

**SLAYING THE HYDRA: THE HISTORY OF QUACK
MEDICINE, THE OBESITY EPIDEMIC AND THE FDA’S
BATTLE TO REGULATE DIETARY SUPPLEMENTS
MARKETED AS WEIGHT LOSS AIDS**

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I. INTRODUCTION

The United States' obesity crisis is gaining momentum. Studies released in 2008 project that, in only fifteen years, eighty percent¹ of Americans will be either overweight or obese.² Being overweight or obese places an individual at

1. Youfa Wang et al., *Will All Americans Become Overweight or Obese? Estimating the Progression and Cost of the US Obesity Epidemic*, 16 *OBESITY* 2323, 2323 (2008), <http://www.nature.com/oby/journal/v16/n10/full/oby2008351a.html>. Approximately 91 % of Mexican-American men and 96 % of non-Hispanic black women will be affected by 2030. By 2034, all black women will be either overweight or obese and by 2048, all American adults will have reached this condition. *Id.*

2. According to current standards, adults are overweight if their body mass index ("BMI") is between 25 and 29.9 and are obese if their BMI is 30 or greater. *Study Suggests 56 Percent Of Americans Could Be Overweight By 2030*, *SCIENCE DAILY*, July 29, 2008, <http://www.sciencedaily.com/releases/2008/07/080728192936.htm>.

significant risk of developing hypertension, Type II diabetes, heart disease, stroke and cancer.³ If this epidemic goes unchecked, conservative estimates predict that the health care costs associated with this crisis will reach \$956.9 billion in the 2020s, with one in every six dollars spent on health care related to the conditions of being overweight and obese.⁴ Moreover, for the first time in over a century, children and young adults will have a shorter life expectancy than their parents.⁵

The obesity epidemic has triggered a correspondingly massive growth in the weight loss supplement⁶ industry. Overweight consumers desperate to lose weight are being lured by ‘magic bullet’ claims into purchasing ‘quick-fix’ weight loss supplements in order to lose weight and decrease their risk for disease.⁷ Many of these consumers, and their physicians, incorrectly believe that the Food & Drug Administration (“FDA”) requires premarket testing to establish the validity of these claims.⁸ Taking advantage of consumers’ vulnerability and misperceptions regarding FDA oversight, the sale of weight loss supplements in the United States reached \$4.7 billion in 2001,⁹ with projected increases of ten to twenty percent annually.¹⁰ Weight loss supplements are the fastest growing segment of the dietary supplement industry.¹¹

However, the majority of these products are ineffective.¹² The Federal Trade Commission (“FTC”) reports that more consumers are defrauded by weight loss products than any other product it has examined.¹³ Like Hercules and his attempts to slay the many-headed hydra, for every weight loss supple-

3. *Treating Obesity Vital for Public Health, Physicians Say*, SCIENCE DAILY, Dec. 5, 2006, <http://www.sciencedaily.com/releases/2006/12/061201180423.htm>.

4. *Id.*

5. S. J. Olshansky et al., *A Potential Decline in Life Expectancy in the United States in the 21st Century*, 352 NEW ENG. J. MED. 1138, 1138-45 (2005).

6. When this Article refers to weight loss supplements, it is adopting the same definition as the General Accounting Office by “referring to individual ingredients, not specific products or brands, some of which might contain multiple ingredients. Weight loss supplements include herbal or other botanical ingredient such as aloe, ephedra, fiber, and green tea; minerals such as chromium and pyruvate; as well as amino acids, enzymes, and tissues from organs or glands.” DIETARY WEIGHT LOSS SUPPLEMENTS: LTD. FED. OVERSIGHT HAS FOCUSED MORE ON MARKETING THAN SAFETY: BEFORE THE SUBCOMM. ON OVERSIGHT OF GOV. MGMT., RESTRUCTURING, AND THE DIST. OF COLUMBIA, COMM. ON GOV. AFFAIRS, U.S. SENATE, 1 (JULY 31, 2002) (statement of Janet Heinrich, Director, Public Health Issues, U.S. General Accounting Office), www.gao.gov/new.items/d02985t.pdf [hereinafter Statement of Director Heinrich, GAO].

7. See *infra* notes 54-71 and accompanying text.

8. See *infra* notes 65-66 and accompanying text.

9. CONSUMER HEALTHCARE PROD. ASSOC., <http://www.CHPA-info.org> (last visited on May 10, 2009).

10. Statement of Director Heinrich, GAO, *supra* note 6, at 1 n.1.

11. *Id.*

12. See *infra* notes 67-71 and accompanying text.

13. FED. TRADE COMM’N., CONSUMER FRAUD IN THE UNITED STATES: THE SECOND FTC SURVEY 15 (Oct. 2007), <http://www.ftc.gov/opa/2007/10/fraud.pdf>. See also FED. TRADE COMM’N., WEIGHT LOSS ADVERTISING: AN ANALYSIS OF CURRENT TRENDS 30 (Sept. 2002), <http://www.ftc.gov/bcp/reports/weightloss.pdf> (55% of claims made by over-the-counter weight loss products were false or misleading).

ment that the FTC successfully removes from the market, it appears that dozens more are spawned.¹⁴ Thus, U.S. consumers are being thwarted in their weight loss and disease reduction efforts and the obesity crisis continues to mushroom.

Why isn't the FDA using its premarket approval authority to keep these sham products from entering the market in the first place? Not surprisingly, the weight loss supplement industry is marketing its products as dietary supplements and is claiming the safe haven protections from FDA regulation offered under the Dietary Supplement Health Education Act ("DSHEA")¹⁵ and the National Labeling Education Act of 1990 ("NLEA").¹⁶ What is surprising is that the FDA appears to agree.¹⁷ Are the weight loss supplement industry and the FDA correct?

In order to answer this question, this Article reviews the history of the regulation of quack medicines under the Food, Drug and Cosmetic Act ("FDCA") and outlines the events and legislative history that preceded the passage of DSHEA and NLEA. In conducting this inquiry, this Article examines the historical relationship between the state of scientific uncertainty over the effectiveness and safety of new products intended to treat abnormal health conditions and predatory commercial practices.

A look at this historical relationship informs the debate over the proper regulatory balance between the protection of individual choice in matters involving self-regarding behavior, such as making food choices, and the need to protect vulnerable consumers from harm from third parties who are marketing health care products, including weight loss supplements. The proper balance between these interests is achieved by linking the level of product regulation with the health status of the product's targeted population. Historically, the greatest amount of regulatory protection has been applied when products are targeted at *vulnerable, unhealthy* populations and claim to aid in an individual's struggle to return to normal health. Examples of products that fall into this category include drugs and devices. Conversely, the FDCA requires less regulatory protection when products are targeted to *healthy* populations to maintain

14. Sheila F. Anthony, Comm'r, Fed. Trade Comm'n, *Combating Deception in Dietary Supplement Advertising*, Remarks at the Food and Drug Law Institute 45th Annual Educational Conference (Apr. 16, 2002), <http://www.ftc.gov/speeches/anthony/dssp2.shtm>. In its role of preventing unfair or deceptive practices in the market place, the FTC oversees dietary supplement advertising in an attempt to ensure that product claims are both truthful and substantiated. Statement of Director Heinrich, GAO, *supra* note 6, at 1 n.1. Weight loss supplement manufacturers claim that their products work by reducing appetite or cravings, increasing metabolic rate, having a laxative effect, and blocking the digestion of carbohydrates, fat, and sugar. *Id.* Complicating the picture, manufacturers often combine multiple ingredients into the same product and claim several different mechanisms through which their products work to achieve weight loss. *Id.* The FTC can insist false, exaggerated, or unsubstantiated claims be removed from product advertising. The FTC can also seek monetary relief for conduct that causes damages to consumers. *Id.*

15. *See infra* notes 216-257 and accompanying text.

16. *Id.*

17. *Id.*

or improve a normal state of health. Examples of products that fall into this category are traditional foods, a very limited number of functional foods under NLEA and a similarly narrow category of dietary supplements as defined by DSHEA.

Moreover, the history of quack medicines teaches that the need for this dichotomy that protects unhealthy, vulnerable populations is strongest when there is a high degree of scientific uncertainty¹⁸ over the effectiveness and safety of products intended to treat abnormal health conditions. Time and events establish that there is a direct relationship between scientific uncertainty and high levels of predatory profiteering. Currently, there is a high level of scientific uncertainty over the safety and effectiveness of the vast majority of supplements, including those marketed for weight loss.¹⁹

This Article is arranged as follows. After this Introduction, Part II documents the public health crisis facing this country from the epidemic of overweight and obese individuals who are at serious risk for Type II diabetes, cardiovascular disease and cancer. Part III discusses the remarkable growth of the weight loss supplement industry that tracks the expanding obesity epidemic and points out that this market exists even though a large portion of these products are either ineffective or unsafe. Part IV chronicles the 100 year history of the FDA's regulation of quack medicines and explains how the FDA's historic transition from post-market policing to premarket prevention protects public health from predatory commercial interests, especially when there is scientific uncertainty over safety and effectiveness. Part V unravels the history behind NLEA and DSHEA and explains why these Acts were intended by Congress to deregulate products only to the extent that they target healthy populations to maintain or improve a normal state of health. Further, this section explains why interpreting the safe harbor provisions of these Acts to include products that target vulnerable, unhealthy populations is detrimental to public health. Part VI demonstrates how history has repeated itself with an unintended regulatory rollback that opens the door to modern day snake oil salesmen who are contributing to the obesity crisis. Part VII outlines how the FDA can assert its pre-

18. The level of scientific uncertainty over health risks should also play an important role in the FDA's decisions regarding the level of regulation of new technologies (like genetically modified food) that are marketed for direct human consumption. See Katharine A. Van Tassel, *Genetically Modified Plants For Food, Risk Assessment And Uncertainty Principles: Does The Transition From Ignorance To Indeterminacy Trigger The Need For Post-Market Surveillance?*, 15 B. U. J. Sci. & Tech. L. 220 (2009). Using genetically modified food and the newly discovered characteristics of the networked gene as a case study, this Article discusses the public health, regulatory, legal and ethical issues that are raised as the science over the public safety of a new technology moves through its natural phases from ignorance, to indeterminacy and finally to the point when classical probability analysis can be applied. See also Katharine A. Van Tassel and Rose Goldman, *Manufacturing the Wings of Icarus: FDA Regulation of Nanotechnology Used in Products for Direct and Indirect Human Consumption* (work in progress), www.katharinevantassel.com/selectedpublications.html.

19. See *infra* notes 292-297 and accompanying text.

market approval process to prevent sham weight loss supplements from entering the market.

II. THE OBESITY EPIDEMIC AND THE STATUS OF BEING OVERWEIGHT AS A SIGNIFICANT, INDEPENDENT RISK FACTOR FOR CHRONIC DISEASE

Under the FDCA, products that target vulnerable, unhealthy populations by claiming to either treat disease (“disease claims”) or by claiming to alter the structure and function of the body (“structure and function claims”) must undergo clinical testing to establish their safety and effectiveness for their intended use.²⁰ Products that make these types of claims are considered to be either drugs or devices.²¹ If a product is a drug or device it must obtain pre-market approval from the FDA prior to distribution.²²

Taking a look at the disease claims category first, the FDA has recognized that obesity is a disease.²³ Therefore, all products that are intended to treat obesity are either drugs or devices and must undergo clinical testing to establish safety and effectiveness prior to distribution.²⁴ Unfortunately, based on the state of the science in 2000, the FDA concluded that being overweight (a separate weight category from being obese) did not mean that an individual was suffering from a disease.²⁵ Because the FDA opined that being overweight is not a disease, the current FDA position is that weight loss supplements are not making “disease claims.” Consequently, according to the FDA, a manufacturer’s claims that its product will treat an individual’s overweight status does not trigger the obligation to obtain premarket approval for that product from the FDA.²⁶

Since 2000, the scientific understanding of the relationship between being overweight and the risks of serious, chronic diseases has changed dramatically. In the past decade, a series of studies have been performed that conclusively demonstrate that being overweight is a significant and *independent* risk factor

20. See *infra* notes 169-179 and accompanying text.

21. *Id.*

22. *Id.*

23. FDA Final Rule: Regulations on Statements Made For Dietary Supplements Concerning the Effect of the Product on the Structure and Function of the Body, 65 Fed. Reg. 1000, 1027 (Jan. 6, 2000) (hereinafter FDA Final Rule on Structure and Function Claims). The definition of disease is the “state of health leading to the dysfunction of an organ, part, structure, or system of the body.” 21 C.F.R. § 101.93(g)(1) (2005).

24. FDA Final Rule on Structure and Function Claims, *supra* note 23, at 1027.

25. *Id.*

26. *Id.* In order to establish that a drug is safe and effective, a manufacturer must produce “substantial evidence.” U. S. v. 50 Boxes More or Less, 909 F.2d 24, 27 (1st Cir. 1990). ‘Substantial evidence’ consists of “adequate and well-controlled investigations, including clinical investigations, by experts . . . which ‘adequate and well-controlled investigations’ must satisfy a host of technical scientific requirements including ‘a valid comparison with a control’ such as an ‘active treatment trial’ that includes ‘randomization and blinding of patients or investigators’ (double blind studies).” *Id.* at 26 (internal citation omitted).

for developing serious chronic diseases including Type II diabetes,²⁷ cardiovascular disease²⁸ and certain types of cancer.²⁹ In addition, those who are overweight are likely to progress to obesity over time.³⁰ Consequently, as introduced in the next paragraphs and fully set forth in Section VII, C, products that claim to treat the status of being overweight are making disease claims that trigger premarket approval obligations.

In addition to falling into the disease claim category, weight loss supplements also make structure and function claims placing them in the second category of products that merit drug status. As discussed in Section IV, a look at the history of quack medicine, together with the legislative history behind the passage of the FDCA, demonstrates that Congress was specifically targeting sham weight loss products when it added the structure and function claims category. Sections V, VI and VII evaluate the history and goals of DSHEA and NLEA. These Sections will explain why neither of these statutory amendments to the FDCA changes the regulatory status of weight loss supplements. Thus contrary to the current FDA position, this Article asserts that weight loss supplements must obtain premarket approval from the FDA

A. Being Overweight as a Significant Risk Factor for Type II Diabetes, Cardiovascular Disease and Cancer

Being overweight is a serious and independent risk factor for numerous chronic health conditions. Significant life style changes, including diet modification and exercise habits, can mitigate these risks and short circuit this progression. But making these changes can be arduous. Sham weight loss supplement manufacturers take advantage of this situation by falsely claiming that their products provide an easy way to lose weight that allows consumers to continue unhealthy lifestyles, leading many down a path of no return.

1. Type II Diabetes

In 2007, according to the CDC, 23.6 million people or 7.8 percent of the population of the United States have diabetes.³¹ Devastating complications of

27. See *infra* notes 31-46 and accompanying text.

28. See *infra* notes 47-50 and accompanying text.

29. See *infra* note 51 and accompanying text.

30. Unfortunately, it is common to progress from being overweight to the heartbreak of obesity. Young adults in their early twenties who are mildly to moderately overweight are significantly more likely to be obese by the time they reach their mid to late thirties. K.M. McTiague et al., *The Natural History of the Development of Obesity in a Cohort of Young U.S. Adults Between 1981 and 1998*, 136 ANNALS INTERNAL MED. 857, 857-64 (2002) (a study that followed 9000 young adults for approximately twenty years). And, as pointed out earlier, children born to overweight mothers are more likely to be overweight, and, ultimately, obese.

31. CTRS. FOR DISEASE CONTROL AND PREVENTION, DEP'T OF HEALTH AND HUMAN SERVS., NATIONAL DIABETES FACT SHEET: GENERAL INFORMATION AND NATIONAL ESTIMATES ON DIABETES IN THE UNITED STATES 4 (2007), http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf

diabetes include blindness, kidney failure and limb amputation.³² Those with diabetes have a risk of death “about twice that of people without diabetes of similar age.”³³ There is a direct correlation between being obese or overweight and diabetes.³⁴ Over ninety percent of those who have diabetes II are overweight or obese.³⁵ Scientists are predicting that the well-publicized childhood obesity epidemic will lead to a corresponding epidemic of Type II diabetes among young adults.³⁶ A vicious cycle is being created as the children of young women with Type II diabetes have a higher risk for obesity and Type II diabetes.³⁷

The longer that one lives with diabetes, the greater the chance of developing life threatening and disfiguring consequences.³⁸ Unless overweight and obese children lose weight, they are likely to have higher rates of diabetes complications and heart disease than older generations with Type II diabetes, which will ultimately decrease their life expectancy.³⁹

[hereinafter FACT SHEET].

