbal supplements instead of prescriptive medicines for several reasons: (1) herbal remedies are less expensive; (2) herbal supplements are easier to purchase; and (3) dietary supplements "offer a sense of control to consumers 'who are suspicious of the medical establishment.'"\(^{137}\) Ephedra is merely one type of herbal remedy that consumers have used, but there are many others that provide important health benefits as alternatives to pharmaceuticals. While some herbal remedies have adverse side effects, the public health benefits that the herbs provide are great enough that they should remain available to the public.

For example, many consumers have used St. John's wort to treat depression, insomnia, and anxiety.\(^{138}\) In fact, in Germany, doctors commonly prescribe products made from St. John's wort for the treatment of depression instead of prescribing other pharmaceuticals.\(^{139}\) In the United States, St. John's wort was the fifth most popular herbal remedy purchased in 1997,\(^{140}\) and between 1995 and 1998, demand for the herb increased from 500 tons per year to 6,000 tons.\(^{141}\) Although demand for St. John's wort has decreased in the last few years, the herbal remedy offers a more cost-effective treatment for depression than other pharmaceutical anti-depressants and might have fewer side effects for consumers.\(^{142}\)

However, the FDA and other research organizations have questioned the safety and effectiveness of St. John's wort, despite the fact that the herb has undergone rigorous testing in Germany.\(^{143}\) For example, in February 2000, the National Institute of Health ("NIH") and the National Center for Complementary and Alternative Medicine ("NCAAM") conducted a study and found an adverse effect resulting from the interaction between St. John's wort and indinavir, commonly known as Crixivan, which is a protease inhibitor used to treat HIV.\(^{144}\) This spurred the FDA to issue a public

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\(^{137}\) Sloane, supra note 39, at 331–32 (citation omitted).

\(^{138}\) Id. at 333–34; but see Nat'l Ctr for Complementary and Alternative Med., St. John's Wort and the Treatment of Depression, at http://nccam.nih.gov/health/stjohnswort/index.htm (last visited Mar. 15, 2005) (stating that recent studies suggest that St. John's wort is not beneficial in treating major depression of moderate severity).

\(^{139}\) RICHTER, supra note 50, at 103.

\(^{140}\) Id. (citing Peggy Brevoort, The Booming U.S. Botanical Market: A New Overview, HERBALGRAM 44, 33–46 (1998)).

\(^{141}\) Id. (citing Manuel Collado Campos, Address at the American Herbal Products Association's International Symposium on St. John's Wort, Anaheim, Cal. (Mar. 16–17, 1998)).

\(^{142}\) Id. at 104.

\(^{143}\) Id. at 104–05.

health advisory warning to consumers about these dangers of using St. John's wort even though the warnings would affect only a relatively small percentage of consumers. The mere fact that St. John's wort may cause some adverse effects when combined with other drugs should not prevent consumers from using it. Germany, along with many other European countries, and Australia have recognized the positive effects of the herbal remedy for many years, and Americans should have access to it as an alternative to other drugs.

Other herbal remedies have provided consumers with treatment for various ailments. For example, Echinacea, a treatment for the common cold, and Kava Kava, which promotes relaxation and relieves tension, stress, and anxiety, have provided consumers with a range of health benefits. In addition, a recent study published in the *Archives of Neurology* found that the combination of taking vitamins E and C reduced the incidence of Alzheimer's disease by about 64 percent. The herb Ginkgo Biloba has also been helpful in treating Alzheimer's. Consumers have recently turned to dehydroepiandrosterone (“DHEA”) to “hinder or stop the aging process, combat depression and cancer, increase memory, and strengthen the immune system.” Taking a simple stroll down the aisle of any local grocery store, pharmacy, or natural foods store reveals hundreds of varieties of herbal remedies, including products containing herbs such as Ginseng and Echinacea, that provide consumers with cheap alternatives to pharmaceuticals.

