

RECREATIONAL WEIGHT LIFTINGAND REGULATION OF THE DIETARY SUPPLEMENT MARKETPLACEby: **Brian D. Sims**

“

Yeah, I train pretty hard.”<sup>1</sup>

“

Would you say that you train extremely hard?”

“Yes. You see, I’m a life long athlete. My parents encouraged me to compete athletically at a very young age. I used to be a nationally ranked tennis player—I went to college on a tennis scholarship. I’ve trained pretty much my whole life, but my weight training has gotten more intense and more consistent over the last three years.”

“When did you start using dietary supplements?”

“I’d say ever since I started heavy, weight training. That’d be about a year and a half.”

“What made you start using them?”

“Well, solid training gets you only so far. Diet is an essential factor if you want to get really ripped up.”<sup>2</sup>

“My weight training partner has also influenced me a lot. He was a college athlete, too—he played baseball at a Division I college—and he comes from a family of athletes. His diet habits started at home and he’s always eaten only high calorie, low fat, low sodium foods.”

“But the truth is that the stuff is engineered. They’re designed so that it’s easy to eat exactly the right food and the right amount of calories that you need to train.”

“What’s your goal? Why do you train so hard?”

“I want to bulk up. You see, I’ve got a tall frame, and the main problem with my physique is that I’m too skinny. I’m 6’3” and up until 3 years ago I’d never weighed more than 185 pounds.”

“Another benefit to taking supps is definition. Just piling on calories will help you bulk up, but there’s always the potential for getting fat—the stuff I take gives you mass **and** definition.” (emphasis in original)

“You can look around the gym and see the guys who don’t eat right.

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<sup>1</sup>This conversation is a compilation of several, informal interviews with “Jerry.” Jerry is a twenty-five year old male, recreational weight lifter. Jerry confessed that he spends approximately one-third of his total food budget each month on dietary supplements. Jerry’s written responses to the author’s ‘Dietary Supplement Questionnaire’ are included in the appendix of this article.

<sup>2</sup>“Ripped up” is body building jargon for extreme muscle definition.

Sure, they train hard and they're strong, but they're just marshmallows with no definition. I'd rather not even work out than look like that."

"What's in the supplements that you take?"

"Proteins and amino acids, mainly. You know, BCAAs."<sup>3</sup>

"The best stuff I use is 'Kick Some Mass' from American BodyBuilding. It's a creatine monohydrate product which helps to increase the amount of free glycogen in the bloodstream. Free glycogen is extremely important for muscle building."

"The presence of BCAAs like creatine monohydrate has been proven to be directly linked with the release of human growth hormone. That's the stuff body builders are injecting nowadays instead of steroids."

"What about ephedrine products? Or ma huang?"

"Yeah, I use that stuff, too. You drink one shake right before you work out and the stuff hits you about 30, maybe 45, minutes in. It really works."

"When I first used that stuff, you know 'Ripped Force', right after it came on the market I knew it was different than all the hype. It makes your sweat!"

"When I didn't know any better, I drank two of those things in a row. After about 15 minutes, I started shaking... I had to lay down I got so dizzy."

"Do you know that there have been 16 reported deaths associated with ephedra related products and somewhere between 400-600 reported adverse health events?"<sup>4</sup>

"Yeah, I've heard about that, but aren't all those cases where people abused the stuff? I mean, it's obvious how strong they are and if you go psycho with the stuff you'll probably run into trouble. It doesn't take a genius to realize that 4 Ripped Forces and a Coke will mess you up pretty bad...."

Weight training is a lifestyle. From recreational to professional athlete, the behavior, social perspective, and body image of the heavy weight trainer differ from what most would consider normal. "Definition," "mass," "bulking up," and "getting ripped" are the goals, and an obsession with the body and its nourishment is the result.

Page through any popular fitness magazine and this obsession becomes painfully obvious. Bulging chests, biceps, and quadriceps jump out from ev-

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<sup>3</sup>Branched chain amino acids.

<sup>4</sup>See Richard Saltus, *Death Spurs FDA Warning on Stimulant*, BOSTON GLOBE, Aug. 3, 1996, at A1; Richard Obert, *A Consuming Interest; U.S. Eating Up Diet Supplements, But Do Results Live Up to Hype?*, ARIZONA REPUBLIC, Jul. 5, 1996, at C1.

ery page and advertisements for dietary supplements and energy products, like ma huang, predominate.<sup>5</sup> Since their introduction, herbal products containing ephedra, the plant form of ephedrine, (or ma huang) have been linked to at least 16 U.S. deaths.<sup>6</sup> Products like ‘Ultimate Xphoria,’ ‘Ripped Force,’ and ‘Energy Boost’ are marketed as “energy enhancers” and create a caffeine-like effect in their users. Weight lifters use these products to enhance their workout intensity. The general consensus is that an ephedra containing shake (like ‘Ripped Force’) before a workout offers a noticeable energy boost approximately thirty minutes into the routine<sup>7</sup>; for a bigger kick, take two. These products are readily available in every health food store and are part of the training regimen for many recreational athletes.<sup>8</sup>

