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REGULATING THE DIETARY SUPPLEMENTS INDUSTRY: SOMETHING STILL NEEDS TO CHANGE

Debra D. Burke* and Anderson P. Page**

I. INTRODUCTION

As Americans have become increasingly interested in diet and good health, it is not surprising that the dietary supplement industry has enjoyed a substantial level of sales and an impressive growth curve. Dietary supplement products generated sales of nearly $13 billion in 1997\(^1\) — up from $10 billion in 1996.\(^2\) A recent report estimated that Americans spend over $18 billion annually on over 29,000 supplements sold in the United States.\(^3\) Consumers have embraced supplements, because of a perception that such aids are safer and more natural than prescription drugs.\(^4\) By regulatory definition, a dietary supplement is a product taken by mouth that

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4. Robertson, supra note 1, at 318-19.
contains a "dietary ingredient" intended to supplement a diet. The "ingredient" may be vitamins, minerals, herbs, botanicals, amino acids, and substances such as enzymes, organ and glandular tissues, concentrates, constituents, extracts, and metabolites. Supplements can be formulated into tablets, capsules, softgels, gelcaps, liquids, powders, or bars.

The most widely used supplements include vitamins, minerals, herbs, and botanicals. In all, nearly $5 billion worth of vitamins were sold in 1996, accounting for nearly half (48 percent) of all dietary supplement sales. While thirteen substances have been identified as vitamins necessary for humans, one, Vitamin C, drives the industry with 60,000 tons produced annually. Other widely used supplements include minerals, defined as "[i]norganic substances that humans require in quantities greater than 100 milligrams per day," and trace elements, which are "[inorganic substances] required in quantities less than 100 milligrams per day." Minerals are required for numerous biological and physiological processes necessary for the maintenance of health.

Botanicals are also classified by the U.S. Food and Drug Administration (FDA) as a dietary ingredient. Botanical supplements, including teas, are produced from fresh, dried, or otherwise preserved plants or parts of plants. These botanicals are "becoming increasingly valued by some consumers for their perceived medicinal properties; however, FDA regulations prevent statements that these products are intended to diagnose, treat, cure, or prevent disease. Beyond actual

6. Id.
7. Id.
10. Id. at § 2 tbl.2.1, at http://vm.cfsan.fda.gov/~comm/ds-econ2.html#1.
13. OVERVIEW OF DIETARY SUPPLEMENTS, supra note 5.
15. Id.
springs, consumers are spending their money on information; sales of books on botanicals and herbs amounted to $94 million in 1996 alone.17

There are now 1,555 manufacturing facilities for dietary supplements, with 268 distributors and 209 importers.18 In 1997, the total sales for the top fifteen companies were over $3 billion.19 One company alone, Leiner Health Products, a private-label supplement manufacturer, reported sales of $425 million in 1994.20 Another company, Lederle (now Wyeth), had sales of $67 million in 1994 from just one product, Centrum, the number-one selling dietary supplement.21 In many cases, supplement manufacturers and distributors are able to generate huge sales volumes, because of the lack of government regulation of their products.22

As is true for the food industry, ensuring the safety of the goods ranks highest with manufacturers of dietary supplements as well.23 Since the FDA can attempt to regulate dietary supplements only after they enter the market,24 consumers can be at risk, sometimes great risk, of injury from using unsafe products. This article will examine the role of the FDA in regulating the dietary supplement industry, as well as the role of the FTC in regulating supplement advertising, taking into account First Amendment concerns. It will conclude that reforms are needed to assure an informed consumer choice with respect to safety issues. The article proposes that the FDA assume a more proactive stance with respect to the substantiation of safe use, including the evaluation of risks associated with the ingestion of dietary supplements, while permitting the FTC to police misleading claims regarding effectiveness claims by marketers of supplements.

17. Id. at § 4.3.2, at http://vm.cfsan.fda.gov/~comm/ds-econ4.html#1.
18. Id. at § 3 tbl.3.1, at http://vm.cfsan.fda.gov/~comm/ds-econ3.html#1.
19. Id. at § 3 tbl.3.5, at http://vm.cfsan.fda.gov/~comm/ds-econ3.html#1.
20. Id.
22. Consider, for example, that the FDA can remove a supplement from the marketplace only after it is shown to pose a “significant or unreasonable” health risk. Robertson, supra note 1, at 321. Also, consider that the Federal Trade Commission (“FTC”) can force a supplement advertisement off the air only after it finds the claims to be false or misleading. FTC, A BRIEF OVERVIEW OF THE FEDERAL TRADE COMMISSION’S INVESTIGATIVE AND LAW ENFORCEMENT AUTHORITY, at http://www.ftc.gov/ogc/brfovrvw.htm (last modified Sept. 2002).
24. OVERVIEW OF DIETARY SUPPLEMENTS, supra note 5.
II. FEDERAL FOOD AND DRUG ADMINISTRATION REGULATION

A. BACKGROUND

The FDA, as it is known today, clearly illustrates the evolution of government regulation. What began in the early 1900’s as the Bureau of Chemistry has become the government’s primary tool in overseeing the laws concerning most “food products, human and animal drugs, therapeutic agents of biological origin, medical devices, radiation-emitting products, cosmetics, and animal feed.” Early regulatory acts passed by Congress include the Drug Importation Act of 1848, which banned the importation of adulterated drugs, and the Biologics Act of 1902, which was designed to ensure the purity and safety of serums and vaccines. The Food and Drug Act of 1906 banned adulterated or misbranded food or drugs from interstate commerce, and made the manufacture of these products unlawful, while the Sherley Amendment to the Act passed in 1912 prohibited false and fraudulent curative claims on labels.

The responsibilities of the FDA in this regulatory scheme have been systematically expanded by, for example, the 1938 Federal Food, Drug,
and Cosmetics Act (the "FDCA"), which added regulatory power and functions to the Agency's scientific mission. This Act was for "preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicine, and liquors, and for regulating traffic therein, and for other purposes." Although providing evidence of safety before marketing was first required by the FDCA, it was not until the Kefauver Drug Amendments of 1962 that firms also had to show a drug's effectiveness before marketing. These acts, along with subsequent legislation, put substantial regulatory power in the hands of the FDA.

B. FDA DRUG APPROVAL PROCESS

Under the FDCA, the FDA has the power to regulate drugs, food, and cosmetics. Located within the FDA are centers with specialized responsibilities to insure that the risk posed by the product versus the benefit to be gained through its use, is carefully evaluated. The Center for Drug Evaluation and Research (the "CDER") is the one responsible for assuring that drugs are safe and effective.

29. FDA HISTORY, supra note 25. The 1938 Act was passed in response to the Sulfanilamide elixir tragedy, in which many children died after taking the self-proclaimed "wonder drug." FDA, THE EVOLUTION OF U.S. DRUG LAW, at http://www.fda.gov/fdac/special/newdrug/benlaw.html (last visited Mar. 16, 2005) [hereinafter DRUG LAW EVOLUTION]. The amendments provided that no new drugs could be marketed until they had been declared safe by the FDA, gave the FDA injunctive power, regulated cosmetics for the first time, and gave the FDA the authority to set food standards. DRUG REGULATION TIME LINE, supra note 28.

