WEIGHT-LOSS ADVERTISING TOO GOOD TO BE TRUE: ARE MANUFACTURERS OR THE MEDIA TO BLAME?

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INTRODUCTION

Obesity afflicts nearly one-third of adult Americans,[1] and the condition is on the rise.[2] However, the average television viewer would not realize such an epidemic exists as images of the thin body ideal bombard American television viewers.[3] The socio-cultural pressure to be thin leads to an internalization of the thin ideal and body dissatisfaction, placing people at risk for negative feelings, eating pathology, and frequent dieting.[4] The obsession

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[1] Approximately sixty-one million individuals are obese, defined as having a body mass index greater than thirty. Moreover, nearly two-thirds of Americans, or one hundred twenty-six million adults, are overweight. *See* National Institute of Health, *Weight-control Information Network, at* http://win.niddk.nih.gov/statistics/index.htm (last visited Feb. 7, 2005). *See also* Richard L. Cleland et al., Federal Trade Commission Study, *Weight Loss Advertising: Analysis of Current Trends, available at* http://www.ftc.gov/bcp/reports/weightloss.pdf (last visited Feb. 7, 2005). The FTC conducted a study analyzing three hundred samples of weight-loss advertisements to note trends in claims, types of products, number of products, and amount of advertising from 1992 to 2002. The FTC referred to health statistics to explain the significance of the weight-loss industry on American culture in light of its obsessions with weight loss and the obesity epidemic. *Id.* at 9-10. *See also* Michael Specter, *Miracle in a Bottle,* NEW YORKER, Feb. 2, 2004, *available at* http://www.newyorker.com/fact/content/?040202fa_fact (last visited Feb. 7, 2005). Besides adults, child obesity is spreading. *Id.*

[2] The prevalence of obesity and overweight bodies has increased among both genders, all ages, and all racial and ethnic groups. *See Weight-control Information Network, supra* note 1. Moreover, "if current trends continue, over forty percent of Americans will be clinically obese within five years." Specter, *supra* note 1.

[3] Popular television shows illustrate that viewers do not have to go far to witness the glorification of the thin ideal. Examples include reality shows *America's Next Top Model, Are You Hot?,* and *The Swan,* as well as teenage icons scantily clad on MTV revealing thin, sculpted bodies. And, when those teenage icons themselves attempt to lose weight through weight control supplements, the obsession mounts. In September 2003, Britney Spears was spotted with a bottle of Zantrex-3, one of the most popular weight-loss supplements currently sold in the United States. London's *Daily Express* published a page of pictures under the headline, *Exclusive: Pop Princess Spotted at Airport with Pot of Slimming Tablets. See* Specter, *supra* note 1.

Females associate the thin body ideal that inundates the media with control, willpower, discipline, autonomy, and liberation. *See* KANDI M. STINSON, WOMEN AND DIETING CULTURE: INSIDE A COMMERCIAL WEIGHT LOSS GROUP 8 (2001). A woman can demonstrate her ability to limit her appetite and transcend the material form through maintaining a slender body. *See id.* (discussing feminist scholarship that emphasizes the body as a place of control, domination, and struggle). Moreover, society's constant scrutiny of female bodies produces a type of prison where women internalize others' critical gazes and police themselves by hiding food, eating alone, or developing eating disorders. By continuingly scrutinizing each other and critically examining themselves, women perpetuate the obsession with slenderness. *See id.* Eve Ensler's one woman play "The Good Body" was inspired by her stomach and can be analogized to many women's relationships with their body images. She explains in her play, "It [my stomach] has become my tormentor, my distractor. It's my most serious committed relationship. It has protruded through my clothes, my confidence and my ability to work." Eve Ensler quoted in Emily Eakin, *The Season of Weighty Dreams,* N.Y. TIMES, Nov. 14, 2004, § 2, at 7.

[4] *See generally* Eric Stice, *Risk & Maintenance Factors for Eating Pathology: A Meta-Analysis Review,* 128 PSYCHOLOGY BULLETIN 825 (2002) (a meta-analytic review of factors that lead to eating pathologies in Americans). *See also* Alison E. Field et al., *Peer-Parent, and Media Influences on the Development of Weight Concerns and Frequent Dieting Among Preadolescent and Adolescent Girls and Boys,* 107 PEDIATRICS 54 (Jan. 2001) (concluding parents and the media have a significant impact on weight concerns); Alison E. Field et al., *Exposure to the Mass Media and*

with thinness has developed through history, where the ideal body type has become increasingly slender.[5] As a result of battling the obesity epidemic and social pressures to become slim, seventy million Americans are currently trying to lose weight or prevent weight gain.[6] Weight loss has become a major business enterprise as adults invest $30 billion in weight-loss products and services every year.[7]

As a result, the dieting industry has experienced dramatic changes in the last decade. From 1992 to 2002, the amount of dietary supplement products available on the market increased dramatically.[8] This boost in supplement production has been accompanied by controversy surrounding the validity and truth of marketing.[9]

The dietary supplement phenomenon repeats a familiar story in American commerce. In the early twentieth century, "patent

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Weight Concerns Among Girls, 103 PEDIATRICS 660 (Mar. 1999) (finding that exposure to fashion magazines has a strong influence on girls' body perceptions with 47% of girls wanting to lose weight after viewing images of thin models in print media).

5 *See* ROBERTA POLLACK SEID, NEVER TOO THIN: WHY WOMEN ARE AT WAR WITH THEIR BODIES 10-11 (1989). The repulsion towards body fat developed in the nineteenth and twentieth century in response to modernization, affluence, and democratization of American culture as an attempt to exert control during a time of constant change beyond human control. Desires to be thin seemed consistent with American values of egalitarianism as the rich had no unfair advantage in the competition for a beauty dependent on slenderness, rather than clothing or money. Furthermore, thinness resonated with feminist values because it seemed to liberate women from former oppressive fashions. However, as women tried to actually imitate the standards of beauty showcased in film and media, fashion proved confining rather than liberating. Thinness became a status symbol, where the perfect body functioned much like fashion as a mode of competitive display. The beauty standard became a struggle and a moral imperative referred to by *Vogue* magazine in 1980 as "The New Discipline." *Id.* at 258-59.

6 *See* Cleland, *supra* note 1, at v.

7 *See id.* at 2. In 2000, Americans spent $35 billion on products that advertisers told them would help them lose weight, including videos, tapes, books, medications, foods for special dietary purposes, dietary supplements, medical treatments, and other products and services. *Id.* This popularity is part of a larger movement with supplements known as "nutraceuticals" found in fortified foods with added vitamins, sports drinks, enriched water, and even candy. *See* Specter, *supra* note 1.

A recent patent registration for a new weight-loss product exemplifies both the ridiculous nature of the products as well as the obsession with these products. "A method of weight reduction in human beings, wherein a human ingests a laxative effective dosage of non-pathogenic Escherichia coli to produce a weight loss of up to two pounds within one week." *See* U.S. Patent No. 6,573,083 (issued June 3, 2003), *available at* http://patft.uspto.gov. (search performed Feb. 28, 2005).

8 *See* Cleland, *supra* note 1, at 21. Between 1992 and 2001, the number of products increased by 157%, and the number of times weight-loss advertisements appeared in these magazines increased 129%. Moreover, between 1997 and 2001, sales revenue for weight loss supplements increased from 10% to 20% annually. *Id.*

9 *See id.* at 24. The number of FTC weight-loss product law enforcement cases filed in the last decade equals the number of cases filed in the last seven decades. After a study examining weight-loss product advertisements from 1992 to 2001, the FTC concluded that false or misleading claims are common in weight-loss product advertisements, and these deceptive claims have increased since 1992. *See id.* at vii.

medicines"[10] advertised as curing diseases became popular among consumers. Subsequently, however, researchers discovered that some of the substances were laced with cocaine, morphine, opium and other harmful substances.[11] Moreover, after muckrakers disclosed corruption, fraud and improper economic activity, including conditions within the food processing industry, Congress responded with the Pure Food and Drug Act of 1906.[12] Although the legislation addressed some concerns, the law did not allow for governmental review of products before the manufacturers marketed them to the public.[13] Finally, after further deaths, injuries, and ineffective products, Congress passed the Federal Food, Drug and Cosmetic Act ("FDCA"), which implemented standards for products and instituted pre-market review of new drugs.[14] Continu-

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[10] "Patent medicines" are defined as "a proprietary medicine made and marketed under a patent and available without a prescription." NEW OXFORD AMERICAN DICTIONARY 1252 (Oxford Univ. Press 2001); *see also* JAMES HARVEY YOUNG, PURE FOOD SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 25 (1989) (explaining that patent medicines became more popular during a time of self-help and democratization of medicine where patent medicine advertisements consumed more newspaper advertising space than any other product, promising purchasers quick cures for all types of diseases through mild, tasty remedies). Despite the name, few of these products were actually patented, as obtaining patents required revealing ingredients which the shrewd patent medicine promoters refused to disclose. *See id.* at 26.

[11] *See* Specter, *supra* note 1. Throughout the eighteenth and nineteenth centuries, salesmen traveled the United States promoting and promising miraculous products that cured any imaginable ailment. Much of the problem stemmed from the population's overall lack of knowledge of how nutrients worked in the body. In 1914, American Medical Association officials investigated a few of the specimens and learned that some of the products included such substances as alcohol, cocaine, caffeine, and opium. *Id.*

[12] In addition to the American Medical Association's determination that "patent medicines" actually contained dangerous substances, the revelations made in Upton Sinclair's THE JUNGLE initiated passage of the Pure Food and Drug Act in 1906. The legislation grants the Food and Drug Administration ("FDA") authority to regulate food and drug manufacturers. *See* Specter, *supra* note 1; *see also* YOUNG, *supra* note 10, at 253-54. Public outcry over impure meat and food, and exposure of "patent medicine" salesmen defrauding consumers, led to a heated congressional debate over legislation that ultimately resulted in the Pure Food and Drug Act of 1906. While describing the inevitable, though seemingly indefensible opposition to the pure food bill, New York Representative Joseph Goulden stated, "It seems strange that good can only be accomplished after a determined fight. I believe that if a movement was started to abolish the kingdom of Satan that the usual mighty opposition would at once arise, even in this House." 40 CONG. REC. 8979 (1906) (statement of Rep. Goulden).

[13] *See* YOUNG, *supra* note 10, at 253-54.

[14] *See* Specter, *supra* note 1. Regulations often followed tragic events. For instance, Sulfanilamide, a drug prescribed to treat streptococcal infections, was adapted to a liquid solution so that children could easily ingest it. Researchers found that the mixture dissolved in a diethylene glycol solution. Unfortunately, researchers overlooked the fact that the solution, normally used as antifreeze, was a deadly poison. Within weeks, scores of children died. One year later, after 137 deaths, Congress passed the FDCA, giving the FDA the authority to regulate such products. *See id.* The FDCA arose after heated congressional debates, resulting from tensions between the need for direct regulation of food and drugs and the deep distrust of New Deal administrators. *See* Joel E. Hoffman, *Administrative Procedures of the Food & Drug Administration*, *in* 1 FUNDAMENTALS OF LAW AND REGULATION 13, 17, 19 (Robert P. Brady et al. eds., 1997). The act gave the FDA authority to create industry

ing to protect consumers through legislation, the Federal Trade Commission Act established the Federal Trade Commission ("FTC") in 1914 as an independent administrative agency.[15]

The Food and Drug Administration ("FDA") and FTC both serve to protect consumers by ensuring safe, effective products and accurate marketing to consumers. Generally, while the FDA regulates food labeling,[16] the FTC regulates validity of advertising.[17] The FDA ensures many things: foods are safe and wholesome; drugs and medical devices are safe and effective; and electronic products emitting radiation do not harm the public. Moreover, the FDA helps to assure that the public receives accurate information regarding these substances through labeling.[18] The FTC's jurisdiction extends to promotional claims for consumer products, including claims made through package labeling or media advertising.[19] Thus, the FTC's jurisdiction overlaps with the FDA's jurisdiction over misbranding or adulteration of foods, food and color additives, and drugs.

