

ARE YOU SURE YOU WANT TO EAT THAT?: U.S. GOVERNMENT AND PRIVATE REGULATION OF DOMESTICALLY PRODUCED AND MARKETED DIETARY SUPPLEMENTS

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I. Introduction

The dietary supplement industry has been quite the buzz in the past few years. The supplement industry is massive—almost half of the American population consumes dietary supplements every year²—and views regarding the industry could not be more disparate. Some scorn supplement manufactures as being unregulated Wild West bandits who take advantage of a lax regulatory system in order to beguile innocent consumers into spending a fortune on ineffective snake-oil-like products. Not only are supplements accused of being ineffective, but it also seems that newspapers are all too often filled with lurid headlines regarding untimely deaths resulting from deleterious dietary supplement consumption. On the flip side, dietary supplement manufacturers and many consumers believe that supplements are a great way to improve one’s physical and emotional well-being. By having access to a broad range of dietary supplements, consumers can determine for themselves what areas of life they

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² Press Release, Council for Responsible Nutrition, *New Industry Initiative Targets Deceptive, False and Misleading Dietary Supplement Advertising*, http://www.crnusa.org/pdfs/CRN_NAD_New_Advertising_Initiative.pdf (last visited Sept. 21, 2010) [hereinafter *New Industry Initiative*].

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would like to improve and can tailor a specific dietary supplement regime to meet their individual needs. Whether one wants to lose weight, needs more energy, or desires an all-natural method of lowering blood pressure, the supplement industry can provide an effective and relatively easy regime to help consumers achieve their individual goals.

So who's right? Are dietary supplements really so out of control and harmful to U.S. consumers that individuals should grab a tight hold of their pocket books and run whenever they see an advertisement for a weight loss supplement? Or should Americans embrace supplements as being a relatively cheap and easy way to increase one's health and physical well-being? Do we need a massive regulatory overhaul to protect American consumers?

The evidence shows that while supplements do provide many benefits, the current regulatory system in place does in fact leave the public vulnerable to substantial risk. The Food and Drug Administration ("FDA"), the Federal Trade Commission ("FTC"), and the National Advertising Division ("NAD") employ a variety of regulatory and enforcement measures to combat unscrupulous supplement companies. However, while the agencies provide a robust regulatory regime, it is currently insufficient to fully protect consumers from deleterious products and misleading advertisements. Fortunately, there are several relatively inexpensive and minimally burdensome measures that the FDA and FTC can take to substantially augment consumer protection.

This article will analyze the strengths and weaknesses of the current regulatory system in place to protect consumers and will suggest several methods of improvement. While this essay will tangentially touch on the issues of foreign product regulation and importation, a robust discussion of international regulation is complex—such a discussion would require an in-depth analysis of the United States' relationships with several foreign nations—and is beyond the scope of this article. Instead, this article will focus on one of the most fundamental requirements necessary to establish a safe supplement industry: domestic regulation. The United States faces a sizeable challenge with simply monitoring and regulating domestically produced supplements that are marketed to U.S. consumers. Before we can focus our efforts abroad, we must first ensure that we have established quality practices at home.

A. What is a Dietary Supplement?

Congress defines the term “dietary supplement” in the Dietary Supplement Health and Education Act (“DSHEA”).³ According to the DSHEA, a dietary supplement is a product taken by mouth that contains a dietary ingredient.⁴ Dietary ingredients include: vitamins, minerals, herbs or other botanicals, amino acids, dietary substances used to supplement the diet by increasing the total dietary intake, or concentrates, metabolites, constituents, and extracts.⁵ Dietary supplements can exist in a variety of forms such as tablets, liquids, powders, or bars.⁶ Furthermore, the DSHEA classifies dietary supplements as foods, not drugs.⁷ This distinction has important implications for how dietary supplements are regulated under the DSHEA.

B. What is the DSHEA?

The DSHEA was signed into law by President Clinton in October of 1994 and it created a new regulatory framework for the safety and labeling of dietary supplements.⁸ Under the DSHEA, the company who manufactures the dietary supplement, not the FDA, is responsible for determining if the supplement is safe.⁹ The manufacturing company is also responsible for determining that the claims it makes about the supplement are true and not misleading.¹⁰ The implications of these two rules are substantial: in most cases, dietary supplements do not need prior approval by the FDA before they reach the market.¹¹ Consequently, companies are free to manufacture and

³ Press Release, U.S. Food and Drug Administration, *Overview of Dietary Supplements*, <http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm> (last modified Oct. 14, 2009) [hereinafter *Overview of Dietary Supplements*].

⁴ 21 U.S.C. § 321(ff) (2009).

⁵ *Id.*

⁶ *Overview of Dietary Supplements*, *supra* note 3.

⁷ 21 U.S.C. § 321 (ff) (2009).

⁸ *Overview of Dietary Supplements*, *supra* note 3.

⁹ 21 U.S.C. § 343(r)(6) (2010).

¹⁰ *Id.*

¹¹ *Overview of Dietary Supplements*, *supra* note 3 (stating that dietary supplements will not need prior approval by the FDA as long as the supplement does not contain a “new dietary ingredient.” A new dietary ingredient is defined in the DSHEA as an ingredient that was not sold in the U.S. as a dietary supplement before October 15, 1994. If the supplement

sell dietary supplements at their own discretion. While a company is still required to have evidence to substantiate the claims it makes, the company is not required to provide any of the data to the FDA before the supplement is sold to the public. This means that there is essentially no barrier between an unscrupulous dietary supplement manufacturer and the public.