30. Pub. L. 75-717, 52 Stat. 1040 (1938). Further, the 1951 Durham-Humphrey Amendment defined the kinds of drugs that cannot be used without medical supervision and a prescription. Drug Law Evolution, supra note 29.

31. DIXIE FARLEY, BENEFIT VS. RISK: HOW FDA APPROVES NEW DRUGS, FDA CONSUMER SPECIAL REPORT (FDA, Washington, DC), Jan. 1995, available at http://www.fda.gov/fdac/special/newdrug/benefits.html (last visited Mar. 16, 2005). The Kefauver-Harris Amendments were passed in 1962 in response to the Thalidomide incident, in which a physician for the FDA successfully blocked approval of the sleeping pill for U.S. sales, until it was discovered that the drug had caused deformities in Europe in children whose mothers had taken thalidomide. DRUG LAW EVOLUTION, supra note 29. The amendments established a mandatory reporting system for drug safety, and required drug manufacturers to prove to the FDA the effectiveness of their product prior to marketing it. Id.

largest of FDA’s five centers. It has responsibility for both prescription and over-the-counter drugs, whereas other centers have responsibility for medical and radiological devices, food, cosmetics, biologics, and veterinary drugs. The path to approval for pharmaceutical companies is not a short and easy one, but rather one that is characterized by substantial testing.

A company seeking to market a drug must submit evidence that it is safe and effective by submitting a New Drug Application (“NDA”), which is made after clinical tests are conducted. Even before clinical tests can begin, researchers must first analyze the drug’s main physical and chemical properties in the laboratory, and study its pharmacologic and toxic effects in laboratory animals. If the laboratory and animal study results show

33. Id.
34. Id.
35. Recognizing the prolonged approval process, Congress modified regular patent law specifically for drugs and pharmaceutical devices by providing for an extension of time to compensate a patent holder for marketing time lost in satisfying the requirement that the drug be not only useful under patent law, but safe and effective as well under the FDA regulations. The Drug and Patent Term Restoration Act of 1984 modified regular patent law specifically for drugs and pharmaceutical devices. Pub. L. No. 98-417, 98 Stat. 1585 (1984). First, it allows an extension for up to five years, not to exceed a fourteen year period of exclusivity, to compensate a patent holder for marketing time lost in satisfying the Food & Drug Administration requirement that the drug be not only useful (patent law) but safe and effective as well. See generally 35 U.S.C. § 156 (2004). Second, it provides an exemption (Bolar exemption) from claims of patent infringement for the acts of making, using, or selling a patented invention which are “reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.” 35 U.S.C. § 271(e)(1) (2004). In other words, in seeking FDA approval to market a drug, drug manufacturers are exempt from claims of infringements for using patents to develop drugs, provided that no commercial use occurs before the patent expires. Id. Third, there are special procedures for challenging the validity or infringement of drug patents, which guarantee the patent owner a thirty-month preliminary injunction period unless the dispute is adjudicated sooner. 21 U.S.C. § 355(c) (2004); 35 U.S.C. § 271(e)(2)-(4) (2004). Finally, there is a 180 day period of market exclusivity for the first generic applicant to file a challenge to patent validity, infringement, or enforceability for any approved drug. 21 U.S.C. § 355(j)(5)(B)(iv) (2004).
promise, then the sponsor applies for an Investigational New Drug ("IND") application to begin testing on people. It is the cumulative results of these tests that are detailed in the NDA and reviewed by CDER.

Once the FDA has seen the sponsor’s plans and a review board approves the protocol for clinical trials, investigators may give the drug to a small number of healthy volunteers or patients for Phase I tests, which assess the most common acute adverse effects, and examine the size of doses that patients can take safety without a high incidence of side effects. If Phase I studies reveal no major problems, such as unacceptable toxicity, then researchers may conduct a clinical study in which the IND is given to patients who have the condition it is intended to treat, in an effort to determine whether or not the drug has a favorable effect on that condition (Phase II). Phase III is typically a more expansive study with

38. Id. Before clinical tests can begin, researchers must first analyze the drug’s main physical and chemical properties in the laboratory and study its pharmacologic and toxic effects in laboratory animals. Id. If the laboratory and animal study results show promise, then the sponsor applies for an Investigational New Drug (IND) application to begin testing on people. Id. The IND describes the chemical structure of the drug, how it works in the body, the results of preclinical testing including any toxic side effects, the location and protocol for the clinical tests, and how the drug will be manufactured. Id. During this period the FDA offers sponsors opportunities to discuss the critical studies and overall plans, so that they know what is expected with respect to study design, conduct, and analysis. Id.

39. The Prescription Drug User Fee Act of 1992 required drug companies to pay fees when submitting an NDA to the agency. Pub. L. No. 102-571, 106 Stat. 4491 (1992). The Act also provided funds to hire more reviewers, and as a result, reduced the median time for the completion of an NDA review. Id. The fee system continues as updated by the Prescription Drug User Fee Amendments of 2002, 21 U.S.C §§ 301-509 (2004). The order in which applications are looked at is determined with the aid of a classification system that gives priority to drugs with the greatest potential benefit. FDA, Drug Review Priorities, at http://www.fda.gov/fdac/special/newdrug/benrev.html (last visited Mar. 16, 2005). Priority drugs are those appearing to represent an advance over available therapy, whereas standard drugs are those appearing to have therapeutic qualities similar to those of an already marketed drug. Id.

40. CTR. FOR DRUG EVALUATION AND RESEARCH, FDA, CDER HANDBOOK 8 (1998), available at http://www.fda.gov/cedr/handbook/handbook.pdf [hereinafter CDER HANDBOOK]. Initial clinical studies also clarify what happens to a drug in the human body, such as whether or not it is metabolized, how much of it gets into the blood and various organs, how long it stays in the body, and how the body gets rid of the drug and its effects. Id. Under federal regulations, proposed Phase I studies are evaluated almost exclusively for safety reasons. Id.

41. Id. In a controlled trial, patients in one group receive the investigational drug, while those in a control group get either no treatment at all, a placebo, a drug known to be
tests being conducted on a larger population, and is designed to prove conclusively that the drug is effective and better than the standard available treatment. Once all of the clinical trials have been conducted, the sponsor submits the NDA, documenting what happened during the clinical tests, how the drug is constituted, the results of the animal studies, how the drug acts in the body, how it is manufactured, processed, and packaged, especially the quality controls, and samples of the drug and its proposed labels.

Next, the review teams of CDER medical officers, chemists, pharmacologists, statisticians, and other scientists review the sponsor’s NDA containing the relevant data and proposed labeling. Basically, the

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42. CDER HANDBOOK, supra note 40, at 8-9. The FDA gives drug sponsors greater freedom during Phase I, providing the investigations do not expose participants to undue risks. Id. In evaluating Phase II and III investigations, however, FDA reviewers also must ensure that these studies are of sufficient scientific quality to yield data that can support marketing approval. Id.