To ensure effective enforcement, the two agencies entered into a "liaison agreement" where the FTC exercised primary responsibility for the regulation of false or deceptive advertising claims for FDA-regulated products, and the FDA maintained primary jurisdiction over false and misleading labeling of those products.[20] The regulatory scheme helped assure safe and effective

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requirements and implemented pre-market approval for new drugs. Specifically, the act instituted standards for identity, quality, and fill of food containers; rules for poisonous and harmful substances in food; lists of harmless coal-tar colors used in food, drugs, and cosmetics; and drug standards for strength, quality, and purity. Finally, the act created pre-market review authority over new drugs. *Id.*

15 *See* Hoffman, *supra* note 14, at 91-92. The Commission investigates and prosecutes "unfair methods of competition . . . and unfair or deceptive practices or acts in or affecting commerce," focusing on antitrust and consumer protection. 15 U.S.C. § 45(a)(1) (2000). The FTC has authority over persons, partnerships, or corporations where an FTC proceeding would benefit the public interest. *See* Hoffman, *supra* note 14, at 93.

16 *See* U.S. Food and Drug Administration, *What FDA Regulates, at* http://www.fda.gov/comments/regs.html (last visited Feb. 7, 2005).

17 The FTC's primary goals are to protect consumers from fraud and deception and allow for accurate, informed decisions. To accomplish the agency's goals, the FTC enforces federal consumer protection laws that prohibit deception, fraud, and unfair business practices. For more information regarding the FTC goals and responsibilities, *see* U.S. Federal Trade Commission, *Guide to the Federal Trade Commission, at* http://www.ftc.gov/bcp/conline/pubs/general/guidetoftc.htm (last visited Feb. 7, 2005).

18 *See What FDA Regulates, supra* note 16.

19 In 1938 Congress expanded FTC powers to make unlawful "unfair or deceptive acts or practices" in order to assure effective consumer protection. The FTC may initiate actions against companies that produce misleading promotional materials based on complaints from consumers, consumer organizations, members of Congress, state officials, or the Commission's own initiative. *See* Casey O. Hobbs, *Overview of the Federal Trade Commission, in* 1 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 14, at 91-93; *see also Guide to Federal Trade Commission, supra* note 17.

20 *See* Hoffman, *supra* note 14. To avoid duplicative enforcement actions, the FTC regu-

foods, food additives, and drugs, but excluded dietary supplements. However, the lack of regulation over diet supplements did not become problematic until the supplement industry soared in the 1990s.

Dietary supplements resemble the "patent medicines" of the early twentieth century as they promise almost miraculous results through ingestion of herbal combinations.[21] Congress attempted to address dietary supplements in 1994 through the Dietary Supplement Health and Education Act ("DSHEA"), although this legislation has proved inadequate in protecting consumers. DSHEA limits regulation of dietary supplements, causing substantial injury to individuals, and creating the need for added regulation to ensure safe, effective products.

This Note explores government agencies' modes of regulating the dietary supplement industry, concluding that the regulatory scheme is inadequate. First, this Note discusses the impact of DSHEA on the diet supplement industry. Second, it explores the relationship between the FDA and FTC, and how DSHEA altered this framework ineffectively for dietary supplements. Third, the Note discusses the study of ephedra to illustrate how the current dietary supplement regulatory scheme is inept: the inability to regulate products before they hit the market could result in waiting until bodily injury and death occur before agencies can regulate. Finally, because the primary source of dietary supplement regulation is advertising, a discussion of commercial speech's status in First Amendment jurisprudence is necessary. Specifically, this

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lates false advertising, but excludes labeling, which is covered by the FDA. "False advertising" refers to the following:

> [A]n advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.

15 U.S.C. § 55(a)(1) (2000).

[21] Obesity has become an important issue in medical schools and scientific institutes, which are currently increasing spending on research in this field. Thousands of studies about weight-loss solutions have uncovered no evidence that prescriptions, over-the-counter ("OTC") products, or supplements have ever kept a person's weight down for longer than a few months. *See* Specter, *supra* note 1. In fact, diet and exercise are the best ways to shrink fat cells and eliminate visceral fat, the type of fat that many researchers explain is a cause of obesity related health problems, including high blood pressure, diabetes, and heart problems. Quick-fix solutions, such as liposuction, remove subcutaneous fat but do not improve health. Scientists are studying visceral fat and fat cell size to learn the best way to overcome the obesity epidemic in a manner that decreases weight and improves health. *See* Denise Grady, *Fat: The Secret Life of a Potent Cell*, N.Y. TIMES, July 6, 2004, at F1.

Note contends that the FTC proposal of media screening threatens First Amendment protected commercial speech.

If the media portrays images of the thin ideal and then sells advertising space for effortless weight-loss measures to help Americans achieve that ideal, should the media be found liable for the harms to consumers? Although the FTC maintains that media screening of faulty weight-loss claims would be the most effective means of combating false advertising, current First Amendment jurisprudence suggests courts will protect commercial speech.[22] Instead of increasing liability for the media, which places restraints on speech, added educational measures would aid Americans in learning healthy lifestyles.[23] Moreover, the case of ephedra demonstrates that the FDA should have more authority to act before a substantial risk to consumers is realized. Congress should amend DSHEA to authorize the FDA to regulate products before they hit the market.[24] Treating dietary supplements more like drugs than foods would give manufacturers incentives to perform serious research on their products, decrease strain on the FTC to regulate advertising, prevent injury and death resulting from unsafe products, and provide consumers adequate assurance that product claims are reliable.

I. DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT LIMITS GOVERNMENT REGULATIONS

The passage of the DSHEA significantly altered the regulatory framework for weight-loss supplements by creating a category of

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[22] *See* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (finding restrictions on tobacco product advertising curtailed commercial speech and holding that the restrictions did not fit well with the legislative goal of stopping minors from smoking and, in some cases, constituted "onerous burdens on speech."). *Id.* at 565.

[23] Although most dietary supplement weight-loss products promote nearly effortless weight loss, health experts maintain the best means of ensuring long-term success is to decrease caloric intake, increase physical activity, and alter lifestyle behavior and attitudes. *See* George L. Blackburn, M.D., PhD., *Introduction* to Cleland, *supra* note 1, at iv-v. Moreover, although drugs and supplements have become popular as quick fixes to suppress appetite, doctors maintain that the drive to eat has to be managed on a personal level, and that pills and supplements alone cannot be relied upon to cause weight loss. *See* Mary Duenwald, *Slim Pickings: Looking Beyond Ephedra*, N.Y. TIMES, Jan. 6, 2003, at F1.

[24] Congress is currently considering a bill to modify DSHEA and treat thousands of currently unregulated botanical substances as drugs rather than foods. *See* Specter, *supra* note 1. Just as drugs require pre-market clearance before entering the marketplace, supplements that claim to affect the body should have enhanced regulation to provide manufacturers with incentives to create safe and effective products. It is important to distinguish between single vitamin products, such as vitamin C supplements, and herbal combination supplements that claim to promote weight loss. While regulation of a single vitamin supplement may not be necessary, federal regulation over herbal combinations that claim to affect body functioning, but which have been shown to be ineffective and cause bodily harm, is essential to consumer protection.

dietary supplements, regulated more like foods than OTC products, that formerly required pre-market clearance.[25] DSHEA prohibited the government from regulating dietary supplements as food additives or drugs.[26] While drugs require FDA pre-market clearance,[27] dietary supplements no longer require such pre-market review.[28]

Thus, the FDA may only regulate after the product is on the market through examining labeling content.[29] DSHEA restricted the FDA's ability to control dietary supplements but did not alter the FTC's authority to investigate truthfulness of advertising.[30] As a

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25 *See* Cleland, *supra* note 1, at 28. Before 1994, OTC products labeled for weight control were considered misbranded unless they were either generally recognized as safe and effective or the FDA approved the products as new drugs. In 1992, the FDA required that OTC products labeled for weight control, other than phenylpropanolamine hydrochloride ("PPA") or benzocaine, required some form of pre-market clearance for safety and effectiveness. Since the implementation of DSHEA, two classes of weight control products now exist. The first is obesity-treating products and non-dietary supplements that must still receive FDA pre-market approval. The second category consists of dietary supplements that must contain truthful labeling but do not require pre-market approval.

26 Products made of essential nutrients such as vitamins, minerals or proteins did not require pre-market clearance and, after DSHEA's passage, dietary supplements fell within the category of products that did not require FDA clearance before entering the market. Dietary supplements are thus effectively regulated as foods. *See* Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years After Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD DRUG L.J. 567 (1999). Regulatory authority over dietary supplements may be even weaker than foods as DSHEA excludes dietary supplement ingredients from food additives. The Food Additive Amendment of 1958 constitutes the FDA's most powerful tool in ensuring a safe food supply because it required FDA pre-clearance if the ingredient was not "generally recognized as safe" ("GRAS"). However, this provision no longer applies to dietary supplement ingredients, freeing the supplement industry from facing the Food Additive Amendment for existing ingredients. *See* William R. Pendergast, Dietary Supplement, *in* 1 FUNDAMENTALS OF LAW AND REGULATION, *supra* note 14, at 257, 277.

27 The FDCA defines "drug" as either 1) an "article[ ] intended for use in the diagnosis, mitigation, treatment or prevention of disease," or 2) any "article[ ] (other than a food) intended to affect the structure or function of the human body . . . ." 21 U.S.C. § 321(g) (2000).

28 Dietary supplements include the following:

> A product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

21 U.S.C. § 321(ff) (2000).

29 *See* Cleland, *supra* note 1, at 28. The FDA requires that dietary supplement manufacturers make truthful and non-misleading statements on their product labels. In addition, claims must be substantiated. However, without pre-market approval requirements, the FDA cannot enforce labeling requirements until after the product has entered the market. *Id.*

30 *See* Pinco & Halpern, *supra* note 26, at 579. The FTC has primary jurisdiction over advertising for OTC drug products, devices, and dietary supplements. DSHEA does not affect the FTC's ability to file claims against companies that falsely advertise products or make unsubstantiated claims. However, since DSHEA limited the FDA's ability to control dietary supplements before they enter the market, the FTC has taken a greater role in examining product advertising. *Id.*

result, claims have arisen that dietary supplements do not lead to permanent weight loss and, in fact, cause actual harm.[31] The FTC has become the primary regulator of false claims in dietary supplements through truth-of-advertising investigations and prosecutions.[32]

Congress had three primary motivations for enacting DSHEA. According to the legislative history, Congress supported DSHEA to combat obesity health problems, respond to the reality that Americans use dietary supplements, and promote economic well-being by accommodating the booming industry.[33] The dramatic reduction of regulatory control over dietary supplements[34] prompted the increase of weight-loss supplement products by lifting barriers of entry to the market.[35] In addition to creating the third category of "dietary supplements," DSHEA liberalized the law regarding label-

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31 The FDA referred to more than 16,000 case reports, identifying "two deaths, four myocardial infarctions, nine cerebrovascular accidents, one seizure, and five psychiatric cases." The U.S. Food and Drug Administration, *Evidence on the Safety and Effectiveness of Ephedra: Implications for Regulation, at* http://www.fda.gov/bbs/topics/NEWS/ephedra/whitepaper.html#six (last visited Feb. 7, 2005) (quoting Paul G. Shekelle et al., *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*, EVIDENCE REPORT/TECHNOLOGY ASSESSMENT (Agency for Health Care Research Quality, Rockville, Md.), Feb. 2003, *available at* www.fda.gov/OHRMS/DOCKETS/98fr/95n-0304-bkg0003-ref-07-01-index.htm). Other factors associated with ephedra use could exacerbate health risks including strenuous activity, use of other stimulants such as caffeine, and underlying medical conditions that limit cardiovascular capacity. *Id.*

32 *See* Pinco & Halpern, *supra* note 26, at 579.