Congress deliberately made this policy decision. When passing the DSHEA, Congress' goal was to increase the public's access to dietary supplements in order to promote the general wellness of the American population.¹² Congress believed that there may be a positive relationship between dietary supplement use and disease prevention, and that supplement use positively correlated with reduced health-care expenses.¹³ By eliminating the regulatory burdens placed on the dietary supplement industry, Congress believed that it had created an effective and inexpensive method of simultaneously keeping Americans healthy while saving them money.

The easy-access policy was sure to be a hit with the American population. The dietary supplement industry in the United States is enormous. Over a thousand manufactures market over 29,000 supplement products, creating a \$20 billion industry.¹⁴ And the industry is not simply composed of a niche class of individuals, such as bodybuilders or health gurus. Over 150 million Americans consume dietary supplements every year.¹⁵ With a total population of just over 300 million, that means about half of the entire American population uses dietary supplements every year.¹⁶ With such a widespread popularity, Congress was surely going to craft a policy that would allow relatively easy access to supplements. Disappointing 150 million Americans would be political suicide. On top of that, the \$20 billion dollar

contains a new dietary ingredient the product requires pre-approval by the FDA before marketing. The manufacturer must notify the FDA of its intentions to sell the new dietary ingredient and must either demonstrate why the ingredient is expected to be safe or show that the ingredient has been recognized as a food substance and is present in the food supply).

¹² *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1038 (10th Cir. 2006); *Pharmanex v. Shalala*, 221 F.3d 1151, 1158-59 (10th Cir. 2000).

¹³ *Nutraceutical Corp.*, 459 F.3d at 1038; *Pharmanex*, 221 F.3d at 1158-59.

¹⁴ Lars Noah & Barbara A. Noah, *A Drug by any Other Name...?: Paradoxes in Dietary Supplement Risk Regulation*, 17 STAN. L. & POL'Y REV. 165, 165 (2006).

¹⁵ *New Industry Initiative*, *supra* note 2.

¹⁶ Press Release, U.S. Census Bureau, *Data Finders*, <http://www.census.gov/> (last visited Sept. 21, 2010).

supplement industry has tremendous clout with Congress and would fervently oppose any type of policy that might infringe on the industry's profits. The easy-access policy seemed to be ideal: Congress could create an effective, inexpensive policy that was popular with both corporate America and the general population.

Such a policy, when implemented properly, can have many benefits. Supplements can indeed promote the general wellness of the population at a relatively cheap price. As long as supplements are labeled and advertised accurately, dietary supplements are a great addition to the food supply: Americans can decide what types of supplements will be the most beneficial for their own wellness goals. Americans can rely on the labeling and advertisements of supplements to tailor specific programs to their individual lifestyles. However, the crucial factor is that supplements must be labeled and advertised accurately. If misleading, supplements can be extremely pernicious to the average American. For example, supplements might hurt Americans by convincing them to spend money on snake-oil-like products that have no benefits at all. Even worse, some products that purport to be safe might be seriously deleterious to the consumer. Therefore, the success or failure of the DSHEA's easy-access policy relies on the validity and accuracy of advertisement claims. There are several public and private institutions that exist to ensure the supplement industry accurately and truthfully advertises its products to the public. These government agencies and private regulatory institutions combine to create a robust regulatory force, but unfortunately, their efforts are insufficient to effectively police the entire supplement industry. Consequently, the DSHEA's easy-access policy is leaving supplement consumers vulnerable to health and pecuniary risks, and several policy changes need to be implemented in order to remedy the predicament.

II. Regulation and Enforcement of Dietary Supplement Advertising

A. Government Regulation

The Federal Government regulates food supplements using a combination of agencies. Under a longstanding liaison agreement, the FDA and FTC have shared jurisdiction over the food supplement industry: the FDA is responsible for the labeling

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of supplements and the FTC is responsible for policing advertisements.¹⁷ Courts have interpreted the term “labeling” very broadly, so it does not strictly refer to the actual labels on containers. The term “labeling” includes any materials distributed at the point of sale, and thus the FDA has jurisdiction over audio and visual displays, or inserts or promotional materials distributed at the point of sale.¹⁸ The FTC, on the other hand, is responsible for regulating all non-labeling advertising claims. Thus, the FTC is responsible for regulating advertisements made through a variety of media sources, including print and broadcast advertisements, infomercials, websites, catalogs, and similar direct marketing materials.¹⁹ The two agencies work closely together to ensure that their policies are consistent.²⁰ In fact, the FDA is so deeply intertwined with the FTC that it is essentially impossible to give a thorough analysis of consumer protection against misleading supplement claims without discussing the role of both agencies.

1. Food and Drug Administration

a. FDA Regulatory and Enforcement Action

While the FDA’s official jurisdiction is limited to labeling, the agency in fact takes broad action to police unscrupulous dietary supplement manufacturers. The FDA’s role consists of a wide range of enforcement, surveillance, and prophylactic measures.

The FDA can combat potentially dangerous supplements in a variety of ways. If the FDA deems a supplement to be a potentially serious threat, it can pursue several judicial or administrative courses of action.²¹ The agency’s most powerful

¹⁷ Press Release, Federal Trade Commission, *Business Guide For Dietary Supplement Industry Released by FTC Staff*, <http://www.ftc.gov/opa/1998/11/dietary.shtm> (last modified Nov. 18, 1998) [hereinafter *FTC Business Guide*].