43. CDER HANDBOOK, supra note 40, at 7. Per recommendation from the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the FDA has published an ICH-developed guideline for the drug industry on creating appropriate clinical study reports for FDA review. FDA, GUIDELINE FOR INDUSTRY: STRUCTURE AND CONTENT OF CLINICAL STUDY REPORTS 1 (1996), available at http://www.fda.gov/cder/guidance/iche3.pdf (originally published in International Conference on Harmonisation; Guideline on Structure and Content of Clinical Study Reports; Availability, 61 Fed. Reg. 37,320 (July 17, 1996)) [hereinafter ICH GUIDELINE]. The guideline has sections in which the sponsor should describe the overall study design and plan (Investigational Plan), the patients participating in the study, and an evaluation of both the drug’s efficacy and safety, along with suggestions for supporting information appropriate for inclusion. Id. at 1-3.

44. CDER HANDBOOK, supra note 40, at 22-23. The medical/clinical reviewers (medical officers) are almost exclusively physicians. FDA, THE REVIEW TEAM, at http://www.fda.gov/fdac/special/newdrug/benteam.html (last visited, Mar. 16, 2005). Clinical reviewers take the lead role in the NDA review and are responsible for synthesizing the results of the animal toxicology, human pharmacology, and clinical reviews to formulate the overall basis for a recommended agency action on the application. Id. The chemistry reviewers address issues related to drug identity, manufacturing control, and analysis. Id. The reviewing chemist evaluates the manufacturing and processing procedures for a drug to ensure that the compound is adequately reproducible and stable. Id. The pharmacologists and toxicologists evaluate the results of animal testing, and attempt to relate animal drug effects to potential effects in humans. Id. Statisticians evaluate the statistical relevance of
evaluators are examining whether the results of well-controlled studies provide substantial evidence of effectiveness, and whether or not the results of the clinical tests show that the product is safe under the conditions of use in the proposed labeling, in the sense that the benefits of the drug appear to outweigh its risks. Regulatory law provides that clinical investigators, including a sponsor-investigator, can be disqualified to receive investigational new drugs if the investigator submits to the FDA or to the sponsor false information in any required report. Additionally, the FDA may refuse to approve a NDA, or withdraw approval of an application, if either is found to contain an untrue statement of a material fact.

C. FDA Regulation of Dietary Supplements

If supplements were classified as drugs, manufacturers would be subject to this process, and required to obtain FDA approval, complete with scientific testing of product efficacy and safety, before marketing their product to the public. Instead, supplements are a subcategory of food, and regulated by the Dietary Supplement Health and Education Act of 1994.

the data, including the methods used to conduct studies and to analyze the data, to give the medical officers a better idea of the power of the findings to be extrapolated to the larger patient population in the country. Id.

45. CDER HANDBOOK, supra note 40. The ICH guideline suggests that in the section of the NDA concerning the safety evaluation of the drug data is to be analyzed at three levels: 1) the extent of exposure (dose, duration, number of patients), 2) the more common adverse events and laboratory test changes, and 3) serious adverse events and other significant adverse events. ICH GUIDELINE, supra note 43, at 25. The report should describe in a brief narrative these adverse events, supported by more detailed summary tables of tabulations and data analyses, which include both the test drug and control treatment groups so that a comparison can be made between them, and the events evaluated in context. Id.

46. 21 C.F.R. § 312.70 (2004). If a danger to the public health exists as a result, the FDA can terminate the IND immediately, and notify the sponsor of the determination, who then may have an opportunity for a regulatory hearing. Id.


49. States have also attempted to regulate dietary supplements in intrastate commerce. However, such controls implicate federal preemption issues. For a discussion of such issues, see Stephanie Kauflin, Comment, Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme, 33 SETON HALL L. REV. 411, 429-435 (2003). Clearly state regulation of truth-in-advertising is more pervasive than state regulation of the marketing of drugs. See infra notes 92-101 and accompanying text.

A significant step in the direction of deregulation spurred by consumer demands for ready access to dietary supplements, this Act changed the role of the FDA in the regulation of such products by prohibiting their classification as food additives or drugs, which would necessitate pre-market approval.

Equally significant is the statutory presumption under DSHEA that supplements are safe, which shifts the burden to prove otherwise to the government. FDA regulatory authority is not triggered unless the supplement poses a significant or unreasonable risk of illness or injury under either conditions of use recommended in labeling, or in the absence of such suggestions, under ordinary conditions of use. As a result, a dietary supplement such as Cellasene, a product touted as being an anti-cellulite agent, is presumed safe and unabashedly marketed as being effective by its manufacturer without the need to supply proof of such claims, as long as the claims concern the structure or function of the

51. Pub. L. No. 103-417, 108 Stat. 4325 (1994). The Act defines a dietary supplement as a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients, which is intended for ingestion in pill, capsule, tablet, or liquid form, not represented for use as a conventional food or as the sole item of a meal or diet, and is labeled as a “dietary supplement.” 21 U.S.C § 321 (2004). For a discussion of the legislation, see Overview of Dietary Supplements, supra note 5.


55. 21 U.S.C. § 342(f) (2004). The FDA also may regulate a dietary supplement if it contains a new dietary ingredient. Id. at § 350b.
That is, DSHEA permits sellers to make statements about the ability of dietary supplements to affect the structure or function of the body (e.g., promote weight loss), provided there is a disclosure that 1) the FDA has not evaluated the veracity of the claim, and 2) the product is not intended to affect disease in a positive manner.\textsuperscript{57} The FDA does have the authority to exercise greater pre-marketing regulatory authority for new ingredients, however.\textsuperscript{58} In the case of new ingredients, there must be an evidentiary basis that supports a reasonable expectation of safety for the marketed use, and the FDA must be given information to support this expectation within seventy-five days prior to marketing the supplement.\textsuperscript{59}

In practice, the FDA, through its Center for Food Safety and Applied Nutrition, must rely heavily on consumers, health professionals, and FDA-regulated companies to report any problems experienced by someone using a dietary supplement.\textsuperscript{60} Once a report is filed, the agency evaluates the seriousness of the problem, and requests additional information from the filer if necessary.\textsuperscript{61} In essence, the public must first buy a product and use it long enough to develop health problems; in other words, the product

\textsuperscript{56} See Leticia M. Diaz, Cellasene or Endermologie, The Administrative Battle Against Cellulite: Does FDA Approval Impress Consumers?, 20 QUINNIPIAC L. REV. 169 (2000), for a discussion on the legal and public policy implications of a non-FDA approved anti-cellulite agent in comparison to one that is FDA approved.

\textsuperscript{57} 21 U.S.C. § 343(r)(6) (2004). See Margaret Gilhooley, Deregulation and the Administrative Role: Looking at Dietary Supplements, 62 MONT. L. REV. 85, 95-110 (2001), for a discussion on the scope of claims that can be made with respect to dietary supplements, including structure and function claims.

\textsuperscript{58} New ingredients are defined as those not marketed in the United States prior to October 15, 2004. 21 U.S.C. § 350b(c) (2004). Unfortunately, there is no apparent system for monitoring whether or not new ingredients are being introduced without the proper notification. 10 Years After the Implementation of DSHEA: the Status of Dietary Supplements in the United States: Hearing Before the Subcomm. on Human Rights and Wellness of the House Comm. on Government Reform, 108th Cong. 102 (March 24, 2004) (statement of Dr. Annette Dickinson, President, Council for Responsible Nutrition).