**C. The FDA's Initiatives to Further Implement the DSHEA**

As a step toward improving its ability to identify harmful effects in dietary supplements, in April 2004, the FDA sponsored a study, conducted by the National Council of the National Academies and the Institute of Medicine (“IOM”), to offer science-based processes and guidelines for evaluating the safety of dietary supplements. The report described the various scientific assessments that can be used to identify supplement ingredients that may pose risks, categorized different kinds of data that the FDA can use to assess safety, and offered guidelines for determining the significance of the evidence available on a particular substance.

Furthermore, following the ban on ephedra, the FDA demonstrated its efforts to further implement the DSHEA by announcing three major regulatory initiatives designed to achieve this goal. In the first initiative, a regulatory strategy, the FDA
pledged to work with organizations such as NIH, the Office of Dietary Supplements ("ODS"), and NCAAM to improve the process by which the FDA makes safety and enforcement decisions about the regulation of dietary ingredients and dietary supplements. Specifically, the FDA vowed to pay closer attention to "signal detections," or signals of possible safety concerns originating from federal and state agencies, adverse event reports, media reports, information from consumer groups, and consultations with experts.

The FDA's second initiative was to hold a public meeting in November 2004, designed to "seek public comment on the type, quantity, and quality of evidence manufacturers should provide [the] FDA in a new dietary ingredient notification." As its third initiative, the FDA asked for comments from leaders in the dietary supplement industry on a "draft guidance document on the amount, type, and quality of evidence a manufacturer should have to substantiate a claim" arising under the FDCA, which would help establish a clearer standard for substantiation and thus may help preserve consumer confidence in dietary supplements.

While the issuing of these initiatives represents the FDA's commitment to fully implement the DSHEA, the actual benefits derived from these initiatives is left unseen. Because many of the actions promised in the initiatives have yet to occur—aside from the public meeting—we cannot be certain whether the initiatives will lead to increased regulation of dietary supplements. From the strategies outlined in the press releases and announcements, however, the FDA appears to be taking the right steps by pledging to improve its evaluation process for responding to adverse event reports, by gathering scientific data on dietary supplements, and by consulting consumers and industry leaders about the manufacturing requirements for dietary supplements. As long as the initiatives do not lead to the adoption of the proposals suggested by IOM, such as regulating dietary supplements as drugs are regulated, the initiatives are the appropriate responses to help ensure consumers have continued access to safe dietary supplements.

D. Subsequent Efforts to Ban More Dietary Supplements

Despite the well-documented public health benefits that dietary supplements provide to consumers, several public leaders and consumer organizations are currently advocating for legislation that would more heavily regulate dietary supplements and


153. Id.

154. Id.


156. Press Release, FDA Announces Major Initiatives for Dietary Supplements, supra note 152.

157. See discussion infra Part IV.D.3.
would subsequently decrease consumer access to herbal remedies. For example, organizations such as Consumers Union\textsuperscript{158} argue that the ban on ephedra does not go far enough to protect consumers from potentially dangerous supplements.\textsuperscript{159} Charles Bell, the program director for Consumers Union, called ephedra the "poster child for a failed policy," and urged the federal government to give the FDA more authority to regulate all dietary supplements.\textsuperscript{160} In addition, several members of Congress recognize that consumers are interested in the issues involving dietary supplements and have proposed solutions to the problem of how to ensure that consumers are not exposed to unsafe products.