Yet energy products are only a single component of the dietary supplement regimen for many weight trainers. Professional weight trainers have used other dietary supplements throughout the history of the sport. “From the first Mr. Olympia to the present champ, every one used body building supplements.”<sup>9</sup> Recreational athletes take their cues from the professional role models who are consistently featured in advertisements for these products. From protein powders, BCAAs, and chromium to multivitamins/minerals, ketoisocaproate (a BCAA), and omega-3 fatty acids, popular magazines tout the effectiveness of

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<sup>5</sup>There were over 50 advertisements for dietary supplements (ranging from powders, pills, and snack bars) in the most recent edition of *Joe Weider’s Flex Magazine*, a popular fitness magazine.

<sup>6</sup>*See id.*

<sup>7</sup>Interview with “Jerry,” recreational weight lifter, in Cambridge, Mass. (compilation of sessions Aug. 1996-Jan. 1997)

<sup>8</sup>Saltus, *supra* note 4, at A1, “. . . the products are sold on the street, at rock concerts, on college campuses and in health food stores.”

<sup>9</sup>Joe Weider, *When the Truth Hurts*, MUSCLE & FITNESS, Feb. 1997, at 112.

these products not only through advertisements, but through the testimony and instruction of their professional weight trainers/authors.<sup>10</sup>

The danger inherent in this situation is obvious: here is a segment of the population which consumes dietary supplements as a large component of regular diet, but the safety of many of these products has yet to be completely understood. Weight trainers take supplements so ritualistically that their use approaches a form of medical practice. Add the specter of ephedra-related deaths over the past several years and the magnitude of the health risks to which recreational (and professional) body builders are potentially exposed at the hands of dietary supplements becomes apparent. In recent years, the safety of some dietary supplements has been called into question. Certain amino acids (e.g. L-tryptophan) have been associated with disease, prompting the FDA to rethink its position on the regulation of dietary supplements. As a result of recent legislation, the definition of the term “dietary supplement” has blossomed into a broad class of products including vitamins, minerals, herbs and other botanicals, and amino acids<sup>11</sup>—thus the need for close regulatory attention. From the 1990, Nutrition Labeling and Education Act (NLEA)<sup>12</sup> through the present, dietary supplements have been subject to a host of administrative and legislative restrictions, yet the current state of regulation may need finer tuning to ensure consumer safety and to prevent fraud.

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<sup>10</sup>Chris Aceto, *Super Supplements*, JOE WEIDER'S FLEX MAG., Feb. 1997, at 68-70, “It takes three clear-cut factors to create an anabolic state—that best case scenario for bodybuilders in which the body packs more protein into muscles than it breaks down. . . .training. . . diet. . . and supplementation.”

<sup>11</sup>See Stephen H. McNamara, *FDA Regulation of Ingredients in Dietary Supplements After Passage of the Dietary Supplement Health and Education Act of 1994: An Update*, 51 FOOD & DRUG L.J. 313, 313-315 (1996).

<sup>12</sup>Pub. L. No. 101-535, 104 Stat. 2353 (1990).

## I. Early FDA Regulation of Dietary Supplements.

Commentators<sup>13</sup> and congressmen<sup>14</sup> alike have held that FDA holds an animosity toward the dietary supplement industry. Before passage of the Nutrition Labeling and Education Act of 1990,<sup>15</sup> FDA's main enforcement tool against manufacturers of dietary supplements was through the application of drug standards to dietary supplement products which made health and nutritional claims which FDA thought suspect. An early example of this practice is *V.E. Irons, Inc. v. United States*<sup>16</sup> where the second count of the FDA's complaint charged that the product in question ('Vit-Ra-Tox 21A') was misbranded under 21 U.S.C. s.352(a) for false representation<sup>17</sup> and misbranded under 21 U.S.C. s.352(f)(1) for failure to bear adequate directions for use.<sup>18</sup> Under the *Irons* theory, FDA used the overlapping definitions of "food" and "drug" from the Food, Drug and Cosmetic Act<sup>19</sup> to target dietary supplements whose manufacturers made extraordinary claims.

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<sup>13</sup>See e.g. Bruce A. Silverglade, *Regulating Dietary Supplement Safety Under the Dietary Supplement Health and Education Act: Brave New World or Pyrrhic Victory?*, 51 FOOD AND DRUG L.J. 319 (1996).

<sup>14</sup>See e.g. 139 CONG. REC. 919 (1993); 139 CONG. REC. 4,576 (1993).

<sup>15</sup>McNamara, *supra* note 11.

<sup>16</sup>244 F.2d 34 (1957).