¹⁸ John E. Villafranco & Andrew B. Lustigman, *Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission, Food and Drug Administration, and Nation Advertising Division*, 62 FOOD & DRUG L.J. 709, 711 (2007).

¹⁹ *Id.*

²⁰ *FTC Business Guide*, *supra* note 17.

²¹ UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, DIETARY SUPPLEMENTS: FDA SHOULD TAKE FURTHER ACTIONS TO IMPROVE OVERSIGHT AND CONSUMER

tool is its ability to institute a complete product ban.²² However, while the ability to institute a complete ban is immensely powerful, it is rarely used and is ultimately a fairly impractical enforcement mechanism. Since the DSHEA's enactment, the FDA has only successfully banned one dietary supplement, ephedra.²³ Ephedra had been linked to numerous deaths²⁴ and over 16,000 adverse events²⁵ during the years that it was legally sold to U.S. consumers. However, despite the overwhelming evidence against ephedra, it still took the FDA nearly ten years to ban the ingredient from the market.²⁶ Long and costly legal battles, coupled with the fact that the FDA has the burden of proving that a product poses a "significant or unreasonable risk" to consumer health, makes instituting a complete product ban a tremendously onerous and expensive endeavor.²⁷ Consequently, the FDA has developed other methods of policing the supplement industry. First, the FDA can attempt to persuade a company to voluntarily recall its supplement.²⁸ While the FDA does not have mandatory recall authority, it has been successful at convincing several companies to voluntarily recall their products. Between 2003 and 2008, the FDA successfully worked with companies to recall forty-five dangerous or defective dietary supplements products that posed a serious health concern.²⁹ Twenty-seven of the recalls were due to unapproved pharmaceuticals being illicitly marketed as, or included in, dietary supplements.³⁰ The FDA also has the option of pursuing legal action against the supplement company.³¹ The FDA successfully obtained twenty-seven seizures and six injunctions between 2002 to 2008, most of which were against supplement manufacturers who illicitly claimed that their

UNDERSTANDING, 2, <http://www.gao.gov/new.items/d09250.pdf> [hereinafter *GAO*] (January 2009).

²² *Id.*

²³ *Id.* at 20.

²⁴ Press Release, *Center for Science in the Public Interest, FDA Can't Protect Americans from Dangerous Dietary Supplements, GAO Says*, <http://www.cspinet.org/new/200903022.html> (Mar. 2, 2009).

²⁵ Online Lawyer Source, *Hydroxycut Ephedra*, <http://www.onlinelawyersource.com/hydroxycut/ephedra/> (last visited Sept. 17, 2010).

²⁶ *GAO*, *supra* note 21, at 20.

²⁷ *Id.* at 17.

²⁸ *Id.* at 20.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

supplements could treat, cure, or prevent diseases.³² The agency also filed criminal charges and won convictions in nineteen cases over the same time period.³³ Finally, if an imported supplement poses a serious risk to consumers, the FDA can either detain the product or refuse to allow it into the country altogether.³⁴ The FDA detained 3,225 supplement import entry lines during the period of 2002 to 2008, fifty percent of which were due to the potential presence of a poisonous or unsafe substance.³⁵ Over the same time period, the FDA also refused 3,604 lines of dietary supplements by citing 5,560 violations.³⁶ Twenty-five percent of the violations were due to the potential presence of an unsafe substance.³⁷

In addition to taking judicial and administrative action, the FDA can also rely on a medley of advisory actions to protect consumers from deleterious supplements. For starters, the FDA can conduct informal meetings with supplement companies in which FDA agents speak with company executives to explain their concerns.³⁸ At the meetings, the FDA does not necessarily attempt to compel the company to act in a certain way, nor does the FDA collect agency-wide data; the meetings are simply informative.³⁹ As an alternative to actually meeting with the company, the FDA can also issue warning letters.⁴⁰ From 2002 to 2007, the FDA issued 293 warning letters, seventy percent of which related to dietary supplements that the FDA deemed to be either unapproved or misbranded drugs.⁴¹ The FDA delivers both physical letters and “cyber letters” to marketers of dietary supplement products.⁴²

The FDA also employs several surveillance mechanisms in an attempt to gather and maintain current data concerning the

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *The Status of Dietary Supplements in the United States: Hearing Before the Subcomm. on Human Rights and Wellness of the H. Comm. on Gov't Reform, 103rd Cong. (March 24, 2004) (statement of Robert E. Brackett, Director, Center for Food Safety and Applied Nutrition), available at <http://www.fda.gov/NewsEvents/Testimony/ucm114758.htm>.*