33 Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994). Congress' findings listed in the session law include the following: improving citizen health constitutes a major federal government priority; proper nutrition and ingestion of dietary supplements can promote a healthy lifestyle, prevent diseases, and save health care costs; studies show that consumers increasingly rely on non-traditional remedies such as dietary supplements to avoid costs of more conventional medical services; almost half of American citizens consume dietary supplements to improve their health; the dietary supplement industry is a critical component of the United States economy; and safety problems with supplements are relatively rare. *Id.*

34 The "anti-regulatory sentiment" of 1994 served as the "driving force behind Congress' agenda" that led to legislatively-diminished FDA enforcement discretion. Hoffman, *supra* note 14, at 50. Senator Orrin Hatch sponsored DSHEA and argued that the different marketing and utility between traditional foods and dietary supplements requires different health claim standards and more lenient criteria. *See* Pendergast, *supra* note 26, at 272. Thus, DSHEA lifted economic barriers to dietary supplement manufacturers as a response to Congress' belief that "the Food and Drug Administration has pursued a heavy-handed enforcement agenda against dietary supplements for over 30 years," and that "congressional action [was needed] to assure citizens have continued access to dietary supplements and information about their benefits." S. REP. NO. 103-410, at 14 (1994).

35 *See* Pinco & Halpern, *supra* note 26, at 567. The Hartman Group has reported that sales of dietary supplements in the United States from July 1998 to June 1999 reached $10.4 billion. This figure represents a 3% increase over sales for the prior period. *Id.* at 586 n.2. Thus, although Congress articulated several reasons for enacting DSHEA, the legislation ultimately proved most effective in promoting the industry's economic well-being. The industry has grown dramatically, while obesity problems continue to mount and individuals are experiencing the harms of dietary supplement ingredients.

ing content.[36] Dietary supplement manufacturers may make statements of nutritional support without pre-clearance and without subjecting them to drug regulations.[37] Regarding the promotion of unsafe products, DSHEA shifted the burden to the FDA to prove that the product is unsafe before the agency receives authorization to remove the allegedly harmful product from the marketplace.[38] DSHEA also created agencies, such as the Office of Dietary Supplements[39] within the National Institutes of Health ("NIH"), to explore the role dietary supplements may play in benefiting public health and a commission to conduct a study on the regulation of label claims for dietary supplements.[40]

From the law's inception, agency officials and federal legislators have debated DSHEA's legitimacy and the validity of a separate category of dietary supplements that may not differ significantly from products classified as drugs.[41] DSHEA's goal of increasing

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[36] *See* S. REP. NO. 103-410, at 14 (1994). Labels include the following:

> [A] display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if there are any, of the retail package of such article, or is easily legible through the outside container or wrapper.

21 U.S.C. § 321 (2000). DSHEA liberalized labeling rules by permitting dietary supplement manufacturers to make nutritional support claims under certain conditions without pre-clearance and without subjecting dietary supplements to the same procedure as drug companies. The FDA regulates dietary supplements as foods, so that pre-approved health claims on labeling are available to dietary supplements. Furthermore, certain "third party literature" such as articles or books that discuss the benefits of specific ingredients may be exempt from classification of labeling. *See* Pinco & Halpern, *supra* note 26, at 567.

[37] *Id.* at 569.

[38] *Id.*; *see also* Sheryl Gay Stolberg, *U.S. to Prohibit Supplement Tied to Health Risks*, N.Y. TIMES, Dec. 31, 2003, at A1. The FDA, for the first time, announced the removal of ephedra products after proving the product poses "an unreasonable risk to the public health." *Id.*

[39] To examine the role of dietary supplements in improving health, the Office of Dietary Supplements ("ODS") plans, organizes, and implements conferences, workshops, and symposia on scientific topics related to dietary supplements. *See generally* Office of Dietary Supplements, *at* http://ods.od.nih.gov (last visited Feb. 7, 2005). The ODS often works with other NIH centers, government agencies, professional organizations, and public advocacy groups. *Id.*

[40] *See* Pinco & Halpern, *supra* note 26, at 569.

[41] *See* Christopher Drew & Ford Fessenden, *Expert Panel Finds Flaws in Diet Pill Safety Study*, N.Y. TIMES, July 23, 2003, at A16. Former FDA Commission and DSHEA opponent David Kessler argued that the law "tied the agency's hands" on substances such as ephedra that are actually drugs "masquerading as nutritional supplements." *Id.* He identified the crux of the problem with DSHEA: "The problem is that the supplement industry doesn't have to report adverse events, so the FDA doesn't have the data. How do you prove something is unsafe if you don't have the data? It's the ultimate Catch-22. It's also a colossal failure of protecting the public health." *Id.*

In response, Utah Republican, and DSHEA's chief sponsor, Orrin Hatch maintained, "It is extremely hard to take action if you never try." *Id.* Hatch argued that the agency did not go far enough to regulate ephedra in the past and if the FDA had imposed restrictions,

consumer access to truthful and non-misleading information on dietary supplements has stirred the greatest amount of controversy.[42] Since DSHEA's passage in 1994, the increased amount of dietary supplement products, specifically products geared toward weight loss, has been accompanied by a rise in false advertising claims.[43] Instead of preventing harm by eliminating inferior products from store shelves, FDA and FTC regulation of dietary supplements occurs after the products reach the market.[44]

II. Role of Administrative Agencies in Regulating the Diet Supplement Industry

A. *FDA Regulation of Dietary Supplements*

The FDA is responsible for regulating food, drug, and dietary supplement labeling. Labeling includes packaging, inserts, and additional promotional materials included in the point-of-sale purchase.[45] DSHEA provides that manufacturers must have substantiation at the time the claim is made, establishing that the statement is truthful and non-misleading.[46] Moreover, the label must clearly and prominently state in boldfaced type, "[T]his statement has not been evaluated by the Food and Drug Administration.

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then the courts would have the ability to examine the law's effectiveness. *Id.* Athlete Steven Bechler's death in February 2003 affected the political climate by leading to tougher labeling standards and enhanced public scrutiny of the diet supplement industry for products claiming weight loss and sports performance enhancement. *See id.* Currently, Hatch remains involved in the dietary supplement controversy as he is co-sponsoring a bill with Senator Joseph Biden that would list steroid hormone precursors such as androstenedione under the Controlled Substances Act. The bill would ensure that these popular performance enhancers, the object of debates regarding athletes' use of such substances, are not classified as dietary supplements to avoid regulation. *See US Dietary Supps Associations Support Biden/Hatch Steroids Legislation*, Nutraceuticals International (Nov. 2003) [hereinafter *Dietary Supps*].

42 Provisions related to acceptable promotional claims were intended to improve consumer awareness about dietary supplements. However, the crux of the controversy regarding dietary supplements has been manufacturers' claims about effects of their products. *See* Pinco & Halpern, *supra* note 26, at 570.

43 *See* Cleland, *supra* note 1, at 24.

44 *Id.* at 28. The agencies can regulate dietary supplement weight control products through labeling and promotional materials after they enter the marketplace, but dietary supplement manufacturers do not need pre-market clearance. *Id.*

45 *See* Federal Food, Drug, and Cosmetic Act Definitions, 21 U.S.C. § 321(m) (2000).

46 *See* Misbranded Food, 21 U.S.C. § 343(r)(6)(B) (2000). In addition, manufacturers may make statements regarding dietary supplements if:

> [T]he statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.

21 U.S.C. § 343(r)(6)(A) (2000).

This product is not intended to diagnose, treat, cure or prevent any disease."[47] The specific definition of "disease" informs what label claims the FDA permits.[48]

The manufacturer must notify the FDA that the label includes the claim after a period not to exceed thirty days.[49] If the FDA disapproves of the claim,[50] then the agency sends a "courtesy letter" to the manufacturer, putting the company on notice that continued use of the claim could lead to regulatory action, such as another warning letter or seizure of the product.[51]

The FDA remains wary of dietary supplements due to the invalidity of most health claims and its inability to effectively regulate before manufacturers place the supplements on the market.[52]

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47 21 U.S.C. § 343(r)(6)(C) (2000). The statute explains that a label statement may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. *Id.* If the manufacturer of a dietary supplement proposes to make a claim, the manufacturer shall notify the Secretary no later than thirty days after the first marketing of the dietary supplement. *Id.* One of the challenges facing dietary supplement manufacturers is to steer clear of "drug claims" that profess to diagnose, cure, mitigate, treat or prevent a disease, rendering the product a drug and not a dietary supplement. *See* Pinco & Halpern, *supra* note 26, at 576. Drug claims contrast with the DSHEA permitted "structure/function" claims that aim to use a nutrient or dietary ingredient to alter the structure or function in humans. *Id.* While manufacturers must carefully remain cognizant of the distinction between permitted dietary supplement claims and drug claims, the FDA proposed in 1998 to expand the definition of "disease" so as to prohibit a greater expanse of claims and permit more government regulation. *Id.* at 577. However, the FDA proposal has not yielded much support from legislators or the public. *Id.*

48 *See id.* at 572. By expanding the definition of "disease," the FDA sought to increase the prohibited class of claims made by dietary supplement manufacturers. Under DSHEA, dietary supplement manufacturers cannot claim to cure a disease, but no prohibition exists for references to "signs or symptoms" of diseases. *Id.* at 575.

49 *See* 21 U.S.C. § 343(r)(6) (2000).

50 DSHEA authorizes four types of nutritional support claims: claims benefiting a classical nutrient deficiency; claims describing the role of the supplement intended to affect the structure or function of humans; claims characterizing the mechanism by which an ingredient serves to maintain such structure or function; and claims describing a general well-being that results from use of the supplement. *See* 21 U.S.C. § 343(r)(6)(A) (2000).

51 *Id.* The FDA website features a sample warning letter for products containing ephedra. The letter explains to manufacturers the following:

> This review shows what we believe to be violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your products EPH833, Dymetadrine Xtreme, and 3-Andro Xtreme. You can find the Act and the dietary supplement labeling regulations through links on FDA's Internet home page at: http://www.fda.gov.
>
> Under the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or a function of the human body. To be permissible under the Act, these 'structure/function' claims must be truthful and may not be misleading.

Letter from Joseph R. Baca, Director, Center for Food Safety and Applied Nutrition Office of Enforcement, to AST Sports Science World Headquarters (Feb. 28, 2003), *available at* http://www.fda.gov/foi/warning_letters/g3850d.htm.

52 In *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the FDA sought to reject four separate folic acid health claims made by a dietary supplement company arguing that the claims lacked significant scientific agreement. The company argued, and the court agreed, that the First Amendment demanded less restrictive means, such as including disclaimers, instead of chilling speech. The court remanded the case, ordering the FDA to define

However, the popularity of dietary supplements makes the diet supplement industry a powerful one that will continue to garner support from Congress.[53] Currently, the FDA cannot exercise enforcement power over unsafe dietary supplements unless the FDA proves the supplement poses an imminent health hazard.[54] Because the FDA cannot pre-screen new diet supplements for safety and effectiveness, the FTC has become the predominant regulator of dietary supplements after products become available on the market.

B. *FTC Regulation of Dietary Supplements*

DSHEA altered FDA regulation authority and decreased its enforcement power, but it did not change the FTC framework for regulating advertising.[55] The FTC regulates advertising in a variety of media, including print, broadcast, infomercials, catalogues, direct marketing, and Internet promotions.[56] The FTC analyzes two

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"significant scientific agreement" and consider the validity of claims in light of disclaimers. For discussion of the case, see Pinco & Halpern, *supra* note 26, at 571. The *Pearson* case illustrates the FDA's frustration in regulating dietary supplements. Because the FDA cannot demand pre-market clearance, the agency and the public must rely on manufacturers' claims. On remand, the district court held that the FDA's refusal to authorize the folic acid claim violated the First Amendment. Moreover, the FDA abused its discretion by arbitrarily classifying the claim as "inherently misleading." Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001).

53 *See* Pinco & Halpern, *supra* note 26, at 585. The strength of the dietary supplement industry and its popularity among consumers will make future regulations difficult to implement. In addition, dietary supplement producers have clout among politicians as supplement manufacturers contribute millions of dollars to politicians each year. *See* Specter, *supra* note 1.

54 The primary FDCA violations include "adulteration," involving filthy foods, poisonous food ingredients, unapproved color additives, and ingredients which fail manufacturing standards, and "misbranding," where the agency bases determinations on verbal and visual representations as well as failure to disclose material facts pertinent to claims. Hoffman, *supra* note 14, at 58. When the FDA finds a violation, the agency may institute enforcement actions ranging from warning letters to recalls to felony prosecutions. However, diet supplements receive weaker regulation since emergency adulteration power over diet supplements can be exercised by the Secretary of the Department of Health and Human Services when supplements pose an imminent health hazard. *Id.* In other words, the enforcement power over diet supplements differs from the enforcement power over foods and drugs, because adulterated supplements are defined as products that pose an imminent threat to health and safety, while adulterated foods include poisons that "render [them] injurious to health." 21 U.S.C. § 342(a)(1) (2000).