<sup>17</sup>*Id* at 34, "...in that their accompanying labeling—consisting of certain leaflets and various issues of a newsletter—falsely represented 'when viewed in [their] entirety as well as through specific claims... that nearly everyone in this country is suffering from malnutrition or in danger of such suffering because of demineralization and depletion of soils and the refining and process of foods, that particularly all illnesses and diseases of mankind are due to improper nutrition, that said article[s] possessed nutritive properties superior to any other vitamin and mineral supplement, that said article[s] would be effective in the cure, treatment, and prevention of the ills and diseases of mankind,' including certain specific diseases;..."

<sup>18</sup>*Id* at 34, "...in that their labeling failed to bear adequate directions for the use of which they were intended, namely, for treatment of the specific diseases which appellants represented that the drugs could cure or prevent."

<sup>19</sup>21 U.S.C.A. ss. 321(f)(1),(g)(1)(B).

Another FDA regulatory practice which targeted the dietary supplement industry was the use of the “food additive” provision of the FD&C Act to hold dietary supplement products adulterated.<sup>20</sup> The FDA interpreted the old statutory language<sup>21</sup> regarding food additives as equally applicable to ingredients in dietary supplement products. Thus, a substance added to a dietary supplement had to meet the safety requirements for any food additive (the substance must be generally recognized as safe by experts based on published, scientific literature).<sup>22</sup> According to commentators on the subject, application of the food additive provision of the Act in this fashion places a great burden on any product:

Typically, preparation of a food additive petition, including conducting needed research (often including extensive animal feeding studies) and participation in the ensuing administrative proceedings, can cost a petitioner \$1,000,000 or more; in addition, it often takes the FDA five years or more after receiving a food additive petition before the agency issues a food additive regulation. . .

The “bottom line” of all this for dietary supplements was that FDA allegations of food additive status and the absence of a food additive regulation approving use as a dietary supplement had resulted in the end or curtailment of marketing for many products.<sup>23</sup>

Therefore, requiring a dietary supplement manufacturer to undergo the food additive regulation process was a “fatal in fact” determination.

Yet, this case-by-case approach to the regulation of the dietary supplement industry has proven extremely costly to FDA and has, quite recently, been questioned as overreaching. The multiplicity of prosecutions carries with it the

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<sup>20</sup>21 U.S.C.A. s. 321(s).

<sup>21</sup>This interpretation of the Act has since been foreclosed by amendment, *see infra* note 26.

<sup>22</sup>*See supra* note 20, s. 321(s): “generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; . . .”

<sup>23</sup>McNamara, *supra* note 11.

coordinate repeat expense of litigation which has proven quite taxing given the FDA's constrained budget:

The *Irons* case is illustrative of literally hundreds of court actions that FDA instituted against false or misleading nutritional claims in product labeling under both the food and drug sections of the Act. At least prior to 1970, FDA and the FTC undoubtedly expended more enforcement resources in the area of nutrition than in any other single field. The failure of this case-by-case approach to stem the tide of deception explains why both agencies turned to rulemaking.<sup>24</sup>

Beginning in the early 1990s, the FDA's food additive theory came under attack from another direction: the courts. As commentators on recent FDA regulation have pointed out, FDA prosecutions of dietary supplements under the guise of the food additive sections of the Act smack of administrative overreaching.<sup>25</sup> In 1993, Congressman Richardson of New Mexico cited this FDA practice as "arbitrar[y] classifi[cation]"<sup>26</sup> in his introduction of the Dietary Supplement Health and Education Act of 1994.<sup>27</sup> This piece of legislation, introduced in the House of Representatives by Congressman Richardson and in the Senate by Senator Hatch of Utah, is a single confrontation in the turbulent history of the regulation of the dietary supplement industry and it demands further scrutiny.

## **II. Events Leading Up to the Passage of the Dietary Supplement Health and Education Act of 1994**

On April 7, 1993, Senator Orrin Hatch of Utah introduced S. 784 and Rep. Richardson introduced its counterpart in the House (H.R. 1709), the legislation

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<sup>24</sup>Peter Barton Hutt & Richard A. Merrill, *FOOD AND DRUG LAW*, Ch. II, pt. E., 1 at 207 (2<sup>nd</sup> ed. 1991).

<sup>25</sup>See McNamara, *supra* note 11, at n. 7: "Even before enactment of DSHEA, however, courts had expressed the view that the FDA sometimes overreached in attempting to regulate dietary ingredients in dietary supplement products as 'food additives.' See, e.g., United States v. Two Plastic Drums...Black Currant Oil, 984 F.2d 814 (7<sup>th</sup> Cir. 1993). . . ; United States v. 29 Cartons...Oakmont Investment Co., 987 F.2d 33 (1<sup>st</sup> Cir. 1993).

<sup>26</sup>139 CONG. REC. 919, 920 (1993).