supplement industry. The FDA's surveillance efforts begin at the nation's borders. The FDA reviewed 616,464 import entry lines of dietary supplements during the period of 2002 to 2008, and on average either sampled or examined approximately three to five percent of them.⁴³ Within the United States, the FDA also conducts routine facility inspections.⁴⁴ The FDA worked with state authorities to conduct 909 inspections of dietary supplement firms from 2002 to 2008.⁴⁵ Furthermore, the FDA maintains a database of any adverse events related to supplement use.⁴⁶ Between 2002 and 2008, the FDA received 1,018 consumer complaints, forty-two percent of which (i.e., 428 complaints) involved adverse symptoms from dietary supplements.⁴⁷ The complaints involving adverse symptoms triggered 236 FDA active surveillance operations, which included inspections and sample collections.⁴⁸ The legislature attempted to improve the accuracy of the FDA's database in 2006 with the passage of The Dietary Supplement and Nonprescription Drug Consumer Protection Act ("DSND Consumer Protection Act").⁴⁹ The DSND Consumer Protection Act, which went into effect in 2007, requires supplement companies to submit any serious adverse event reports they receive to the FDA.⁵⁰ Serious adverse events include instances such as death, life-threatening experiences, inpatient hospitalization, birth defects, or episodes which require medical or surgical intervention to prevent such serious outcomes.⁵¹ The DSND Consumer Protection Act, however, does not require companies to report mild or moderate adverse events, but they may do so voluntarily.⁵² Such mild and moderate adverse events include afflictions such as headaches or stomach aches.⁵³ Consumers and health practitioners may also voluntarily submit reports to the FDA concerning all types of adverse events related to dietary supplements.⁵⁴ The good news is that The DSND Consumer Protection Act seems to be having a significant

⁴³ *GAO*, *supra* note 21, at 18.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.* at 11.

⁴⁷ *Id.* at 18.

⁴⁸ *Id.*

⁴⁹ *Id.* at 11.

⁵⁰ *Id.* at 2.

⁵¹ *Id.*

⁵² *Id.* at 2-3.

⁵³ *Id.*

⁵⁴ *Id.* at 3.

positive effect on reporting volume: since the mandatory reporting requirement went into effect in December 2007, the FDA has seen a threefold increase in the number of all adverse events reported to the agency compared with the previous year.⁵⁵ Unfortunately, even with the recent passage of the DSND Consumer Protections Act, the FDA's database is still significantly incomplete due to underreporting. Recent FDA estimates indicate that the actual number of annual total side effects relating to dietary supplements—including mild, moderate, and severe side effects—was most likely over 50,000.⁵⁶ The FDA is currently trying to combat such widespread underreporting by making the reporting process simpler and easier to understand. The FDA has attempted to simplify the process in two ways. First, the agency has reached out to businesses by teaching them about the new reporting requirements and helping them draft forms.⁵⁷ Second, the FDA is currently developing a new Internet-based reporting mechanism called MedWatchPlus.⁵⁸ With the new Internet site, the FDA hopes to simplify the reporting process by reducing the time and cost it takes to report adverse events.⁵⁹

Finally, in addition to its enforcement and surveillance efforts, the FDA also attempts to protect consumers from dubious supplements through several prophylactic measures. The FDA aims several of these prophylactic-measures at supplement manufacturers. In June 2007, the FDA finalized its Current Good Manufacturing Practice (“CGMP”) regulations to establish quality control standards for dietary supplements.⁶⁰ These rules went into effect in August of 2007, but some companies, depending on their size, had until June 2010 to become fully compliant.⁶¹ The CGMP regulations are intended to ensure that

⁵⁵ *Id.* at 12.

⁵⁶ *Id.* at 6.

⁵⁷ *Id.* at 12.

⁵⁸ *Id.* at 17.

⁵⁹ *Id.*

⁶⁰ *Id.* at 11.

⁶¹ Small companies have the most time to comply with the requirements. Large companies had to comply with the requirements by June 2008, companies with less than 500 employees had until June 2009, and companies with less than 20 employees had until June 2010. Press Release, U.S. Food and Drug Administration, *Dietary Supplement Current Good Manufacturing Practices (CGMPs) and Interim Final Rule (IFR) Facts*, 1 (June 22, 2007), <http://www.fda.gov/Food/DietarySupplements/GuidanceComplianceRegulatoryInformation/RegulationsLaws/ucm110858.htm> (last visited Sept. 16, 2010).

“proper controls are in place for dietary supplements so that they are processed in a consistent manner...and meet quality standards.”⁶² Such quality controls include provisions relating to proper manufacturing operations, testing procedures, the handling of consumer complaints, and record maintenance procedures.⁶³ Ideally, the CGMPs will help reduce the amount of deleterious and adulterated products that reach consumers.

The FDA has also attempted to prevent harmful exposures to pernicious supplements by targeting consumers themselves. The FDA maintains information on its website concerning dietary supplements and its jurisdiction over them. The FDA’s website provides clear and easy-to-understand descriptions of how supplements are regulated in the United States and also provides suggestions for how consumers can avoid being scammed by unscrupulous supplement companies.⁶⁴ The FDA has also distributed brochures containing similar information.⁶⁵ Overall, the FDA’s prophylactic measures have sought to inform consumers about industry-related risks before consumers are exposed to harmful products.

However, in the unhappy and all-too-frequent case where the FDA is not able to prevent consumer harm and identifies a deleterious supplement only after it has caused negative effects, the agency strives to alert consumers and supplement manufacturers about the substance as quickly as possible. The FDA has several mechanisms aimed at providing efficient and widespread alerts in order to prevent as many exposures as possible. For example, the FDA tries to reach consumers by posting alerts on its website. The FDA posted twelve alerts on its website between 1999 and 2008.⁶⁶ Such alerts included warnings about taking kava, aristolochic acid, and St. John’s wort, among others.⁶⁷ To reach supplement companies, the FDA can issue industry-wide advisory letters in an attempt to prevent businesses from using certain ingredients in their products or advertisements.⁶⁸ As of November 2008, the FDA had issued five

⁶² *Id.*

⁶³ *Id.*

⁶⁴ U.S. Food and Drug Administration, *Dietary Supplements*, <http://www.fda.gov/food/DietarySupplements/default.htm> (June, 18 2009).