55 *See* Pinco & Halpern, *supra* note 26, at 579. Since DSHEA altered the regulatory framework relevant to product labeling, the law left the FTC regulatory authority over advertising intact. Thus, the FTC has instituted actions against fraudulent advertisers and "attempted to step into the void left by FDA." *Id.*

56 The Division of Advertising Practices primarily enforces the nation's truth-in-advertising laws. Enforcement focuses on claims for health products, food, drugs, and diet supplements; weight-loss advertising; advertising and marketing directed toward children; performance claims for technological products; tobacco and alcohol advertising and promotions; and claims about product performance made through radio and television broadcasts, infomercials, magazines and newspapers, direct mail, or through Internet advertising. *See Guide to the Federal Trade Commission, supra* note 17.

issues related to advertising claims: 1) whether the advertisement is truthful and non-misleading, and 2) whether the advertiser has adequate substantiation for all objective product claims before the advertisement is disseminated.[57]

Rather than a balanced sharing of power between the agencies,[58] DSHEA shifted the power structure so that the FDA has extremely limited authority over dietary supplements. Because of the FDA's lack of pre-clearance regulation authority, the FTC has become especially active in regulating dietary supplement advertising and bringing fraudulent advertisers to court.[59] In the new drug regulation context, the FDA has the authority to restrict market entry for dangerous or ineffective products, so that consumers can presume most claims have been substantiated. Dietary supplements, however, do not receive pre-market clearance; thus, the FTC remains skeptical of most claims that appear too good to be true and do not receive sufficient scientific substantiation.

Consequently, the sole regulation for dietary supplements is post-market regulation in the form of false advertising claims. The FTC has recognized common claims made in dietary supplement advertisements that purport to promote weight loss.[60] The claims include consumer testimonials, before-and-after photographs, rapid weight loss claims, weight loss without diet or exercise, permanent weight loss, guaranteed weight loss notwithstanding previous dieting failures, scientifically proven and endorsed products, money-back guarantees, and safe and all-natural products.[61] The FTC has brought several false advertising claims against the dietary supplement companies.[62]

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57 Both express and implied claims must be truthful and must not mislead the public. Moreover, the substantiation standard requires "competent and reliable scientific evidence." *See FTC Dietary Supplements Advertising Guide for Industry* (1998), *quoted in* Pinco & Halpern, *supra* note 26, at 581. Substantiation has been defined as tests, analyses, research, studies, or other evidence based on professionals' expertise. The FTC has based its challenges to dietary supplement manufacturers' claims mainly on a lack of substantiation. *See id.*

58 The FDA and FTC created a "liaison agreement" to ensure effective regulation over foods and drugs while not duplicating authority. Hoffman, *supra* note 14, at 91. DSHEA ineffectively disrupted the balance of power between the FDA and the FTC by excluding dietary supplement regulation from the scope of the liaison agreement. *Id.*

59 *See, e.g.*, McClan v. Metabolife Int'l Inc., 193 F. Supp. 2d 1252 (N.D. Ala. 2002) (denying defendant's motion for summary judgment against plaintiff's claims of deceptive advertising for marketing of product containing ephedrine and caffeine).

60 The FTC has regulated weight-loss advertising since its first weight-loss case in 1927. *See* Cleland, *supra* note 1. However, the FTC filed more than half of its weight-loss cases since 1990. *Id.* Since this time, cases that challenge deceptive claims for diet pills, programs, and other products have resulted in administrative and court orders that required manufacturers to pay more than $48 million in consumer compensation. *Id.*

61 *Id.* at 24.

62 *See* Ford Fessenden, *Studies of Dietary Supplements Come Under Growing Scrutiny*, N.Y.

The FTC conducted a study of weight-loss advertising in 2002, finding that the number of products and advertisements has dramatically increased in the past decade.[63] In addition, the nature of products offered has changed from meal replacements, constituting 57% of the weight-loss products in 1992, to dietary supplements that currently constitute 66% of the industry.[64]

Although the NIH recommends reducing caloric intake and increasing cardiovascular activity as the only ways to ensure healthy weight loss, most Americans prefer purchasing weight-loss products that promise results with little or no effort.[65] As a result, many of the claims by dietary supplement manufacturers turn out to be false and misleading.[66] Supplement manufacturers defend their claims by arguing that the First Amendment protects their advertising as long as it contains a scintilla of truth.[67] Besides continuing

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TIMES, June 23, 2003, at A1; *see also* Delahunt v. Cytodyne Tech., 241 F. Supp. 2d 827 (S.D. Ohio 2003). The Cytodyne label claimed "Xenadrine's phenomenal fat-burning, muscle-sparing benefits can help you lose body-fat, increase your strength and energy, and produce visible improvements in muscle tone within just weeks of use." *Id.* at 830. After taking Xenadrine daily for three months, the plaintiff suffered psychotic episodes and seizures and filed a lawsuit on behalf of the class. The court found the following causes of action available: unfair trade practice, fraud on behalf of the plaintiff, unjust enrichment on behalf of the plaintiff and the class, and inadequate warning on behalf of the plaintiff. *Id.*

63 *See* Cleland, *supra* note 1, at 21.

64 Although meal replacements constituted most of the weight-loss products in 1992, alternatives included drugs and exercise equipment. *See id.* at 21. In 2001, dietary supplements overwhelmingly represented most weight-loss products. *Id.* In addition, meal replacements, topical treatments, food, and diet centers comprised less popular alternative products. *Id.*

65 *Id.* Examples of weight loss claims include: "Lose up to 2 pounds daily . . . without diet or exercise!" or "Clinically proven . . . use this technology to give you a better body without spending countless hours dieting or working out." *Id.*

66 The knowledge of consumers' desire to effortlessly lose weight provides great incentive for weight-loss supplement manufacturers to promise results of thin bodies with no effort. However, what consumer protection advocates call false claims, weight loss manufacturers call "hope." "This is really a belief system, almost a religion. Americans believe they have the right to address their health problems in the way that seems most useful to them. Often, that means supplements . . . . They are ready to believe anything if it brings them a little hope." *See* Specter, *supra* note 1. Religious rhetoric associated with weight loss is not always positive. "Our new religion has trapped us in a painful and futile quest. It offers no salvation, only a perpetually escalating cycle of sin and precarious redemption." Seid, *supra* note 5, at 257. The increasing desire to become slimmer has escalated to a "new religion" where beauty standards move to an unachievable extreme and no limit exists where a woman is deemed "too thin." *Id.* at 257-62. Thus, weight-loss supplements provide consumers with a false hope for an unachievable ideal that creates a self-destructive belief system rather than a positive, hopeful "religion." *Id.*

67 *See* Specter, *supra* note 1. The diet supplement industry considers its advertising claims to be protected commercial speech, worthy of First Amendment protection. Although false advertising does not receive First Amendment protection, diet supplement manufacturers contend that some amount of truth in their claims should grant them protection. However, commercial speech protection does not extend to misleading or deceptive claims. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557 (1980). Thus, a scintilla of truth will not serve to save advertising speech if the overall promotional materials mislead the public.

to institute false advertising cases against the manufacturers and marketers,[68] the FTC has three proposals for protecting consumer health, safety, and awareness.[69] First, trade associations and self-regulatory groups should educate their members about the creation and enforcement of tougher standards. Second, health groups should inform consumers about proper means of losing weight. Finally, the FTC believes the most effective measure is to promote media screening of advertisers that make weight loss claims.[70]

III. EPHEDRA CASE STUDY ILLUSTRATES THE FALLACIES OF THE CURRENT DIETARY SUPPLEMENT REGULATORY FRAMEWORK

Recent deaths associated with ephedra[71] have made the general public more aware of harms caused by the notorious dietary supplement.[72] Most notably, Baltimore Orioles pitcher Steve

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[68] Former FTC Chairman Timothy Muris announced law enforcement actions against three weight-loss product marketers due to false advertising claims that consumers could lose substantial amounts of weight without reducing caloric intake or participating in vigorous exercise. *See* U.S. Federal Trade Commission, *FTC Announces Law Enforcement Actions Against Marketers of Fraudulent Weight-Loss Products, at* http://www.ftc.gov/opa/2003/12/weightlosscases.htm (last visited Feb. 7, 2005). First, the FTC filed an action against Canadian marketers of seaweed based patches called "Hydro Gel Slim Patch" and "Slenderstrip" which the company claims will cause consumers to lose weight quickly without limiting caloric intake or increasing physical activity. Canadian health authorities are assisting in the action. *Id.*

Second, Universal Nutrition Corporation, MTM Marketing & Consulting Inc., and their owner, Robert J. Michnal, have agreed to pay $1 million in consumer redress to settle allegations that the defendants made false and unsubstantiated claims for "ThermoSlim," a weight-loss product containing ephedra, among other ingredients. *Id.* The company claimed in a thirty minute infomercial that consumers could safely lose ninety-five pounds in sixty days and that the weight-loss did not require eating less or exercising more. In addition to the payment, the settlement requires the company to refrain from faulty advertising and prohibits the sale of consumer lists to other companies. Finally, the company Mark Nutritionals settled by paying $1 million, half going to the states of Texas, Illinois and Pennsylvania, and the other half to the federal government. In addition, the company must post a $1 million bond before future product sales. *Id.* The settlement also requires truthful advertising and forbids the use of the term "weight loss" on the product information unless there is legitimate scientific support of the product's effects. *Id.*

[69] *See* Cleland, *supra* note 1, at 31-32.

[70] The FTC argues that respected media outlets exacerbate consumer deception when they publish advertising, making the claims more credible. The FTC study reported that while 74% of tabloid publications included at least one certainly false claim, 55% of newspapers and free-standing inserts also contained false claims. *See id.* at 28-30.

[71] Ephedra comes from the Chinese herb Ma Huang. The principal active ingredient is ephedrine, which when chemically synthesized, is regulated as a drug. Traditional Chinese medicine has used natural ephedrine alkaloid products to treat respiratory symptoms. The substance has been heavily marketed with the goals of weight loss and sports performance enhancement. *See* Press Release, U.S. Food and Drug Administration, HHS Acts to Reduce Potential Risks of Dietary Supplements Containing Ephedra (Feb. 28, 2003), *available at* http://www.fda.gov/bbs/topics/NEWS/2003/NEW00875.html.

[72] *See* Stolberg, *supra* note 38. Ephedra products have been linked to heart attack, strokes, and death. The FDA has reported 16,000 adverse effects stemming from ephedra use. Moreover, Dr. Wolfe, of the Public Citizen's Health Research Group, reported 155

Bechler died on February 17, 2003, the day after he collapsed during a workout in Fort Lauderdale, Florida.[73] A bottle of supplements, Xendrine RFA-1, containing ephedra remained in his locker, and doctors speculated ephedra use contributed to his death.[74]

Bechler's death sparked a number of policy decisions to ban ephedra in sports.[75] Studies concerning effects of ephedra use on the body indicated that ephedra poses a graver risk to athletes than other consumers.[76] Thus, the movement to ban ephedra use in competitive sports became especially prevalent.[77]

The risks associated with ephedra in sports, along with adverse effects reports from the general population, led to prohibitions outside of competitive athletics.[78] Illinois and New York became

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deaths caused by ephedra use. *See id.* The dietary supplement industry reported that twelve million Americans used ephedra products in 1999. *See* U.S. Food and Drug Administration, *Evidence on the Safety and Effectiveness of Ephedra*, *supra* note 31. Moreover, the FDA is investigating 17,000 complaints describing harms resulting from ephedra use. *See* Christopher Drew, *Official Urges Ban of Ephedra by Baseball*, N.Y. TIMES, July 25, 2003, at D1.

73 Robert Pear & Denise Grady, *Government Moves to Curtail the Use of Diet Supplement*, N.Y. TIMES, Mar. 1, 2003, at A1. General Counsel of the trade group Ephedra Education Council, Wes Siegner, contended that doctors too quickly linked ephedra use to Bechler's death and maintained that ephedra helps healthy, overweight people lose weight more effectively than diet and exercise. However, the government had received thousands of "adverse events" reports that linked ephedra to strokes, heat strokes, heart arrhythmia, and psychotic episodes. Additionally, more than one hundred people died after using ephedra. These reported dangers still did not satisfy the standard of posing an "imminent hazard" or significant unreasonable risk of injury. *Id.* Thus, the FDA did not announce a national ban until almost one year after Bechler's death.