32. *Id.* at 10-11. The risk for developing other diseases is increased when an individual is overweight, including the risk of osteoarthritis, respiratory problems (including sleep apnea), gall bladder disease, psoriasis, and fatty liver disease. NAT'L INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, DO YOU KNOW THE HEALTH RISKS OF BEING OVERWEIGHT (Dec. 2007), http://win.niddk.nih.gov/publications/health_risks.htm.

33. FACT SHEET, *supra* note 31, at 9.

34. G.A. Colditz et al., *Weight as a Risk Factor for Clinical Diabetes in Women*, 132 A. J. OF EPIDEMIOLOGY 501, 501-13 (2007) (Nurses' Health Study data documenting association between diabetes and weight); G.A. Colditz et al., *Weight as a Risk Factor for Clinical Diabetes Mellitus in Women*, 122 ANNALS OF INTERNAL MED. 461, 461-66 (1995) (Nurses' Health Study data reveals that association between diabetes and weight starts at BMI of 22); F.B. Hu et al., *Diet, Lifestyle and the Risk of Type 2 Diabetes in Women*, 345 N. ENG. J. MED. 790, 790-97 (2001) (status of being overweight increased risk of diabetes ten fold); A.E. Field et al., *Impact of Overweight on the Risk of Developing Common Chronic Diseases during a 10-Year Period*, 161 ARCHIVES OF INTERNAL MED. 1581, 1581-86 (2001) (data from Health Professionals Follow-up Study, involving men, and the Nurses' Health Study demonstrates that the risk of diabetes increases progressively as BMI increases); J.P. Burke et al., *A Population Perspective on Diabetes Prevention: Whom Should We Target for Preventing Weight Gain*, 26 DIABETES CARE 1999, 1999-2004 (2003) (risk of diabetes for overweight Mexican-Americans is 2.7 times those with normal weight and risk of diabetes for non-Hispanic overweight whites four times greater than normal weight); M.P. St-Onge et al., *Metabolic Syndrome in Normal Weight Americans: New Definition of the Metabolically Obese, Normal Weight Individual*, 27 DIABETES CARE 2222, 2222-28 (2004) (association of BMI and metabolic syndrome which consists of risk factors for diabetes, hypertension and dyslipidemia).

35. AM. DIABETES ASSOC., <http://www.diabetes.org> (last visited Apr. 14, 2009).

36. *Coming Epidemic of Type 2 Diabetes in Young Adults*, SCIENCE DAILY, July 12, 2008, <http://www.sciencedaily.com/releases/2008/07/080708193249.htm> (quoting endocrinologist Joyce Lee of the University of Michigan C.S. Mott Children's Hospital) [hereinafter *Coming Epidemic*].

37. *Id.*

38. *Id.*

39. *Id.* “Recent studies suggest that there have been dramatic increases in type 2 diabetes among individuals in their 20s and 30s, whereas it used to be that individuals developed type 2 diabetes in their late 50s or 60s.” *Id.*

2. *Pre-Diabetes*

Approximately fifty-seven million people in the United States have pre-diabetes.⁴⁰ Pre-diabetics have high blood glucose levels, just not high enough to be warrant the diagnosis of diabetes.⁴¹ However, pre-diabetics have an increased risk of developing Type II diabetes, heart disease and stroke.⁴² “Adults with pre-diabetes are at more than ten times the normal risk for developing diabetes and twice the risk for heart attack or stroke.”⁴³

Progression to diabetes is not inevitable; “[s]tudies have shown that people with pre-diabetes who lose weight and increase their physical activity can prevent or delay diabetes and return their glucose levels to normal.”⁴⁴ For example, participants in a program run at a YMCA that was designed to promote life-style changes to help prevent disease took a series of sixteen classes on “building knowledge and skills for goal setting, self-monitoring and problem solving.”⁴⁵ The participants had significant, long-term weight loss, a substantial decrease in the risk of developing diabetes and a marked decrease in cholesterol levels. The YMCA has approximately 2,500 facilities serving approximately 10,000 communities in the inner city, suburban and rural areas. The YMCA, and other similar organizations which have long histories of successful implementation of health promotion programs, are ideally situated to reach many individuals with pre-diabetes. However, it appears that many overweight pre-diabetics are being lured away from making these types of major lifestyle changes by deceptive, quick-fix weight loss products.⁴⁶

3. *Cardiovascular Disease*

There are over eighty million Americans who struggle with atherosclero-

40. FACT SHEET, *supra* note 31, at 4.

41. *Id.* at 3.

42. *Id.*

43. *Dance to the Music: Learning and Exercising at YMCA Can Prevent Diabetes, New Study Says*, SCIENCE DAILY, Sept. 11, 2008, <http://www.sciencedaily.com/releases/2008/09/080909074058.htm>. [hereinafter *Dance to the Music*].

44. *Coming Epidemic, supra* note 36.

45. *Dance to the Music, supra* note 43. This program was part of a study involving the enrollment into two groups of ninety-two individuals at a YMCA. The intervention group attended sixteen classroom meetings which “focused on building knowledge and skills for goal setting, self-monitoring and problem solving. The control group was given standard diabetes prevention advice.” *Id.* At a follow-up visit held four to six months afterwards, the intervention participants had decreased their body weight by six percent, while the controls had only decreased by two percent. This translates into a mean weight loss of 12.5 pounds for the intervention group and two pounds for the control group. The weight loss in the intervention group was clinically significant as was their decrease in cholesterol. These differences persisted at a twelve to fourteen month follow-up. *Id.*

46. See *infra* notes 60-64 and accompanying text.

sis, stroke, hypertension, coronary artery disease and hypertension.⁴⁷ Over one million new cases of heart disease are diagnosed yearly⁴⁸ and there is a direct link between heart disease and being overweight.⁴⁹ The odds of heart disease, hypercholesterolemia and hypertension are significantly increased for those who are overweight.⁵⁰ In addition, a higher BMI during childhood is associated with an increased risk of heart disease in adulthood.

4. Cancer

In 2007, the American Institute for Cancer, along with the World Cancer Research Fund, corroborated studies that demonstrated that individuals who are overweight are at an increased risk of certain types of cancer, including cancers of the kidneys, esophagus, pancreas, endometrium, uterus and ovaries, as well as colorectal cancer, esophageal adenocarcinoma and postmenopausal breast cancer and non-Hodgkin's lymphoma.⁵¹

47. AM. HEART ASSOC. & AM. STROKE ASSOC., HEART DISEASE AND STROKE STATISTICS: 2008 UPDATE AT A GLANCE 2 (2008), http://www.americanheart.org/downloadable/heart/1200078608862HS_Stats%202008.final.pdf.

48. *Id.*

49. W.C. Willett et al., *Weight, Weight Change, and Coronary Heart Disease In Women*, 273 JAMA 461, 461-65 (1995) (risk of coronary heart disease in women increased progressively with increased weight with risk doubling when becoming overweight); E.B. Rimm et al., *Body Size and Fat Distribution As Predictors for of Coronary Heart Disease Among Middle-Aged and Older Men*, 141 AM. J. EPIDEMIOLOGY 1117, 1117-27 (1995) (findings for men similar to findings for women with risk of coronary heart disease doubling when becoming overweight); J.W. Anderson et al., *Obesity and Disease Management: Effects of Weight Loss on Comorbid Conditions*, 9 OBESITY RESEARCH 326, 326-34 (2001 Supp.) (same); R.H. Eckel et al., *American Heart Association Call To Action: Obesity as a Major Risk Factor For Coronary Heart Disease*, 97 CIRCULATION 2099, 2099-2100 (1998) (same); A.E. Field et al., *Impact of Overweight on the Risk of Developing Common Chronic Diseases during a 10-Year Period*, 161 ARCHIVES OF INTERNAL MED. 1581, 1581-86 (2001) (data from Health Professionals Follow-up Study involving men and Nurses' Health Study demonstrates that the risk of hypertension, hypercholesterolemia and heart disease is significantly higher when overweight); P.W.F. Wilson et al., *Overweight and Obesity as Determinants of Cardiovascular Risk: The Framingham Experience*, 162 ARCHIVES OF INTERNAL MED. 1867, 1867-72 (2002) (same); I. Jansen et al., *Waist Circumference and Not Body Mass Index Explains Obesity-Related Health Risk*, 79 AM. J. OF CLINICAL NUTRITION 379, 379-84 (2004); J.L. Baker, *Childhood Body-Mass Index and the Risk of Coronary Heart Disease in Adulthood*, 357 NEW ENG. J. MED. 2329, 2329-37 (2007).

50. See sources cited *supra* note 49.

51. AM. INST. FOR CANCER RESEARCH & WORLD CANCER RESEARCH FUND, *Body Composition, Growth and Development: Body Fatness, in FOOD, NUTRITION, PHYSICAL ACTIVITY, AND THE PREVENTION OF CANCER: A GLOBAL PERSPECTIVE* 210 (2007), <http://www.dietandcancerreport.org>; E.E. Calle et al., *Overweight, Obesity and Cancer: Epidemiological Evidence and Proposed Mechanisms*, 4 NATURE 579, 579-91 (2004) (evaluating the association between weight and risk of cancer based on a literature review of current epidemiological studies); E.E. Calle et al., *Overweight, Obesity, and Mortality From Cancer in a Prospectively Studied Cohort of U.S. Adults*, 348 N. ENG. J. MED. 1625, 1625-38 (2003) (as BMI increases, so does the overall risk for cancer); CENTERS FOR DISEASE CONTROL AND PREVENTION, NCHS DATA ON CANCER, <http://www.cdc.gov/nchs/data/factsheets/cancer.pdf>.

III. THE GROWTH OF THE WEIGHT LOSS SUPPLEMENT INDUSTRY

Consumers in the United States have been exposed to a steady diet of information regarding the relationship between weight and disease. The major networks' nightly news shows, the popular morning shows *Good Morning America* and *The Today Show* as well as the powerhouse *Oprah* show, repeatedly air stories explaining this relationship. Consumer surveys confirm that the vast majority of Americans who are overweight understand the link between being overweight and increased health risks for serious chronic conditions.⁵² In fact, the primary motivation to lose weight for many is to improve their health to avoid or mitigate these health risks.⁵³

As the result of prodigious marketing campaigns, both adults and adolescents are turning to weight loss supplements being marketed as dietary supplements to either aid in their weight loss efforts or as an alternative to diet modification and exercise.⁵⁴ Advertisements for the 'quick-fix' product that works to melt off pounds without diet or exercise, some even while you sleep, are everywhere.⁵⁵ Enforma Natural Products, Inc. ran an infomercial marketing its product *Exercise in A Bottle* claiming it "helps your body burn more calories while you're just standing or sitting around doing nothing – even while you are sleeping" and "[y]ou can enjoy all those delicious foods like fried chicken, pizza, cheeseburgers, even butter and sour cream, and stop worrying about the weight."⁵⁶ The manufacturer of a similar product called *Maxiline* advertised heavily by taking out full-page newspaper advertisements stating "[s]leep ... and lose weight in just a few nights ... you eat whatever you want."⁵⁷ The advertisement stated that the product worked because "the body's fat cannot defend itself from attack while asleep."⁵⁸

Commercials on television and radio, lengthy infomercials, magazine advertisements, mass mailings of brochures and Amway and "Avon-Calling" type visits from friends and neighbors hawking miracle potions for magical weight

52. CTR. FOR SURVEY AND RESEARCH ANALYSIS & CTR. FOR WEIGHT LOSS, THE LANDMARK SURVEY (2006), http://www.csra.conn.edu/pdf/National_Dietary_Survey.pdf (survey of approximately 12,000 households and in-depth interview of sample of 3,500 individuals performed by centers at the University of Connecticut and the University of Pennsylvania, respectively) [hereinafter THE LANDMARK SURVEY].

53. *Id.* (43% stated that their goal in losing weight was to improve their health while only 10% were motivated to improve their appearance).

54. Statement of Director Heinrich, GAO, *supra* note 6, at 3. These products claim to cause weight loss by increasing energy expenditure, changing carbohydrate metabolism, increasing a feeling of satiation or decreasing appetite, increasing fat oxidation, reducing the accumulation of fat, or blocking the absorption of fat. H.M. Blanck et al., *Use of Non-prescription Dietary Supplements Among Americans is Common*, 107 J. AM. DIETETIC ASSOC. 441, 441-47 (2007); P.A. Sharpe et al., *Availability of Weight-Loss Supplements: Results of an Audit of Retail Outlets in a Southeastern City*, 106 J. AM. DIET. ASSOC. 2045, 2045-51 (2006).

55. Anthony, *supra* note 14.

56. *Id.*

57. *Id.*

58. *Id.*

loss flood the American consciousness.⁵⁹ In 2000, the sale of weight loss supplements in the United States reached \$4.7 billion,⁶⁰ with a projected increase of ten to twenty percent annually.⁶¹

In the book *Through the Looking Glass*, Alice said, “[o]ne can’t believe impossible things.”⁶² The White Queen answered: “I daresay you haven’t had much practice When I was your age . . . I’ve believed as many as six impossible things before breakfast.”⁶³ Like Alice, for many, the impossible weight loss claims made by the current breed of snake oil salesmen defy credibility.⁶⁴ However, viewed in context, these beliefs are more understandable. Many of these consumers, and, shockingly, their physicians, incorrectly believe that the FDA requires premarket testing to establish that these weight loss supplements are both safe and effective.⁶⁵ In fact, the FDA does not require that these products undergo clinical testing for safety or efficacy prior to being

59. *Id.* “Many egregious claims – particularly for weight loss products – often appear in the mainstream media. Major national newspapers, magazines, television, cable and radio stations seem too ready to accept the substantial advertising dollars of this industry without question, often airing patently fraudulent ads with claims of extreme, instant, effortless weight loss. . . . Ads promising as much as ninety-three pounds of quick and easy weight loss without dieting, ran in magazines like *Cosmopolitan*, *Esquire*, *McCall’s*, *Redbook*, and *Women’s Day*, in major newspapers like the *Atlanta Journal-Constitution*, the *Denver Rocky Mountain News* and *USA Today* as well as “Smart Source,” a coupon-insert publication.” *Id.*

60. CONSUMER HEALTHCARE PROD. ASSOC., *supra* note 9.

61. Statement of Director Heinrich, GAO, *supra* note 6, at 1. In their desperation to lose weight, many consumers will try one product after another. Blanck et al., *supra* note 54, at 441-47.

62. LEWIS CARROLL, *THROUGH THE LOOKING GLASS* (1865), *reprinted in* THE COMPLETE WORKS OF LEWIS CARROLL 184 (Barnes & Noble, 1994).

63. *Id.*

64. The courts disagree over the standard that should be applied to determine when claims are misleading. On one end of the spectrum, courts state that the purpose of the FDCA is “to protect the public, the vast multitude which includes the ignorant, the unthinking and the credulous who, when making a purchase, do not stop to analyze.” *U.S. v. 62 Packages, More of Less, of Marmola Prescription Tablets*, 48 F. Supp. 878, 884 (W.D. Wis. 1943); *U.S. v. An Article of Food . . . Manischewitz . . . Diet Thins*, 377 F. Supp. 746, 749 (E.D.N.Y. 1974) (quoting *U.S. v. An Article – Nuclomin*, 482 F.2d 581 (8th Cir. 1973)) (“the test is not the effect of the label on a ‘reasonable consumer,’ but upon ‘the ignorant, the unthinking and the credulous’ consumer.”). On the other end of the spectrum, other courts have held that the test is that of “purchasers who are of normal capacity and use that capacity in a common sense way.” *U.S. v. Piraud*, 1938 FDLI JUD. & ADMIN. REC. 526, 529 (S.D.N.Y. 1949); *U.S. v. Two Cases of Chloro-Naptholeum Disinfectant*, 217 F. 477, 484 (D.C. Md. 1914). In 2002, the FDA announced that the standard that it will apply is the reasonable consumer standard. Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements, 67 Fed. Reg. 78002, 78003 (Dec. 20, 2002) (“In assessing whether food labeling is misleading, FDA will use a ‘reasonable consumer’ standard.”). An interesting question is whether the “reasonable person” standard used to assign fault, and thereby liability, in tort law is appropriate in a public health context when the mission of the FDA is consumer protection.