In March 2003, Sen. Dick Durbin (D-Ill.) introduced a bill, the Dietary Supplement Safety Act of 2003 ("Dietary Supplement Safety Act"), which intended to amend the FDCA to "require that manufacturers of dietary supplements submit to the [FDA] reports on adverse experiences with dietary supplements . . . .\textsuperscript{161} The bill, which is co-sponsored by Senators Hillary Clinton (D-N.Y.), Dianne Feinstein (D-Calif.), John McCain, (R-Ariz.), and Charles Schumer (D-N.Y.), would also eliminate a provision of the FDCA that requires the FDA to bear the burden of proof to show that the dietary supplement is adulterated due to a safety violation.\textsuperscript{162} The bill creates new definitions, such as "adverse dietary supplement experience,"\textsuperscript{163} and requires the manufacturer of the dietary supplement to conduct extensive premarket and postmarket analyses of their products.\textsuperscript{164}

The Dietary Supplement Safety Act would also prohibit the delivery of any dietary supplement containing a stimulant into interstate commerce unless approved by the government.\textsuperscript{165} The bill defines "stimulant" as anything that has a "stimulant effect on the cardiovascular system or the central nervous system," including anything that speeds the metabolism, increases heart rate, constricts blood vessels, or causes the body to release adrenaline.\textsuperscript{166} According to this provision, products that are intended to increase muscle hardness and other steroid precursors that are currently available could no longer be marketed freely.\textsuperscript{167} Sen. Durbin positioned his bill to address the dangers.

\begin{thebibliography}{1}
\bibitem{158} Consumers Union is an independent, nonprofit testing and information organization that provides "unbiased advice" about products and services, health and nutrition, and other consumer concerns. See Consumers Union, About Consumers Union, \textit{at} http://www.consumersunion.org/aboutcu/about.html (last visited Feb. 7, 2005).
\bibitem{160} Id.
\bibitem{162} Id.
\bibitem{163} The term "adverse dietary supplement experience" means "an adverse event that is associated with the use of a dietary supplement in a human, without regard to whether the event is known to be causally related to the dietary supplement." \textit{Id.} § 2.
\bibitem{164} Id.
\bibitem{165} Id. § 3.
\bibitem{166} Id. § 3(a).
\end{thebibliography}
that ephedra presents to consumers, as ephedra has been linked to several deaths, and he therefore argues that all stimulant supplements must undergo a rigorous premarket FDA approval process.\footnote{168}{See U.S. Senator John McCain (R-AZ) Holds a Hearing on Dangers of Dietary Supplements Before Sen. Comm. on Commerce, Science & Transportation, Federal Document Clearing House, Inc., Political Transcript (Oct. 28, 2003) (statement of Sen. Durbin) [hereinafter Statement of Sen. Durbin].}