<sup>27</sup>Pub. L. No. 103-417, 108 Stat. 4325 (1994).

which would be passed on October 25 of the proceeding year as the Dietary Supplement Health and Education Act; but the history of this legislation and the current regulatory state of the \$4 billion dollar dietary supplement industry begins with the NLEA.

The Nutrition Labeling and Education Act of 1990<sup>28</sup> was passed in October, 1990 to “clarify and strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods,”<sup>29</sup> but it did not completely resolve the problem of supplement regulation. Throughout the NLEA debates and after the passage of the Act, its disposition of the proper standard for health claims on dietary supplements and the requirements for package labeling thereof remained vague.<sup>30</sup> The reluctance of the electorate to unleash the full, regulatory power of the Food and Drug Administration on the dietary supplement industry was at once obvious. In his comments about the new legislation on the date of passage of the NLEA, Senator Metzenbaum remarked that the effects of the Act on the supplement industry were somewhat less than certain.<sup>31</sup>

As a result of intense FDA pressure to bring dietary supplements into line with food regulation standards and an influx of constituent concern for con-

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<sup>28</sup>*Supra* note 12.

<sup>29</sup>H.R. REP. NO. 538, 101<sup>st</sup> Cong., 2<sup>nd</sup> Sess. (1990).

<sup>30</sup>136 CONG. REC. S16,607-02, 16,607-8 (Comments of Senator Metzenbaum): “It is obvious from the language of the amendment. . . that the Secretary [of the Department of Health and Human Services] has complete discretion to decide the appropriate standard for establishing the validity of health claims for dietary supplements. . . . Whatever approach the Secretary takes, he must establish a system that evaluates the validity of health claims for dietary supplements. The system must be based on the same considerations that guide other agency decisions: public health, sound scientific principles and consumer fraud.”

<sup>31</sup>*See id.*

tinued choice in the dietary supplement market, the 102<sup>nd</sup> Congress enacted the Dietary Supplement Act.<sup>32</sup> This piece of legislation was an attempt to stave off agency pressure until more research could be pursued regarding the regulation of the dietary supplement industry.<sup>33</sup> The greatest source of controversy was the fear that the face of the dietary supplement industry would be distorted by the intensified FDA involvement that would result from a newly published set of regulations. Dietary supplement manufacturers were concerned about their continued prosperity and the continuing marketability of their products. The millions of U.S. consumers who used supplements were concerned that FDA regulation would effect a market contraction, resulting in their loss of choice in the marketplace. Apparently, consumers (among other industry participants) instituted a large letter-writing campaign to entice their representatives in Congress to take on this pressing issue<sup>34</sup> (amidst manufacture propaganda at the point-of-source—health food stores).<sup>35</sup> As the result of publicity about the poten-

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<sup>32</sup>Senator Hatch offered this moratorium as an amendment to the Labor-HHS appropriations bill that was discussed on the Senate floor on Sept. 18, 1992. See 138 CONG. REC. 13,969 (comments of Senator Hatch) (1992); Dietary Supplement Act of 1992, Pub. L. No. 102-571.

<sup>33</sup>See 136 CONG. REC. 4,576, 4,577: “The legislation also called for the Office of Technology Assessment and the General Accounting Office to issue reports to Congress on the regulation of dietary supplements so that a more complete analysis of these problems could be presented and understood.”; see also 139 CONG. REC. 16,868, 16,868: “The [Dietary Supplement Act of 1992] was intended to provide us with an opportunity to learn more about supplements and to ensure that any regulations would be appropriate.”

<sup>34</sup>See e.g. 139 CONG. REC. 4576, 4577: “Many Americans felt that the FDA’s position prevented consumers from receiving useful information and making informed decisions about how to maintain or improve their health, and they let their Senators and Representatives know of their concerns. I know of few congressional offices that were not deluged with mail on this topic.”; Ian Jones, *Public Duped By Vitamin Makers, CSPI Claims Detractors Counter FDA Is Biased Against Supplements, Supports Drug Industry*, FOOD & DRINK DAILY, Dec. 15, 1993, Vol. 3, No. 673: “Congressional offices are being flooded with letters condemning the law, which consumers fear will make vitamin supplements into prescription drugs, limit dosage or remove them from the market. The letters urge support of supplements bills by Sen. Orrin Hatch, R.-Utah, and Rep. Bill Richardson, D.-N.M.”

<sup>35</sup>See *Vitamin Supplements: Hearings on the Dietary Supplement Health and Education Act of 1994 Before the Subcomm. On Agriculture, Rural Development, Food and Drug Administration, and Related Agencies*, 102<sup>nd</sup> Cong., 1<sup>st</sup> Sess. (October 18, 1993) (statement of Stephen Barrett, M.D., National Council Against Health Fraud): “To support these bills,

tially harmful (and perhaps, deadly) effects of certain amino acids<sup>36</sup> and other untested supplements, the FDA felt the need to bring the regulation of dietary supplements into compliance with the law.<sup>37</sup> Thus, the stage was set for a confrontation between the FDA and Congress.