65. Of those physicians who had completed an internal medicine residency program, a stunning one-third were unaware that dietary supplements did not need premarket approval from the FDA for safety and effectiveness. B.H. Aschar et al., *Physicians’ Understanding of the Regulation of Dietary Supplements*, 167 ARCHIVES INTERNAL MED. 966, 966-99 (2007).

placed on the market.⁶⁶ This vast market exists in spite of the fact that there is little to no evidence that most of these products actually work.⁶⁷ To the contrary, there is growing evidence that many are ineffective⁶⁸ and unsafe.⁶⁹ In 2002, the FTC issued a report that fifty-five percent of the claims made within advertisements of over-the-counter weight loss products were either false or misleading.⁷⁰ According to the FTC, more consumers are defrauded by weight loss products than any other product it has examined.⁷¹

With tens of millions of pre-diabetics on the cusp of entering the vast ranks of those who already struggle with Type II diabetes, and with similar numbers battling cardiovascular disease and cancer, preventing quack weight loss products from sabotaging consumers' efforts to lose weight by making the necessary life style changes in order to reduce their health risks must be a national public health priority.

IV. A HISTORY OF FDA REGULATION OF DECEPTIVE AND UNSAFE PRODUCTS: THE TRANSITION FROM POST-MARKET POLICING TO PRE-MARKET PREVENTION

A look back through the history of the relationship between the FDCA, the FDA and predatory commercial interests adds a clarifying perspective to the argument that the FDA currently has the authority to deal expeditiously with deceptive weight loss products to both remove those that are currently on the market and prevent others from entering the market.

Over the 100 year history of the FDA, Congress has been steadfast in balancing the protection of individual choice in matters involving self-regarding behavior, such as food choices, with the need to protect vulnerable consumers

66. See *infra* notes 252-257 and accompanying text.

67. J.T. Dwyer et al., *Dietary Supplements in Weight Reduction*, 105 J. AM. DIETETIC ASSOC. 80, 80-86 (2005 Supp.) (scientists at the National Institutes of Health opine that evidence on the effectiveness of weight loss supplements is "inconclusive at present"); R.B. Saper et al., *Common Dietary Supplements for Weight Loss*, 70 AM. FAMILY PHYSICIAN 1731, 1731-38 (2004) (according to Harvard Medical School researchers, randomized clinical studies have never been performed on many weight loss supplements; in addition, "no weight loss supplement meet criteria for recommended use"); M.H. Pittler et al., *Dietary Supplements For Body-Weight Reduction: A Systematic Review*, 79 AM. J. CLINICAL NUTRITION 529, 529-36 (2004) (little evidence exists to support claims that any dietary supplement works to reduce weight).

68. The common active ingredients contained in weight loss supplements are bitter orange, chromium, guar gum, hoodia, garcinia, conjugated linoleic acid, pyruvate, and chitosan. For each ingredient, there was either strong evidence of no effect on weight loss or inconclusive evidence. Some of these substances have serious, toxic side effects associated with their use. For a chart of the most common weight loss supplement ingredients and attendant adverse reactions, see Statement of Director Heinrich, GAO, *supra*, note 6, app. at 21-24.

69. *Id.*

70. FED. TRADE COMM'N, WEIGHT LOSS ADVERTISING: AN ANALYSIS OF CURRENT TRENDS 30 (Sept. 2002), <http://www.ftc.gov/bcp/reports/weightloss.pdf>.

71. CONSUMER FRAUD IN THE UNITED STATES: THE SECOND FTC SURVEY, *supra* note 13, at 15.

from harm from third parties who are marketing health care products.⁷² It has done so by linking the level of product regulation with the health status of the product's targeted population. Accordingly, the greatest amount of regulatory protection has been applied when products are targeted at *vulnerable, unhealthy* populations and claim to aid in an individual's struggle to return to normal health.⁷³ Examples of products that fall into this category include drugs and devices.

For these products, the modern FDCA establishes a premarket enforcement process that places the majority of the cost and burden on the product manufacturer to establish safety and efficacy through the clinical trial process prior to distribution to the public. Without premarket approval from the FDA, these products will be deemed both adulterated and misbranded as a matter of law. Conversely, the FDCA requires less regulatory protection when products are targeted to *healthy* populations for use in maintaining or improving a normal state of health. Examples of products that fall into this category are foods and narrow categories of functional foods and dietary supplements. For these products, the FDA carries the burden of removing an unsafe or ineffective product by proving that it is adulterated or misbranded.

A review of the history of quack medicines supports this public health strategy. The late nineteenth and early twentieth centuries saw a remarkable growth in the marketing of sham products to treat and cure disease. At that time, the rate at which quack medicines were being introduced into the market far outpaced the development of the science necessary to establish the efficacy and identify the risks associated with each new product. This scientific lag time created a period when there was an information void that predatory commercial interests were quick to use to their advantage. As the FDA carried the burden of proof to show that a product did not work or was unsafe in order to remove the product from the market, during this lag time predatory commercial interests were able to profit from scientific uncertainty to the detriment of public health.

During this long period in U.S. history, the curative claims of predatory sham medicine salesmen were limited only by the gullibility of their targets. In

72. In the context of the protection of public health, the line between the legitimate and illegitimate role of paternalism in government regulation is crossed when regulation moves from the prevention of harm from third parties into the regulation of self-regarding behavior. (Self-regarding behavior consists of choices that impact the individual making the choices and not third parties). In this context, the harm from third parties is the provision of misleading information to consumers who rely on this information in making health treatment or health maintenance choices: the more unhealthy the consumer, the greater the degree of harm that results from the provision of misinformation. For sham products, the harm is the delay in obtaining necessary and effective treatment. For a product containing harmful ingredients, there is direct physical damage. The potential harm is less when misinformation is provided to consumers who are using the information to make choices on how to maintain or improve normal health.

73. *Whitaker v. Thompson*, 353 F.3d 947, 951 (D.C. Cir. 2004) (“[B]ecause the health of diseased populations is particularly vulnerable, greater regulation may be justified for products intended for their consumption.”).

many cases, the degree of gullibility was proportional to the level of desperation of the individual for a cure. The more dire the condition, the more vulnerable an individual was to the 'flim flam' of the greedy snake oil salesman. And the more dire the condition, the greater the degree of harm when the sham medicine did not work, causing injury over and above the original illness and/or causing a delay in seeking effective medical treatment. Thus, this lag time between initial marketing of a sham product and the development of the science necessary to resolve uncertainties over the new product's safety and effectiveness was very costly in terms of human suffering and loss of life.

It took a series of highly publicized public health crises to create the political will needed to pass legislation to close this 'space between' created by scientific uncertainty. This was accomplished by switching the burden of proof of safety and effectiveness from the FDA and onto manufacturers. As more fully discussed in the following sections, it was not until 1962 that legislation was passed that required manufacturers to obtain premarket approval for new drugs from the FDA by producing "substantial evidence" that the product is both safe and effective for its intended use. The Drug Amendments of 1962 allowed the FDA to make the transition from its former inefficient and costly police role of enforcing specific statutory prohibitions by removing adulterated and misbranded products from the market, to its current gatekeeper role of preventing those products from entering the market in the first place. Thus, from 1962 until 1994, manufacturers were no longer able to 'play in the grey' and take commercial advantage of the scientific uncertainty over the safety and effectiveness of a product to the detriment of public health.

The legislative history of the FDCA makes it clear that Congress also intended that weight loss products fall into the same regulatory category as drugs and devices specifically to deal with predatory profiteering by product manufacturers that targeted a vulnerable population of those who were overweight or obese. In the legislative record, members of Congress expressed their intent to deal with the massive number of "worthless" products being marketed for weight loss at the time. Thus, prior to the passage of DSHEA and NLEA, the FDCA required that manufacturers of weight loss supplements obtain premarket approval by establishing the safety and effectiveness of their products before distributing them.

With the passage of DSHEA in 1994, which allegedly shifted the burden of proof back onto the FDA with relation to dietary supplements marketed to both healthy populations and vulnerable, unhealthy populations, predatory commercial interests are again being allowed to exploit scientific uncertainty. Based upon an overbroad interpretation of the intent of Congress in passing DSHEA, the door has been opened to the same deceptive advertising that ran rampant in the late nineteenth and early twentieth centuries. And unfortunately, tens of millions of vulnerable and desperate individuals who are overweight and at grave risk of developing a serious, chronic disease are being lured into this predatory playground. The United States has now come full circle and returned to the era of the snake oil salesman. The very public health problem that

the FDCA was originally promulgated to deal with, fraudulent and deceptive products that put the nation's health at risk, has reared its ugly head once again.

A. The Rise of the Quack Remedy

In the mid-nineteenth century, two-thirds of Americans still worked on farms.⁷⁴ Thousands of local mills ground grain and hundreds of small packing plants located in rural areas packaged locally produced foods.⁷⁵ By the end of the century, a majority of the nation had moved to the city, the number of mills grinding grain was exponentially smaller and operated on a much grander scale and the packaging companies were few and located in large cities.⁷⁶

Locally produced foods were now shipped into the great maw of city factories, and returned in cans and jars, watered down, preserved and cheap. . . . The creation of goods *en masse* was soon matched by the ability to move them. Great distances were shrunk by rapid transport. People who had once made food, clothing and medicines, and simple tools for themselves or their neighbors, no longer did. The modern estrangement between the people who create goods and the people who consume them now emerged.⁷⁷

Adulteration and deception were easy and profitable as manufacturers of food and medicines no longer had to face their customers.⁷⁸ Under *laissez-faire* regulation, corruption and abuse were rampant.⁷⁹ Food producers scammed consumers by adding fillers to food to increase weight (such as chalk, clay, or plaster of paris to flour and ground up insect carcasses, commonly lice, to brown sugar).⁸⁰ Large amounts of untested chemicals (such as formaldehyde, sulfites, borax, salicylic acid and benzoic acid) were used liberally to preserve food for transport and to disguise the taste and appearance of food that was spoiled.⁸¹

74. PHILLIP J. HILTS, *PROTECTING AMERICA'S HEALTH THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* 11 (2003).

75. *Id.*

76. *Id.* at 12.

77. *Id.*

78. FOOD & DRUG ADMIN., *THE LONG STRUGGLE FOR THE 1906 LAW* (June 1981), <http://www.cfsan.fda.gov/~lrd/history2.html>.

79. *Id.* at 21.

80. HILTS, *supra* note 74, at 22.

81. *Id.* at 21-22 ("Copper sulfate can make faded vegetables appear green again; sodium benzoate can prevent decayed tomatoes from rotting altogether; stearins can stretch lard; borax can make odorous ham acceptable when canned."); RICHARD M. COOPER, *THE STRUGGLE FOR THE 1906 ACT*, in *FDA: A CENTURY OF CONSUMER PROTECTION* 28 (Wayne L. Pines ed., 2006) ("Milk was one of the most adulterated products in America at the turn of the century; it was

In the context of medicines, the nineteenth century was known as the “grand era of the quack remedy,” where medical fraud was perpetrated on a scale never before seen in this country.⁸²

Medicine was split into the inadequate but seriously intended treatment by doctors and the predatory commercial medicine that had no basis but the desire for profit. And, as it happened, medicine was one of the first fully national markets that used nationwide advertising. Quack medicines, of which there had always been a trickle, suddenly became a flood as tradesmen, not doctors, saw the possibilities for profit.⁸³

A good example of one such quack remedy is Swaim’s Panacea, which pictured Hercules wrestling with the hydra as its logo. Swaim’s Panacea claimed to cure “cancer, scrofula, rheumatism, gout, hepatitis, and syphilis.”⁸⁴ These fake remedies hawked by snake oil salesmen were referred to as “patent medications,” not because they were patented, but because their ingredients were labeled as “secret formulas.”⁸⁵ Common ingredients included arsenic, cocaine, opium and alcohol.⁸⁶ It was commonplace to give teething infants medications containing opium, which is thought to have cost tens of thousands of lives.⁸⁷

These sham remedies grew in direct proportion to the rapid growth of inexpensive newspapers and magazines and mass literacy. By the end of the nineteenth century, manufacturers of patent medications were the largest advertisers in the country.⁸⁸ The ability to advertise also brought novel and aggressive marketing techniques to bear.⁸⁹ With cheap postal rates for bulk mailings, the direct to consumer advertising movement was born as manufacturers created simulated newspapers and pamphlets touting the curative power of their products.⁹⁰ Operating in an area almost completely devoid of regulation, vast fortunes were made as the quack medicine man was free to prey on the desperate and the vulnerable. A prominent historian captured the enormity of the

frequently watered down and preserved with formaldehyde.”).

82. HILTS, *supra* note 74, at 23.

83. *Id.*

84. *Id.* at 24-25. Another example is Liquozone which was sold as a cure for “everything from dandruff to dysentery, and contained 99 percent water and one percent sulfuric acid to give it a bite.” *Id.* at 48.

85. JAMES HARVEY YOUNG, *THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN TWENTIETH CENTURY AMERICA* 14 (1967) [hereinafter *MEDICAL MESSIAHS*].

86. COOPER, *supra* note 81, at 28.

87. *Id.*

88. *Id.* at 25.

89. *Id.*

90. *Id.*

rewards that were reaped by these unscrupulous predators in the title of his book on the era, *The Toadstool Millionaires*.⁹¹

B. The Pure Food and Drug Act of 1906: A Victory for Predatory Commercial Interests

The Progressives of the early twentieth century recognized that phony medicines not only cheated consumers, these concoctions put consumers' health, and even their lives, at risk.⁹² The problem involved toxic ingredients as well as harmless, but ineffective, ingredients.⁹³ If a proven remedy existed, a fake potion could divert or delay a consumer from seeking out necessary treatment.⁹⁴

In an attempt to deal with the problems of adulterated food and drugs, as well as rampant fraud, the Pure Food and Drug Act of 1906⁹⁵ was passed banning adulterated or misbranded food or drugs.⁹⁶ The 1906 Act defined a drug as an article that is intended to "diagnose, mitigate, treat, cure or prevent" a disease and provided that labels on drugs could not be "false or misleading in any particular."⁹⁷ Unfortunately for the chances of success of the 1906 Act, the scientific understanding of the effects of purported cure-alls was in its infancy. Consequently, little scientific data existed on either the effects of, or the health risks associated with, these products. This high level of uncertainty gave a decided advantage to the quack remedy manufacturers as the 1906 Act placed the

91. JAMES HARVEY YOUNG, *THE TOADSTOOL MILLIONAIRES* (1961).

92. MEDICAL MESSIAHS, *supra* note 85, at 29-32.

93. COOPER, *supra* note 81, at 25-69.

94. *Id.*

95. Federal Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (commonly referred to as the "Wiley Act" or the "Pure Food and Drug Act") [repealed by 21 U.S.C. § 329(a) (1938)]; Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 *FOOD, DRUG & COSMETICS L.J.* 2 (1984).

96. *U.S. v. Johnson*, 221 U.S. 488, 495 (1911); Cooper, *supra* note 81, at 34-37. Upton Sinclair's book, *The Jungle* (1905), had a great deal to do with the passage of the Pure Food and Drug Act of 1906. The book provided graphic details regarding families who were struggling to live while working in the meat packing industry that were so disturbing that it made some readers sick while others wept. HILTS, *supra* note 74, at 49.

Particularly disturbing were accounts of workers, sick with tuberculosis spitting onto the floor, then dragging butchered meat across it. There were tales of meat in storage rooms, rotting and covered with rat droppings, which was then made into sausage, detritus and all. There were even tales of workers who had fallen into the great acidic lard vat, and become, after their bones had been fished out, a part of 'Durham's Pure Leaf Lard.'

Id. Within weeks of the publication of *The Jungle*, sales of meat dropped in half. *Id.* Even after packing plants worked triple shifts to clean their plants for coming inspections, inspectors sent into the plants to investigate by Teddy Roosevelt were appalled by the filthy conditions. The public was outraged and the Pure Food and Drug Act that had been stalled in Congress for years was passed in 1906. *Id.*

97. *Johnson*, 221 U.S. at 495; COOPER, *supra* note 81, at 34-37.

burden of proof squarely on the shoulders of the FDA to show that the problem product was unsafe or that its labeling was false.⁹⁸

This advantage was quickly realized when the FDA first attempted to use its new authority under the 1906 Act to pursue quack medicines. In *United States v. Johnson*,⁹⁹ decided in 1911, the United States Supreme Court handed the quack medicine industry a major victory. In *Johnson*, the product at issue was Dr. Johnson's Mild Combination Treatment for Cancer, which allegedly cured almost any cancer.¹⁰⁰ The United States Supreme Court held that the 1906 Act did not apply to therapeutic claims as the relationship between a patent medicine and disease cures was often a matter of conflicting medical opinion and uncertainty.¹⁰¹ With this case, the quack medicine industry was able to stake out a territory in which it would thrive for the next five decades. As long as there was scientific uncertainty over the effectiveness and safety of a "cure," the quack medicine purveyor could operate with virtual impunity.