This proposed legislation would drastically reduce consumer access to many currently approved dietary supplements.\footnote{169}{See Kelly Patricia O'Meara, Regulating Vitamins: Under Proposed Legislation Dressed Up as a Public-Safety Concern, the Standard for Natural Dietary Supplements Would Be Set Far Above that for Highly Profitable Drugs Being Pushed by Pharmaceutical Giants, INSIGHT ON THE NEWS, Sept. 16, 2003, available at http://www.findarticles.com/p/articles/mi_ml571/is_2003-Sept-16/ai_107543542 (last visited Apr. 2, 2005).} It would require dietary supplement manufacturers to conduct incredibly expensive tests on all of their products, and if the supplement failed any of the tests, the FDA would have full authority to remove it from the market.\footnote{170}{Id.} Project: Freedom of Access to Nutritional Supplements ("Project: FANS"), a grassroots organization created to ensure that Americans have access to dietary supplements, asserts that Sen. Durbin's legislation could potentially call for the ban on vitamins used everyday by Americans, including calcium, vitamins E and C, and even the Flintstones vitamins.\footnote{171}{See Project: Fans, Comparison of Current Legislation, at http://www.projectfans.com/docs/S722.pdf (last visited Feb. 6, 2004) [hereinafter Project: Fans, Comparison of Current Legislation]; see also Press Release, Project: FANS, Senator Durbin Seeks Big Brother Government Regulation of “Dangerous” Supplements, Y'know Like Flintstone Vitamins (July 22, 2003), available at http://www.projectfans.com/docs/FlintstoneVitamins.pdf (last visited Feb. 7, 2005).} Sen. Orrin Hatch (R-Utah) reinforces that such a result could occur: "[T]here are a number of current bureaucrats at the FDA who hate dietary supplements and want to get pre-market approval, which would drive the costs of [v]itamin C and other vitamins and minerals and even herbal products out of sight."\footnote{172}{See U.S. Senator John McCain (R-AZ) Holds a Hearing on Dangers of Dietary Supplements Before Sen. Comm. on Commerce, Science & Transportation, Federal Document Clearing House, Inc., Political Transcript (Oct. 28, 2003) (statement of Sen. Orrin Hatch) [hereinafter Statement of Sen. Hatch].} Sen. Durbin responded to these allegations by stating that his bill does not require safety testing for vitamins, minerals, or the majority of dietary supplements, but only for stimulants.\footnote{173}{Sen. Dick Durbin, The Truth About the Dietary Supplement Act, INSIGHT ON THE NEWS, Dec. 8, 2003, available at http://www.findarticles.com/p/articles/mi_m1571/is_2003_Nov_24/ai_110364131 (last visited Apr. 2, 2005).} However, David Seckman, executive director of the National Nutritional Foods Association ("NNFA"), criticizes Sen. Durbin's bill because it would allow the FDA to make the manufacturer prove that a multivitamin is safe after only one adverse reaction complaint, which will inevitably occur.\footnote{174}{O'Meara, supra note 169 (citation omitted).} Seckman further argues that when Congress addressed concerns regarding the dietary supplement industry, it did not expect that "every time there is an issue with a supplement we [would] need Congress to decide whether vitamin C or any other natural supplement should be banned."\footnote{175}{Id.} Another potential consequence of Sen. Durbin's bill is that many smaller businesses producing dietary supplements would become insolvent.\footnote{176}{See Project: FANS, Comparison of Current Legislation, supra note 171.} The testing
requirements that the bill would impose upon all manufacturers of dietary supplements would be too costly for small manufacturers to remain in business.177 The unavoidable result would be that dietary supplements will no longer be affordable alternatives to prescription drugs, which runs contrary to what Congress sought to ensure in passing the DSHEA.178 If smaller manufacturers of dietary supplements become insolvent, they will have to sell out to larger pharmaceutical companies, and inevitably, the price of common herbal remedies, such as Echinacea, St. John’s wort, and even vitamin C, will increase.179

Another pitfall of Sen. Durbin’s approach is that it assumes that the supplement will no longer present any potential danger to consumers if the FDA approves the dietary supplement. However, many drugs that the FDA approves do harm consumers,180 despite the fact that the FDA has approved the drug before the drug reaches the market.181 For example, a common over-the-counter pain reliever is responsible for more than 17,000 deaths annually, and prescription drugs are estimated to be one of the top five leading contributors of deaths in the United States.182 Additionally, the chemical stimulant methylphenidate, a drug that helps children with the symptoms of attention deficit hyperactivity disorder (“ADHD”), has serious potential side effects in children, such as decrease in bone growth, sleep disturbance, increased blood pressure, tics, nausea, hypersensitivity, anxiety, tension, and nervousness.183 Between 1990 and 1997, the FDA reported that 160 deaths and 569 hospitalizations were associated with children taking Ritalin,184 yet the drug remains on the market. For more recent examples, recall the withdrawal of Vioxx from the market in the fall of 2004185 and the warnings issued about other non-steroid anti-inflammatory drugs, such as Bextra and Celebrex.186 Furthermore, many other FDA-approved drugs

177. See id.
178. See discussion supra Part II.B.
179. See discussion supra Part IV.B.
182. Testimony of Seckman, supra note 180.
184. O’Meara, supra note 169.
ranging from Prozac, which is used for the treatment of depression, to Accutane, which is used for treating acne, have had serious adverse reactions reported against them.\textsuperscript{187}

In contrast, the FDA has received a small number of reports of adverse events associated with the consumption of dietary supplements. For example, the FDA received a mere 1,214 reports of adverse events regarding all dietary supplements in 2001, which includes reports of injuries with varying levels of seriousness.\textsuperscript{188} Thus, even if the FDA does approve the product, whether it is a prescription drug or a dietary supplement, adverse reactions to the products may still occur. A requirement that the dietary supplement receives FDA premarket approval will therefore not ensure the safety of the supplement.