74 *Id.* Although news of Steve Bechler's death opened eyes for many Americans as to the dangers of ephedra, harms related to ephedra use were known prior to Bechler's untimely death. In 2001, Health Canada issued a warning not to use ephedra products for weight loss or energy and it noted that the FDA had documented at least ten cases of deaths related to ephedra use and thirteen cases of permanent injury from 1997 to 1999. *See* Press Relase, Health Canada, Advisory Not to Use Products Containing Ephedra or Ephedrine (June 14, 2001), *available at* http://www.hc-sc.gc.ca/english/protection/warnings/2001/2001_67e.htm.

75 *See* Drew, *supra* note 72. Major League Baseball is also under pressure to ban ephedra. The National Football League, Major League Soccer, Minor League Baseball and the National Collegiate Athletic Association have already prohibited ephedra use. *Id.*

76 *See id.* Although the FDA had considered banning ephedra for all individuals, FDA commissioner, Dr. Mark D. McClellan, maintained that medical evidence supports at least banning ephedra for sports, as studies show that ephedra has minimal performance enhancement effects and poses serious health risks to athletes, who are already pushing their bodies to the limit. Yet studies on average people using ephedra to lose a few pounds do not have clear results. *Id.* As of 2003, however, enough evidence supported the FDA move to ban ephedra use for all Americans. *See* Stolberg, *supra* note 38.

77 FDA Commissioner McClellan argues that ephedra use can pose more harm to professional athletes than for others since they already heavily exert their bodies. *See* Drew, *supra* note 72.

78 Although the FDA recently implemented the consumer alert in 2003, adverse effects reports had caused the agency to closely scrutinize ephedra manufacturing since 1997. *See* Press Release, U.S. Food and Drug Administration, Consumer Alert: FDA Plans Regulation Prohibiting Sale of Ephedra-Containing Dietary Supplements and Advises Consumers to Stop Using these Products (Dec. 30, 2003), *available at* http://www.fda.gov/oc/initiatives/

the first states to outlaw ephedra.[79] Moreover, retail outlets ceased selling ephedra products to accommodate consumer apprehensions about the product.[80] After the voluntary ephedra product removals,[81] the FDA announced that ephedra would be banned on a national level,[82] and the prohibition became effective on April 12, 2004.[83]

The FDA ephedra ban marked a historic regulatory move[84] because it was the first time a dietary supplement was banned subsequent to the DSHEA's passage in 1994.[85] About five months prior to the ban, the FDA issued a consumer alert and warning to manufacturers[86] to notify them of the upcoming ban.[87] The regulatory

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ephedra/december2003/advisory.html. During the summer of 1997, the FDA first proposed a rule that manufacturers should place content on labels warning consumers not to use ephedra products for more than seven days. The FDA modified the rule in 2000. Finally, in 2003, the FDA announced a series of measures including strong enforcement against ephedra product companies that make unsubstantiated claims. These actions prompted voluntary recalls, warnings, seizures, injunctions, as well as joint enforcement actions with the FTC and Department of Justice. *See id.*

79 *See* Fessenden, *supra* note 62. Pressure from courts adjudicating false advertising cases and regulatory agencies caused manufacturers to engage in self-regulation by substituting substances for ephedra and prompted Illinois and New York state legislatures to ban ephedra products.

80 *See* Rich Thomaselli, *Drug Store Chains to Cease Ephedra Diet Sales*, ADAGE.COM, July 16, 2003. CVS, Eckerd, Walgreens, and General Nutrition Centers ("GNC") have stopped selling ephedra products. Although drug stores accounted for a total of $125 million in profits from ephedra diet supplement products last year, CVS spokesman Mike DeAngelis said that he did not expect a material loss in sales. *Id.*

81 On May 2, 2003, GNC, the nation's largest specialty retailer of nutritional supplements, announced it would discontinue sales of ephedra-based products by the end of June 2003. At that time, it would remove all remaining inventories to adhere to the current business climate, although GNC maintained that ephedra products were safe if used as directed. Thus, GNC President and CEO Michael K. Meyers explained that the launch of ephedra-free dietary supplement, Total Lean, responded to the consumer trend toward ephedra free products. GNC, GNC's Statement on the Discontinuation of the Sale of Ephedra-Based Products (May 2, 2003), *at* http://www.gnc.com/about_gnc/pr_detail.aspx?=150&lang=en.

82 *See* Stolberg, *supra* note 38.

83 *See* Dan Hurley, *As Ephedra Ban Nears, a Race to Sell the Last Supplies*, N.Y. TIMES, Apr. 11, 2004, at 23.

84 *See* U.S. Food and Drug Administration, *FDA Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra, at* http://www.fda.gov/oc/initiatives/ephedra/december2003 (last visited Feb. 7, 2005). On December 30, 2003, the FDA issued a consumer alert advising consumers not to purchase or consume ephedra products. In addition, the FDA warned manufacturers that the agency intends to publish a rule that dietary supplements, which contain ephedrine alkaloids, pose an unreasonable risk of sickness or injury.

85 *See* Stolberg, *supra* note 38. Officials from the Bush Administration announced on December 30, 2003, that ephedra would be banned in the United States due to the unreasonable risk the substance poses to the public in the form of stroke, heart attacks, and death. Ephedra has become popular among Americans for losing weight or improving athletic performance. *See id.*

86 In an example letter to manufacturers of ephedra-containing products, the FDA maintained it intended to publish a rule in the following weeks finding that dietary supplements containing ephedrine alkaloids presented an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling of the product; if no conditions of use were suggested in the labeling, the rule would find such a risk under

move sparked mixed reactions. Ephedra product manufacturers argued that the ban was unreasonable since products were safe if used as directed.[88] Meanwhile, other dietary supplement manufacturers lauded the FDA for taking action before Congress could tighten the agency's authority over all dietary supplements by repealing or amending DSHEA.[89] Finally, consumer advocacy groups claimed the action was insufficient and that the FDA should have been able to regulate before a substantial amount of people suffered injuries and death.[90]

DSHEA requires the FDA to satisfy a high standard of significant and unreasonable risk of illness and injury before the agency can pull the product from the market.[91] Eighteen thousand adverse effects reports and 164 deaths[92] finally satisfied the standard

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ordinary conditions of use, and so the products were, therefore, adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the Act). This rule would become effective sixty days after publication so as to allow for congressional review in accordance with 5 U.S.C. 801-808. *See* General Letter from Joseph R. Baca, Director, Office of Compliance, Center for Food Safety and Applied Nutrition of the U.S. Food and Drug Administration, to companies marketing ephedra dietary supplements (Dec. 30, 2003), *available at* http://www.fda.gov/oc/initiatives/ephedra/december2003/warningltr.html. The final rule became effective April 12, 2004. *See* Dietary Supplements Containing Ephedrine Alkaloids, 21 C.F.R. § 119.1 (2004).

87 *See* Stolberg, *supra* note 38. The ban marks the first time the FDA has removed a supplement product from the market since the passage of the 1994 DSHEA law.

88 *See id.* According to Secretary of Health and Human Services Tommy G. Thompson, the FDA should expect court actions brought by ephedra product manufacturers who contend their products are safe when used properly.

89 *See id.* The Executive Director of the Utah Natural Products Alliance, Loren Israelsen, expressed relief after the ephedra ban since the product has harmed the dietary supplement industry through negative publicity.

90 *See id.* Dr. Sidney M. Wolfe, Director of Public Citizen's Health Research Group, petitioned the FDA to ban ephedra in September 2001 and argued that its announcement more than two years later in 2003 was too late. He maintained that the FDA merely waited until more people died before the agency acted. However, the FDA defends the timing of its actions on its website. "In contrast to drugs, which must be proven safe and effective to be marketed, DSHEA requires FDA to develop evidence post marketing that a dietary supplement presents an 'unreasonable risk of illness or injury.'" FDA, *Questions and Answers about FDA's Actions on Ephedra Dietary Supplements Containing Ephedrine Alkaloids, at* http://www.fda.gov/oc/initiatives/ephedra/february2004/qa_020604.html (last visited Feb. 7, 2005).

91 *See Consumer Alert, supra* note 78. To satisfy the standard of unreasonable risk to human health, the FDA conducted extensive studies about the effects of ephedra use including clinical studies, adverse effect reports, and independent scientific institution RAND Corporation studies. The studies concluded that ephedra has limited effectiveness other than short-term weight loss, raises blood pressure and stresses the circulatory system. In turn, these reactions to ephedra are linked to heart attacks and strokes. *Id.* If the FDA did not have to prove such a high burden of harm, then the agency could have stepped in earlier to regulate ephedra products and prevent deaths and injuries.

92 *See* Dan Hurley, *Judge Clears the Way for U.S. Ban on Ephedra*, N.Y. TIMES, Apr. 13, 2004, at F7. Although two ephedra manufacturers, NVE Pharmaceuticals of Andover, New Jersey, maker of Stacker 2, and the National Institute for Clinical Weight Loss of Birmingham, Alabama, producer of Thermalean, had attempted to implement a restraining order against the ephedra ban, a district court judge in New Jersey upheld the ban, noting the substantial amount of injuries and deaths reported to the FDA. *Id.*

of "significant and unreasonable risk," warranting the ephedra ban.

Despite the ephedra ban's intent to reduce ephedra related injuries, weight-loss and performance enhancing diet supplements may still pose a risk to users due to the industry's lack of pre-market regulation.[93] Courts that have found ephedra product corporations liable for deceptive advertising have criticized the weight-loss diet supplement industry that, overall, receives the same minimal regulation.[94] Although the highly publicized harms of ephedra have led manufacturers to produce products with ephedra substitutes, these products also lack adequate scientific research and could potentially lead to harmful results as well.[95]

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[93] *See* Duenwald, *supra* note 23. Individuals seeking weight-loss products may have a problem finding a product as effective as ephedra. Moreover, ephedra substitutes have not been studied in the long-term so their efficacy is unknown and adverse effects may still result. For instance, products advertised as "ephedra free" may substitute bitter orange containing synephrine, a stimulant with pharmacological properties comparable to ephedra. Similar to effects of ephedra, synephrine constricts blood vessels and a very few number of investigations have concluded the substitute product is safe. *See id.*

In the spring of 1999, a letter by Drs. Firenzuoli, Calapai, and Gori presented data they gathered from experiments conducted using extracts of Citrus X aurantium, the herb that contains synephrine. The letter noted that the smallest dosage caused death in 10% of animals tested, while the highest dosage caused deaths in 50% of animals after twenty-eight days. The doctors concluded the experiment exemplifies the potential danger medicinal plants may cause to humans. However, a response to the letter noted that while products utilizing the medicinal herbs may pose danger, the herbs themselves do not cause harm. *See* Heather S. Oliff, Ph.D., *Is Synephrine from Bitter Orange Safe? A Response Promoted by a Spring 1999 HerbalGram Letter*, HERBCLIP (June 30, 2004), *available at* http://www.herbalgram.org/herbclip/review.asp?i=43868.

After the ephedra ban, about two-thirds of ephedra users began using alternative products, which could pose comparable health risks. Just as the combination of ephedra and caffeine caused harmful results, the herbal combinations, including ephedra substitutes, may lead to dangerous results. The herbs alone, however, might be safe. As of July 2004, consumers had already reported 169 reactions from bitter orange products. Animal studies suggest bitter orange causes similar effects as ephedra, including raised heart rate, respiratory rate, and blood pressure, especially among people who should avoid stimulants in general. *See* Shari Roan, *Ephedra-Free Weight-Loss Supplements Scrutinized*, L.A. TIMES, July 19, 2004, at F1. According to Yale psychology department chairperson Kelly Brownell:

> The idea that a pill, a mixture of herbs, or anything else will allow people to lose weight and keep it off without any other effort is completely ridiculous . . . . You look at a study that, in the end, followed seven people for a year and you can conclude nothing from that.