⁶⁵ *GAO, supra* note 21, at 7.

⁶⁶ *Id.* at 20.

⁶⁷ *Id.*

⁶⁸ *Id.*

such advisory letters.⁶⁹

b. FDA Shortcomings

Unfortunately, while the FDA employs a variety of methods to protect consumers from dangerous supplements, its efforts are not entirely sufficient. There are several significant weaknesses in the FDA's surveillance and enforcement regime, and the impact of these weaknesses is exacerbated. The agency has been unable to effectively educate consumers about the risks associated with the supplement industry.

One of the FDA's most glaring shortcomings is that the agency is severely limited by a lack of information.⁷⁰ The FDA lacks complete and accurate information concerning several important facets of the dietary supplement industry. First, the FDA is unlikely to be aware of all the dietary supplement companies that exist within the United States.⁷¹ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 amended the Federal Food, Drug, and Cosmetic Act to require dietary supplement manufacturers to register with the FDA and identify themselves as dietary supplement firms.⁷² However, some supplement companies may be exempt from registration. For example, firms who manufacture products that exclusively contain herbs, such as ginseng and echinacea, are not required to register as dietary supplement firms under current law.⁷³

Second, even if supplement companies register themselves, the FDA could still lack vital information about them. Under the Public Health Security and Bioterrorism Preparedness and Response Act, supplement companies are only required to provide their names and addresses; they are not required to provide detailed information about the products they sell, such as their products' names and ingredients.⁷⁴ Detailed product information could help the FDA better analyze and respond to adverse event reports concerning specific supplements and

⁶⁹ In its advisory letters, the FDA advised marketers against using products or advertisements containing aristolochic acid, comfrey, androstenedione, Lipokinetix, and ephedra. *Id.*

⁷⁰ *Id.* at 6.

⁷¹ *Id.* at 22.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

ingredients.⁷⁵

Finally, the FDA does not have a complete database of supplement-related side effects. Dietary supplement firms are only required to report serious adverse events; they are not required to report moderate or mild events.⁷⁶ Consequently, the FDA lacks a rich and vital source of information. The FDA could use reports of mild and moderate side-effects in at least two important ways. First, the reports could help the FDA identify deleterious substances.⁷⁷ Additionally, and perhaps more importantly, the FDA could also use the reports to provide evidence that a particular supplement poses a “significant or unreasonable risk” to consumer health;⁷⁸ the burden on the FDA to ban an ingredient is already extremely onerous, so the FDA would benefit from any additional information concerning a supplement’s negative impact on consumers. The FDA’s lack of information limits its ability to both identify pernicious substances and take action to prevent them from harming consumers.

The FDA’s enforcement and surveillance regimes also have significant deficiencies. Most importantly, the FDA lacks mandatory recall authority.⁷⁹ Without mandatory recall authority, the FDA must either attempt to institute a product ban, pursue onerous and costly legal action, or plead with a company to voluntarily issue a recall.⁸⁰ As previously discussed, initiating a ban is not a very practical enforcement measure because it is an incredibly onerous, expensive, and time-consuming process. Similarly, initiating legal action against a company, either by seeking criminal convictions or injunctions, is relatively costly, time-consuming, and expensive as well. Legal battles are also undesirable because consumers are left susceptible to harmful supplements while the legal action takes places. Therefore, in order to quickly protect consumers from deleterious products, the FDA is often reduced to nudging companies to issue voluntary recalls themselves.⁸¹

Another limitation of the FDA’s enforcement regime is that most of its enforcement measures are reactionary. In order to

⁷⁵ *Id.*

⁷⁶ *Id.* at 23.

⁷⁷ *Id.*

⁷⁸ *Id.* at 17.

⁷⁹ *Id.* at 6.

⁸⁰ *Id.* at 20.

⁸¹ *Id.*

institute a ban, take legal action, or encourage companies to voluntarily issue a recall, the FDA has to first discover that a supplement has caused harm to consumers. Since the FDA commonly relies on consumer complaints to identify such harmful products,⁸² it means that some consumers will be harmed before the FDA can take action. The FDA's surveillance regime is also tenuous. The FDA dedicates relatively few resources to supplement oversight. The FDA dedicates about four percent of the Center for Food Safety and Applied Nutrition's⁸³ resources to supplement oversight, and the FDA dedicates only about one percent of its total field resources to supplement oversight.⁸⁴

Furthermore, inspection of dietary supplement facilities represents less than one percent of FDA's total food establishment inspections.⁸⁵ Foreign inspections suffer far more than domestic ones. Between 2002 and 2008, the FDA did not conduct one foreign inspection of a dietary supplement firm.⁸⁶ The FDA's rationale for devoting so few resources to supplement oversight is that dietary supplements are generally considered to be a lower risk than other causes of illness, such as foodborne pathogens.⁸⁷ Due to its weaknesses in enforcement and surveillance power, the FDA has limited ability to identify and protect the public from deleterious supplements.

Since the FDA's regulatory regime has several significant shortcomings, it seems especially important for consumers to be educated about the dietary supplement industry. However, several studies have shown that consumers are not well informed. A 2002 Harris Poll indicated that a majority of adults believe that a government agency approves dietary supplements before they reach the market.⁸⁸ Another study conducted in 2003 by the Department of Health and Human Services' Inspector General indicated that dietary supplement labels do not present information in a way that facilitates consumer understanding.⁸⁹ These studies demonstrate that consumers do not seem to be especially knowledgeable about the supplement industry, which

⁸² *Id.* at 23.