Essentially, the Dietary Supplement Safety Act would grant the FDA unprecedented—and nearly unlimited—power to remove dietary supplements from the market, and many dietary supplements that consumers have enjoyed taking for many years without experiencing any harmful side effects could suddenly be banned. As Julian Whitaker, a medical doctor who founded the Whitaker Wellness Institute in California, stated, "[T]his legislation isn't about safety at all. It's about loss of control that the FDA has experienced . . . when it comes to regulation of the nutritional-supplement industry with the passage of the [DSHEA]."\textsuperscript{189} This proposed legislation is not the appropriate solution for ensuring that consumers are safe from dangers that dietary supplements such as ephedra may pose.

2. The Better Solution: DSHEA Full Implementation and Enforcement Act of 2003

Several months after Sen. Durbin introduced the Dietary Supplement Safety Act, Sen. Tom Harkin (D-Iowa), along with Sen. Hatch, introduced the DSHEA Full Implementation and Enforcement Act of 2003 ("DSHEA Full Implementation and Enforcement Act"),\textsuperscript{190} which offers a different, and more sensible, approach to addressing the problems of dietary supplements than Sen. Durbin's approach.

The DSHEA Full Implementation and Enforcement Act’s stated purpose is to "ensure that the goals of the [DSHEA] are met by authorizing appropriations to fully enforce and implement" the DSHEA.\textsuperscript{191} In contrast to Sen. Durbin’s drastic and unduly restrictive proposal, which essentially requires a rewriting of the DSHEA, Sen. Harkin’s approach would provide the FDA with sufficient resources to be able to implement the current law.\textsuperscript{192} For example, the bill would give the FDA $20 million beginning in the fiscal year ("FY") 2004\textsuperscript{193} and an increasing amount each proceeding year until FY

\textsuperscript{187} See id.; see also Letter from Janet Woodcock, Director, Ctr. for Drug Evaluation and Research, to Consumers (Jan. 9, 2001), at http://www.fda.gov/cder/drug/infopage/accutane/accutane-ltr.htm (last visited Mar. 15, 2005) (indicating that Accutane, while effective for treating acne, is known to cause a range of birth defects).

\textsuperscript{188} Testimony of David Seckman, supra note 180.

\textsuperscript{189} O'Meara, supra note 169.

\textsuperscript{190} S. 1538, 108th Cong. (2003). The DSHEA Full Implementation and Enforcement Act of 2003 is a proposed bill separate to Hatch’s proposed amendment to the DOD Authorization Bill.

\textsuperscript{191} Id.

\textsuperscript{192} Id. § 3.

\textsuperscript{193} Id. § 3(a)(1).
The bill also gives funds to ODS for expanded research and development of consumer information on dietary supplements. According to this bill, the DSHEA would remain the controlling law, but the FDA would receive more resources in order to investigate adverse event reports associated with dietary supplements. One major problem with the DSHEA is the difficulty in enforcing it; the FDA simply does not have the funds to adequately respond to the adverse reports that it receives. Sen. Harkin's proposal, however, offers a good solution by appropriating sufficient funds to the FDA to effectively enforce the law. As Sen. Hatch has stated, "[T]he FDA must use [the DSHEA] for it to be effective, and Congress must support the agency in that effort." If the FDA had more funds, the agency could conduct more detailed investigations into dietary supplements that harm a large number of people. At the same time, Sen. Harkin's proposal keeps the current law in place so that consumers are ensured access to affordable alternative medicines.