In a rapid response to the *Johnson decision*, in 1912 Congress passed the Shirley Amendment which banned misbranding claims on drug labels that were "false and fraudulent" regarding curative or therapeutic effect.¹⁰² In reaction, the United States Supreme Court once again hobbled efforts to remove sham remedies by holding in *Seven Cases of Eckman's Alternative v. United States*¹⁰³ that the Shirley Amendment required that claims be both false *and* fraudulent, regardless of how outrageous the claims of therapeutic benefit.¹⁰⁴ After this decision, the government was required to establish an intent to defraud.¹⁰⁵ This meant that manufacturers could defend by claiming that they had a good faith belief in their curative claims regardless of the lack of any evidence in support. The Court in *Seven Cases* established a *de facto* license for the "ignorant nostrum vendor who sold inefficacious drugs in good faith."¹⁰⁶ Consequently, predatory commercial interests claimed a victory in the court battles over the enforcement of the 1906 Act.

98. *Johnson*, 221 U.S. at 495; COOPER, *supra* note 81, at 34-37.

99. *Johnson*, 221 U.S. at 495.

100. *Id.* at 496.

101. *Id.*

102. Shirley Amendment, ch. 352, 37 Stat. 416 (1912). *See also* COOPER, *supra* note 81, at 17.

103. *Seven Cases of Eckman's Alternative v. U.S.*, 239 U.S. 510 (1916) (product label made claims that the potion cured pneumonia and tuberculosis).

104. *Id.* at 516.

105. *Id.* at 516-18.

106. David Cavers, *The Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 34 (1939). The *Seven Cases* decision also extended the length of time that the quack medicine man could take advantage of scientific uncertainty. Absent other evidence, a lack of a good faith belief could only be established when the science had reached that point in time when it was so well-developed that it would defy credibility that anyone could hold a good faith belief in the curative claims. As science moves in fits and starts, large amounts of time could pass before the degree of certainty over the health effects, both good and bad, of any product could be established to such a high level of certainty.

1. Sham Weight Loss Supplements Under the 1906 Act

While the FDA was able to win some cases involving the most obviously fraudulent concoctions - for example colored water marketed to have curative abilities - ¹⁰⁷ critics of the 1906 Act pointed out that some forms of quackery could not be prevented at all, such as quack concoctions “promising to put flesh on the skinny or take it off the fat.”¹⁰⁸ This gap in the 1906 Act allowed a massive growth in quack remedies for weight loss that started in the twenties¹⁰⁹ when “[s]tyle decreed that men must be lithe and athletic and women slim to the point of emaciation.”¹¹⁰ In a speech titled “Fraudulent Advertising” given on the NBC network, then Federal Trade Commissioner William E. Humphrey stated that “[f]abulous sums are being spent for . . . anti-fat frauds . . . since the female skeleton has become the fashion of the country.”¹¹¹

a. Marmola I

Riding this wave was a product called Marmola, containing the dried thyroid gland of different animals and laxatives.¹¹² Advertising headlines for Marmola included “Beneath Your Fat a Graceful Figure Dwells” and “Famous Beauties Never Get Fat.”¹¹³ These advertisements explained that “grand ladies might indulge in a ‘lifelong loaf,’ drink liquor ‘not illiberally,’ and abandon ‘table restraint,’ all without the risk of obesity – if they used Marmola.”¹¹⁴ These advertisements were convincing and sales of Marmola soared.¹¹⁵ Ironically, these advertisements are the mirror images of modern-day products, like Exercise in a Bottle, discussed *supra*, that also claim that a person can consume calorie and fat-packed foods with abandon and still lose weight simply by taking a pill or a powder.

When physicians were using thyroid extracts for weight loss only in certain low-risk patients with great caution, the manufacturers of Marmola were simultaneously advertising the use of thyroid extracts for everyone without reservation.¹¹⁶ In 1928, the FTC (not the FDA which was powerless to act against

107. COOPER, *supra* note 81.

108. MEDICAL MESSIAHS, *supra* note 85, at 54.

109. *Id.* at 123.

110. *Id.* The editor of the *Journal of the American Medical Association* wrote “[t]here seems, indeed, to have come upon the women of America a veritable craze for reduction which has passed the bounds of normality and driven women and young girls to a type of self-mutilation impossible to explain on any other basis than the faddism of the mob.” *Id.*

111. *Id.*

112. *Id.* at 122.

113. *Id.* at 123.

114. *Id.* Along with the advertisements came the testimonial of famous movie actress Constance Talmadge: “The demand for slender figures is so universal that movie stars must have them. Not only beauty, but good health and vitality argue against excess fat.” *Id.*

115. *Id.*

116. *Id.* at 124.

Marmola under the 1906 Act) brought suit claiming false advertising in Marmola I.¹¹⁷ The FTC's expert physician witnesses explained that, even for the most healthy, thyroid preparations carry significant, serious side effects, and for many with other ailments, extra thyroid could be deadly.¹¹⁸ Additionally, Marmola's advertisements claimed that "[p]eople used to think that excess fat all came from over-eating or under-exercise," in fact "fat people, it was found, generally suffered from an under-active thyroid."¹¹⁹ To the contrary, the FTC's experts pointed out at trial that only five percent of people who were overweight owed their condition to low thyroid.¹²⁰ So for ninety-five percent of overweight consumers, thyroid preparations would do no good.¹²¹

The manufacturer of Marmola was able to find expert physicians who testified that Marmola was both safe and effective (several of whom later expressed contrition at being finagled into testifying).¹²² While the FTC prevailed at the trial court level, the decision was overturned on appeal as it was found that the issue of Marmola's safety and effectiveness was a matter of conflicting medical opinion and uncertainty.¹²³ Consequently, Marmola remained on the market, even though it was ineffective for ninety-five percent of consumers and carried significant health risks for many others. Just as was the case in *Johnson and Seven Cases*, a predatory product manufacturer was able to take advantage of scientific uncertainty over the effectiveness and safety of a product at the expense of public health. Thus, until 1938, quack medicine men, like the manufacturer of Marmola, continued to operate with almost complete freedom from regulation when it came to weight loss potions. Deceptive and unsafe products flowed freely onto the market and profits poured into the pockets of the unscrupulous.

As discussed *infra*, the hurdles that the FDA faced in its attempts to remove Marmola in the first part of the nineteenth century foreshadowed its almost decade-long battle to remove Ephedra, a supplement for weight loss with many of the same unsafe properties as Marmola, in the first part of the twentieth century.¹²⁴

C. *The Food, Drug and Cosmetic Act of 1938: The Public Health Costs of the Post-Market Policing of Deceptive and Unsafe Products*

It took the Elixir Sulfanilamide crisis of 1937, when over 100 people died - mostly children - to finally trigger the passage of a law to provide the FDA

117. *Raladam Co. v. Fed. Trade Comm'n*, 42 F.2d 430 (1930), *aff'd*, 283 U.S. 643 (1931).

118. *Raladam*, 42 F.2d at 432-35.

119. MEDICAL MESSIAHS, *supra* note 85, at 54.

120. *Id.*

121. *Id.*

122. *Raladam Co.*, F.2d at 432, n.2.

123. *Id.* at 432-35.

124. See *infra* notes 263-273 and accompanying text.

with the tools to begin its fight against quack medications.¹²⁵ Sulfanilamide was a new antibiotic that was successful for the treatment of disease-causing bacteria, most often venereal diseases and streptococcal infections that caused sore throats in children.¹²⁶ While effective, the taste of sulfanilamide was unpleasant and the large pills were difficult for children to swallow.¹²⁷ The manufacturer added diethylene glycol creating a liquid form of the product which was both palatable and easy to swallow.¹²⁸ The product was tested for taste, color and appearance, but not for safety.¹²⁹ “Within weeks, scores of infants suffered slow, painful death as the diethylene glycol – today’s antifreeze – produced irreversible liver toxicity.”¹³⁰ In response to the public outcry over this tragedy, Congress enacted the Federal Food, Drug and Cosmetic Act in 1938 to replace the 1906 Act.¹³¹

1. *Safety and Efficacy under the FDCA of 1938*

Under the FDCA of 1938, “new drugs were required to be safe for the uses recommended in labeling.”¹³² The FDCA of 1938 provided for premarket *notification*, as contrasted with the modern day requirement of premarket *approval*.¹³³ Under the 1938 FDCA, a new drug manufacturer only submitted premarket notice called a new drug application (NDA). If the FDA did not object within sixty days, the manufacturer was free to market the new drug immediately.¹³⁴

If the FDA did object and requested information on the safety of the new drug, the manufacturer only had to produce a comparatively small amount of evidence to establish safety¹³⁵ that was based solely on the opinion of medical

125. J. Richard Crout et al., *FDA's Role In The Pathway To Safe And Effective Drugs*, in *FDA: A CENTURY OF CONSUMER PROTECTION* 162 (Wayne L. Pines ed., 2006). The company produced 240 gallons of this product and shipped it to druggists all over the country in 4 ounce bottles. HILTS, *supra* note 71, at 91. A total of 107 people died in the two months the product was on the market, most of them children. *Id.*

126. HILTS, *supra* note 74, at 89-93.

127. Crout et al., *supra* note 125, at 163.

128. *Id.*

129. *Id.*

130. *Id.* at 162.

131. *Id.*

132. Crout et al., *supra* note 125, at 162.

133. *Id.* According to the thinking at the time, the word “safe” inherently implied some sort of risk/benefit assessment of efficacy as well as risk. *Id.* No one in 1938 thought the safety standard required an extensive effectiveness evaluation. *Id.* But in 1962, FDA Commissioner George Larrick told Congress that the FDA had been reviewing new products for effectiveness under the 1938 safety standard. *Id.* When a drug presented serious toxicity, he explained, the agency would weigh the advantages of the drug against its disadvantages. *Id.*

134. *Id.*

135. While the importance of controlled, randomized, double-blinded clinical trials was fully realized by the late 1940s, in the early 1960s the pharmaceutical industry still did not apply clinical trials to the evaluation of new drugs. “Instead they relied on small studies aimed at elucidating the mechanism of action or demonstrating a short-term pharmacologic effect, such as

experts based on anecdotal evidence.¹³⁶ If the FDA refused approval of the new drug, it was likely that the manufacturer would appeal this decision to the courts. The FDA still carried the burden at trial of demonstrating that a product was unsafe or ineffective by proving that it was harmful or that therapeutic advertisements were misleading.¹³⁷ And, until 1962, there was no obligation to test a product prior to distribution for efficacy.¹³⁸ This meant that the underfunded and under-staffed FDA had to face the time and expense of a trial for every product it refused to approve or targeted after it was on the market.¹³⁹ And, of course, the FDA had to wait until the science had been sufficiently developed so that it could produce the evidence necessary to meet its burden of proof.

This lag time provided the opportunity for profit at the expense of the consumer who was relying on an often times unsafe and ineffective product to meet his or her health needs. This 'harm first, removal second' inefficiency greatly weakened the FDA's enforcement efforts and allowed numerous products to remain on the market that were detrimental to public health.

2. *Misrepresentations under the FDCA of 1938*

The 1938 Act also banned misleading labeling or advertising and provided that "there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . ."¹⁴⁰ Medical disagreement over efficacy was considered to be a material fact which must be disclosed.¹⁴¹ Thus, if the claims for a product were not generally supported by medical opinion, this fact had to be disclosed under the 1938 Act.¹⁴² This addition foreclosed the tactic that was used so successfully with Marmola I under the 1906 Act of producing one or two experts at trial whose opinion ran counter to general medical opinion in order to create the "difference of medical opinion" dilemma focused on by the *Johnson* and *Seven Cases* courts.¹⁴³

With the 1938 Act, Congress created the basic framework for the zone of regulatory protection that insulates vulnerable, unhealthy populations from pre-

lowering blood pressure or relieving pain. The medical literature consisted largely of collected series of patients' case reports, a few small clinical studies, and review articles. . . ." *Id.* at 165. The FDA's role was also limited. "In 1960, the agency had a small handful of medical officers, toxicologists, and chemists (and no statisticians) devoted to the review of drugs. The publically accepted standard for judging the effect of drugs at the time was the opinion of medical experts." *Id.*

136. *Id.* at 162.

137. *Id.* at 162-63.

138. *Id.* at 163.

139. Crout et al., *supra* note 125, at 163.

140. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

141. *Id.*

142. Cavers, *supra* note 106, at 2.

143. *Id.*

datory commercial interests. This regulatory boundary was fully constructed by the 1962 Amendments to the FDCA and still exists today.

3. *Sham Weight Loss Supplements under the FDCA of 1938*

Finally, the 1938 Act also gave the FDA the tools to begin to chip away at the substantial percentage of quack medications advertised for weight loss which were already on the market.¹⁴⁴ The Act provided for a greatly expanded definition of “drugs” to include not only substances intended for use in the cure, mitigation, treatment or prevention of disease but also all substances, other than food, intended to affect the *structure and function* of the body.¹⁴⁵ Senator Copeland, who sponsored the Act, stated that the addition of “structure and function” claims to the definition of “drug” was added specifically to deal with, among other fraudulent products, the large number of products being marketed that made specious weight loss claims:

The present law defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation or prevention of disease. This narrow definition permits escape from legal control . . . *preparations which are intended to alter the structure or some function of the body, as, for example, preparations intended to reduce excessive weight.* There are many worthless and some dangerous devices and preparations falling within these classifications. S. 2800 contains ample authority to control them.¹⁴⁶

This regulatory expansion was an acknowledgment that increased regulation was warranted not only to protect the vulnerable, unhealthy portion of the population, but also to protect desperate, overweight and obese individuals who were similarly vulnerable to deceptive advertising and ineffective products.¹⁴⁷ Just as is the case today, many overweight and obese individuals were especial-

144. *Id.* at 118.

145. *U.S. v. Bacto-Unidisk*, 394 U.S. 784, 794-95 (1969).

146. *Id.* (emphasis added). This expansion also included claims to affect the structure and function of the body made by sleep aids, tranquilizers and by products that create recreational effects. *Nutrilab v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983) (dealing with weight control products) (quoting *Food, Drug and Cosmetic Act of 1938: Hearings on S. 1944 Before a Subcomm. of the S. Comm. on Commerce*, 73rd Cong. 2d. Sess. 15-16 (1933) (statement of Walter G. Campbell, Chief of Food and Drug Administration)).

147. MEDICAL MESSIAHS, *supra* note 85, at 118. For example, a creme called “Reducine” that was advertised in *True Romances* magazine in 1926, came under regulation for the first time. The Reducine advertisements explained that, upon applying the creme to the body, “a harmless chemical reaction takes place during which the excess fat is literally dissolved away, leaving the figure slim and properly rounded, giving the lithe grace to the body every man and woman desires.” *Id.*

ly susceptible to being deceived into purchasing and ingesting sham ‘magic bullet’ weight loss products. By expanding the definition of drugs to include structure and function claims, Congress recognized that this special vulnerability justified the extra regulation of those sham products that targeted the overweight and obese.

a. Marmola II

After decades of effort, in 1943, the FDA was finally able to successfully remove the weight loss product Marmola from the market in Marmola II.¹⁴⁸ Foreshadowing the modern-day challenges that the FDA faced in the Ephedra weight-loss supplement litigation under DSHEA,¹⁴⁹ in order to contest Marmola’s safety in 1941, the FDA performed a survey of 2,000 members of the American College of Physicians and called nineteen notable scientists as expert witnesses in order to establish that self-medication with dried animal thyroid glands to lose weight carried a significant risk of serious health consequences, including heart attack. The Government also called numerous witnesses who had actually suffered severe health effects.¹⁵⁰

In addition to calling several of its own expert witnesses, the defense of Marmola included allegations that the Government was engaged in a power grab by trying to take away the individual’s “inalienable right” to self-medication.¹⁵¹ A man named Royal Lee, the manufacturer of Marmola, claimed that the Government was conspiring with the American Medical Association to limit access to all medications except through a prescription granted by paying money to a doctor.¹⁵² This defense would later turn into the “freedom of choice” slogan used in the massive lobbying efforts that culminated in the passage of DSHEA in 1994.¹⁵³

Four years after the institution of the cause of action in Marmola II, after an expenditure of “uncounted thousands of dollars . . . and hundreds of hours by legal and medical experts[,]” and after fighting an appeal up to the United States Supreme Court, the FDA prevailed and the Marmola saga was at an end.¹⁵⁴ Next, the FDA began the same elaborate preparation and expense to litigate cases against other major players.¹⁵⁵ “With personnel short and resources scanty, the FDA could in any fiscal year work up only a relatively few

148. *Id.* at 210-15; U.S. v. 62 Packages of Marmola Prescription Tablets, 48 F. Supp. 878 (W.D. Wis. 1943).