\textsuperscript{59} The procedures are specified at 21 C.F.R. § 190.6 (2004). To date, the FDA has objected to 68 pre-market notifications. For a discussion of these cases and an overview of the process, see Michael McGuffin & Anthony L. Young, Premarket Notifications of New Dietary Ingredients – A Ten-Year Review, 59 FOOD & DRUG L. J. 229 (2004).


\textsuperscript{61} FDA, HOW TO REPORT PROBLEMS WITH PRODUCTS REGULATED BY FDA, at http://www.fda.gov/opacom/backgrounders/problem.html (last visited Mar. 16, 2005).
must first hurt someone before the FDA will examine it. Clearly, the tragic results produced by herbal fen-phen supplements in some cases illustrate the deficiencies in the current regulatory system. Furthermore, proving that a product is dangerous can be difficult, since Section 401 of the FDCA specifies that “a reasonable standard of quality” is all that is required for companies to manufacture, distribute, and sell food.

On the other hand, beyond producing and distributing safe products, supplement manufacturers must comply with FDA specification regarding accurate labeling. Dietary supplements must be labeled as such, and carry a “Supplement Facts” panel that includes information such as the appropriate serving size and a listing of nutrients, the percent of the daily value of all dietary ingredients, and if it contains botanicals, it must identify the part of the plant from which the ingredient was derived. If the FDA concludes that a product has a false or misleading label, it will work with the Federal Trade Commission (FTC), the agency primarily responsible for truth in advertising regulation for the protection of consumers to address it.

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64. 21 C.F.R. § 101.36 (2004).

65. As a result of overlapping jurisdiction and shared inter-agency responsibilities, the FDA has been seen as acting too slowly to protect the public from dangerous products, it has even been sued, because of perceived slow response time. See Public Citizens Health Research Group v. FDA, 740 F.2d 21 (D.C. Cir. 1984), where the Commissioner was sued for delaying the imposition of mandatory warning labels on aspirin bottles, despite the considerable scientific evidence that children with influenza or chicken pox who take aspirin face a greatly increased risk of developing the often-fatal Reye’s Syndrome. Id. However, because an FDA investigation can dramatically affect sales, the agency should move cautiously to fully validate the information before releasing any warnings to the public. The FDA may even withhold information under the Freedom of Information Act, 5 U.S.C. § 552 (2004), while it investigates complaints, since records or information compiled for law enforcement purposes are exempt under the Act. 21 C.F.R. § 20.64 (2004).
III. ADVERTISING REGULATION

Many of the claims asserted by sellers of dietary supplements contain extraordinary claims of effectiveness, such as “discover the secret to permanent weight loss,” and “get weight off and keep it off.”\textsuperscript{66} In addition to claims of effectiveness, safety attributes are flaunted as well. For example, almost half of the ads analyzed in one study made safety-related claims, such as “proven 100 percent safe,” “safe, immediate weight loss,” and “safest weight management system in the world.”\textsuperscript{67} If the product itself is not subject to pre-market proof of safety and effectiveness, is the regulation of truthfulness in advertising sufficient to deter marketing supplements based on deceptive advertising claims?

A. THE FEDERAL TRADE COMMISSION

The Federal Trade Commission Act (FTCA) was passed by Congress in 1914,\textsuperscript{68} which established the Federal Trade Commission.\textsuperscript{69} The FTC’s mandate was to prevent entities from using unfair methods of competition in commerce,\textsuperscript{70} as well as to protect “not just the sophisticated, but rather that ‘vast multitude which includes ignorant, unthinking, and credulous, who, in making purchases, do not stop to analyze, but are governed by appearances and general impressions.’”\textsuperscript{71} Consequently, under Section 5 of the FTCA, the FTC is empowered and directed to regulate deceptive acts or practices in, or affecting, commerce,\textsuperscript{72} which are defined as material

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\textsuperscript{66} These claims appeared in twenty-three percent of the ads surveyed. BUREAU OF CONSUMER PROTECTION, FTC, TIPPING THE SCALES? WEIGHT-LOSS ADS FOUND HEAVY ON DECEPTION, at http://www.ftc.gov/bcp/conline/features/wgtloss.htm (last modified Sept. 2002) [hereinafter TIPPING THE SCALES].

\textsuperscript{67} Id.


\textsuperscript{70} FTC v. Klenser, 274 U.S. 145, 151 (1927). In other words, part of the agency’s mission is to regulate unfair competition among businesses.

\textsuperscript{71} Floresheim v. Weinburger, 346 F. Supp 950, 957 (D.D.C. 1972) (citing Florence Mfg. Co. v. J.C. Dowd & Co., 178 F. 73, 75 (2d Cir. 1910)).

representations, omissions, or practices that are likely to mislead consumers acting reasonably under the circumstances.\textsuperscript{73}

Deeming an act deceptive does not require a finding of fraud or an intention to deceive.\textsuperscript{74} In determining how deceptive a product claim may be, however, the FTC does make a distinction between actual deception and sales puffing, which refers generally to “expressions of opinion not made as representation of fact, and while the seller has some latitude in puffing his goods, he is not authorized to misrepresent them or assign to them benefits or virtues they do not possess.”\textsuperscript{75}

Additionally, the FTC monitors unfair practices.\textsuperscript{76} Unfair practices are defined as those that cause or are likely to cause “substantial injury to consumers which [are] not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.”\textsuperscript{77} The evaluation of unfairness considers such factors as whether or not the practice offends public policy, is immoral, unethically oppressive or unscrupulous, and causes substantial injury.\textsuperscript{78}

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\textsuperscript{73} In re Cliffdale Assocs., Inc., 46 Antitrust & Trade Reg. Rep. (BNA) 703 (1984). See also FTC v. World Travel Vacation Brokers, Inc., 861 F.2d 1020 (7th Cir. 1988) (defining deception as a practice, representation or omission that would likely mislead consumers acting reasonably to their detriment). Previously, the standard for deception was more lenient, focusing instead upon whether or not an advertisement had the capacity or tendency to mislead consumers. See Charles of the Ritz Distrib. Corp. v. FTC, 143 F.2d 676 (2d Cir. 1944); Jack E. Karns & Alan C. Roline, The Federal Trade Commission’s Deception Policy in the Next Millennium: Evaluating the Subjective Impact of Cliffdale Associates, 74 N.D. L. REV. 441 (1998) (discussing the new standard).

\textsuperscript{74} An intention to deceive, however, may affect the severity of the violation. Chrysler Corp. v. FTC, 561 F.2d 357 (D.C. Cir. 1977). For an overview of the regulatory standard, see note, Developments in the Law: Deceptive Advertising, 80 HARV. L. REV. 1005 (1967).

\textsuperscript{75} Gulf Oil Corp. v. FTC, 150 F.2d 106, 109 (5th Cir. 1945).

\textsuperscript{76} The Wheeler-Lea Amendment to the FTCA passed in 1938 clarified the roles of the FDA and FTC in the regulation of advertising. See generally FTC v. Sperry Hutchinson Co., 405 U.S. 233, 244 (1972). It also assured that the unfair practices prohibition was intended to protect consumers, and not just claims of unfair competition between businesses. Id. at 244.