In conjunction with his proposed Dietary Supplement Safety Act, Sen. Durbin made a second attempt to increase the regulation of dietary supplements by offering another proposal in May 2004. The proposal, outlined in Amendment 3225 to the National Defense Authorization Act for Fiscal Year 2005 ("DOD Authorization Bill"), would have required manufacturers who sell dietary supplements containing stimulants on military installations to turn over to the FDA any serious adverse event reports relating to the products. Thus, the amendment would have restricted access to dietary supplements containing caffeine as an ingredient and drinks containing stimulants on military bases and implemented a mandatory reporting scheme from manufacturers of dietary supplements sold on military bases to the FDA. As justification for the amendment, Durbin stated, "Military personnel are under unusual pressure to be physically fit, making dietary supplements particularly attractive . . . . Soldiers face enough danger in the field. They shouldn’t have to worry about purported health products that are sold at military commissaries, but not monitored for safety."

Sen. Durbin's proposal received heavy criticism, particularly from Sen. Hatch, who has been an outspoken critic of increased regulation of the dietary supplement industry. Stating that the proposal was "a solution in search of a problem," Sen. Hatch
opposed Amendment 3225 for three primary reasons. First, Hatch highlighted the inconsistency in singling out military personnel when the issue is of national concern and does not just concern military installations. Second, Hatch objected to the separation of those dietary supplements containing stimulants from other dietary supplements. Third, Hatch said that the timing of this amendment was "premature," as no agency, including the FDA, has taken a position regarding the issue Sen. Durbin proposed in his amendment. Moreover, Hatch cautioned against using the DOD Authorization Bill as the place to work through issues involving the regulation of dietary supplements as the serious shortcomings of the existing adverse event reporting system should be reformed before a mandatory reporting system is implemented.

In response to Sen. Durbin’s proposed amendment, Sen. Hatch, along with Sen. Harkin, presented an alternative amendment to the DOD Authorization Bill, Amendment 3463. Amendment 3463 proposed the following: (1) to require the FDA to make it a priority to “fully and effectively” implement the DSHEA, including taking appropriate enforcement action against unsafe dietary supplements; (2) to require HHS to develop a plan for mandatory reporting of serious adverse events resulting from taking dietary supplements; and (3) to increase the resources and funding available to the FDA for overseeing dietary supplements and for scientific research on the effects of dietary supplements.

Following the introduction of Amendment 3463, Sen. Durbin responded to the criticism against his proposed amendment by agreeing to collaborate with Sen. Hatch and Sen. Harkin to develop a comprehensive law to address the FDA’s inability to respond effectively to adverse event reports. In agreeing to work together to reach a solution, the senators agreed to withdraw their proposed amendments to the DOD Authorization Bill.

The senators made no significant progression towards achieving this agreement until a federal district court in Utah issued its ruling in Neutraceutical Corp. v. Crawford. Immediately following the release of this decision, Sen. Hatch and Sen. Durbin met to discuss the introduction of a reporting bill that likely would give the FDA authority to mandate adverse event reporting. FDA Week reports that the bill may require the manufacturer, distributor, or retailer of a dietary supplement to report adverse events to the FDA and would hold these same actors responsible for the

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204. Id.
205. Id.
206. Id.
207. Id.; see also Pledge, supra note 201.
209. Id.
210. Id. (statements of Sen. Hatch and Sen. Durbin); see also discussion supra Part.II.B.
213. Hatch Pushes Bill, supra note 212.
accuracy and completeness of the adverse event reports. However, to date, neither senator has released an official version of the bill.

4. Institute of Medicine Panel Calls for Higher Standards

In addition to the flurry of legislative action directed toward changes in the dietary supplement law, a private organization backed by the federal government has contributed to the controversial issue. In early January 2005, a panel convened by the IOM, at the bequest of NCCAM, released a report urging Congress to revise the DSHEA to heighten the regulation standards for dietary supplements.