See Specter, *supra* note 1. Thus, the dietary supplement industry, as a whole, performs minimal research, so effectiveness and safety cannot be guaranteed.

[94] *See* Fessenden, *supra* note 62. The court found Cytodyne Technologies, maker of Xenadrine RFA-1, the supplement implicated in the death of a Baltimore Orioles pitcher, had exaggerated the findings of commissioned clinical trials and deceived some researchers into manipulating results in published scientific articles. The court found the evidence demonstrated that researchers conducted studies to justify money being spent to ensure continued business from the company. The judge criticized the diet supplement industry for employing problematic research methods that fail to adhere to strict standards. *Id.*

[95] *See* Duenwald, *supra* note 23. Little research exists for ephedra-substitute products, especially the new product ingredient synephrine. Studies for diet supplements often rely on only twelve subjects. Moreover, studies published in short meetings or obscure journals may lead to statements claimed to be "clinically proven." *Id.* Thus, relying on manufactur-

IV. Imposing Media Responsibility Over Weight-Loss Product Advertising Threatens First Amendment Freedoms

Not only has the current regulatory scheme proven inept, as demonstrated by the ephedra case study, but the existing scheme is also constitutionally suspect because it threatens publishers' First Amendment rights. In the effort to fight obesity and simultaneously guard against deceptive advertising, the FTC proposes enhancing media responsibility.[96] In May 2000, the Partnership for Healthy Weight Management embarked on a campaign to promote media responsibility for screening false claims in weight-loss products.[97] However, the media has not responded. Although media companies screen for taste and appropriateness of advertising content for their particular audiences,[98] the media is reluctant to screen for validity of claims.[99] Exceptions include the major television networks NBC, CBS, and ABC, which do maintain stringent advertising clearance standards requiring advertisers to submit proposed advertisements with adequate substantiation for all claims.[100]

A. *FTC Proposal to Impose Media Responsibility over Advertising Conflicts with the First Amendment Protections of Commercial Speech*

Although the FTC maintains that media screening would be a valuable means of ensuring consumer safety, prior efforts to advance media responsibility have failed in favor of First Amendment protected speech.[101] Government attempts to regulate advertising

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ers to conduct their own scientific research leads to faulty findings because the investigators have a stake in the results.

96 *See* Cleland, *supra* note 1, at 28-30. The FTC argues that although government agencies and self-regulatory groups can take action after false ads have been distributed and viewed by the public, only the media can halt deceptive advertising before an unsuspecting public can view the ads.

97 *See id.* at 29. The Partnership named the campaign Ad Nauseam in an effort to promote media responsibility for weight-loss advertising. The Partnership identified such claims as "Lose up to 2 Pounds Daily . . . Without Diet or Exercise"; "U.S. Patent reveals weight loss of as much as 28 lbs. in 4 weeks and 48 lbs. in 8 weeks"; "Eat all your favorite foods and still lose weight (the pill does all the work)"; "You lose weight even if you eat too much"; and "You will lose at least 16 pounds in the first two weeks. And at least six pounds every week thereafter." These claims, among others, appeared in such publications as *Cosmopolitan, Esquire, McCall's, Redbook*, etc. Despite the campaign, the media has not responded, and advertising including comparable claims continues to appear in the mainstream media. *See id.* at 29.

98 *See* Cleland, *supra* note 1, at 29.

99 *Id.* Magazine publishers argue that placing liability on media for false advertising would result in automatic rejection for all products claiming weight loss results. Ira Teinowitz, *Publishers Attack Diet Ad Screening Plan*, ADAGE.COM, Nov. 20, 2002.

100 *See* Cleland, *supra* note 1, at 29.

101 In the area of defamation, the courts uphold a high standard of proving the media's "actual malice" in order to promote robust debate and the marketplace of ideas. *See* N.Y.

are subject to a court's intermediate scrutiny.[102] Courts engage in a four-part balancing test to determine the validity of the government regulation. The four elements of the test are the following: 1) the legality of the commercial activity; 2) the substantiality of the government interest; 3) whether the regulation directly advances the government interest; and 4) the extensiveness of the regulation.[103] Because the First Amendment affords protection to commercial speech and freedom of the press, courts should not uphold regulations that restrict too much speech in an attempt to accomplish the government's interest.[104]

While the Supreme Court has identified First Amendment protection for commercial speech, false, misleading speech is never protected.[105] The FTC maintains that in order to combat the problem of false advertising in weight-loss products, advertisers, publishers, and endorsers should assume some responsibility for misleading the public. Although the FTC has the authority to prosecute advertisers after the ads have been disseminated, the FTC argues media pre-screening ads would prevent harm to the public.[106] Media publishers, however, do not have a legal duty to

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Times v. Sullivan, 376 U.S. 254, 269 (1964). Moreover, the Supreme Court recognized a First Amendment protection for commercial speech in 1976 in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 777 (1976).

> In contrast to the press, which must often attempt to assemble the true facts from sketchy and sometimes conflicting sources under the pressure of publication deadlines, the commercial advertiser generally knows the product or service he seeks to sell and is in a position to verify the accuracy of his factual representation before he disseminates them.

Id. (Stewart, J., concurring).

102 *See* 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 484 (1996) (holding a Rhode Island statute unconstitutional that prohibited advertising alcoholic beverage prices). The Court found a tailoring problem with the statute since the state legislature could have used alternative means to combat deceptive advertising that did not restrict truthful speech. *Id*; *see also* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 569 (2001) (holding that restricting advertising space for tobacco products did not adequately achieve the goal of reducing sales to minors). In *Lorillard Tobacco,* the Court articulated the value of commercial speech and that spot zoning cannot be utilized to heavily restrict advertising when alternative means are available to achieve the legislative purpose. *Id.* Although commercial speech receives intermediate scrutiny by the courts, the Supreme Court has applied a strong tailoring requirement to ensure that truthful advertising is not curtailed when less restrictive means are available to benefit the public welfare.

103 Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564-66 (1980).

104 *See* Daniel E. Troy, *Advertising: Not "Low Value" Speech*, 16 YALE J. ON REG. 85 (1999) (arguing that commercial speech has a history of containing a high value to society and that attempts to restrict truthful commercial messages should face the same court review as attempts to limit content of other speech deemed to have high value such as political speech).

105 *See id.* at 564.

106 *See* Cleland, *supra* note 1, at 28-30. Industry professionalism in the late nineteenth century led to a growth in advertising. *See* Troy, *supra* note 104, at 114-15. The growth of advertising prompted government checks on advertising that the public perceived as faulty. Magazines such as the *Ladies Home Journal* and *Collier's* led the campaign against

screen advertising for truthfulness.[107]

In addition to dietary supplement manufacturers, the FTC has brought actions against parties it holds responsible for delivering misleading messages to the public.[108] The FTC maintains that particular formats have higher potential for deception than others.[109] Advertisements in the form of infomercials have greater potential for fraud – they disguise traditional advertisements, appear as honest testimonials, and are more comparable to talk shows than average commercials.[110] Thus, when baseball player Steve Garvey hosted an infomercial, endorsing the dietary supplement product Enforma Natural to promote weight loss, the FTC brought an action against the endorser Steve Garvey and his corporation, Garvey Management Group.[111] The court found that the endorser or ad-

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fraudulent claims made by the medicine industry. Moreover, some newspapers, including those within the Scripps McRae League of Newspapers, appointed censors to examine all advertising copy to guard against suspicious claims.

The public concern led to an outcry over dangerous foods and drugs and, ultimately, to the passage of the Federal Food and Drug Act of 1906. The act forced manufacturers to justify the claims and ingredients listed on their products. *Id.* Although publishers initiated the reform movement, with some media companies instituting censors to prescreen advertisements, the passage of the Federal Food and Drug Act of 1906 illustrates that federal agencies, not manufacturers, are best equipped to substantiate claims.

107 *See generally* Consuelo Lauda Kertz & Roobina Ohanian, *Recent Trends in the Law of Endorsement Advertising: Infomercials, Celebrity Endorsers and Nontraditional Defendants in Deceptive Advertising Cases*, 19 HOFSTRA L. REV. 603 (1991). *See also* Pittman v. Dow Jones & Co., 662 F. Supp. 921 (E.D. La. 1987) (dismissing newspaper readers' complaints against the Wall Street Journal ("WSJ") when the readers invested in an unstable financial institution after viewing the institution's advertisements in the newspaper; the plaintiffs made no allegations that the WSJ had any knowledge of the falsity of the statements). The court found that "a newspaper has no duty, whether by way of tort or contract, to investigate the accuracy of advertisements placed with it which are directed to the general public, unless the newspaper undertakes to guarantee the soundness of the products advertised." *Id.* at 922. *See also* Walters v. Seventeen Magazine, 241 Cal. Rptr. 101 (Cal. Ct. App. 1987) (holding that the magazine, which has heavy teenage readership, was not liable in tort to a minor who contracted toxic shock syndrome after using Playtex tampons advertised in the magazine). The California Court of Appeals expressed reluctance to create a new tort that required publishers to scrutinize advertisements and test products before publication. *Id.*

A legal cause of action does exist, however, where a publisher specifically undertakes to endorse an advertised product. *See* Hanberry v. Hearst, 81 Cal. Rptr. 519 (Cal. Ct. App. 1969) (holding that Hearst, publisher of *Good Housekeeping*, could be liable where the monthly magazine permitted its advertisers to attach the "Good Housekeeping Consumer's Guaranty Seal" to their products, certifying quality products and truthful claims). The court relied on a negligence theory of liability as the magazine voluntarily used its reputation to help promote the sale of a product. *Id.*

108 *See* FTC v. Garvey, No. 00-9358 GAF (CwX), 2002 U.S. Dist. LEXIS 25725 (C.D. Cal. Nov. 25, 2002).

109 *See* Kertz & Ohanian, *supra* note 107, at 615-16. For instance, the FTC has expressed concern over infomercials, or five to thirty minute advertisements that often take the form of interviews, talk shows, product demonstrations, or consumer information programs. Infomercials tend to disguise the commercial nature of the program that often includes unsubstantiated claims for items of questionable value.

110 *See* Kertz & Ohanian, *supra* note 107, at 605.

111 *See Garvey*, 2002 U.S. Dist. LEXIS 25725, at *3. Steve Garvey agreed to serve as spokesperson for Enforma Natural's product, Fat Trapper, by completing two infomercials

vertising agency should not be found liable for what ultimately surfaced as misleading claims.[112] Important to the inquiry of liability for misleading consumers is the degree of control over the fraudulent activities.[113] The court found Garvey did not have adequate control over the misrepresentation to make him liable, thus declining to create additional liability for advertising agencies and endorsers.[114]

B. *First Amendment Jurisprudence Protects Commercial Speech*

The FTC has created guidelines for media publishers to encourage pre-screening of submitted advertisements[115] that threaten

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as well as off-screen events including trade shows and radio broadcasts promoting the product. *Id.* In addition, Enforma retained the agency Modern Media to produce the television infomercials. Garvey read from preexisting scripts or acted under the direction of Modern Media and Enforma representatives. *Id.* at *10-11.

112 *Id.* at *20-21. The court found that Garvey did not possess actual knowledge of manufacturer misrepresentations nor did he act recklessly indifferent toward the truth of his representations. *Id.* Moreover, to be found liable under section 5(a) of the FTC Act, Garvey must have either controlled or participated in the creation and/or dissemination of the unlawful advertising claims. *Id.* at *18-19. Under a participant theory of liability, Garvey should still not be liable because the FTC could not prove that Garvey's statements were unsubstantiated or that Garvey knew the statements were inadequately unsubstantiated. All that is required is that Garvey's statements reflect his good faith belief and opinions and that his statements are reasonably substantiated. *Id.* at *20.

113 *Id.* at *17 (distinguishing from other participant defendants found liable in cases such as *FTC v. Publ'g Clearing House*, CV-S-94-623-PMP (LRL), 1995 U.S. Dist. LEXIS 19560 (D. Nev. Mar. 8, 1995) (where defendants actively participated in fraud) and *FTC v. Affordable Media, LLC*, 179 F.3d 1228 (9th Cir. 1999) (holding corporate officers with day-to-day control over fraudulent activities were liable, but the celebrity recording artist who appeared in the commercial was not)).