As volatility of the issue increased, regulation of the supplement industry stood still as a result of the Dietary Supplement Act of 1992.<sup>38</sup> The moratorium on Department of Health and Human Services regulation of dietary supplements like amino acids, herbs, vitamins and minerals was set to expire in late 1993, yet debate continued to rage surrounding the legislation which Senator Hatch and Rep. Richardson had introduced in April. In June of 1993, FDA released an advance notice of proposed rule making which set forth its new attitude toward the regulation of dietary supplements.<sup>39</sup> The new position stood firmly on the grounds of FDA's public health mission:

To fulfill its public health mission with regard to dietary supplements FDA must ensure that these products are safe, and that claims made for their use are scientifically supported, truthful, not misleading, and otherwise in accord with applicable legal standards. Indeed, ensuring safety and proper labeling is FDA's most basic and traditional responsibility with respect to dietary supplements.<sup>40</sup>

This advance notice requested public comment and promised future "rule-proponents are generating mail from 'health food' manufacturers, retailers, and distributors, as well as from health-food store shoppers, customers of mail-order companies, multilevel distributors, 'natural health' practitioners, and bodybuilding and fitness enthusiasts who use supplements."

<sup>36</sup> See *Regulation of Dietary Supplements: Hearings on the Dietary Supplement Health and Education Act of 1994 Before the Subcomm. On Health and Environment, 102<sup>nd</sup> Cong., 1<sup>st</sup> Sess. (July 29, 1993)* (statement of Dorothy Wilson, EMS victim) (testifying that L-tryptophan may present a danger to health in susceptible individuals).

<sup>37</sup> See 58 Fed. Reg. 3,3690 (1993) (to be codified at 21 C.F.R. Ch. I) (ANPRM issued on June 13, 1993)

<sup>38</sup> *Supra* note 32.

<sup>39</sup> See Regulation of Dietary Supplements, *supra* note 36.

<sup>40</sup> *Supra* note 37, at 33,691.

making, enforcement action, or other appropriate activities.”<sup>41</sup> Yet popular sentiment about the issue and the manner in which FDA seemed to be approaching it did not bode well for the success of FDA’s proposed regulations.

In a set of subcommittee hearings in late 1993, it became apparent that Senator Hatch’s and Rep. Richardson’s legislation was backed by a large group of industry supporters in addition to its holding large, consumer support; Commissioner Kessler’s stance on the dietary supplement industry also held the support of several constituent groups. Testimony from the Council for Responsible Nutrition<sup>42</sup>, the National Nutritional Food Association<sup>43</sup>, and several members of the medical community<sup>44</sup> (among others) demonstrated constituent concern with the FDA’s approach. The proponents of the DSHEA argued for the proposition that the right of consumers to choose freely what products are available in the dietary supplement market is paramount.<sup>45</sup> Senator Hatch’s testimony demonstrated his vested interest in the regulation of the industry—his home state of Utah represents a large fraction of the national dietary supplement industry.<sup>46</sup> His most persuasive argument in favor of self-regulation for the dietary supplement industry was the comparison of cost between the \$8

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<sup>41</sup>*Supra* note 37, at 33,699.

<sup>42</sup>*See Dietary Supplement Issues Involving FDA: Hearings Before House Subcommittee on Agriculture, Rural Development, FDA and Related Agencies*, 102<sup>nd</sup> Cong., (October 18, 1993) (statement of J.B. Cordaro, President, Council for Responsible Nutrition).

<sup>43</sup>*See Regulation of Dietary Supplements: Hearing Before House Subcommittee on Agriculture*, 102<sup>nd</sup> Cong., (Oct. 18, 1993) (statement of Martie Diate, past President, National Nutritional Food Association).

<sup>44</sup>*See Vitamin Supplements: Hearings Before House Subcommittee on Agriculture, Rural Development, FDA and Related Agencies*, 102<sup>nd</sup> Cong., (Oct. 18, 1993) (statement of Joan Priestley, M.D. and statement of Fred Bingham, executive director of Direct AIDS Alternative Information Resources)

<sup>45</sup>*See e.g.* Dietary Supplement Issues, *supra* note 42, Regulation of Dietary Supplements, *supra* note 43.