149. *See infra* notes 263-273 and accompanying text.

150. MEDICAL MESSIAHS, *supra* note 85, at 212-16.

151. *Id.*

152. *Id.*

153. *See infra* notes 208, 212, 248-251 and accompanying text.

154. MEDICAL MESSIAHS, *supra* note 85, at 212-16

155. *Id.*

important cases in the fringe area of self-medication. Many promoters of dubious drugs and devices were left to wait their turn.”¹⁵⁶

*D. Safety and Effectiveness and the Kefauver-Harris Amendments of 1962:
The Public Health Benefits of Pre-Market Prevention*

Once again, a crisis gave the impetus for change. Thalidomide was widely distributed in Germany, Japan and the United Kingdom for sedative purposes and for the treatment of nausea in pregnancy for several years. In 1960, William S. Merrell Company, the manufacturer of the American version of Thalidomide, Kevadon, applied for FDA approval.¹⁵⁷ However, it was clear to Dr. Frances Kelsey, one of the FDA officers examining the application, that the drug had not been adequately tested for safety before distribution.¹⁵⁸ In spite of pressure to approve the drug placed by the manufacturer on both the FDA and Dr. Kelsey individually, Dr. Kelsey insisted that the drug needed additional testing to prove safety before FDA approval could be granted.¹⁵⁹ In 1961, Dr. Kelsey learned of a possible connection between nerve damage in adults and Thalidomide.¹⁶⁰ She requested that Merrell provide studies on the use of its Thalidomide product on pregnant women.¹⁶¹ In 1962, it was discovered that Thalidomide was causing serious birth defects in children.¹⁶² While the application for Thalidomide was pending for FDA approval, hundreds of severely deformed babies were being born in Germany.¹⁶³ Without the FDA's knowledge, Thalidomide had already been provided to 20,000 patients in the United States as part of a “investigational study.”¹⁶⁴

In response to public outrage, the Kefauver-Harris Amendments to the FDCA were passed which switched the burden of proof for safety and efficacy from the FDA onto the manufacturers.¹⁶⁵ Under these Amendments, the pharmaceutical industry was required to test all new drugs for both safety and effectiveness and to provide this testing data to the FDA in its initial NDA in order

156. *Id.*

157. Crout et al., *supra* note 125, at 163.

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. These babies were born with phocomelia, which is a Greek word that combines the words ‘seal’ and ‘limb.’ MEDICAL MESSIAHS, *supra* note 85, at 416-17. A description of two cases of phocomelia provided a pediatric convention described “[p]hotographs and long bone x-ray pictures showed that the long bones of the infants’ arms had almost completely failed to grow; their arms were so short that their hands extended almost directly from their shoulders. Their legs were less affected but showed signs of a similar distortion of growth . . .” *Id.* Worldwide, it is estimated that 8,000 severely deformed babies were born because of thalidomide. HILTS, *supra* note 74, at 154.

164. Crout et al., *supra* note 125, at 165.

165. *Id.* at 163.

to obtain premarket approval.¹⁶⁶ The nature and weight of the evidence was also strengthened. These Amendments required manufacturers to produce “substantial evidence” obtained through “adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved.”¹⁶⁷ In addition, “an elaborate regulatory system was established for investigational drugs that specifically includes a requirement that research subjects sign written informed consent forms.”¹⁶⁸

E. The Modern FDA Regulatory Structure and the FDA’s Gatekeeper Role

The Kefauver-Harris Amendments allowed the FDA to transition to its modern role as the gatekeeper for the prevention of the marketing and distribution of unsafe and ineffective disease treatment products.¹⁶⁹ This role allows the FDA to operate at an exponentially more efficient manner, maximizing its ability to use its limited budget and staff to protect public health from unsafe and ineffective products targeted to vulnerable, unhealthy populations. With the 1962 Amendments, Congress optimized the zone of protection around the portion of the population that is exceptionally vulnerable as a result of their altered health status in order to shield them from unsafe and ineffective products and to insulate them from predatory commercial practices. Thus, until DSHEA was passed in 1994, manufacturers were no longer able to take advantage of the scientific uncertainty over the safety and effectiveness of a product to the detriment of public health.¹⁷⁰

As described earlier, under the current regulatory structure created by the FDCA, the FDA regulates products according to their intended use.¹⁷¹ To reite-

166. *Id.* at 166-70.

167. *Id.*

168. *Id.* at 170

169. The “agencies activities have changed from court enforcement of clear-cut statutory prohibitions to approval of products based upon an administrative choice among closely balanced alternatives in controlling advanced technologies.” Hutt & Hutt, *supra* note 95, at 2. This gatekeeper role allowed public health considerations to play a larger role in FDA decision-making. In fact, the Food & Drug Modernization Act of 1997 added section 903 (b) which made the protection of public health the FDA’s primary mission. Food & Drug Modernization Act of 1997, Pub. L. No. 110-85, 121 Stat. 823 (2007).

170. The 1962 Amendments acted on knowledge gained from the Food Additives Amendment Act of 1958 (“FAAA”). Joseph A. Levitt, *Keeping America’s Food Supply Safe*, in FDA: A CENTURY OF CONSUMER PROTECTION 140 (Wayne I. Pines ed., 2006). The FAAA placed the burden of proof on the manufacturers, rather than on the FDA, to show that a newly discovered substance added to food is safe if used within specified quantities. *Id.* This change fixed a major flaw in the 1938 FDCA that had placed the burden of proof on the FDA to prove that a food additive was unsafe. *Id.* “This required substantial time, during which the industry could market the potential injurious additions to the consuming public.” *Id.*

171. 21 U.S.C. § 321 (g)(1)(B) (1938); *United States v. Lane Labs*, 324 F. Supp. 2d 547, 556-69 (D.N.J. 2004) (“[T]he ‘intended use’ referred to within the FDCA framework contemplates ‘the objective intent of those legally responsible for the labeling of drugs.’ 21 C.F.R. § 201.128. ‘The intent is determined by such persons’ expressions or may be shown by the

rate, products that make disease claims or products that make structure and function claims are considered to be either drugs¹⁷² or devices.¹⁷³ For drugs and devices, the modern FDA relies on a premarket enforcement process that places the majority of the cost and burden on the product manufacturer to establish safety and efficacy through the clinical trial process¹⁷⁴ prior to distribution to the public.¹⁷⁵ Without premarket approval from the FDA, these products will be deemed both adulterated and misbranded as a matter of law.¹⁷⁶

On the other hand, products that are intended to be used as food are presumed to be safe and do not require premarket testing.¹⁷⁷ Little regulatory protection is needed from the Government as thousands of years of use of traditional food provides consumers with the common knowledge, and thus the ability, to protect themselves from the ordinary risks associated with different traditional food products. This common knowledge and ability to self-protect supports the presumption of safety that is granted to traditional food under the FDCA. If a particular food poses a safety risk over and above those which are

circumstances surrounding the distribution of the article.”). See also *United States v. Storage Spaces Designated Nos. “8” & “9”*, 777 F.2d 1363, 1366 (9th Cir. 1985) (“[I]ntent may be derived or inferred from labeling, promotional material, advertising, or any other relevant source.”).

172. 21 U.S.C. § 321(g)(1) (1994). See also *Lane Labs*, 324 F. Supp. 2d at 556-69 (finding products containing shark cartilage, rice bran and sand brier to be subject to FDCA requirements for drugs as the products were advertised to treat cancer and Human Immunodeficiency Virus); *United States v. Writers & Researchers, Inc.*, 113 F.3d 8, 11 (2d Cir. 1997) (finding a homeopathic substance is subject to FDCA requirements for drugs if it is promoted as a cure or treatment for existing disease, such as cancer, AIDS, or other diseases)..

173. 21 U.S.C. § 321 (h) (1994).

174. 21 U.S.C. §355(a) (1994) and 21 U.S.C. § 360e (1994), respectively.

175. 21 U.S.C. §355(a) (1994) and 21 U.S.C. § 360e (1994), respectively.

176. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761-76 (1996).

177. Katharine A. Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. Cinn. L. Rev. 1645, 1651 (2004); Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 4706 (Jan. 18, 2001) (“[m]ost foods derived from plants predate the establishment of national food laws, and the safety of these foods has been accepted based on extensive use over many years (or even centuries)”). Congress has defined “food” in Section 321(f) as articles “used as food.” “This definition is not too helpful, but it does emphasize that ‘food’ is to be defined in terms of its function as food, rather than in terms of its source, biochemical composition or ingestibility.” *Nutrilab, Inc. v. Schweiker*, 713 F.2d 355 (7th Cir. 1983). According to the lower court, the definition of food includes both the common sense definition and the statutory definition. The common sense definition is “articles used by people in the ordinary way most people use food – primarily for taste, aroma, or nutritive value.” *Id.* The statutory definition expands this by adding gum. *Id.* The court of appeals remarked, “[t]o hold as the district court did that articles used as food are articles used solely for taste, aroma or nutritive value is unduly restrictive as some products such as coffee and prune juice are consumed on occasion for reasons other than for taste, aroma or nutritive value.” *Id.* This debate appears to miss the mark as it is the use intended by the manufacturer that defines a product’s regulatory category as a “food” under the FDCA, not the actual end use by the consumer. For example, if prune juice is marketed as a “food,” i.e. for taste, aroma or nutrition, it is a “food” for the regulatory purposes of the FDCA. If prune juice is marketed as a laxative, it is claiming to treat an abnormal health condition and it is a “drug” for the purposes of the FDCA. Unless there is exclusive use by consumers of prune juice for either purpose, the end use of the prune juice by consumers for taste, aroma or nutrition (as a food) or as a laxative is not relevant.

normally associated with a food product, such as salmonella in peanut butter, the FDA carries the burden of proving that the food is adulterated or misbranded¹⁷⁸ before it can be removed from the market.¹⁷⁹

V. A HISTORY OF THE DIETARY SUPPLEMENT HEALTH EDUCATION ACT:
THE PUBLIC HEALTH COSTS OF RETURNING THE FDA TO POST-MARKET
POLICING OF DECEPTIVE AND UNSAFE PRODUCTS

In a series of skirmishes with the FDA that began in the 1960s, the supplement industry, which included the manufacturers of vitamins, minerals, amino acids (some of which have nutritional value and some of which do not) and herbal remedies that have no nutritional value, fought for its products to be minimally regulated by the FDA as food. The FDA disagreed with this characterization based on its view that, among other reasons, many of these products had no nutritional value and that the industry was making “structure and function claims” and “disease claims” that were targeting both healthy populations and vulnerable, unhealthy populations. This conflict ultimately resulted in a resounding victory for the supplement industry in the form of the Vitamin Amendments of 1976, The Nutritional Health Education Act of 1990 (NLEA) and the Dietary Supplements Health Education Act of 1994 (DSHEA). Collectively, these amendments to the FDCA have been interpreted to strip the FDA of its ability to prevent many deceptive and unsafe supplements from reaching the market. With regard to supplements, these regulatory roll-backs mean that the FDA has been relegated to the ineffective and inefficient role as a post-market policeman tasked with removing problem products from the market.

Unfortunately, the science on the safety and effectiveness of many of these products, especially herbal remedies, is uncertain. In a repeat of decades of past performances, predictably, predatory commercial interests were quick to move in and take advantage of this uncertainty. Thus, the 1980s and 1990s marked the return to the era of the snake oil salesman. In 1994, when DSHEA was passed, there were 4,000 supplement products on the market.¹⁸⁰ By 2004, after deregulation, this number rose to 30,000, with a projection that 1,000 new products would be placed on the market every year.¹⁸¹ Supplements that are marketed for weight loss make up a substantial number of these products. And, as the FTC has pointed out, consumers are defrauded by supplements marketed for weight loss more than any other product the FTC has examined.¹⁸² Of the

178. Van Tassel, *supra* note 177, at 1651.

179. *Id.*

180. FRED H. DEGNAN, CREATIVE APPLICATION OF THE LAW: NOT MERELY A COLLECTION OF WORDS 171 (2d ed. 2006).

181. *Id.* at 173.

182. *See supra* notes 67-70 and accompanying text

claims made in the advertisements of these products, 55% were either false or misleading.¹⁸³

A. The Supplement Industry Wins the Battle Over the Regulation of Vitamins

The term “vitamin” was coined by Casimien Funk in 1911.¹⁸⁴ By the 1940s, more than forty vitamins and other nutrients were discovered to be necessary to an adequate diet.¹⁸⁵ “The word ‘vitamin’ had acquired golden glamour and the use of the word ‘health’ to market common foods was a theme ‘so distorted and exaggerated’ that one FDA official lamented ‘the magic words ‘health giving’ are today the most overworked and loosely applied in the advertising lexicon.’”¹⁸⁶

According to noted historian James Harvey Young, the 1938 Act may have been one of the factors that triggered the growth of the sham vitamin and nutritional supplement industry.¹⁸⁷ By making traditional medical quackery more difficult, the field of nutritional deception appeared to be greener grounds.¹⁸⁸ Add to this proposed explanation the fact that the body of science regarding the safety and effectiveness of quack medications was growing at an astounding rate. This growth acted to shrink the areas of uncertainty where the sham medicine man was able to make his profits. Hence, a move by the quack medicine men into an area where there was greater scientific uncertainty made a great deal of business sense.

Moreover, consumers were vulnerable to alarm tactics that their health was at risk because of perceived problems with their diet as a result of the diet surveys of depression America and the food shortages of WWII.¹⁸⁹ The quack nutritional product purveyor exploited the publicity that came out of government programs to enrich bread and other grain products and the publication in 1941 of the first “Recommended Daily Allowances for Specific Nutrients.”¹⁹⁰ Coupling the new public awareness of nutrition with folklore about foods, dietary supplement salesmen marketed their products based on the myth that al-

183. See *supra* note 70 and accompanying text.

184. JAMES HARVEY YOUNG, *AMERICAN HEALTH QUACKERY* 168 (1992) [hereinafter *AMERICAN HEALTH QUACKERY*].

185. *Id.* By this time, a number of these vitamins and nutrients had been synthesized and marketed. *Id.*

186. *Id.* FDA officials were so concerned that they “chastised the industry and warned the public” that health claims on product labels were convincing the public that “our ordinary diet is sorely deficient in such vital substances as vitamins and minerals, and that these so-called ‘health foods’ are absolutely necessary to conserve life and health.” *Id.* Fast forward to the state of the industry today to see that the phenomenon has repeated itself as the terms ‘healthy’ and ‘natural’ are equally ubiquitous.

187. *Id.* at 170.

188. *Id.*

189. *MEDICAL MESSIAHS*, *supra* note 85, at 333-59, 401-05.

190. *Id.*

most all disease was the result of improper diet.¹⁹¹ This marketing gambit is referred to generally as “the nutritional myth.”¹⁹² Thus, scientific uncertainty, coupled with vulnerability, made for fertile grounds for the growth of the sham vitamin and nutritional supplement industry.

Comparatively little of this marketing was done on the product labeling because of the 1938 Act.¹⁹³ Instead, analogous to current web and e-mail advertising, door-to-door salesmen pitched their products directly to consumers.¹⁹⁴ For example, Nutrilite had a sales force of 20,000 and Nutri-Bio had a sales force of 75,000.¹⁹⁵ The FDA was able to win a number of cases by taping the outrageous health claims of the door-bell ringing salesmen.¹⁹⁶ However, these victories were a very small percentage of the overall problem and did little to stem the tide.¹⁹⁷

In the 1960s,¹⁹⁸ door-to-door sales decreased as health food stores proliferated.¹⁹⁹ Radio and television talk shows grew in popularity as health food gurus counseled the public on the intricacies of the nutritional myth, aroused anxiety over health concerns and insisted that the cure to a wide range of health problems and diseases lay in the use of various herbs and vitamins.²⁰⁰ Hundreds of books were written with twisted views of the role that supplements and vitamins play in health.²⁰¹ For example, a common theme was that “cancer . . .