⁸³ The Center for Food Safety and Applied Nutrition is a division within the FDA that is responsible for ensuring the safety of human food, including dietary supplements. *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.* at 24.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.* at 8.

⁸⁹ *Id.*

makes them especially vulnerable to pernicious supplements. The FDA, however, has been largely unable to remedy the situation.

Another one of the FDA's shortcomings has been its inability to effectively reach out to consumers and educate them about dietary supplements.⁹⁰ To the FDA's credit, it has taken some initiative. In 2004, the FDA developed an educational brochure that received approximately 171,000 website views and had a distribution of over 40,000 paper copies.⁹¹ However, data from the 2007 National Health Interview Survey indicated that about 114 million individuals take dietary supplements.⁹² Therefore, the FDA's educational endeavors are reaching only a small minority of supplement consumers.

Overall, the FDA employs a variety of effective enforcement, surveillance, and prophylactic measures in its mission to police the colossal and dynamic supplement industry. However, the FDA's regime has significant limitations and lacks the resources to sufficiently tackle the challenge. Fortunately, another government organization, the FTC, is able to augment the FDA's regulatory capabilities and help better protect consumers.

2. Federal Trade Commission

Although the FDA has several shortcomings, the FTC assumes substantial responsibility in policing dietary supplements. The FTC has broad authority to regulate false, misleading, and unsubstantiated claims, and the agency proactively seeks out unscrupulous supplement companies. The FTC plays a vital role in protecting consumers' health and pocket books from deleterious and ineffective dietary supplements.

a. FTC Regulatory Policies

The FTC has clear and robust policies regarding dietary supplement advertising. In 1998, the FTC released a business guide to describe its policies concerning dietary supplement advertising.⁹³ The guide is written in plain-English and includes numerous examples to illustrate key ideas, thus serving as a very

⁹⁰ *Id.*

⁹¹ *Id.* at 7-8.

⁹² *Id.* at 8.

⁹³ *FTC Business Guide*, *supra* note 17.

practical and helpful tool to both potential supplement companies and consumers.⁹⁴ The FTC organizes its policies into three main areas: identifying claims, substantiating claims, and a section dedicated to a variety of miscellaneous claims, including testimonials and expert opinions.

Identifying Claims. The FTC holds advertisers accountable for both the implicit and explicit claims made in their advertisements.⁹⁵ For example, if an advertiser claims that “university studies have proved” an outcome, then the advertiser is responsible for both its explicit claim, that multiple universities have indeed come to that result, and also for its implicit claim, that the universities’ methods were sound.⁹⁶ Furthermore, the advertisement is considered as a whole.⁹⁷ When an advertisement lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating all reasonable interpretations.⁹⁸ For example, suppose a product claims that it will boost the immune system and help maintain a healthy nose and throat during the flu season. The product is called “Cold Away” and the commercial advertisements include images of people sneezing and coughing. The advertiser will be responsible for substantiating that the product will help prevent all symptoms of colds, not simply a healthy nose and throat, because the advertisement and product name imply that the product can be used to prevent colds.⁹⁹

Furthermore, even a truthful claim may ultimately be misleading. If an advertiser omits material information, when considered in light of how a consumer would reasonably interpret the claim, then the advertisement can be considered deceptive.¹⁰⁰ For example, say that an advertiser claims its herbal supplement can relieve pain “without the side effects of over-the-counter pain relievers.” The herbal supplement manufacturer, however, knows that its supplement has negative side effects, but the side effects merely differ from those of over-the-counter pain relievers. The advertiser would most likely be required to include a disclaimer

⁹⁴ *Id.*

⁹⁵ Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry*, 3, <http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf> (last modified Apr. 2001) [hereinafter *FTC Advertising Guide*].

⁹⁶ *Id.* at 4.

⁹⁷ *Id.* at 3.

⁹⁸ *Id.* at 3-4.

⁹⁹ *Id.* at 4-5.

¹⁰⁰ *Id.* at 5.

or qualifying statement concerning the known side-effects in order to establish that its advertisement was accurate and veracious.¹⁰¹ The advertiser's disclosure statement must be clearly and prominently displayed in the advertisement as well. A statement that is displayed in fine print at the bottom of an advertisement, is buried in a body of text, or located on a website in an easily missed location may not be sufficient.¹⁰²

Substantiating Claims. The advertiser is responsible for substantiating all of the explicit and implicit claims in its advertisement.¹⁰³ The advertiser must have a reasonable basis for all of its claims before the product is marketed to the public.¹⁰⁴ Determining whether a specific claim is substantiated is tricky and very difficult to regulate with bright-line rules, since advertisements can present almost an infinite number of claims that may or may not be deemed misleading in different situations. The FTC has recognized the need to form a policy that is adaptable to numerous types of claims and advertisements on the market. Therefore, as opposed to crafting bright-line rules in an attempt to address every type of advertising claim, the FTC crafted a flexible set of guidelines that inform companies what is expected of their advertisements.

According to the guidelines, "[t]he FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous to ensure that consumers have confidence in the accuracy of information presented in advertising."¹⁰⁵

Whether a specific claim is misleading is determined on a case-by-case basis.¹⁰⁶ The FTC considers a number of factors when assessing a claim's validity. Special emphasis is placed on certain factors such as the type of product, the type of claim, and the amount of substantiation that experts in the field believe to be reasonable.¹⁰⁷ In general, products that relate to consumer health and safety require a greater level of substantiation.¹⁰⁸ Similarly, the repercussions of a false claim are taken into account. If a

¹⁰¹ *Id.* at 6.