Expressing concern over the reliability of dietary supplements, the panel called for stronger quality controls on dietary supplements, including a requirement that dietary supplements be held to the same clinical standards as drugs. Dr. David Eisenberg, director of research into complementary therapies at Harvard Medical School and a member of the panel, said that the panel was most concerned about quality because “you can’t be assured from batch to batch” that the products are reliable. Furthermore, Dr. Stephen E. Straus, director of NCCAM, said that requiring the same research standards for dietary supplements and drugs would “further the scientific investigation of this new field, increase its legitimacy as a research area and ultimately improve public health.” In addition to the recommendations for stronger quality controls, the panel called for the DSHEA to improve standards for label accuracy and to institute stronger enforcement against false and misleading claims of adverse events associated with dietary supplements.

Unsurprisingly, Sen. Durbin praises the IOM’s report as further proof that the DSHEA should be changed, and he will undoubtedly use this report as fuel to continue his push for Congress to adopt his proposed Dietary Supplement Safety Act. Equally predictable, the dietary supplement industry is criticizing the IOM report, blasting the panel for being misinformed about the DSHEA and about dietary supplements in general. For example, the Council for Responsible Nutrition (“CRN”) called the IOM report “an unwarranted hatchet job” that “focus[e] entirely on repeating a few shopworn criticisms with little attention to the positive science underlying the safety and benefits of a wide variety of products and no attention

214. See id.
215. The Institute of Medicine is part of the National Academy of Science, a private organization created by Congress to advise the government on scientific and technical matters.
217. Id.
220. IOM: Revise DSHEA, supra note 216.
221. Id.
222. Id.
... to the outstanding quality assurance and manufacturing controls that are typical of leading companies in the industry." 224 Furthermore, CRN criticizes the report’s recommendation to hold dietary supplements to the same standards as drugs since dietary supplements have always been classified as food and have never been considered drugs. 225 Finally, CRN argues that, instead of amending the DSHEA as the report suggests, the more appropriate action is for the FDA to continue its goal of improving enforcement of the DSHEA and of finalizing the cGMP rule that it has set forth to complete. 226

Although the consequences of this report are yet to be realized, the report highlights the line drawn between those calling for stronger regulation of dietary supplements and those advocating for better enforcement of the law already in place. The DSHEA is adequate to deal with the problems surrounding dietary supplements and should not be amended; however, increased enforcement of the DSHEA is necessary.

E. The Ban on Ephedra Shows that the DSHEA Works

The FDA proved that the DSHEA does indeed work when it banned ephedra in December 2003. The FDA has the ability to exercise its power, authorized under the DSHEA, to ban a dietary supplement determined to present a significant risk to consumer health. Ephedra presented such a risk, and the FDA was successful in removing it from the market. Instead of threatening the safety of consumers, the DSHEA ensures consumers that they may have access to dietary supplements and do not have to rely solely on prescription drugs to relieve their ailments.

When Congress passed the DSHEA, it found "a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis" 227 and that "healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty . . . ." 228 Congress further relied on "national surveys [that] have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition" 229 and that "supplements are not drugs, have never been drugs, and will never rightly be considered drugs. Congress has carefully reviewed the food/drug issue on three separate occasions in the last 65 years and has come down on the food side every time." 224 See also discussion supra Part II.A (addressing dietary supplements being regulated as food additives and not drugs under the FDCA).

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225. Id. (Annette Dickenson, CRN President, states, "Dietary supplements are not drugs, have never been drugs, and will never rightly be considered drugs. Congress has carefully reviewed the food/drug issue on three separate occasions in the last 65 years and has come down on the food side every time."); see also discussion supra Part II.A (addressing dietary supplements being regulated as food additives and not drugs under the FDCA).