191. J.R. Bell, *Let 'Em Eat Hay*, 36 TODAY'S HEALTH 22 (1958).

192. *Id.*

193. AMERICAN HEALTH QUACKERY, *supra* note 184, at 170.

194. *Id.*

195. R.M. DEUTCH, THE NUTS AMONG THE BERRIES 215 (1961).

196. MEDICAL MESSIAHS, *supra* note 85, at 333-59, 401-05.

197. *Id.* An example of these products was Catalyn which was a well-known and popular product created by Royal Lee, who would play a large role in the later FDA vitamin battles. FOOD AND DRUG ADMINISTRATION, REPORT ON THE NATIONAL HEALTH FEDERATION (1963). Royal Lee claimed that Catalyn delivered vitamins A through G and could cure “high and low blood pressure, Bright’s disease, dropsy and goutier.” *United States v. Lee*, 107 F.2d 522 (1939). After being convicted of false and fraudulent claims under the 1906 Food and Drug Act, Royal Lee reformulated the product and removed the disease claims from the product’s labels. *Id.* He then produced pamphlets and circulars that made the same disease curing claims and directed his team of salesmen to hand them directly to the consumer at the point of sale. *Id.* This ruse eventually led to Royal Lee’s conviction under the 1938 Act as the product was considered to have been labeled with false and fraudulent disease claims when the pamphlets accompanied the product. *United States v. Lee*, 131 F.2d 464 (1942).

198. At the same time, questions were being raised and Congressional hearings were held on pesticide use and chemical additives in food. Laws were passed to ensure premarket testing for safety was performed, but questions remained over the safety and ethics of the food processing industry as a whole. AMERICAN HEALTH QUACKERY, *supra* note 184, at 173. “These events . . . occurred within a wider climate of suspicion: physicians, scientists, ‘egg-heads’ generally, surveys revealed, were regarded by a significant minority with antagonism. Events beginning in the following decade, from the Vietnam war on through Watergate, broadened and deepened mistrust of established leadership. Health scientists continued suspect.” *Id.*

199. DEUTCH, *supra* note 195, at 215.

200. M. Gunther, *Quackery and the Media*, in S. BARRET & G. KNIGHT, THE HEALTH ROBBERS 285-300 (1976).

201. AMERICAN HEALTH QUACKERY, *supra* note 184, at 172.

is a disease caused by a deficiency of B-17, pancreatic enzymes, or both.”²⁰² The nutritional myth also worked in efforts to target the sales of herbal remedies to the obese and overweight.²⁰³ It was estimated that, in 1954, nutritional supplement sales reached a half billion dollars²⁰⁴ and consumers began to take vitamins in extremely high dosages and encountering serious side effects.²⁰⁵ In 1962, at the same time the thalidomide crisis was unfolding, the FDA finally proposed regulations which would have created standards and upper limits for vitamins and mineral ingredients.²⁰⁶ In addition, the regulations would have required labeling to inform the consumer of the daily allowances and the fact that amounts over the daily allowances were not necessary to health.²⁰⁷ In response, the supplement industry was able to mobilize its constituents and spearhead a massive letter writing campaign directed at members of Congress.²⁰⁸ In 1966, a new version of the regulations was proposed.²⁰⁹ “Marathon” hearings ensued, creating 32,400 pages of transcript.²¹⁰ Ultimately, seven years later in 1973, a final version was announced.²¹¹ In a repeat performance, the supplement industry mobilized and swamped congressmen with over two million letters, more letters than Watergate, demanding that the FDA be reined in.²¹²

In 1976, the supplement industry prevailed and the Vitamin Amendments were passed²¹³ which radically limited the FDA’s authority for the first time in

202. J.A. RICHARDSON & P. GRIFFEN, LAETRILE CASE HISTORIES 6 (1977).

203. AMERICAN HEALTH QUACKERY, *supra* note 184, at 172. “‘Diet books take up some 20 feet of shelf space’ remarked a librarian in Seattle’s main public library, ‘they are the most popular books we have.’” *Id.* Magazines and the sensationalist press added to the hype. *Id.*

204. *Id.*

205. Nat’l Nutritional Foods Ass’n v. Mathews, 557 F.2d 325 (2d Cir. 1977). The FDA consulted with the Food and Nutrition Board in order to determine if there was sufficient scientific support for regulations governing ingredients, formulas, dosage and labeling standards for vitamins and nutritional supplements. 15 FOOD DRUG & COSMETIC REPORTS 4 (Feb. 20, 1954). The answer was that the science was still in its infancy and that there was still a high level of uncertainty over the health effects of high doses of these vitamins and the use of herbs, minerals and amino acids as nutritional supplements. Consequently, the FDA was left with the inefficient product-by-product enforcement tools. 16 FOOD DRUG & COSMETIC REPORTS 2 (Nov. 27, 1954).

Getting wind of the FDA’s inclinations, a group of manufacturers of nutritional supplements and herbal remedies got together and formed the National Health Federation (“NHF”). FOOD AND DRUG ADMINISTRATION, REPORT ON THE NATIONAL HEALTH FEDERATION (1963). Many of its founding members were past targets of FDA litigation, including Royal Lee of Catalyn fame. *Id.* Borrowing from the defense used in the Marmola litigation, the slogan of the NHF was “freedom of choice.” See *supra* notes 151-53 and accompanying text.

206. DEGNAN, *supra* note 180, at 170.

207. *Id.*

208. Nat’l Nutritional Foods Ass’n v. FDA, 504 F.2d 761 (2d Cir. 1974).

209. *Id.*

210. DEGNAN, *supra* note 180, at 170.

211. Final Rule, 38 Fed. Reg. 20,708 (Aug. 2, 1973).

212. Nat’l Nutritional Foods Ass’n v. Mathews, 557 F.2d 325 (2d Cir. 1977).

213. Health Research and Health Services Amendments of 1976, Pub. L. No. 94-278, 90 Stat. 401, 410 (1976) (also referred to as the “Proxmire Amendments”).

nearly seventy years.²¹⁴ The Vitamin Amendments bar the FDA from arguing that vitamins and minerals over a certain dosage are drugs merely because (over a certain amount) these products have no nutritional value. In other words, if a product has no nutritional value and so is not a “food,” the Vitamin Amendments instruct that the product does not automatically become a “drug.”²¹⁵ In addition, the FDA is not permitted to limit the potency of vitamins and minerals on any grounds except safety. And, as is the case with products categorized as foods, the FDA now shoulders the burden of proving that a vitamin or mineral is unsafe over a certain degree of potency.

As the science was, at that time (and still is), evolving, the Vitamin Amendments began the process of reopening the ‘space between’ which allows predatory commercial interests the freedom to hawk massive doses of harmful and ineffective vitamins and minerals for health maintenance. With the passage of the Vitamin Amendments, the supplement industry took the first major step toward the recreation of a commercial playground where it could operate virtually free of regulation as long as scientific uncertainty existed over the health risks and benefits of its products.

B. The Relationship Between the Arrival of Functional Foods and the Dietary Supplement Health Education Act

The 1980s brought in a new wave of health claims, this time relating to herbal remedies. Unlike vitamins, minerals, and amino acids, herbal remedies have no nutritional value. Some herbal remedies have been long used by many in attempts to treat disease. On the other hand, there were many who considered herbal remedies to be a type of food that supplemented the diet, like vitamins. For this group, herbal remedies were used to stay healthy and avoid disease.²¹⁶ Regardless of the purpose for their use, one of the results of the mobilization efforts of the 1960s and 1970s was the solidification of the view of many distributors that, just like traditional food, these herbal remedies were ‘natural’ and therefore safe.²¹⁷ Consequently, according to the supplement industry, just like traditional food, these herbal remedies should not be required to obtain premarket approval.²¹⁸ In a case of history repeating itself, many of these herbal remedies contained the same potentially toxic substances that were used in the patent medicine era, for example ephedra, dried animal thyroid (of Marmola I and II fame), dietary teas, lobelia, caffeine and penny royal.²¹⁹

Before the 1980s, vitamins made up the vast majority of the supplement

214. DEGNAN, *supra* note 180, at 171.

215. *See supra* note 213.

216. DEGNAN, *supra* note 180, at 171.

217. Scott Bass, *Dietary Supplements: Populism and Pirandello*, in *FDA: A CENTURY OF CONSUMER PROTECTION* 226-31 (Wayne L. Pines ed., 2006).

218. *Id.*

219. FDA Advance Notice of Proposed Rulemaking, Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, at 33,698-33,699 (1993).

market. Relative to today, herbal remedies played only a small role compared to the market for vitamins. Thus, herbal remedies chiefly flew under the FDA's regulatory radar.²²⁰ In the 1980s, the FDA, with its limited staff and budget, was saddled with the necessity of bowing to the deregulation dogma of the Reagan administration. Consequently, the FDA ignored many of the herbal remedies that generally seemed harmless and focused its attention on the most dangerous and the ones that made the most outlandish disease curing claims.²²¹

As a result, there was an explosive growth in the herbal remedy industry and the scope of health claims escalated.²²² For example, St. John's Wort was expressly marketed to treat depression. Glucosamine chondroitin was expressly marketed to treat arthritis. Echinacea was expressly marketed to treat the common cold and flu.²²³

By 1992, large corporations dominated the landscape as herbal remedies were cheap to make and could be sold for great profit.²²⁴ By then, this part of the supplement industry had made a strategic transition in the nomenclature of their products from 'herbal remedies' to 'dietary supplements' to better argue that they should be minimally regulated like traditional food.²²⁵ It is unfortunate that Congress and the FDA have adopted this terminology because it appears to have contributed to the confusion over appropriate regulation. As discussed in the next section, it was the push for enhanced FDA regulation by the manufacturers of functional food that resulted in herbal remedies (that have no nutritional value) being minimally regulated as food.

1. The National Labeling and Education Act (NLEA)

Also in the 1980s, as scientific discoveries began detailing the relationship between diet and health, traditional food producers started making health claims, such as "prevents cancer" made by Kellogg's All Bran cereal²²⁶ or "prevents heart disease" made by Quaker Oats on its cereal.²²⁷ These foods are popularly referred to as 'functional foods' because they allegedly function to protect against disease.²²⁸ Some food producers, like Quaker Oats, carried out serious research to substantiate their claims, but others simply jumped on the bandwagon.²²⁹ For example, a manufacturer of doughnuts sprinkled a little oat

220. *Id.*

221. Margaret Gilhooley, *Deregulation and the Administrative Role: Looking at Dietary Supplements*, 62 MONT. L. REV. 85, 90 (2001).

222. Bass, *supra* note 217, at 223.

223. INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, COMPLIMENTARY AND ALTERNATIVE MEDICINE (2005) [hereinafter INSTITUTE OF MEDICINE REPORT].

224. HILTS, *supra* note 74, at 280-81.

225. Bass, *supra* note 217, at 223.

226. FRAN HAWTHORNE, *THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT* 50 (2005).

227. HILTS, *supra* note 74, at 262.

228. *Id.* at 262-63.

229. *Id.*

bran on their product and then claimed a cholesterol reduction effect.²³⁰ While, prior to NLEA, these were clearly disease claims requiring premarket approval from the FDA, consistent with its decision in the context of herbal remedies, the FDA chose not to stop the marketing frenzy.²³¹ The prevailing view of the Regan administration was deregulation and the FDA was politically relegated to dealing with only the worst of these claims.²³²

With the FDA sidelined, within a few years after the first health benefit claim was made by Kellogg's in 1984, an estimated 40% of all new food products had made health or disease reduction claims.²³³ "By 1989, it was estimated that one-third of the entire \$3.6 billion spent on food advertising contained some health message."²³⁴

While the FDA sat virtually idle, the states geared up and actively sued for false and deceptive labeling against major, national manufacturers such as Kellogg's, Kraft and Coca-Cola.²³⁵ Under this era of deregulation, major manufacturers who distributed their products nationally were concerned that a patchwork of fifty different laws would be created and that it would be impossible to conform to all with one label.²³⁶ A call for a uniform labeling law ensuring honesty and fairness came from both manufacturing and consumer groups fed up with deceptive health and labeling claims.²³⁷

Paralleling this development, in 1988, the Center for Science in the Public Interest created a coalition of groups²³⁸ that recognized that detailed labeling on food could be used as an educational tool to promote a public understanding of the relationship between the maintenance of normal health and a healthy diet.²³⁹

In 1989, a major public health reform was introduced in the form of the National Labeling and Education Act ("NLEA").²⁴⁰ The bill called for detailed nutritional information, such as fat, calories, salt and vitamin content, to be listed on the label of foods.²⁴¹ NLEA also required a complete listing of ingredients.²⁴²

Health claims were allowed under the NLEA proposal, but were to be limited to those which targeted people who had a normal health status and who wanted to improve their diet to *maintain* or improve that healthy status.²⁴³ For

230. *Id.*

231. *Id.*

232. *Id.* at 262-63.

233. *Id.*

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.*

238. *Id.* at 261.

239. *Id.*

240. DEGNAN, *supra* note 180, at 171; National Labeling Education Act, Pub. L. No. 1001-635, 104 Stat. 2353 (1990).

241. DEGNAN, *supra* note 180, at 171.

242. *Id.*

243. *Whitaker v. Thompson*, 353 F.3d 947, 950-52 (D.C. Cir. 2004), cert. denied, 543 U.S.

example, an allowable claim under NLEA is that a food product could help *maintain* a normal cholesterol level.²⁴⁴ A claim to lower an abnormally high cholesterol level would be a prohibited disease claim triggering the premarket approval requirements. Therefore, while a functional food could not claim to cure, mitigate or treat an existing disease (a disease claim), a product label that claimed that it could reduce the risk of a disease occurring in a healthy person (a health maintenance claim) was permissible.²⁴⁵ Also, as a manufacturer was not making treatment claims, a lesser burden of proof of scientific support was required for functional foods than that which is applied to drugs.²⁴⁶

Thus, it is clear that NLEA, which was passed in 1990, remains consistent with the long-held position of Congress on the link between the level of product regulation and the health status of a product's targeted population. Functional foods are targeted to the healthy portion of the population with the goals of health maintenance or the improvement of normal health, so less regulation is needed. On the other hand, if a functional food targets a vulnerable, unhealthy

925 (2004).

244. *Id.*

245. *Id.* As pointed out in a recent Citizen's Petition *infra* note 306, at 22-28, NLEA allows claims that ingestion of food products may reduce the risk of developing a chronic disease. It does not appear that NLEA will allow a health claim by the manufacturer of a weight loss supplement that the product will prevent the onset of a chronic disease. This is because the reduction of disease risk must be accomplished through the ingestion of an active ingredient contained in the product itself, i.e. the substance itself reduces the risk. Where the claim is that the product promotes weight loss, which then causes the reduction of disease, there are two separate claims being made: (1) 'eat my product and lose weight'; and then, (2) 'once you lose weight, your risk of developing a chronic disease is reduced.' It is the weight loss that reduces the risk of disease, not the product. Eating the weight loss supplement will not reduce the risk of disease. Thus, a claim that of 'eat my product and reduce the risk of disease' is a false statement. *Id.*

246. NLEA authorizes the FDA to approve "health claims" that a functional food can reduce a healthy person's risk of contracting a chronic disease "subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary." 21 U.S.C. § 343(r)(5)(D) (1994). The FDA promulgated regulations allowing health claims when a significant scientific agreement ("SSA") has been reached regarding the existence of a diet-disease relationship. 21 C.F.R. § 101.14. The SSA requirement calls for relevant and high quality studies that provide qualified scientists with a "high level" of comfort that the claimed relationship is scientifically valid. The FDA also set up a sliding scale for a second category of claims referred to as "qualified health claims." *Id.* These are health claims that a food can reduce a healthy person's risk of contracting a chronic disease that do not have SSA to support them. *Id.* The FDA will grant premarket approval for these claims if a disclaimer is provided so that consumers are not misled. The strength of the disclaimer is related to the amount of evidence there is to support the claim. *Id.* For example, a Category B disclaimer may read "although there is scientific evidence supporting the claim, the evidence is not conclusive;" a Category C claim may read "some scientific evidence suggests . . . , however, FDA has determined that this evidence is limited and not conclusive;" and a Category D claim may read "very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim." If there is no credible evidence to support the claim, FDA premarket approval will be denied. Bass, *supra* note 217, at 225-31. The current state of the science is that there is no credible evidence to support the claims that any of the ingredients in weight loss products work to reduce weight.

population by making a “structure or function claim” or a “disease claim,” it will be considered a drug and the stricter regulatory requirements will apply.