114 The court quoted the Federal Trade Commission Act of 1914, 16 C.F.R. § 255.0(b) (2000), which defines "endorser" as "one who delivers a message that 'consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser.'" The defense in the *Garvey* case called expert witness Dr. Thomas Hollihan, Ph.D., who testified that Garvey did not constitute an "endorser" because it was highly unlikely Garvey invoked his personal experiences when making his televised statements; Hollihan noted that the infomercials portrayed Garvey as naïve and learning about the Enforma products. *See Garvey*, 2002 U.S. Dist. LEXIS 25725, at *15. Moreover, to be found liable for false advertising under the Federal Trade Commission Act of 1914, a person must have either controlled or participated in the creation and/or dissemination of the unlawful advertising claims. *See id.* at *15-16. The *Garvey* case represented a major defeat for the FTC, which had hoped to set a precedent that parties other than manufacturers can be liable for producing misleading claims. Instead, the court agreed with Steve Garvey that, as an actor, he could not be sued for the profits he made from the infomercials. *See* Ira Teinowitz, *FTC to Give Media Cos. Guidelines for Diet Ads*, ADAGE.COM, Jan. 24, 2003.

115 *See* U.S. Federal Trade Commission, *FTC Releases Guidance to Media on False Weight-Loss Claims, at* http://www.ftc.gov/opa/2003/12/weightlossrpt.htm (last visited Feb. 7, 2005). The FTC has announced the agency will provide a free "Red Flag" booklet to notify media of red flags that weight-loss product claims are false so that the media can voluntarily refuse to run those ads in their publications. According to former FTC Chairman Timothy Muris, "[u]nfortunately, there are way too many ads for scientifically impossible weight-loss products in the popular media. The media should institute screening programs to 'red flag' deceitful weight-loss ads and refuse to run them." The goal of the FTC guidance is to allow the media publishers to screen advertisements on a facial review rather than an in-

First Amendment freedoms. During his tenure as FTC Chairman, Timothy J. Muris appealed to the media to act responsibly by refusing to publish "obviously deceptive" ads that "make claims and promises that are clearly implausible and patently false . . . ."[116] To accomplish the goal of consumer protection, the FTC advocates that the media compare submitted advertisement claims to statements the FTC provides on a list of typically false, misleading claims.[117] Encouraging the media to pre-screen material prior to publication based on content resembles prior restraints that First Amendment case law abhors.[118] The First Amendment protection of freedom of the press has been the thrust of publishers' resistance to media screening.[119] Although the United States jurisprudence has historically disapproved of prior restraints in favor of robust debate in a free media and has recognized commercial speech as valuable,[120] the FTC notes that the law does not uphold

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depth analysis. The FTC has identified seven claims popular in weight-loss product advertising that tend to be false: 1) "[c]auses weight loss of two pounds or more a week for a month, or more without dieting or exercise"; 2) "[c]auses substantial weight loss, no matter what or how much the consumer eats"; 3) "[c]auses permanent weight loss (even when the consumer stops using the product)"; 4) "[b]locks the absorption of fat or calories to enable consumers to lose substantial weight"; 5) "[s]afely enables consumers to lose more than three pounds per week for more than four weeks"; 6) "[c]auses substantial weight loss for all users"; and 7) "[c]auses substantial weight loss by wearing it on the body or rubbing it into the skin." *Id.*

116 Muris argued that the abundant placement of advertising in respected publications makes the claims credible and contributes to public deception. He spoke to the Cable Television Advertising Bureau on February 11, 2003, maintaining that the FTC would continue to bring false advertising actions against deceptive manufacturers. However, he warned that the public should not rely on the federal agency alone for its protection. The FTC Chairman explained that rather than hiring scientists to analyze advertiser claims, the media should merely compare the advertising claims to a list the FTC planned to provide cataloging popular fraudulent claims. *See* U.S. Federal Trade Commission, *FTC Chairman Urges Media to Help Combat Deceptive Weight Loss Advertising, at* http://www.ftc.gov/opa/2003/02/weightloss.htm (last visited Feb. 7, 2005). The FTC did provide the media with the list of proscribed claims in its Red Flag booklet recently made available. *See* id. For more information, see the Red Flag site at http://www.ftc.gov/redflag, which advises media publishers to avoid obtaining a reputation for "promot[ing] rip-offs."

117 *See id.*

118 *See* Near v. Minnesota, 283 U.S. 697 (1931) (holding unconstitutional a statute that required prior restraints of newspapers once the publication had defamed someone's character). The Court distinguished punishment for defamation after defamation has occurred from prior restraints that the Court referred to as "the essence of censorship." *Id.* at 713. More recently, the Court struck down a statute mandating licensing for door-to-door solicitation as the statute constituted a prior restraint that chilled commercial and political speech and infringed speakers' anonymity. *See* Watchtower Bible & Tract Soc'y v. Stratton, 536 U.S. 150 (2002).

119 Publishers have argued that detecting false advertising should remain the role of the FTC, not the mass media. Hearst spokesman Paul Luthringer said, "The FTC would, in effect, be exerting prior restraint on what a publisher can or cannot publish, which is an abridgment of freedom of the press guaranteed by the First Amendment." Nat Ives, *Media Companies are Raising their First Amendment Flags*, N.Y. TIMES, Feb. 13, 2003, at C4.

120 *See, e.g., Near*, 283 U.S. at 697; *44 Liquormart, Inc.*, 517 U.S. at 484.

false advertising as protected speech.[121]

The danger of pre-screening suspicious advertising is that the media will curtail legitimate, truthful speech in order to ensure that false speech does not get published.[122] If magazine editors or television broadcasters could be liable for diet supplement advertising, then Internet Service Providers ("ISPs") may similarly be held responsible for Web sites that promote deceptive diet supplement products. However, the American legal system has already rejected ISP liability in favor of promoting Internet access to users.[123] As the line of cases protecting ISPs illustrates, media publishers should not be held responsible for content in order to promote the dissemination of speech and consumers' access to information.

As an alternative to advocating prior restraints on the media, federal agencies could restrict the time, place, and manner of advertising weight-loss supplement products by implementing restrictions that are comparable to those placed on alcohol and tobacco

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[121] Muris defended against the argument that the FTC media screening proposal would harm First Amendment concerns:

> The media, appropriately, do have substantial First Amendment protection. Yet, there is no Constitutional right to run false commercial advertising, just as there is no Constitutional right to make false statements about individuals in your news stories. You take extensive steps to prevent defamation. We are asking for modest steps to prevent fraud.

FTC Chairman Urges Media to Help Combat Deceptive Weight Loss Advertising, *supra* note 116.

[122] Magazine publishers argue that placing more responsibility on the media to prescreen advertisements will cause the media to be more cautious in the content it accepts, and reject more advertisements than necessary. *See* Ira Teinowitz, *FTC Says They Put 'Pocketbook Interests' above 'Public Interest,'* ADAGE.COM, Nov. 20, 2002. Moreover, the courts have become weary of regulating speech instead of conduct when alternative means are available that do not require restricting speech.

> [A]ttempts to regulate speech are more dangerous than attempts to regulate conduct. That presumption accords with the essential role that the free flow of information plays in a democratic society. As a result, the First Amendment directs that government may not suppress speech as easily as it may suppress conduct, and that speech restrictions cannot be treated as simply another means that the government may use to achieve its ends.

44 Liquormart, Inc., 517 U.S. at 512. Justice Stevens explained that alternative methods could be utilized to achieve the government objective of curbing alcohol consumption, such as per capita purchases comparable to prescription drugs or educational campaigns. *Id.* at 507. In the case of weight-loss dietary supplements, increased educational campaigns could be implemented to promote healthy behavior such as lowering caloric intake and increasing physical activity. Placing more speech in the marketplace about healthy lifestyles should be used to combat false ideas rather than invoking prior restraints that chill speech.

[123] *See* Justin Hughes, *The Internet and the Persistence of Law*, 44 B.C. L. REV. 359, 383-386 (2003) (arguing that imposing strict liability on ISPs for third-party defamation and copyright infringement would lead to ISPs gradually going out of business due to adverse judgments or policing costs necessary to keep infringing material off their system). Legislation shielding ISPs from liability includes Section 230 of the Consumer Decency Act of 1996 ("CDA") which shields providers from liability so long as "the provider of 'an interactive computer service' [i]s not responsib[le] 'for the creation or development of [the] information.'" *Id.* at 385 (quoting 47 U.S.C. § 230(c)(1) (2000) (alteration in original)).

advertising.[124] The government has more latitude to regulate conduct or manners of expression that does not involve restricting expression or viewpoints.[125] However, sometimes the line between time, place, and manner restrictions and content restrictions can be a very fine one to draw.

In 1996, the FDA sought harsh advertising and promotion restrictions over tobacco.[126] The tobacco companies agreed to adhere to many of the restrictions after a $206 billion agreement was reached with forty-six states in 1998.[127] Not only do the advertising restrictions limit commercial speech, but evidence suggests the restrictions do not adequately achieve the goal of reducing smoking among minors.[128] Analogously, imposing manner restrictions for

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124 *See Lorillard Tobacco*, 533 U.S. 525 (striking down Massachusetts regulations covering the advertising and sale of tobacco products). The Court found that the regulations involved spot zoning that would effectively prohibit advertising and displays, while not reasonably fitting with the goal of reducing minors' access to tobacco products. *Id.* The Court also noted that alternative means could achieve the ends without a heavy burden on speech. However, the Court upheld the state requirement of placing tobacco products behind sales counters since that directly helped assure minors would not have easy access to the products. This requirement also did not restrict expression, nor an adult's ability to purchase cigarettes, but it did leave open additional channels for vendors to communicate to consumers.

125 *See* Ward v. Rock Against Racism, 491 U.S. 781 (1989) (holding that a city could restrict a rock band performance to regulate noise levels). The government may implement reasonable time, place, and manner restrictions that are not based on speech content, that are narrowly tailored to uphold a significant government interest, and that leave available sufficient alternative modes of communication.

126 *See* Troy, *supra* note 104, at 136-37. The FDA proposed restrictions including a prohibition of imagery or colors in outdoor, print, and direct mail advertising; elimination of outdoor advertising for tobacco products within 1000 feet of a public playground or elementary or secondary school, effectively banning outdoor advertising for urban areas such as Manhattan; banning sponsorship of athletic, social or cultural events under the name of a tobacco product, such as the Virginia Slims Tennis tournament, which would apply to events that did not include large child audiences; outlawing the sale or distribution of non-tobacco merchandise containing names of tobacco product brand names; and forbidding tobacco advertising in any medium not granted FDA approval, unless a tobacco company provided the agency with thirty days advance notice. *Id*; *see also* 21 CFR §§ 801, 803, 804, 807, 820, and 897 (1996) (pertaining to FDA's asserted authority to regulate tobacco as part of the act to regulate drug delivery devices). However, the Supreme Court held that the FDA lacked authority to regulate tobacco and set aside the FDA attempt at advertising regulations in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

127 *See* Bernard Stamler, *Circumscribed by Law, Tobacco Companies Look for New Ways to Get Their Message Across*, N.Y. TIMES, May 2, 2001, at C7. In addition to a pre-existing ban on television and radio advertising, the settlement prohibited cigarette companies from marketing or selling products to young people, sponsoring events with significant numbers of teenagers in attendance, advertising on billboards or public transportation, using cartoon characters in advertisements, and selling clothing with logos.