<sup>46</sup>*See Vitamin Supplements: Hearing Before House Appropriations Subcommittee on Agriculture*, 102<sup>nd</sup> Cong. (Oct. 18,1993) (statement of Senator Orrin Hatch).

trillion health care industry and the \$4 billion dietary supplement industry.<sup>47</sup>

Given the timeliness of this appeal to administrative frugality, it is no doubt that Senator Hatch's argument resounded with the subcommittee:

'This [extensive FDA regulation] drives up the costs to the government, and it can drive up costs to consumers if FDA gets its way and puts up expensive barriers to the marketing and promotion of supplements,' he said. Then parting from his script, he added: '(This is) at a time when we have high healthcare costs and more and more doctors are finding benefits in dietary supplements.'<sup>48</sup>

The trade press also reacted unfavorably to FDA's findings concerning the integrity of the dietary supplement industry's marketing practices which were published in a report which Commissioner Kessler released at a subcommittee hearing on July 29, 1993. The *Food & Drink Daily* released a copy of a staff report to Senator Hatch which attacked the validity of this FDA report.<sup>49</sup>

Kessler's report and the position of the proponents of new FDA regulations of the industry rested on protection of consumer safety and the abolition of fraudulent claims propounded by dietary supplement manufacturers. According to Kessler's testimony at the July 29, 1993 hearing:

'Unsubstantiated claims are becoming more exaggerated, (as these) supplements are becoming more available, and their use is escalating,' he said. 'Allowing the supplement industry to make unsubstantiated claims flies in the face of all (FDA) has tried so hard to achieve.'<sup>50</sup>

Thus, the issue became more clearly framed: can the FDA effectively analyze claims and ensure consumer safety on a case-by-case basis or should the agency

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<sup>47</sup>See *id.*

<sup>48</sup>Linda Gasparello, *Dietary Supplement Drama Plays to Packed Hearing Room*, FOOD & DRINK DAILY, Oct. 20, 1993, Vol. 3, No. 636.

<sup>49</sup>*False and Misleading: FDA's Report 'Unsubstantiated Claims and Documented Health Hazards in the Dietary Marketplace'*, FOOD & DRINK DAILY, Oct. 25, 1993, Vol. 3, No. 639.

<sup>50</sup>Amy Beth Gooen, *Dietary Supplement Rules Hard For Firms to Swallow, House Hears*, FOOD & DRINK DAILY, July 30, 1993, Vol. 3, No. 580.

have the power to require pre-market approval of these products?<sup>51</sup> Hatch, Richardson and the consumer and industry proponents of market self-regulation pointed to the administrative friction which plagued the FDA and would thwart the supplement industry. Proponents of the FDA's position pointed out the obvious absurdity of singling out dietary supplement products for special exemption from the Nutrition Labeling and Education Act requirements:

FDA regulation of supplements would also 'level the playing field' for food manufacturers, who do not see a distinction between vitamin C contained in oranges and the same vitamin contained in supplements, said John W. Bode, legislative counsel for the National Food Processors Association (NFPA).

'In several respects, H.R. 1709 would impose a lower regulatory standard for dietary supplements than applies to foods,' he said. 'There is no basis for lowering regulatory procedures and standards for dietary supplements while holding foods to the current exacting standards. To do so would lower public health protections as well as create an unlevel field of play for competitive industries.'<sup>52</sup>

As it turned out, however, the powerful arguments of the dietary supplement industry lobby survived the FDA appeal to protection of consumer safety and elimination of fraud.

### **III.**

#### **Current State of Dietary Supplement Regulation.**

As with any piece of legislation, the final form of the DSHEA was a compromise between the starkly opposed propositions of the FDA's regulatory scheme and the self-regulation which the proponents of the DSHEA had envisioned. The most notable compromise involved health claims which could be made with

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<sup>51</sup> See *id.*

<sup>52</sup> See *id.*

regard to dietary supplement products.<sup>53</sup> The two sides of the debate were unable to reach agreement regarding dietary supplement health claims; legislators later expressed regret about the compromise.<sup>54</sup> The Act calls for the establishment of a commission, independent of the FDA, to review “how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.”<sup>55</sup> Notice of each meeting of the “Commission on Dietary Supplements,” as it was so-named, is made through notices in the Federal Register, and as of the date of this article, seven such meetings have taken place,<sup>56</sup> but no final report has been forthcoming. Once the commission’s report is submitted, the FDA will have another two years to amend and finalize the regulations in this respect.<sup>57</sup>

Aside from the commission, the Act provides for several other alterations to the regulatory structure which lend flexibility to the dietary supplement industry. First, the DSHEA marks out a broad definition of dietary supplement which “allows the ingredient in a supplement, regardless of its form or composition, to be excluded from regulation as a food additive or drug, both of which

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<sup>53</sup>See *Congress Passes Dietary Supplement Act, Shelves Health Claims*, FOOD LABELING NEWS, Oct. 13, 1994, Vol. 3, No. 2.

<sup>54</sup>See *NNFA States its Case on New Dietary Supplement Bill*, FOOD LABELING NEWS, Sept. 14, 1995, Vol. 3, No. 50: “[Senator Hatch:] I was, as you know, extremely reluctant about the establishment of a commission. I thought it would be better to resolve the claims issue once and for all . . .”