\textsuperscript{78} In re Pfizer, Inc., 81 F.T.C. 23, 61 (1972). See also Southwest Sunsites, Inc., v. FTC, 785 F.2d 1431 (9th Cir.), cert. denied, 479 U.S. 828 (1986); FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 240 (1972) (embracing the definition).\end{flushright}
The process by which the FTC seeks to stop unfair or deceptive practices can be long and arduous. It must first issue and serve a complaint stating its charges to the violator. Only after a hearing in which the party is proven guilty of violations may the FTC order a stop to the unfair or deceptive trade practices. However, if the offender files a review within sixty days of the judgment, he may delay the process. The FTC’s efforts to enjoin unfair practices may be further delayed in the event of an appeal to the Supreme Court, in which case the company may continue its practices until thirty days after the Supreme Court’s ruling even if the FTC ultimately prevails. Such tactics can mean that a deceptive practice might go on for years. Only after a cease and desist order is finalized, can the FTC impose monetary penalties of not more than $10,000 for each violation.

Potential health hazards, as well as a deficiency in knowledge by the public about medicinal qualities of products, have historically precipitated a finding of deception in claims made by manufacturers of health-related products. The FTC has prosecuted and settled a number of cases specifically dealing with the false advertising claims of dietary supplements. For example, the Agency recently settled a case against the marketers of “Focus Factor,” a dietary supplement that claimed to improve concentration, and “V-Factor,” a supplement that claimed to enhance sexual performance, for making untrue statements about scientific research.

79. Generally the Commission issues a complaint when there is reason to believe that a violation has occurred. A company can settle the complaint without admitting liability by entering into a consent decree; alternatively, the FTC can hold an administrative adjudication. Office of the Gen. Counsel, FTC, A Brief Overview of the Federal Trade Commission’s Investigative and Law Enforcement Authority, at http://www.ftc.gov/ogc/brfovrvw.htm (last modified Sept. 2002).
81. Id.
82. 15 U.S.C. § 45(g)(1).
84. 15 U.S.C. § 45(m).
85. See, e.g., Keele Hair & Scalp Specialists, Inc. v. FTC, 275 F.2d 18 (5th Cir. 1960) (male-pattern baldness treatment); J.B. Williams Co. v. FTC, 381 F.2d 884 (6th Cir. 1967) (iron supplement); Simeon Mgt. Corp. v. FTC, 579, F.2d 1137 (9th Cir. 1978) (weight control product); Sterling Drug, Inc. v. FTC, 741 F.2d 1146 (9th Cir. 1984) (potential health hazards associated with product’s use).
supporting their claims. The companies were ordered to pay substantial sums ($1 million for "Focus Factor" and $60,000 for "V-Factor") in consumer redress, yet neither company had to admit they were guilty of deceptive advertising. Although the FTC prevailed after seven years of legal battle, the companies were able to keep on running their ads, and deceiving consumers during those years.

Misleading advertisements are especially prevalent for weight loss products. In a 2001 review of three hundred current ads, the FTC found that over half (55 percent) made at least one false or unsubstantiated claim. Typical were promises such as "you can lose 18 pounds in one week!" Others promised that there was no need for dietary restrictions or exercise, that weight-loss would be permanent, and that the product was safe. Many of the advertisements included unsupported consumer testimonials. The FTC recently charged some marketers of CortiSlim and CortiStress dietary supplements with making false and unsubstantiated claims about the attributes of their products. By agreement, the parties promised to cease making the claims that were the target of the complaint brought by the FTC, and to limit future claims to those supported by reliable scientific information.

Some supplement advertisements go beyond simple deception and help sustain dangerous products. "There are many worrisome, unfounded claims. A lot of these products have not been proven to provide any benefit and in some cases, may even present safety risks." A much-publicized case involving false claims for a dangerous product was the government’s action against Ephedrine Alkaloids. Classified as a dietary supplement, ephedrine was widely marketed to help in weight-loss. In fact, it is

87. Id.
88. TIPPING THE SCALES, supra note 66.
89. Id.
90. Id.
91. Id.
estimated that at least one percent of the U.S. adult population had taken a supplement that contains ephedrine, thus putting them at risk for ischemic and hemorrhagic strokes, until the FDA banned its use for safety concerns.  

B. STATE REGULATION UNDER DECEPTIVE TRADE PRACTICES LEGISLATION

In addition to federal regulatory authority, all states have passed Deceptive Trade Practices Acts ("DTPAs"). Sometimes referred to as "little FTC Acts," DTPAs prohibit deceptive acts or practices in the conduct of trade or commerce along with a laundry list of deceptive trade practices relating to unfair competition. They were enacted in response to the 1960's consumer empowerment movement, and are patterned after the FTCA. Most of these statutes provide for enforcement either by the state

98. The standard under federal law for unfairness and for deception are usually followed under state DTPAs, which focuses on whether or not a reasonable person would likely be misled by the material representation or omission. See supra notes 73-78 and accompanying text. See also William A. Lovett, Private Actions for Deceptive Trade Practices, 23 ADMIN. L. REV. 271 (1971) (discussing the history of the consumer movement and early development of DTPAs).
attorney general’s office, or an administrative agency in charge of consumer protection.

Complementing the state’s enforcement power are private causes of action created by DTPAs for aggrieved consumers. But using such


private litigation as a catalyst for change is likely to proceed in a piecemeal manner and produce patchwork results, which is less desirable than centralized regulatory approach. 101

Even permitting enforcement by state attorney generals, whose authority is limited to their respective states, is not preferable to a federal regulatory scheme because most supplements are marketed nationwide. Therefore, the regulation of advertising and marketing claims is best accomplished by the FTC. However, given the constitutional protection afforded to commercial speech, can claims about the safety and efficacy of dietary supplements be regulated?

IV. FIRST AMENDMENT ISSUES

A. COMMERCIAL SPEECH AND FTC REGULATION

While on the surface, efforts to control deception in the marketplace seem valid, there is a broader constitutional consideration: can these efforts to protect the masses from spending their money, and endangering their health override the protection of free speech? Although the First Amendment guarantees free speech, courts have declared that commercial speech is not as protected as other forms. 102 In fact, courts have stated that transaction-based speech, because of its nature, does not enjoy as much protection from governmental regulation. 103

101. In addition to the FTC and state attorney generals, the National Advertising Division of the Better Business Bureau may assist in the policing of false claims; however, the continued growth of low quality products suggests these efforts are probably insufficient. Pinco & Halpern, supra note 53, at 568. Additionally, supplement sellers are subject to product liability law, which could make them responsible for injuries caused by their products. A discussion of such liability under tort law and the Uniform Commercial Code, however, is beyond the scope of this article. For an overview of the application of such laws to dietary supplements see Robertson, supra note 1, at 328-340.