128 *See id.* Although cigarette companies must comply with restrictions on advertising, companies have been employing alternative methods to communicate their messages and continue to maintain profitable businesses. Advertising methods include substantial direct mailings to adults, magazine advertisements in publications where publishers certify that at least 85% of its readers are adults, and strategic point-of-sale displays. President of the Campaign for Tobacco Free Kids, Matthew L. Myers, maintains that marketing messages can still be reached by teenagers, whom advertisers continue to target. Myers offered examples including point-of-sale displays that are visible to minors and a recent Kool offer of

diet supplement advertisements may pose less risk of encouraging prior restraints but could still prove inadequate in protecting speech. Restrictions aimed at manner rather than content could still curtail truthful speech by legitimate manufacturers, and such restrictions may not achieve the desired goal of reducing risks to consumers who will receive advertising messages anyway.[129]

V. CONGRESS OUGHT TO AMEND DSHEA TO REQUIRE RESEARCH AND SUBSTANTIATION BEFORE DIETARY SUPPLEMENTS ENTER THE MARKET AND CAUSE FATAL INJURIES

Instead of advertising restrictions that could chill First Amendment-protected commercial speech, the legislature should give the FDA more authority to regulate dietary supplements in a manner analogous to the FDA's regulatory power over drugs. Requiring pre-market approval based on serious scientific research and substantiation would help cure current problems regarding minimally regulated dietary supplements. Amending DSHEA would allow the FDA to share regulation responsibilities, alleviating the burdens placed on the FTC, which is currently the primary regulator of dietary supplements.[130] Moreover, regulations for dietary supplements comparable to controlled substances would eliminate the seemingly arbitrary distinctions between dietary supplements and drugs, illustrated by current doping scandals in sports.[131] Finally, pre-

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a free CD-opener with the purchase of a pack of cigarettes. Moreover, the FTC released figures that tobacco advertising of all kinds dramatically increased since the 1998 settlement reaching $8.24 billion in 1999. *Id.*

129 Even if imposing time, place, and manner advertising restrictions on dietary supplements did not threaten to curtail valuable speech, such restrictions would be much more difficult to implement with dietary supplements than with tobacco products. Because the law prohibits minors from purchasing cigarettes, regulating minors' access to tobacco is a legitimate interest. However, the law does not prohibit a specific class of people from purchasing dietary supplements. Thus, altering the manner of advertising without regulating content would not effectively curb false advertising among dietary supplement manufacturers.

130 *See* Pinco & Halpern, *supra* note 26, at 579. While DSHEA limited the FDA's ability to regulate dietary supplements before they enter the marketplace, the FTC has had to take a stronger role in instituting actions against fraudulent advertisers. Meanwhile, the lack of pre-market regulation has led to a substantial increase in products and advertising, further placing demands on the FTC's ability to regulate.

131 *See* Donald G. McNeil, Jr., *Drug Testing: Acting Quickly, U.S. Bans Newfound Steroid*, N.Y. TIMES, Oct. 29, 2003, at D1. The FDA's ability to regulate performance enhancing substances depends on the fine distinction between dietary supplements and controlled substances. The FDA banned a new steroid, tetrahydrogestrinone ("THG"), claiming the product is not a dietary supplement but rather a synthetic designer steroid derived from a banned drug. THG comes from the drug gestrinone, banned by the United States Anti-Doping Agency. "Regulation of anabolic steroids is confused and inconsistent. Other testosterone precursors, like androstendione and DHEA, which have the same body-building properties and the same dangerous side effects, are classified as food supplements and sold in health-food stores." *Id.* Currently, the Senate is considering legislation to bring anabolic steroids under the FDA's jurisdiction as controlled substances. *Id.* Although lessen-

market regulations would help prevent fatal injuries caused by unsafe products.[132] Congress is currently considering bills to amend DSHEA that will, if passed, allow for enhanced regulation over the dietary supplement industry.[133]

Regulating dietary supplements in the same manner that drugs are currently regulated would prevent substantial injury to the public. Dietary supplement manufacturers contend that the FDA's recent ban of ephedra illustrates the efficacy of the current law.[134] However, advertising products as "ephedra-free" does not eradicate consumer health risks.[135]

Just as the FDCA responded to thousands of deaths resulting from unregulated "patent medicines,"[136] legal protections are needed to protect consumers before minimally regulated diet supplements cause more harm. The average consumer assumes that if a product enters the marketplace, then it must have received government approval.[137] False assumptions about the existence of

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ing manufacturers' ability to classify their products as dietary supplements would help solve the confusion and inconsistency that the lack of regulation in this area has caused, narrowing the scope to steroids and sports performance enhancers would not solve the problems still prevalent in the weight-loss product and other industries.

132 *See* Stolberg, *supra* note 38. Before the FDA announced the plan to ban ephedra products, the supplement was linked to heart attacks, strokes, and death.

133 Congress is considering bills to amend DSHEA. *See* Specter, *supra* note 1; *see also US Congress Must Act on Ephedra, House Panel Told; HHS Sec Says "Amend DSHEA,"* NUTRACEUTICALS INTERNATIONAL, Aug. 2003. The House Energy and Commerce Committee subcommittees held hearings in late July 2003. The subcommittees considered amending DSHEA after discussing ephedra-containing dietary supplements and hearing testimony attacking dietary supplement manufacturers' integrity. *Id.* Examples of proposed bills include the following: 1) the Dietary Supplement Information Act, H.R. 724, 108th Cong. (2003), proposing to amend the FDCA to require that manufacturers of dietary supplements register with the FDA and submit adverse experience reports to the agency; and 2) the Dietary Supplement Access and Awareness Act, H.R. 3377, 108th Cong. (2003), proposing to establish the Dietary Supplement Access and Awareness Act and to amend the FDCA with respect to product listing, reporting, post-market surveillance, and other provisions to enhance the safety of dietary supplements. Moreover, Senator Richard J. Durbin, a Democrat from Illinois, has strongly advocated amending DSHEA to implement stringent regulations of diet supplements. According to Senator Durbin, "They have a handful of people monitoring a multibillion-dollar industry. Until we change the basic law, the F.D.A. will never be able to enforce it." Hurley, *supra* note 83. Recently, Senator Durbin has expressed concern over bitter orange, which many consumers welcomed as an alternative to ephedra. Durbin and Senator Orrin G. Hatch, a long-time dietary supplement industry supporter, introduced a bill that would mandate that dietary supplement manufacturers promptly report adverse events. Roan, *supra* note 93.

134 *See* Stolberg, *supra* note 38. Dietary supplement manufacturers expressed relief that the FDA banned ephedra before Congress could create a harsher regulatory framework for the entire industry.

135 *See* Duenwald, *supra* note 23. Ephedra substitutes also receive limited regulation, and long-term effects have not been studied. Thus, the potential for similar adverse effects exists.

136 *See* Specter, *supra* note 1.

137 A recent Harris Poll gathered consumer assumptions about products on the market. According to the poll, most individuals believe that supplements on the market must have had government approval, product claims must be based on data to substantiate those

government regulation create a false sense of security when consumers purchase the ever more popular weight-loss supplements. Thus, Congress should implement claim substantiation and approval requirements before a product enters the market to protect consumers who expect protection from government agencies against harmful substances.

An amendment to DSHEA would alleviate burdens faced by the FTC, currently strained with the primary responsibility of regulating dietary supplement advertising. Treating dietary supplements like drugs would solve problems of confusion when the line between dietary supplements and drugs blurs.[138] In addition, placing the burden on the dietary supplement manufacturers to adequately research effects of their products and substantiate all claims decreases the risk of chilling commercial speech by encouraging the media to cease publishing advertisements for weight-loss supplements. Finally, pre-market regulation would prevent injury and death by authorizing agencies to act before thousands of adverse-effect reports flood agency offices.

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claims, and companies must disclose warnings about potential risks and side effects. Unfortunately, each consumer assumption is false. *See id.*

138 *See* Paul L. Montgomery, *Olympics; I.O.C. Falters in Doping Bid as Summit Ends*, N.Y. TIMES, Feb. 5, 1999, at D1. In 1999, the International Olympic Committee ("I.O.C.") developed a drug policy that banned certain substances from athlete consumption. I.O.C. leaders criticized United States sports' organizations more lenient policies. While Mark McGwire, who admittedly used the supplement androstenedione, was celebrated among American sports fans, the I.O.C. prohibited the same substance and called for disciplinary action against athletes who consumed it.

More recently, anti-doping officials are investigating the dietary supplement manufacturer Bay Area Laboratory Co-Operative ("Balco") for supplying the steroid THG to athletes. Balco owner Victor Conte, Balco vice president James Valente, baseball player Barry Bonds' trainer Greg Anderson, and track coach Remi Korchemny were charged with steroid distribution in a case that implicates well known track and baseball athletes who may have used the substances. *See Conte Accuses 'feds of cheating,'* N.Y. TIMES, November 3, 2004, at D18. Sports psychologist Steven Ungerleider speculates that laboratories work with athletes and chemists to concoct designer drugs that will escape detection. *See* Jere Longman, *Drug Testing: Drugs in Sports Creating Games of Illusion*, N.Y. TIMES, Nov. 18, 2003, at D1. For instance, Yankees rightfielder Gary Sheffield admitted he unknowingly used THG in 2002 when Greg Anderson gave him a Balco cream containing the substance to rub daily on his surgically repaired knee. See Tyler Kepner, *Baseball Will Not Discipline Sheffield*, N.Y. TIMES, Oct. 6, 2004, at D6.

The problems of the doping scandals illustrate that dietary supplements can be as harmful as drugs. More importantly, it is often hard to distinguish between a drug or steroid and a dietary supplement. Notwithstanding identical practical effects on the body, slight chemical alterations in the substances can alter the classification and, in turn, determine the regulatory scheme. Currently, Senators Joseph Biden and Orrin Hatch are cosponsoring a bill that would list steroid hormone precursors such as androstenedione under the Controlled Substances Act. Although THS manufacturers have argued the substance is a diet supplement, the FDA has determined the synthetic steroid is actually an unapproved new drug. Classifying all such performance enhancers as controlled substances would alleviate further confusion between manufacturers and athletes and allow FDA to regulate those products. *See US Dietary Supps, supra* note 41.

CONCLUSION

Dietary supplement manufacturers have become the modern day "patent medicine men," promising to solve Americans' ailments with powerful elixirs. In the context of the obesity epidemic and socio-cultural pressures to become thin, American consumers latch on to dietary supplements that tempt them with lofty promises. Just as substantial injuries and deaths called medical officials' attention to the dangers of "patent medicines," scientists have realized the harms of reliance on dietary supplements that profess to be "miracles in a bottle."[139]

Unfortunately, inadequate regulation has led to increased instances of false advertising and cases of actual harm. The ephedra ban did not solve the problem, as all substances classified as dietary supplements receive no pre-market regulation.[140] Working under DSHEA, the FTC seeks media screening to aid it in its regulation of post-market false advertising cases; such screening threatens First Amendment protected commercial speech.

The best alternative, instead, is to amend DSHEA and allow for pre-market regulation. Added FDA regulatory authority would decrease the burden on the FTC. Furthermore, dietary supplements often are not functionally distinguishable from drugs.[141] More significantly, pre-market regulation would prevent injuries and deaths.[142] In the context of obesity being a factor in hundreds

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139 *See* Specter, *supra* note 1. Dietary supplement advocates and manufactures associate weight-loss supplement popularity with religion, offering hope to consumers who seek solutions for lack of energy and abundance of body fat.

140 Manufacturers can often receive the benefits of minimal regulation by classifying products as dietary supplements, often accomplished by clever linguistics. Although claiming a product treats a disease subjects the product to FDA pre-market approval, manufacturers can assert that the product affects the structure or function of the body without mentioning the disease, thereby avoiding pre-market review. Director of the Office of Dietary Supplements at the NIH, Paul M. Coates, said, "The laws allow manufacturers to make fine legalistic claims. What we now have is an entire cottage industry of creative linguistics dedicated solely to selling these products." *See* Specter, *supra* note 1. Moreover, limited research requirements mean that consumers do not actually have a firm basis to believe the claims dietary supplement manufacturers do make.

141 In support of this idea, Sideny Wolfe, the director of the Public Citizen's Health Research Group said the following:

> The remedy for all this is to stop dangerously pretending that pharmacologically active substances called dietary supplements should be treated completely different from pharmacologically active substances called drugs. You cannot determine if they are safe or effective without doing the studies. And with supplements the studies are almost never done.

Specter, *supra* note 1 (quoting Public Citizen's Health Research Group director Sidney Wolfe).

142 Although the FDA had information regarding the harmful effects of ephedra, the high standard of proving significant and unreasonable risk of illness and injury left the FDA unable to act until thousands of injuries and scores of deaths occurred. *See supra* note 24 and accompanying text.

of thousands of American deaths annually and tens of millions currently attempting to lose weight, the products people rely on ought to give them some assurance of safety and efficacy. Rather than waiting until after a substantial number of fatal injuries occur, dietary supplements require regulation before they enter the booming weight-loss market.

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