<sup>55</sup>See *supra* note 27 at 4333, Sec. 12(c).

<sup>56</sup>See 61 Fed. Reg. 63,849 (Dec. 2, 1996), 61 Fed. Reg. 51,117 (Sept. 30, 1996), 61 Fed. Reg. 45,975 (Jun. 27, 1996), 61 Fed. Reg. 24,798 (May 16, 1996), 61 Fed. Reg. 14,102 (Mar. 29, 1996), 61 Fed. Reg. 7,005 (Feb. 23, 1996), 61 Fed. Reg. 3,714 (Feb. 1, 1996).

<sup>57</sup>See *supra* note 27 at 4333, Sec. 12(d)(3).

require premarket approval.”<sup>58</sup> Second, the Act reconfirms the necessity of a case-by-case analysis by the FDA with regard to dietary supplement products. “The burden of proof is placed on the U.S. Government to make the determination that a supplement or its ingredient is unsafe.”<sup>59</sup> Perhaps one of the largest victories for supplement manufacturers is the result of the DSHEA’s provision which declares that third party publications which are “used in conjunction with the sale of” a dietary supplement are not labeling under the FD&C Act.<sup>60</sup> “Exempting this information from the definition of labeling means that these materials will not be subject to the preclearance provisions and scientific standards that other health claims must meet.”<sup>61</sup> The Act does contain several provisions which take a step forward in the regulation of supplement products. First, the Act contains certain labeling mandates.<sup>62</sup> Also, although the Act grandfathers in dietary ingredients which have proven safe, historically, the use of new dietary ingredients is subject to certain conditions.<sup>63</sup> Finally, the Act requires that dietary supplement manufacturers follow established GMPs (good manufacturing processes) which are “established by modeling them after those practices for conventional food. . . .”<sup>64</sup>

Since the passage of the DSHEA, FDA has proposed four new regulations

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<sup>58</sup>See Donna V. Porter, *Dietary Supplement Health and Education Act of 1994: P.L. 103-417*, NUTRITION TODAY, Apr. 1, 1995, Vol. 30, No. 2.

<sup>59</sup>See *id.*

<sup>60</sup>See *supra* note 27 at 4329, Sec. 5.

<sup>61</sup>See Porter, *supra* note 58.

<sup>62</sup>See *supra* note 27. Name and quantity of each ingredient, labeled as a supplement, herbal products must specify part of plant used, nutrition information must list ingredients which are essential and nonessential dietary ingredients.

<sup>63</sup>See *supra* note 27 at 4331, Sec. 8.

<sup>64</sup>See Porter, *supra* note 58.

regarding dietary supplement products.<sup>65</sup> The first three proposals were issued on December 28, 1996 and dealt with three regulatory problems: the first with nutrient claims, health claims, and statements of nutritional support; the second with the definitions of the terms “high potency” and “antioxidant;” and the third with supplement and ingredient labeling. The original comment deadline for the trio of proposals was June 6, 1996, but this date has since been extended beyond Jan. 1, 1997.<sup>66</sup> The fourth proposal was issued by the FDA on September 27, 1996,<sup>67</sup> and sets out the procedures whereby a manufacturer or distributor of dietary supplements, or of a new dietary ingredient, is to submit its research about the safety of its product/dietary ingredient.

These proposals are an attempt by FDA to remain on course in their mission to prevent consumer fraud. The FDA has explained the rationale which has driven these proposals:

‘Requiring that ‘dietary supplement’ be included as part of the statement of identity of such foods will ensure that a term that accurately describes the basic nature of the food will appear prominently on the label of each dietary supplement. It will also ensure that there is consistency in the labelling [sic] of dietary supplements by requiring that they bear a consistent term.’<sup>68</sup>

Thus, FDA has sought and continues to seek consistency in food labeling generally as a tool for consumer education.

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<sup>65</sup>60 Fed. Reg. 67,176 (Dec. 28, 1995), 60 Fed. Reg. 67,184 (Dec. 28, 1995), 60 Fed. Reg. 67,194 (Dec. 28, 1995), 61 Fed. Reg. 50,774 (Sept. 27, 1996).

<sup>66</sup>See 61 Fed. Reg. 16,423 (Apr. 15, 1996).

<sup>67</sup>61 Fed. Reg. 50,774.

<sup>68</sup>See *FDA Seeks Consistent Supplement Labelling*, OTC BUSINESS NEWS, Feb. 7, 1996, at 18.

Comments regarding the most recent FDA proposals have once again fallen on both sides of the fence. The NNFA (National Nutritional Foods Association) has declared that the December 28 proposals represent FDA reliance on “incorrect interpretations of the Nutrition Labeling and Education Act and the Dietary Supplement Health and Education Act.”<sup>69</sup> The NNFA has taken issue with the FDA’s statement of identity requirement, the nutrition labeling requirement, the declaration of names requirement, and the requirements for nutrient content claims, health claims, and statement of nutritional support.<sup>70</sup> However, others have supported FDA’s efforts to interpret the 1994 legislation:

... The Akron, Ohio, Department of Public Health urged the agency to list all of the effects of each herb on the ingredient listing of any product and said possible drug interactions of each herb should also be listed. . .