In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council Inc.*, the Supreme Court recognized that "a different degree of protection is necessary to insure that the flow of truthful and legitimate commercial information is unimpaired." Two years later, this finding was repeated and clarified in *Ohralik v. Ohio Bar Association*. In *Ohralik*, the Court ruled that not only does commercial speech deserve a different level of protection, it deserves a lesser degree of protection. Commercial speech is granted governmental protection only if it concerns a lawful activity, and is not misleading; furthermore, under *Central Hudson Gas and Electric Corp. v. Public Service Commission of New York*, the government interest in regulation must be substantial, the regulation must directly advance the interest asserted, and be no more extensive than necessary to further the governmental interest. Therefore, the dietary supplement industry's misleading and deceitful speech should be afforded no First Amendment protection.

Unfortunately, with volumes of new advertisements airing daily, some even targeting children, FTC's old method of using official letters and

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109. Id. at 566. While the means asserted must be no more extensive than necessary to further the governmental interest, the regulation need not be the least restrictive means of protecting the governmental interest. Bd. of Trustees v. Fox, 492 U.S. 469 (1989). See Todd J. Locher, Comment, *Board of Trustees of the State University of New York v. Fox: Cutting Back on Commercial Speech Standards*, 75 IOWA L. REV. 1335 (1990).
warnings to regulate product claims seem to be ineffective.\textsuperscript{111} On the other hand, the government has a significant interest in regulating deceptive advertisements that promise miracles to the public, and in requiring that a company have a reasonable basis for believing that a claim is true before it is made, particularly with respect to pharmaceutical products.\textsuperscript{112} Can the FTC go beyond the product manufacturer to regulate speech, and impose fines on a company that broadcasts or prints a deceptive advertisement?

The FTC has prosecuted advertising agencies for developing campaigns that they know, or should have known, to be false or misleading.\textsuperscript{113} Yet holding a media company responsible for airing a false advertisement is still considered taboo (not to mention implicating serious First Amendment concerns), since it would require the broadcaster to examine the products it agrees to advertise.\textsuperscript{114} However, if the company has a reason to believe that a commercial is deceptive, should it be required to refuse to air the claim without proof of legitimacy? On occasion, the courts have held the medium for a false advertisement responsible if it knowingly or recklessly publishes a false claim.\textsuperscript{115} For example, a print medium was held accountable when it acted maliciously and without regard to the consequences that a reasonable person could have anticipated,\textsuperscript{116} but not for a failure to investigate the truth of the claim.\textsuperscript{117}

\begin{enumerate}
\item See Thompson Med. Co., v. FTC, 791 F.2d 189 (D.C. Cir. 1986) (affirming FTC decision requiring a company to provide the results of at least two well-controlled, double-blinded studies before making efficacy claims for an over-the-counter drug).
\item Doherty, Clifford, Steers & Shenfield, Inc. v. FTC., 392 F.2d 921, 927 (6th Cir. 1968) ("The advertising agency was an active participant in the preparation of the advertisements and that the agency knew or had reason to know that [company]'s claims were false or deceptive."). See also Gillette Co. v. Wilkinson Sword, Inc., 795 F. Supp. 662 (S.D.N.Y. 1992) for the proposition that in a non-FTC case, liability can attach unless the advertising agency lacked actual knowledge of falsity, and had no reason to question truthfulness.
\item Many states have statutes that exempt the media from false advertising claims as long as they do not act recklessly, or with knowledge of falsity. See Jeffery S. Edelstein, Self-Regulation of Advertising: An Alternative to Litigation and Government Action, 43 IDEA 509 (2003) for a list of these statutes, and an overview of media liability for false advertising).
\item See, e.g., Goldstein v. Garlick, 318 N.Y.S.2d 370 (Sup. Ct. 1971).
\item Id. at 375.
\end{enumerate}
Other media were found liable for carrying an advertisement that it should have known was deceptive, and for the repetition of false advertisements. Additionally, a publisher was held liable because it carried an advertisement which, any reasonable person could have appreciated, would pose a substantial danger.

These cases are unusual, however, because there “have been few false advertising lawsuits against the media, and fewer still have been successful.” To date, the FTC has not gone so far as to aggressively regulate these media firms; instead it has held workshops and seminars in the hope of inspiring self-regulation to control the flow of false and misleading commercials. Most recently, a Commissioner from the FTC implored the dietary supplement industry to regulate itself better, and called for assistance from the media in weeding out “obvious fraud.” This tactic may be effective with conscientious companies. For example, the National Broadcasting Corporation monitors all advertising aired on its networks for accuracy, reviewing over 50,000 commercials annually. But not all firms airing dietary supplement claims are conscientious. Some companies make millions through false advertising touting worthless or even hazardous products. The simple truth is, it is extremely lucrative to lie to consumers. Further, it should not be the responsibility of the media to police dietary claims, particularly since that is not its area of expertise.

118. Thomas v. Times Mirror Mag., Inc., 159 Cal. Rptr. 711 (1979) (holding that a publisher was liable for publishing classified advertisement for a licensed patent engineer when the publisher was on notice that the engineer was excluded from practicing before the Patent Office).
120. Braun v. Soldier of Fortune Mag., Inc., 968 F.2d 1110 (11th Cir. 1992) (finding that the advertisement could have reasonably been interpreted as an offer to commit a crime).
121. Edelstein, supra note 114, at 514. See Edelstein, supra note 114 for a discussion of the ways in which the media exercises self-regulation of advertising claims.
123. HEALTH SUPPLEMENT RETAILER, FTC COMMISSIONER CALLS ON INDUSTRY, MEDIA TO WEED OUT FALSE CLAIMS, at http://www.hsrmagazine.com/hotnews/24h18151855.html (last updated Apr. 18, 2002).
124. Dateline NBC (NBC television broadcast, Nov. 16, 1997) (on file with author).
B. COMMERCIAL SPEECH AND FDA REGULATION

A few cases raising free speech concerns have emerged even with respect to the FDA’s rather laissez-faire approach to the regulation of dietary supplements. In Pearson v. Shalala, marketers of nutritional supplements challenged the FDA’s refusal to allow them to make a health claim concerning the reduction in particular health risks (including cancer, coronary disease, and neural tube defects) related to the consumption of their products (e.g., antioxidant vitamins, fiber, omega-3 fatty acids and folic acid). The FDA standard for the approval of health claims on dietary supplements was whether the claim was supported by “significant scientific agreement.” The FDA had concluded that claims unsupported by such proof were inherently misleading, because of their overwhelming impact upon consumers. While the appeals court acknowledged that the government has a substantial interest under Central Hudson to prevent consumer fraud, it questioned the fit between the goal and the means chosen to advance it. In sum, the court concluded that disclaimers on labels concerning the degree of effectiveness could suffice to reduce consumer confusion while still respecting commercial speech rights.