2. *The Dietary Supplement Health Education Act (DSHEA)*

The push to adopt NLEA gave the FDA the long-awaited opportunity to finally put to rest the question of the proper method for regulating herbal remedies. Thus, as proposed, NLEA also covered herbal remedies that were being marketed as dietary supplements. NLEA made it clear that these herbal remedies would not be regulated like traditional food, but would have to obtain pre-market approval to establish that they were safe and effective for their claimed uses.²⁴⁷

Repeating the cycle, this attempt to regulate the supplement industry spurred a massive lobbying and public relations campaign to exempt all supplements from NLEA.²⁴⁸ The supplement industry, which included the manufacturers of vitamins, minerals, amino acids and herbal remedies, was by this time dominated by large corporations with extensive marketing resources.²⁴⁹ A new group, the National Health Alliance (“NHA”) was formed to lobby Congress and launched a major marketing campaign based on fear and exaggeration, claiming that the FDA was trying to remove all supplements, including the public’s cherished vitamins, from the market.²⁵⁰ The FDA’s protests that vitamins were not covered under NLEA at all and that the FDA’s focus was on herbal remedies were to no avail.²⁵¹

247. Bass, *supra* note 217, at 225-31; 21 U.S.C. § 355(d) (1994).

248. *Id.* at 225.

249. HILTS, *supra* note 74, at 283.

250. *Id.* at 285. One flyer sent out to health food stores by the NHA claimed: THE FDA WANTS TO PUT YOU OUT OF BUSINESS. . . . Every health food store is under immediate threat of siege. Congress wants to give the FDA police powers so they can seize products without notification and use heavy fines and court penalties to close you down. FDA wants to destroy your supplement business by making many items prescription only. FDA wants to make it illegal to sell the majority of your best selling products.

Id. Action alerts were circulated claiming that the FDA was trying to turn vitamins into prescription drugs, that the FDA was hiring 100 criminal investigators and that these new “G-men” would be unleashed on health food stores, individual citizens and the whole dietary supplement industry. *Id.* “The industry fed money and materials to their supporters, including the ubiquitous supplement stores. The campaign that was cranked up included radio and TV spots, fax blitzes, “hot lines” for call-in persuasion, celebrity videos, petitions, and “grass roots” lobbying kits. Stores offered 20 % discounts on purchases if customers would send a letter of protest to Congress. The store would supply the paper, the pencil and the language. The industry staged a nationwide “blackout” day in supplement stores, on which black draping was hung (over the products that industry claimed would be unavailable under the regulations) to draw media coverage.” *Id.* at 286.

251. The Washington Post commented that “[t]he supplements battle has been wacky even by Hill standards. The enormous lobbying effort against the labeling law . . . was directed at an outcome – loss of access to such remedies without a prescription – that the law never con-

In spite of the fact that no scientific evidence was offered that herbal remedies were safer or more beneficial than other regulated products,²⁵² this public relations blitz was so successful that, not only were all supplements excluded from NLEA,²⁵³ Congress passed the Dietary Supplement Health Education Act (“DSHEA”)²⁵⁴ that gave supplements an exemption from the FDA’s premarket testing and approval process entirely when supplements were marketed to healthy populations.²⁵⁵ This exemption covers supplements that carry labels with “statements of nutritional support” and statements explaining how a supplement may *maintain* or *improve* the “structure and function” of the body.²⁵⁶ DSHEA gives the nod to supplement manufacturers who have claimed for decades that their products should be regulated like food. The term “dietary supplement” now includes both nutritional and non-nutritional substances by embracing not only vitamins, minerals and amino acids, but also herbs or other botanicals which have no nutritional value.²⁵⁷

Like NLEA (but in the context of “structure and function claims” rather than “health claims”), structure and function claims are allowed under DSHEA but are limited to those which target people who have a normal health status who want to improve their diet to maintain or improve that healthy status. For example, St. John’s Wort is permitted to claim to enhance normal mental health, Glucosamine chondroitin is permitted to claim to enhance healthy joints and Echinacea is permitted to claim to enhance a healthy immune system. All three of these claims are that the products should be used to maintain or improve a normal state of health. Thus, as was the case with NLEA, on its face DSHEA remains consistent with Congress’s long-held position on the link be-

tained.” *Id.*

252. *Id.* at 284.

253. NLEA exempts from § 403(r)(3) “dietary supplements of vitamins, minerals, herbs or other similar nutritional substances.” SCOTT BASS & ANTHONY C. YOUNG, *DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS* 297, 300 (1996).

254. Bass, *supra* note 217, at 226-31. Dietary Supplement Health Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 U.S.C.). Under DSHEA, a dietary supplement is “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)(1) (1994).

255. Gilhooley, *supra* note 221, at 95-99.

256. 21 U.S.C. § 321(g). *See also* 21 U.S.C. 343(r)(6) (1994) (substantiation and disclaimer for structure and function claims); *FDA Final Rule: Regulations on Statements Made For Dietary Supplements Concerning the Effect of the Product on the Structure and Function of the Body*, 65 Fed. Reg. 999 (2000). A dietary supplement can also include on its label a statement that “describes the role of a nutrient or dietary ingredient intended to affect the structure and function in humans” or that “characterizes the documented mechanism by which a nutrient or dietary ingredient acts *to maintain* such structure or function.” 21 U.S.C. § 343(r)(6)(A) (emphasis added).

257. Dietary supplements do not include products that contain any other active ingredients such as synthetic ingredients that are regulated as over-the-counter medications or prescription drugs. Statement of Director Heinrich, GAO, *supra* note 6, at 3.

tween the level of regulation needed and the health status of a product's targeted population.

VI. THE IMPACT OF THE DIETARY SUPPLEMENT HEALTH EDUCATION ACT ON THE OVERWEIGHT AND THEIR RISK FOR TYPE II DIABETES, CARDIOVASCULAR DISEASE AND CANCER

This review of the history of the FDCA reveals that Congress has been consistent in its position on the link between the level of product regulation and the health status of the product's targeted population. The 1906 Food and Drug Act, the 1938 Food, Drug and Cosmetics Act, the 1962 Amendments, NLEA, and DSHEA have all dictated that less regulatory protection is needed when products are targeted to healthy populations for the purposes of health maintenance and that the greatest amount of regulatory protection is necessary when products are targeted to vulnerable, unhealthy populations claiming to help them return to normal health.

In just the past decade, it has been conclusively established that being overweight is a *substantial and independent* risk factor for serious diseases such as Type II diabetes, heart disease, and cancer.²⁵⁸ Overweight consumers clearly understand this link and are motivated to lose weight to avoid these risks. However, these unhealthy and vulnerable consumers are being lured away from legitimate weight loss programs by the sham, magic-bullet claims of weight loss supplement manufacturers. Overweight consumers are purchasing these products in the belief that the FDA has tested them for both safety and effectiveness, while the FDA has taken the position that it does not have the power to require any premarket testing. A look at one example, the case of Ephedra used as a weight loss supplement, clearly demonstrates why the current FDA position will provide little protection to those overweight individuals who are being thwarted in their weight loss efforts by sham products.

A. Opening the Door to Predatory Commercial Practices: DSHEA and the Case of Ephedra

As a result of the FDA's interpretation of DSHEA, weight loss supplements are being regulated like traditional food products. As explained earlier, consumers have extensive experience of the risks associated with traditional foods. This common knowledge brings an ability to self-protect and supports the presumption of safety that is granted to traditional food under the FDCA.²⁵⁹

Like traditional food, by virtue of the FDA's interpretation of DSHEA, weight loss supplements can now be placed directly on the market without any testing or premarket approval under a completely unsupported presumption of

258. See *supra* notes 31-51 and accompanying text.

259. Van Tassel, *supra* note 177, at 1651.

safety.²⁶⁰ Not only are supplements cloaked with a baseless presumption of safety, as if they were similar to traditional food, but DSHEA (as applied by the FDA) also grants an equally unwarranted presumption that weight loss supplements are effective as claimed.²⁶¹ Currently, in order to remove an unsafe or ineffective weight loss supplement from the market, the FDA carries the burden of demonstrating that the product poses a “significant or unreasonable risk of illness or injury.”²⁶²

An example of the implications of switching the burden of proof onto the FDA to prove that weight loss supplements are unsafe and ineffective is the case of a product called Ephedra. Ephedra contained ephedrine-alkaloid supplements.²⁶³ Ephedrine alkaloids occur naturally in some plants, work as stimulants and fall into the same category as the street drug referred to as “Speed.”²⁶⁴ Products containing ephedrine-alkaloid supplements were marketed for weight loss and to enhance sports performance.²⁶⁵ Over time, the FDA began receiving adverse event reports from consumers which included numerous complaints of heart attacks, strokes, seizures and deaths associated with the consumption of products containing ephedrine-alkaloid supplements.²⁶⁶ One of the most highly publicized cases of a fatal consequence from the use of a product containing an ephedrine-alkaloid was the death of Steve Bechler, a twenty-three-year-old baseball player with the Baltimore Orioles.²⁶⁷

In a modern day version of the saga of the weight loss product Marmola that occurred seventy years earlier,²⁶⁸ it took seven years for the FDA to complete its investigation of ephedrine-alkaloid supplements. The FDA compiled an administrative record of 130,000 pages, 19,000 adverse event reports and engaged in extensive notice and comment before it passed a regulation banning the sale of ephedrine-alkaloid supplements in 2004.²⁶⁹ In this final rule, the FDA stated that “[t]he best clinical evidence for a benefit . . . supports only a

260. 21 U.S.C. § 321(s) (1994 & Supp. III 1997) (exemption from food additive provisions); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1033-35 (10th Cir. 2006), *cert. denied*, 127 S. Ct. 2295 (May 14, 2007).

261. *Nutraceutical Corp.*, 459 F.3d at 1039 n.5. (“The district court compared the language of DSHEA to the statutory language governing medical devices and drugs and concluded that, unlike manufacturers of medical devices and drugs, manufacturers of dietary supplements do not need to prove effectiveness prior to taking their product to market. The district court is correct.”)

262. *Id.*

263. *Nutraceutical Corp.*, 459 F.3d at 1036.

264. Barry A. Palevitz, *Harmless Energizers or Dangerous Drugs?*, 16 THE SCIENTIST 18-19 (2002) (“Ephedrine is a close relation of amphetamine, sometimes called benzedrine. A little chemical tinkering creates the street drugs methamphetamine and Ecstasy.”).

265. *Nutraceutical Corp.*, 459 F.3d at 1036.

266. *Id.*

267. HAWTHORNE, *supra* note 227, at 226.

268. See *supra* notes 112-124, 149-156 and accompanying text.

269. *Nutraceutical Corp.*, 459 F.3d at 1036; Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present Unreasonable Risk, 69 Fed. Reg. 6788 (2004).

modest short-term weight loss, insufficient to positively affect cardiovascular risk factors or health conditions associated with being overweight or obese.²⁷⁰

The manufacturer of Ephedra filed suit arguing that the FDA had failed to meet its burden of proof of showing that ephedrine-alkaloids were unsafe.²⁷¹ The district court found for the manufacturer. In 2006, the FDA prevailed on appeal.²⁷² The total time and expense involved in this process, including the cost of the harm suffered by consumers, was tremendous.²⁷³

VII. PROPOSALS FOR TRIGGERING THE FDA'S PREMARKET APPROVAL PROCESS TO ELIMINATE SHAM WEIGHT LOSS SUPPLEMENTS

Placing the FDA in a reactive rather than proactive position dooms the FDA's efforts to safeguard public health in the context of weight loss supplements. As the Ephedra litigation demonstrates,²⁷⁴ the FDA does not possess the extraordinary resources that would be necessary to mount a comprehensive, post-market enforcement campaign to police the claims being made by the weight loss supplement industry. Consequently, the FDA has taken little sustained action to remove ineffective and unsafe weight loss supplements from the market.²⁷⁵ The FDA's overbroad interpretation of DSHEA has allowed an exponential growth in the sale of supplements. There were 4,000 supplements on the market before DSHEA; after DSHEA, there are over 30,000.²⁷⁶ And the supplement industry is predicted to grow at a rate of 1,000 new products per year.²⁷⁷ Many of these products make unsubstantiated and misleading claims and their safety is uncertain.²⁷⁸ And a large number of these sham products are

270. *Nutraceutical Corp.*, 459 F.3d at 1036.

271. *Id.* at 1043-44.

272. *Id.* at 1038-39.

273. The latest development in the Ephedra story occurred in September of 2008 when a Texas manufacturer, Pump Nutrition, placed an Ephedra-like product back on the market. Shane Starling, *Supplement Maker Puts Ephedrine Back on Market* (Sept. 22, 2008), <http://www.foodnavigator-usa.com>. By virtue of this gimmick, it appears that the manufacturer could tap into the hype over Ephedra contained in a wealth of publications and web pages simply by labeling their product as containing "Ephedra." *Id.* If the product label made no claims relating to ephedra alkaloids, an argument could be made that it does not violate the FDA regulatory ban. Perhaps failing to realize this possibility, Pump Nutrition's product, "XP2G" lists *ma huang* and *sida cordifolia* as active ingredients, both of which contain the banned alkaloids. And it is marketed to promote weight loss. *Id.*

274. See *supra* notes 263-273 and accompanying text.

275. DEGNAN, *supra* note 180, at 186.

276. Degnan, *supra* note 180, at 185. The Institute of Medicine reports that consumers in the United States spend over \$18 billion yearly on supplements. COMM. ON THE FRAMEWORK FOR EVALUATING THE SAFETY OF DIETARY SUPPLEMENTS, DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES (2004).

277. Degnan, *supra* note 180, at 185.

278. The Institute of Medicine stated in a 2005 Report that the safety of many supplements is uncertain. There is a dearth of data on safety coupled with a striking proliferation of unsubstantiated and misleading claims regarding therapeutic benefit. INSTITUTE OF MEDICINE REPORT, *supra* note 223.

supplements for weight loss. In an example of history repeating itself, snake oil salesmen with access to powerful, modern day marketing tools have returned in force.

A close look at the history of the regulation of quack medicine, in tandem with the legislative history of NLEA and DSHEA, provides persuasive evidence that the FDA has the authority under the FDCA to require that weight loss supplement manufacturers obtain premarket approval for safety and effectiveness before placing their products on the market. First, dietary supplements marketed for weight loss make the type of structure and function claims that Congress, in its legislative history, expressly considered to be drug claims when it passed the FDCA in 1938.²⁷⁹ Since 1962, products making drug claims are required to obtain premarket approval for safety and effectiveness.²⁸⁰ Second, weight loss supplements do not qualify for the application of DSHEA's safe harbor from the premarket approval requirements as weight loss supplements are not intended to maintain or enhance the structure and function of the body.²⁸¹ Third, weight loss supplements do not qualify for "health claim" status under NLEA as they are not intended to maintain health.²⁸² Finally, weight loss supplements make "disease claims" as they "purport to prevent or treat an abnormal or unhealthy condition that, while not itself a disease, is a significant risk factor for disease."²⁸³

A. *Weight Loss Supplements and "Structure and Function Claims"*

It is clear that Congress created the separate and independent category of products intended to effect the structure and function of the body in large part because of the predatory profiteering by product manufacturers that targeted a vulnerable population of those who were overweight or obese.²⁸⁴ Therefore, because weight loss supplements made structure and function claims they were considered to be drugs under the FDCA. In the legislative record of the 1938 FDCA, members of Congress expressed their intent to deal with the massive number of "worthless" products being marketed for weight loss at the time. In 1962, Congress expanded the protection of vulnerable consumers from harm by third parties by requiring that manufacturers of drugs and devices obtain premarket approval for safety and effectiveness.²⁸⁵ Thus, prior to the passage of DSHEA and NLEA, the FDCA required that manufacturers of weight loss supplements obtain premarket approval by establishing the safety and effectiveness of their products before distributing them.²⁸⁶

279. *See supra* notes 144-147, 284-287 and accompanying text.

280. *See supra* notes 171-179 and accompanying text.

281. *See infra* notes 288-297 and accompanying text.

282. *See infra* notes 298-305 and accompanying text.

283. *See infra* notes 306-319 and accompanying text.

284. *See supra* notes 144-147 and accompanying text.

285. *See supra* notes 169-179 and accompanying text.

286. *See supra* notes 144-147 and accompanying text.