¹⁰² *Id.* at 6-7.

¹⁰³ *Id.* at 8.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 8-9.

¹⁰⁸ *Id.* at 8.

misleading claim would cause consumers to waste money or be exposed to possible injury, the claim is more heavily scrutinized.¹⁰⁹ Claims that would be difficult for consumers to assess or verify on their own are held to a more exacting standard as well.¹¹⁰

When determining a claim's validity, the FTC affords great weight to the amount of substantiation that would typically be considered sufficient by experts in the field. Companies must support their claims with "competent and reliable scientific evidence," which is defined in the FTC's business guide as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."¹¹¹ Although the definition seeks to create an unbiased uniform rule, several of the factors within the definition can still be considered subjective. For example, how can one determine whether or not a given supplement company's research procedures were "generally accepted in the profession" or if an advertiser's expert testimony was from a professional whose expertise was in the "relevant area"? In order to more precisely analyze each claim and develop a clear and consistent regulatory policy, the FTC has further detailed the factors that it will consider in order to determine if a particular claim is sufficiently supported by scientific evidence.

The most basic requirement provides that a company making a specific scientific claim must be able to demonstrate that such claim is substantiated.¹¹² For example, if the advertiser claims that its product has been studied by U.S. and foreign governments for many years, the company would be responsible for showing that the product has indeed been studied by U.S. and foreign governments.¹¹³ The company would also be responsible for demonstrating that a substantial body of research on the supplement exists, since the claim implied that such research was conducted.¹¹⁴ Other types of scientific claims, however, are more nebulous and difficult to prove false.

While an advertisement might not outright lie, it might

¹⁰⁹ *Id.* at 9.

¹¹⁰ *Id.* at 8.

¹¹¹ *Id.* at 9.

¹¹² *Id.*

¹¹³ *Id.* at 10.

¹¹⁴ *Id.*

stretch the truth of a scientific study or present the evidence in a misleading fashion. For example, suppose a company wants to claim that its vitamin supplement “U Run” provides longer lasting energy than other brands. To support its claim, the company cites studies finding that lab rats injected with U Run’s active ingredients did indeed perform better on endurance tests than control rats. However, the company neglects to mention that U Run contains ingredients that rats are better able to synthesize than humans. Additionally, the company fails to mention that the rats were injected with a higher concentration of U Run’s active ingredient than is contained in the U Run tablet for human consumption. In such a case, the FTC will assess the totality of the circumstances to determine if the claim is supported. Specifically, the FTC will assess: 1) the amount and type of the evidence, such as the types of studies that were performed (e.g., human testing as opposed to in vitro studies); 2) the quality of the evidence, such as examining how well the study was controlled and the nature of the written reports; 3) the totality of the evidence, such as by ensuring that an advertiser has not unduly referenced one favorable study but discounted ten unfavorable studies; and 4) the relevance of the evidence to the specific claim.¹¹⁵

The relevance issue has proven to be an especially hot topic in academia and in court decisions. Specifically, a salient issue has been whether, and to what degree, advertisers can make claims about the supplement as a whole by relying on scientific studies that focus on one particular ingredient.¹¹⁶ For example, suppose a manufacturer has created an energy bar that contains ingredients X, Y, and Z. Scientific studies of X have shown it to be a safe and effective way to promote muscle growth. However, a study has never analyzed the effects of X, Y, and Z taken together. Can the supplement manufacturer claim that its product is a safe and effective muscle growth supplement? While it depends on the circumstances, courts have typically said no.¹¹⁷ If a study is based on one particular ingredient, then the advertiser’s claim must specifically credit the ingredient for the

¹¹⁵ *Id.* at 10-16.

¹¹⁶ John E. Villafranco & Katie Bond, *Dietary Supplement Labeling and Advertising Claims: Are Clinical Studies on the Full Product Required?* 64 *FOOD & DRUG L.J.* 43 (2009).

¹¹⁷ *E.g.*, *Park v. Cytodyne Technologies*, No. GIC 768364, 2003 WL 21283814, at *13 (Cal. Superior May 30, 2003); *FTC v. Nat’l Urological Group*, 645 F. Supp. 2d 1167, 1196 (N.D. Ga. 2008).

results. In most cases, a claim cannot imply that an entire supplement has been tested if only one of the key ingredients has been tested alone.¹¹⁸ The courts and the FTC have good reason for promulgating such a policy. While an ingredient may be safe when taken alone, the possible interaction effects it may have with other ingredients are unknown and potentially deleterious. Furthermore, consumers might falsely believe that a specific, more expensive product is superior when in reality it is simply a specific ingredient in the product, which may be ubiquitous in many cheaper supplements as well, that is responsible for the effect.

Finally, the FTC understands the difficulty and expense of gathering scientific data to support one's supplement claims.¹¹⁹ The agency understands that if elaborate studies were required for each new product, companies simply would not have an incentive to produce many types of supplements, and therefore, the public would not have access to a wide range of potentially beneficial products. Accordingly, the FTC allows companies to advertise their products without conducting extensive scientific research. However, the FTC does require that the supplement advertisers are candid with their claims. While the courts and the FTC allow and even encourage advertisers to rely on scientific studies of individual ingredients when advertising, the claims must be identified for what they are: key ingredient claims. That way, consumers remain fully and accurately informed of the product.