Subsequently, the FDA reconsidered the folic acid claim concerning the reduction of neural tube defects, and still refused to authorize it, with or without disclaimers. As a result, the district court enjoined the FDA from blocking the claim, concluding that the claim was only potentially misleading, not inherently misleading, and as such, was protected by the First Amendment. In a later case, plaintiffs challenged the application of the FDA guidance concerning “significant scientific agreement,” which

126. Id. at 652.
127. Id. at 653 (citing 21 C.F.R. § 101.14 (1998)).
128. Id. at 655-56.
129. Id. at 657.
130. Id. at 659.
132. Id. at 120. The court found that there was scientific consensus that folic acid substantially reduces the risk of giving birth to an infant with a neural tube defect. Id. As such, the FDA’s classification of the claim as being inherently misleading was an abuse of discretion. Id. The court remanded the case with directions that the FDA draft “one or more appropriately short, succinct, and accurate disclaimers.” Id. See infra notes 145-152 and accompanying text for an overview of the FDA’s response and interim system for implementing a disclaimer-based approach.
was issued subsequent to *Pearson v. Shalala*, and resulted in the FDA blocking claims concerning the effect that anti-oxidant vitamins had upon reducing the risk of certain cancers. In *Whitaker v. Thompson*, the district court again determined that the claims were not inherently misleading, and concluded that the FDA’s prohibition on such advertising violated the First Amendment because it was not the least restrictive means of protecting consumers from misinformation.

While some would argue that deference paid to the FDA in light of First Amendment protection for commercial speech is eroding, both *Pearson* and *Whitaker* involved health claims made by nutritional products, not safety claims associated with other types of supplements, such as those designed to control weight. Arguably, the governmental interest in regulating nutritional value claims is weaker than for safety claims and any substantiation requirements. Concurring in the denial of a rehearing, Judge Silberman of the D.C. Circuit, specifically reiterated that the decision in *Pearson* recognized that the government did not assert that the supplements at issue threatened the consumer’s health and safety.

In other contexts the FDA has been able to control the spin associated with marketing supplements. For example, the FDA successfully seized products marketed as dietary supplements, which were intended to affect the structure and function of the mind, as not falling within the statutory definition of a supplement. Further, the Tenth Circuit upheld the FDA’s

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134. *Id.* at 19. The court again remanded the case with directions that the FDA draft an appropriate disclaimer. *Id.* at 20.
137. *Pearson v. Shalala*, 172 F.3d 72 (D.C. Cir. 1999). In its petition for rehearing, the FDA argued that since First Amendment concerns were not apparently implicated under the previous system, whereby health claims transformed supplements into drugs (and subject to regulatory pre-market approval), the “significant scientific agreement” standard should not trigger such issues. *Id.* at 73. In other words, the FDA contended that it retained power to allow only supplements to make health claims, which in its opinion met the significant scientific agreement test, since previously it could have subjected all supplements that made a health claims to the drug approval process. *Id.* Since the argument was raised on appeal for the first time, the court declined to consider it at the rehearing stage. *Id.*
interpretation that a dietary supplement excludes both active ingredients and finished drug products, thus allowing the FDA to regulate supplements with active ingredients as it does drugs. Therefore, consistent with the constitutional protection afforded commercial speech, should the FDA at least do more with respect to safety claims made by the marketers of dietary supplements?

V. REFORM PROPOSALS

When self-regulation has been tried and failed, the government needs to aggressively pursue alternatives. A study conducted by the U.S. Department of Health and Human Services concluded that FDA’s supervision of dietary supplements was inadequate. Commentators have also called for a reevaluation of FDA’s role with respect to its regulation of dietary supplements to ensure informed consumer choices. Safe use issues are critical, particularly since herbal supplements can be dangerous if taken in combination with other medication. Even when taken alone, some supplements can produce pharmacologic activity, such as changing the heart rate or blood pressure in a user. In addition, physicians have called for reforms in areas ranging from the implementation of mandatory

139. Pharmaneux v. Shalala, 221 F.3d 1151 (10th Cir. 2000). The statutory definition excludes articles approved as new drugs; therefore, if a supplement contains an active ingredient, it must be approved through the FDA’s drug approval process. See Kauflin, supra note 49, at 425-29, for a discussion of the Undetermined Quantities of Articles of Drug and Pharmaneux cases.


141. See Gilhooley, supra note 57, at 124-30 (arguing for a substantiation model for safety claims). See also Sardina, supra note 62, at 123-32 (calling for legislative amendments to DSHEA to regulate purity levels and increased FDA funding); Kauflin, supra note 49, at 435-46 (reforms should include shifting the burden to the manufacturer to prove safety, permitting the FDA to act against dietary supplements as a class rather than individually, and requiring prescriptions for supplements, which can be dangerous in higher dose than that suggested on the label); Valuck, supra note 52, at 311-13 (proposing regulation based upon safety risk, use of third party reviewers, and increased efforts by all affected parties to deter fraudulent marketing).

142. Kauflin, supra note 49, at 411. Adverse side effects may occur as well. Id. at 412.

adverse event reporting requirements for dietary supplement manufacturers, and requirements for mandatory warnings for risks, registration of companies and products, to the identification of the raw materials contained in the products along with their source.¹⁴⁴

To date, the FDA has undertaken several initiatives with respect to improving the regulation of dietary supplements. First, the FDA, pursuant to the mandate in DSHEA to develop regulations to ensure that supplements are pure, promulgated a rule on good manufacturing practices to prevent both super- and sub-potent products.¹⁴⁵ The proposed rule seeks to establish Current Good Manufacturing Practices ("CGMPs") that include provisions on manufacturing, packaging, labeling, testing, quality control, releasing for distribution, and holding of dietary ingredients and dietary supplements— all of which are intended to ensure that manufacturing, packing, and holding practices will not result in an adulterated or misbranded dietary supplement.¹⁴⁶

Second, the FDA has proposed new processes for monitoring health care claims in the wake of Pearson.¹⁴⁷ In one guideline, the FDA illustrates the process for evaluating and ranking health claims.¹⁴⁸ Another guideline details how applicants can seek a qualified health claim, and describes FDA priorities for reviewing such claims.¹⁴⁹ Together, the guidelines

¹⁴⁴. *Id.* at 90.
¹⁴⁵. CTR. FOR FOOD SAFETY AND APPLIED NUTRITION AND OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND DIETARY SUPPLEMENTS, FDA, FACT SHEET ON FDA’S STRATEGY FOR DIETARY SUPPLEMENTS, at http://www.cfsan.fda.gov/~dms/ds3strfs.html (last modified Nov. 4, 2004). Commentators previously had called for the development of such practices, along with their mandatory implementation. See, e.g., Robertson, *supra* note 1, at 343; Sardina, *supra* note 62, at 128.
¹⁴⁶. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12,158 (proposed Mar. 13, 2003). Due to the substantial number of comments, the rule has not yet been finalized, pending further review of the feedback. In addition, CGMPs exist with respect to drugs. See Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 C.F.R. § 211 (2005).
¹⁴⁷. See discussion on the *Pearson* cases, *supra* notes 125-34 and accompanying text.
provide a grading system for health claims based upon an analysis of the scientific data submitted and the level of comfort concerning the validity of the claim, coupled with a correlative standard disclaimer. For example, the qualifying language for evidence ranked with a B grade is: “although there is scientific evidence supporting the claim, the evidence is not conclusive,” while a grade of C has this language: “some scientific evidence suggests . . . however, [the] FDA has determined that this evidence is limited and not conclusive.”

Third, the FDA is preparing to issue another draft guidance concerning substantiation for dietary supplement claims. The FTCA requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim has substantiation that the claim is truthful and not misleading. This proposed guidance, which has been distributed for comment purposes, recommends that the test for compliance with the substantiation standard include an assessment of the meaning of the claims being made, the relationship of the evidence to the claims, the quality of the evidence, and the totality of the evidence.