... Products which are labeled as protein or high-protein supplements should indicate their sources of protein, McGuckin [the department’s public health nutritionist] continued. Protein supplements used for body building ‘should contain a statement that muscle building requires not only protein but calories, especially carbohydrate, for building,’ she said. . .<sup>71</sup>

The debate remains largely polarized and the issue pressingly calls for the attention of FDA administrators and legislators alike.

Legislative action in the realm of the supplement industry has not ceased since enactment of the DSHEA on October 25, 1994. On June 28, 1995, Rep. Pallone introduced a piece of legislation which would have modified the DSHEA in several respects.<sup>72</sup> This legislation would have codified the “truthful and not

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<sup>69</sup>See *NNFA Criticizes Proposed Dietary Supplement Labeling Rules*, FOOD LABELING NEWS, Jun. 13, 1996, Vol. 4, No. 37.

<sup>70</sup>See *id.*

<sup>71</sup>See *Information Seminar on Dietary Supplement Rules Requested*, FOOD LABELING NEWS, Feb. 22, 1996, Vol. 4, No.21.

<sup>72</sup>H.R. 1951, 104<sup>th</sup> Cong. 1<sup>st</sup> Sess.

misleading” standard for health claims made with regard to dietary supplement products in labeling or advertising. Both NNFA and Senator Hatch came out against the new piece of legislation as a step backward from the DSHEA reforms.<sup>73</sup> The Food and Dietary Supplement Consumer Information Act was sent to the House committee on Commerce on June 28, 1995, but has not been reintroduced at present. ON May 23, 1996, Senator D’Amato introduced a piece of legislation targeted specifically at the ephedra crisis.<sup>74</sup> This bill would characterize any dietary supplement making claims about euphoria, heightened awareness, or similar effects as a drug under the Food, Drug, and Cosmetic Act.

#### **IV. Practical Effects of the New Regulatory Scheme.**

From the point of view of the modern, recreational weight lifter, it is important to understand that information on the subject, although accessible, is confusing and often severely biased. Consumers at local health food stores are met with a barrage of information in the form of advice from salespersons, product labeling, and other assorted product information. According to the DSHEA, third party publications used in connection with the sale of a dietary supplement are not policed as strictly as those for foods (which may be subjected to labeling requirements).<sup>75</sup> Policing this literature ex post subjects the consumer

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<sup>73</sup>See NNFA States its Case, *supra* note 69, “The group said that it could not support H.R. 1951 because it would eliminate the following provisions of DSHEA: the specific statutory provision that allows retailers the use of third-party publications directly in connection with the sale of products; the specific statutory protection given to book store sections; and the statutory provision which places the burden of proof on FDA when challenging the use of literature in connection with a sale.”

<sup>74</sup>S. 1806, 104<sup>th</sup> Cong., 1<sup>st</sup> Sess.

<sup>75</sup>See 21 U.S.C. 403B(a),(c).

population, at least initially, to the potential for deception and danger. This may prove harmful, or even deadly (in the case of ephedra products).

It is important to level the playing field between food manufacturers and dietary supplement manufacturers. Where once the dietary supplement industry had been consumed with the proposition that FDA held a regulatory bias against their products, today the market holds legislative grace. From the continued special exemption from the labeling requirements enacted with the Nutrition Labeling and Education Act of 1990 to the DSHEA, dietary supplements presently occupy a privileged position among products marketable as food.<sup>76</sup> The ability to make nutritional claims without FDA approval gives supplement manufacturers large leeway in an arena of close consumer attention—health and nutrition.

Legislation like Senator D’Amato’s proposed S.1806<sup>77</sup> is the type of responsible action with which the electorate must engage themselves. Recent First Amendment jurisprudence has increased protection for commercial speech,<sup>78</sup> yet untested ingredients and unwarranted claims hold a large potential for danger. In the coming months, FDA’s greatest tool may prove to be public education through the use of its facility for publicity. Sounding the alert to the public should be and is the province of FDA in the market of alternative food prod-

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<sup>76</sup> See Goen, *supra* note 50.

<sup>77</sup> See *supra* note 74.

<sup>78</sup> See *Rubin v. Coors*, 115 S.Ct. 1585 (1995).

ucts.<sup>79</sup> After the passage of DSHEA, FDA cannot relax in its vigilance over the dietary supplement industry. FDA must root out unsafe products and increase consumer awareness in this increasingly essential market.

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<sup>79</sup>See McNamara *supra* note 11 at n.21.