226. Press Release, CRN Calls IOM Report, supra note 224; see also discussion supra Part II.B.


228. Id. § 2(4).

229. Id. § 2(9).
Furthermore, when andro appeared to endanger as many people and attracted the same level of media attention as ephedra, the FDA took action to ban that supplement from the market as well. Although the FDA used the wrong method and analysis in effectively removing andro from the market, the fact that the FDA reacted to the dangers presented by andro indicates that the FDA will react again should another supplement present such dangers in the future. Until a supplement presents such dangers, however, the FDA should continue to evaluate the dietary supplements on a case-by-case basis, as provided for in the DSHEA.

If the FDA is granted expansive authority to regulate these dietary supplements, as Sen. Durbin and the IOM report propose, consumers will suffer. Therefore, the DSHEA should remain as originally enacted, but with the additional appropriations that Sen. Harkin proposes in the DSHEA Full Implementation and Enforcement Act. If the FDA had more funding to investigate dietary supplements, and if other organizations, such as ODS, had more money to conduct research on the health benefits and risks of taking dietary supplements, then consumers would be able to experience the best of both worlds—they would be able to continue to have access to the herbal remedies that provide affordable treatments for their ailments, and they would receive better information regarding the side effects associated with dietary supplements.

F. The FDA Should Do More to Educate Consumers about Dietary Supplements

Instead of changing the DSHEA, as Sen. Durbin proposes, the federal government should ensure that consumers receive more information about the safety of dietary supplements. Instead of taking away consumer access to dietary supplements by banning them or making it more difficult for supplement manufacturers to market their products, the FDA should arm consumers with knowledge about the effects of the major dietary supplements so consumers can make informed decisions about which supplements to use.

The FDA can take several actions to accomplish this task. For example, the FDA and ODS could use a portion of the money that Sen. Harkin provides in his proposed bill to create consumer information pamphlets about the potential dangers of using dietary supplements. The FDA should recommend that every grocery store and natural foods store create a display, using these pamphlets, in the dietary supplement aisle so that consumers would have easy access to this information. The FDA should also provide a consumer-friendly website that includes a statistical analysis of the number of adverse event reports associated with each dietary supplement. The website could also contain basic background information on the major dietary supplements and tips for consumers on how often and in what dosage to take the supplement. Finally, the FDA should launch a nationwide advertising campaign to educate consumers about the issues and potential dangers of using dietary supplements. The campaign should include

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230. See discussion supra Part II.B.
231. See discussion supra Part IV.A.
232. See id.
233. See discussion supra Part IV.B.2.
creating television commercials and advertisement placements in health and general consumer magazines and newspapers.

Solutions such as these will not ensure that consumers will experience no adverse effects associated with dietary supplements, but consumers will at least be able to make informed choices about which dietary supplements to purchase and take. Consumers will no longer believe that the products are harm-free and may proceed in using them with more caution.

V. CONCLUSION

Ephedra is only one dietary supplement that has had serious adverse effects amidst many more that have helped consumers improve their health and well-being. The fact that consumers voiced such strong opposition to the FDA's attempt to heavily regulate the dietary supplement industry that Congress had to react shows that consumers want—and demand—access to herbal supplements. The FDA made a bold move in December 2003 by banning a dietary supplement for the first time, and while that move was indeed a necessary and timely reaction to the dangers that ephedra posed to public health and safety, the FDA should not use it as ammunition to launch an attack against the dietary supplement industry.

Consumers will be hurt if the FDA begins to ban more and more dietary supplements, even if some consumers have experienced adverse reactions. Just as prescription drugs, despite all the testing that they undergo, cause some people to experience side effects when taking them, the same may occur with dietary supplements. However, consumers should still be entitled to access those dietary supplements and choose, for themselves, what types of remedies may suit them best. The DSHEA is in place to ensure that consumers do, in fact, have access to dietary supplements, and the legislation must remain to prevent the FDA from stripping these herbal remedies from the public.