In addition to these three reforms, the FDA remains vigilant in its enforcement actions and in seizing misbranded drugs. Yet these improvements and efforts fall short of the mark for a couple of reasons. First, the guidelines issued by the FDA are just that: non-binding recommendations, which permit alternative approaches, so long as the statutes and regulations are satisfied. Second, there is an insufficient barrier to pre-market approval of supplements, since the FDA’s role is

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150. Id. A grade of ‘D’ would indicate an extremely low level of comfort with the evidentiary support of the claim, such that appropriate qualifying language should suggest that: “very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim.” Id.


152. For a further explanation of the proposal, see CTR. FOR FOOD SAFETY AND APPLIED NUTRITION AND OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND DIETARY SUPPLEMENTS, FDA, FACT SHEET ON FDA’S DRAFT GUIDANCE FOR INDUSTRY: SUBSTANTIATION FOR DIETARY SUPPLEMENT CLAIMS, at http://www.cfsan.fda.gov/~dms/dsclmfs.html (last modified Nov. 4, 2004).

either limited to new ingredients or is reactionary in light of a significant or unreasonable risk of illness.\textsuperscript{154}

Safety substantiation, instead, should be regulated in a manner similar to that employed for drugs. Manufacturers of dietary supplements should be required to test their products through a Phase I type of procedure.\textsuperscript{155} Should Phase I studies identify risks, the FDA should mandate that appropriate warnings and dosages accompany the product. Because Phases II and III primarily address effectiveness concerns,\textsuperscript{156} Phase I studies should be sufficient. Why? Consumers want ready access to supplements because they, along with nutrition experts,\textsuperscript{157} believe they are effective. As long as they are safe, such ready access should be permissible. As for protecting the economic interests of the consumers from the bogus claims by supplement manufacturers, both the FTC\textsuperscript{158} and state DTPAs\textsuperscript{159} have the proper authority to pursue these claims.

However, unlike economic losses, unsafe use or unsafe products potentially may pose serious health risks, which are not likely to be appreciated by an ordinary consumer. While the FDA does have a process in place for the reporting of adverse events,\textsuperscript{160} that process would be more controlled and less fortuitous if manufacturers were required to report and monitor adverse events in controlled clinical studies, such as the Phase I trials required for drugs. Additionally, similar to its regulatory authority over drugs, the FDA should be empowered to require post-marketing studies in appropriate cases. Under a section of the Food and Drug

\textsuperscript{154} See supra notes 50-65 and accompanying text.
\textsuperscript{155} See supra notes 36-40 and accompanying text.
\textsuperscript{156} See supra notes 41-43 and accompanying text. As such, they are designed to address efficacy, and are more equivalent to permissible health claims.
\textsuperscript{157} See infra notes 165-68 and accompanying text.
\textsuperscript{158} See supra notes 68-95 and accompanying text, for a discussion on FTC's authority to regulate false advertising. This authority, in conjunction with the health claims rating system and suggested disclaimers should suffice.
\textsuperscript{159} See supra notes 96-101 and accompanying text.
\textsuperscript{160} See CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, FDA, ADVERSE EVENT REPORTING SYSTEM, at http://www.cfsan.fda.gov/~dms/ds-rept.html (last visited Mar. 16, 2005). The Center for Food Safety and Applied Nutrition has a computerized "Adverse Event Reporting System," which records, through one portal, voluntary reports from consumers, health care providers and the industry. Id. But query whether or not consumers are capable of tracing the cause of an adverse health event to the use of a dietary supplement. In other words, would consumers make the connection? Even if they did properly access the alleged cause of their malady, how many would actually report the incident to the FDA?
Administration Modernization Act of 1997, the FDA has the authority to monitor the progress of post-marketing studies that drug and biologics applicants have agreed to conduct.161 The FDA should be empowered to promulgate a rule that addresses those cases in which post-marketing studies should be required.

To this end, there are a few Congressional initiatives that bear mentioning. The Dietary Supplement Information Act proposes to amend the FTCA to require manufacturers of dietary supplements to register with the FDA, and submit reports on adverse events to the FDA.162 Likewise, the Dietary Supplement Safety Act of 2003 would also require manufacturers to submit reports on adverse events to the FDA.163 Both bills provide for a post-market surveillance plan in certain circumstances. The Dietary Supplement Awareness Act provides for manufacturer registration, post-market surveillance and closer scrutiny for supplements that may pose a significant risk to minors.164 This type of initiative, coupled with pre-market FDA approval concerning the safety of the supplement, along with its recommended use and dosage instructions and appropriate risk disclaimers, would go far in improving the system.

VI. CONCLUSION

Certainly, good nutrition is a national concern. Obesity is a serious issue with substantial numbers of Americans being overweight, and suffering health problems as a result.165 It is also clear that the average American diet lacks certain essential nutrients, which dietary supplements could provide.166 Further, a nutritious diet complemented by dietary

161. 21 U.S.C. § 356b (2004). Applicants who are required by FDA, or who have entered into an agreement with FDA, to conduct a post-marketing study are also required to provide the Agency with an annual report on the status of the study until it is completed or terminated. 21 U.S.C. § 356b(a) (2004).
166. For example, calcium supplements can complement a diet that otherwise does not meet the recommended amount of calcium, which is essential for reducing the natural occurrence of bone loss. Dietary Supplements: Nature’s Answer to Cost Effective Preventative Medicine: Hearing Before the Subcomm. on Human Rights and Wellness of the
supplements can reduce the risk of certain diseases, and the related high health care costs.¹⁶⁷ Even physicians embrace dietary supplement therapies as a part of the practice of integrative medicine.¹⁶⁸ Yet more must be done to insure the safety, if not the efficacy, of these products, in order to avert the types of problems encountered in the marketing of such supplements as ephedrine alkaloids (used for weight control and loss) and androstenedione (used for anabolic effects and for enhancing athletic performance).¹⁶⁹ Even Dr. Paul M. Coates, Director of the Office of Dietary Supplements for the National Institutes of Health, recently acknowledged in testimony before a Congressional committee that “of the approximately [30,000] dietary supplements on the market there are many that have not undergone the rigorous scientific testing needed to establish their efficacy and safety.”¹⁷⁰ While the FDA drug approval process is not perfect, as recent incidents involving the drugs Vioxx and Celebrex have shown, it is certainly more rigorous and reliable than the current regime for supplements, and should be a model for FDA regulation of dietary supplements.

¹⁶⁷ Id. at 2-3 (statement by Dr. Jeffrey B. Blumberg, professor of Nutrition at the Friedman School of Nutrition Science and Policy).


¹⁶⁹ This product, marketed as a supplement, is considered to be an anabolic steroid precursor. See CTR. FOR FOOD SAFETY AND APPLIED NUTRITION AND OFFICE OF COMPLIANCE, FDA, QUESTIONS AND ANSWERS: ANDROSTENEDIONE, at http://www.cfsan.fda.gov/~dms/androqa.html (last modified Mar. 11, 2004), for an overview of the product and its effects.