The question then becomes whether either DSHEA or NLEA change this requirement as weight loss supplement manufacturers claim. At the core of this inquiry is the question of whether there is any basis for finding that the overweight and obese are less vulnerable today than they were when the FDCA was originally passed. As the following sections discuss, both DSHEA and NLEA were passed to enhance an individual's ability to choose to pursue a healthy diet by access to nutritional information about food in general and access to dietary supplements targeted to healthy populations to "encourage good health through the use of nutritional supplements"²⁸⁷ Neither DSHEA nor NLEA provide an exception (and any justification therefore) to the premarket approval process for products that target unhealthy, vulnerable populations. Moreover, recent scientific studies both vindicate, and add to, Congress's original assessment of the level of vulnerability of those who are obese or overweight by demonstrating that the condition of being obese or overweight places an individual at high risk of serious, chronic diseases.

1. *The Limitations of DSHEA's Safe Harbor*

The stated goal of DSHEA is to enhance access to dietary supplements targeted to healthy populations so that these individuals can maintain their health through the use of nutritional supplements.²⁸⁸ In furtherance of that goal, DSHEA offers a safe harbor from the premarket approval requirement for dietary supplements that make "structure and function" claims that the dietary supplement will either *maintain* or *enhance* the structure or function of the body.²⁸⁹

Thus, by its plain meaning, DSHEA only allows a manufacturer an exemption from premarket approval if its products are targeted to *healthy* populations for *health maintenance* or to *enhance normal health*. This interpretation is consistent with the stated goals of DSHEA, with the events that led to the passage of DSHEA and with its legislative history.²⁹⁰

Clearly, weight loss supplements are not products that are targeted to healthy populations for health maintenance. Recent scientific studies have definitively linked the condition of being overweight with a significant risk of a number of serious, chronic diseases such as hypertension, Type II diabetes, heart disease, stroke and cancer.²⁹¹ Thus, it is clear that those who suffer from the condition of being overweight fall within a vulnerable, unhealthy population. As such, when a weight loss supplement manufacturer targets its products to those with an overweight condition to help them alter the structure and function of their bodies in order to return to a healthy status, i.e. a healthy weight, weight loss supplement manufacturers are not targeting healthy populations to

287. BASS, *supra* note 217, at 227.

288. *Id.*

289. 21 U.S.C. § 343(r)(6)(A) (2007).

290. *See supra* notes 180-257 and accompanying text.

291. *See supra* notes 31-51 and accompanying text.

maintain or enhance the health of individuals with a normal health status, i.e. to help maintain a healthy weight. Consequently, weight loss supplements do not fall within the safe harbor of DSHEA.

This conclusion is consistent with strong historical evidence of the need to provide overweight individuals with additional regulatory protection from predatory commercial interests until there is a greater scientific understanding of the safety and effectiveness of weight loss supplements. The history of quack medicines teaches that the need for regulation is at its height when there is a high degree of scientific uncertainty over the effectiveness and safety of new products intended to treat abnormal health conditions.²⁹² Time and events have established that there is a direct relationship between scientific uncertainty and predatory profiteering. This is especially the case when health care products are both marketed and sold directly to consumers without physician guidance. This is the current situation with weight loss supplements.

At the present time, there is an information void on the efficacy²⁹³ and safety of the common ingredients contained in weight loss supplements.²⁹⁴ This information void is slowly being filled through scientific experimentation. With some of these ingredients, the level of uncertainty over their efficacy and health risks has progressed from indeterminacy (where scientists *know* what they don't know but can plan the scientific experiments necessary to find out) to a state of knowledge when classic probability analysis can be applied to assess efficacy and predict risk levels to human health. Thus, studies have shown that some of these substances are either ineffective or have serious, toxic side effects associated with their use.²⁹⁵ On the other hand, with many of the other common ingredients, the science is too immature to draw any conclusions.²⁹⁶ Compounding the scientific uncertainty is the fact that many weight loss supplements are a mixture of multiple ingredients in various quantities.²⁹⁷ As the body of science available to restrict the scope of weight loss claims is immature, absent regulatory intervention, the claims of supplement manufacturers are only limited by the gullibility of consumers. In many cases, the level of gullibility will be proportional to the level of desperation of the individual to lose weight.

292. See *supra* notes 72-179 and accompanying text.

293. Dietary supplements that claim to aid in weight loss allege that they cause weight loss by increasing energy expenditure, changing carbohydrate metabolism, increasing a feeling of satiation or decreasing appetite, increasing fat oxidation, reducing the accumulation of fat or blocking the absorption of fat. See Blanck et al., *supra* note 54, at 441-47; P.A. Sharpe et al., *supra* note 54, at 2045-51.

294. The common active ingredients contained in weight loss supplements are: bitter orange, chromium, guar gum, hoodia, garcinia, conjugated linoleic acid, pyruvate and chitosan. Statement of Director Heinrich, GAO, *supra* note 6, app. at 21-24. For each ingredient, there was either strong evidence of no effect on weight loss or inconclusive evidence. *Id.* Some of these substances have serious, toxic side effects associated with their use. *Id.* For a chart of the most common weight loss supplement ingredients and the attendant adverse reactions, see *Id.*

295. *Id.*

296. *Id.*

297. *Id.*

The more dire the weight loss need, the more vulnerable the individual will be to spurious claims. And the more serious the overweight condition, the greater the risk of harm when the weight loss supplement does not work and causes a delay in seeking help in making effective life style changes which causes chronic conditions such as Type II diabetes, heart disease, stroke and cancer.

As indicated above, Congress was clear in its intent to provide overweight individuals additional regulatory protection from predatory commercial interests when it passed the FDCA of 1938. Absent some clear legislative findings that this group no longer requires this additional protection, along with an expressed intent that removes these protections, DSHEA's safe harbor cannot be extended to cover weight loss supplements. Instead, as Congress originally intended when the FDCA was passed, these products continue to fall into the same regulatory category as drugs and devices and premarket approval is required.

B. The Limitations of NLEA's Safe Harbor

This question was also laid to rest in relation to NLEA in *Whitaker v. Thompson*.²⁹⁸ In *Whitaker*, a manufacturer of a product containing saw palmetto to treat the symptoms of benign prostatic hyperplasia submitted a petition for approval to the FDA arguing that it was making permitted health claims under NLEA.²⁹⁹ NLEA offers a safe harbor from the premarket approval requirement for foods and dietary supplements that make "health claims."³⁰⁰ Health claims are claims that "[c]haracterize ... the relationship of any nutrient ... to a disease or health related condition."³⁰¹ The FDA denied the claim drawing

a distinction between claims regarding the use of a product to *maintain* health and to *prevent* disease, on the one hand, and claims that a product could *treat* a disease on the other. The former could qualify as 'health claims,' but the later would always be considered to be 'drug claims.'³⁰²

The Court of Appeals agreed with the FDA's interpretation of NLEA finding "statements in the legislative history indicating that the purpose of the health claims provision was to promote long-term health maintenance and prevention of disease"³⁰³ Consequently, the Court of Appeals limited the

298. *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004), *cert. denied*, 543 U.S. 925 (2004).

299. *Id.* at 949.

300. *Id.*

301. *Id.*

302. *Id.* at 948.

303. *Id.* at 951.

scope of NLEA's safe harbor to dietary supplements that target healthy populations by making claims that the product maintains a healthy state and prevents disease.³⁰⁴

Consistent with the *Whitaker* decision, on multiple recent occasions, the FDA has concluded that supplement products targeting individuals with abnormal health conditions such as high blood pressure, high blood glucose levels and high cholesterol levels are products that target vulnerable, unhealthy populations triggering the need for greater regulatory protection via the imposition of premarket testing requirements.³⁰⁵ Similarly, supplements that target individuals who have the abnormal condition of being overweight are being marketed to vulnerable, unhealthy populations triggering the need for greater regulatory protection via the imposition of premarket testing requirements.

C. Weight Loss Supplements and "Disease Claims"

A recent citizen's petition filed with the FDA suggests that the FDA pursue a new strategy to reclaim its power to protect overweight consumers from products that make sham weight loss claims.³⁰⁶ Instead of focusing on the claims of weight loss supplements as "structure and function" claims, it suggests that the FDA determine that "dietary supplement claims that they promote, assist, or otherwise help weight loss are 'disease claims'" as they "purport to prevent or treat an abnormal or unhealthy condition that, while not itself a disease, is a significant risk factor for disease."³⁰⁷

1. Reduction of Risk Factor Claims

In 2000, the FDA issued regulations that provided the industry with ten criteria that the FDA planned to apply to determine whether a particular claim crossed over the line from being considered a permissible structure and function claim to an impermissible disease claim.³⁰⁸ According to one of these criteria, a statement will be considered a disease claim if it asserts that the product at issue "[h]as an effect on the characteristic signs or symptoms of a specific

304. *Id.* at 951-52.

305. *See infra* notes 308-317 and accompanying text.

306. This argument was first raised in a citizen's petition [hereinafter Citizen's Petition] filed with the FDA on April 17, 2008 on behalf of an interesting quartet of petitioners who discovered that they had joint interests. Citizen's Petition, at 15-20, http://www.obesity.org/news/Final_Petition_04_22_08.pdf. The petitioners included the American Dietetic Association, The Obesity Society, Shaping America's Health and GlaxcoSmithKline Consumer Healthcare, LP ("GSK"). The American Dietetic Association is "the nation's largest organization of food and nutrition professionals." *Id.* at 1. The Obesity Society "is the leading scientific society dedicated to the study of obesity." *Id.* Shaping America's Health was "founded by the American Diabetes Association to reverse the obesity trends and weight loss issues." *Id.* GSK is the manufacturer of the weight loss product called Allie. *Id.*

307. *Id.*

308. 65 Fed. Reg. at 1000.

disease or class of diseases, using scientific or lay terminology.”³⁰⁹ In other words, if its intended use is to “prevent or treat abnormal or unhealthy conditions or clinical measurements that are not themselves diseases but are markers of, or risk factors for, diseases.”³¹⁰ For example, because “an elevated cholesterol level is a sign of hypercholesterolemia and an important risk factor for heart disease,”³¹¹ any labeling that “as a whole implies that the product is intended to lower elevated cholesterol levels” is a disease claim.³¹² Thus, a dietary supplement that is intended to be used to reduce a risk factor for disease will be regulated as a drug and premarket testing will be required.

Other examples of impermissible “reduction of risk factor claims” include statements that a product will reduce high levels of blood glucose or high blood pressure. The FDA has found that a high blood glucose level is a risk factor for diabetes.³¹³ Therefore, a claim to reduce high glucose levels is a claim to treat a risk factor for disease.³¹⁴ The FDA has also found that high blood pressure is a risk factor for hypertension.³¹⁵ Thus, a claim to reduce high blood pressure is a claim to treat a risk factor for disease. Similarly, when weight loss supplements claim that they will return a consumer with an abnormal BMI to a normal BMI, they are claiming to treat a risk factor for serious diseases including, as discussed earlier, Type II diabetes, cardiovascular disease and cancer.

The FDA has also stated clearly that a factor in making its decision on whether a product is making a “reduction of risk factor claim,” triggering the need for increased regulation, is whether there is a link in the public’s mind between the abnormal health condition and the risk of disease. For example, the FDA has stated that “[l]owering cholesterol is inextricably linked in the public mind with treating elevated cholesterol and preventing heart disease.”³¹⁶ In the Landmark Study, 94 % of the respondents recognized that being overweight increased the risk of diseases such as diabetes and cardiovascular disease.³¹⁷ Thus, weight gain and an increased risk of disease are linked in the public’s mind.

The FDA’s position on where to draw the line between permissible and impermissible claims is consistent with the goals of Congress to limit the use of dietary supplements to the maintenance of a normal state of health. An exam-

309. 21 C.F.R. § 101.93(g)(2)(ii)(1994).

310. 64 Fed. Reg. 36,824, 36,826 (July 8, 1999).

311. 65 Fed. Reg. at 1019.

312. *Id.*

313. *See, e.g.*, Healing Power, Inc. Courtesy Letter (Ltr. 885; May 23, 2006); USANA Health Sciences, Inc. Courtesy Letter (Ltr. 879; May 3, 2006); Anabolic Laboratories, Inc. Courtesy Letter (Ltr. 782; Sept. 29, 2004).

314. *Id.*

315. *See, e.g.*, New Chapter, Inc. Courtesy Letter (Ltr. 935; Apr. 3, 2007); New Century Company Courtesy Letter (Ltr. 873; Mar. 29, 2006); Knature Corp. Courtesy Letter (Ltr. 807; Feb. 4, 2005); NOW Foods (Ltr. 799; Dec. 4, 2004); Michael’s Naturophic Programs Courtesy Letter (Ltr. 730; Oct. 15, 2003).

316. 65 Fed. Reg. at 1019.

317. *See supra* note 52 and accompanying text.

ple of a permissible claim is one that states that the product will “help to maintain cholesterol levels that are already within normal range.”³¹⁸ Otherwise, consumers with abnormal health conditions that are risk factors for serious diseases may be lulled into a false sense of security, leading them to avoid a trip to the doctor that might result in a treatment or program that could correct the abnormal condition or prevent the condition from becoming worse. In the context of cholesterol, the FDA has stated that the “use of possibly ineffective therapies in persons with elevated cholesterol, which can delay or prevent effective treatment, poses significant health risk.”³¹⁹ Just as the FDA has found that it is of “compelling importance” to prevent heart disease through the use of drugs that have established that they are safe and effective in lowering cholesterol through clinical testing, it is of compelling importance to prevent Type II diabetes, hypertension, heart disease, stroke and cancer through equally safe and effective programs and treatments for weight loss.

VIII. CONCLUSION

The United States is at the beginning of an obesity crisis that, if unchecked, will mean that 80% of the population will be either overweight or obese in a short fifteen years. The evidence is now overwhelming that there is a direct link between being overweight and the risk of serious diseases such as Type II diabetes, hypertension, stroke, cardiovascular disease and cancer. With regard to the risk of Type II diabetes alone, there are over fifty-nine million Americans with pre-diabetes. Studies have shown that progression to diabetes is not inevitable. Consumers with pre-diabetes can prevent or delay diabetes if they lose weight and increase their physical activity.

However, instead of making lifestyle changes that include diet modification and exercise, overweight consumers desperate to lose weight are being lured by ‘magic-bullet’ claims into purchasing ‘quick-fix’ weight loss products in order to lose weight and decrease their risk for disease. Many of these consumers, and their physicians, incorrectly believe that the FDA requires premarket testing to establish the validity of these claims. Taking advantage of consumers’ vulnerability and misperceptions regarding FDA oversight, weight loss product manufacturers are generating stunning revenues. Remarkably, according to the FTC, the majority of these products are ineffective. Like Hercules and his attempts to slay the many-headed hydra, for every weight loss product that the FTC successfully removes from the market, it appears that dozens more are spawned. Thus, U.S. consumers are being thwarted in their weight loss and disease reduction efforts and the obesity crisis continues to mushroom.

To date, the FDA’s position has been that it has no power to require pre-

318. 65 Fed. Reg. at 1019.

319. Citizen’s Petition, *supra* note 306, at 15-20.

market testing of weight loss supplements. Yet, a close look at the history of the regulation of quack medicine, in tandem with the legislative history of the 1938 FDCA, NLEA, and DSHEA, strongly suggests that the FDA has the authority under the FDCA to require that weight loss supplement manufacturers obtain premarket approval for safety and effectiveness before placing their products on the market. First, weight loss supplements make the type of structure and function claims that Congress, in its legislative history, expressly considered to be drug claims when it passed the FDCA in 1938. Since 1962, products making drug claims are required to obtain premarket approval for safety and effectiveness. Second, weight loss supplements do not qualify for the application of DSHEA's safe harbor from the premarket approval requirements as weight loss supplements are not intended to maintain or enhance the structure and function of the body. Third, weight loss supplements do not qualify for "health claim" status under NLEA as they are not intended to maintain or improve normal health. Finally, weight loss supplements make "disease claims" as they "purport to prevent or treat an abnormal or unhealthy condition that, while not itself a disease, is a significant risk factor for disease."³²⁰

In light of the obesity epidemic and recent scientific studies that have definitively linked being overweight with the risk of a number of life threatening diseases, this Article concludes that it is time for the FDA to reevaluate its position and use its power to regulate weight loss supplements to require premarket approval for safety and effectiveness. Requiring premarket approval results in a proper balance between the protection of individual choice in matters involving self-regarding behavior with the need to protect vulnerable consumers from harm from third parties by linking the level of product regulation with the health status of the product's targeted population.

320. *Id.*