Miscellaneous Claims. In addition to outlining general policies for identifying and substantiating claims, the FTC also devotes a section of its business guide to several specific advertising techniques. In particular, the FTC focuses on consumer and expert testimonials, claims based on traditional use, and the use of the DSHEA disclaimer in advertising.

Perhaps the most important part of the miscellaneous claims section is the portion dedicated to consumer and expert testimony. According to the FTC, it is not enough that a consumer testifier honestly believes his statement.¹²⁰ Rather, the statement's underlying claim must be supportable by scientific evidence.¹²¹ Furthermore, a consumer's testimony must demonstrate the typical results that can be expected from using

¹¹⁸ *Park*, 2003 WL 21283814, at *13.

¹¹⁹ *FTC Advertising Guide*, *supra* note 95, at 9.

¹²⁰ *Id.* at 18.

¹²¹ *Id.*

the supplement, not simply the most optimal results.¹²² A conspicuous disclaimer must accompany the testimony if it does not represent average results.¹²³ In regard to expert testimony, an expert testifier must have appropriate qualifications and must have evaluated the product using appropriate scientific methods.¹²⁴ The advertisement must also disclose any material connection between the expert and the advertiser that may bias the expert's testimony.¹²⁵

Occasionally advertisers assert that their supplements have been used in the past by many different groups of people. These claims are referred to as traditional or historical use claims. The FTC generally permits traditional use claims, however, advertisers must be sure that their advertisements clearly state that the only substantiation for their claims is traditional use and not scientific evidence.¹²⁶ The advertiser must also ensure that it can document the nature of the supplement's historical use.¹²⁷

Furthermore, the DSHEA requires that all dietary supplement labels be accompanied by a two-part disclaimer stating that all claims regarding nutritional support have not been evaluated by the FDA and that the product is "not intended to diagnose, treat, cure or prevent any disease."¹²⁸ While this disclaimer is only required to be on supplement labels and not on advertisements, there are times when the disclaimer could be necessary, or at least helpful, in advertisements as well.¹²⁹ For example, if an advertisement portrays a supplement that resembles a drug and the advertisement seems to suggest that the supplement has been evaluated by the FDA, then the DSHEA disclaimer might be necessary in order to ensure that the advertisement is not misleading.¹³⁰

Overall, the FTC's policy regarding advertising claims can be boiled down to one key principle: companies must make a good faith effort to create an advertisement that fairly and

¹²² *Id.*

¹²³ *Id.* at 18-19.

¹²⁴ *Id.* at 19.

¹²⁵ *Id.*

¹²⁶ If a historical use claim poses a significant threat if misleading—for example, if the supplement claimed to cure cancer—then the FTC requires the claim be substantiated with scientific evidence as well. Historical use will be insufficient to substantiate the claim. *Id.* at 20.

¹²⁷ *Id.* at 21.

¹²⁸ *Id.* at 23.

¹²⁹ *Id.*

¹³⁰ *Id.*

accurately reflects the totality of information and scientific data available about a supplement.

The FTC has created a fantastic policy regarding supplement advertising. The policy is clear, easy to understand, and flexible enough to allow companies to make compelling claims about all types of supplements. Moreover, the policy is also sufficiently robust so as to outlaw misleading claims and protect consumers. Advertisers constructing claims in good faith can easily use these guidelines to help them create honest yet compelling claims. However, simply crafting an effective regulatory framework is insufficient to detect and prevent false and misleading claims from swindling innocent consumers. Accordingly, the FTC also needs a robust enforcement regime.

b. FTC Enforcement Power

The FTC uses several methods to enforce its policies against unscrupulous supplement advertisers.¹³¹ Its methods include bringing settlements and cases against advertisers, and also patrolling the Internet with a cadre of local, state, and federal officials.¹³² Altogether, the FTC's methods pose a significant and powerful threat to false advertisers, but unfortunately the FTC cannot target enough different offenders to significantly deter unscrupulous marketing behavior.¹³³

Cases and Settlements. Perhaps the FTC's strongest and most widely used enforcement technique is taking legal action against false advertisers. The FTC is constantly seeking out false advertisements and bringing civil suits against the perpetrators.¹³⁴ Sometimes the cases go all the way through trial, but typically the cases will result in a settlement.¹³⁵ While the FTC has been as

¹³¹ *Issues Relating to Ephedra-Containing Dietary Supplements: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 108th Cong (2003) (statement of J. Howard Beales, III, Director, Bureau of Consumer Protection), available at <http://www.ftc.gov/os/2003/07/ephedratest.htm> [hereinafter *Issues Relating to Ephedra*].

¹³² *Id.*; Press Release, Federal Trade Commission, *Surf Days: Detection and Deterrence*, <http://www.ftc.gov/reports/fraud97/surfdays.htm> (November 1997) [hereinafter *Surf Days*].

¹³³ *Id.*; Dan Hurley, *Revisiting a Poison Control Database on Supplement Risks*, N.Y. TIMES, Feb. 6, 2007, at 1, available at <http://www.nytimes.com/2007/02/06/science/06dietcxn.html>

¹³⁴ *Issues Relating to Ephedra*, *supra* note 131.

¹³⁵ John B. Reiss, Nichole Alling, Stephen Chuk, & Kristen Hall, *Your*

diligent as ever in policing supplement claims, bringing legal action is significantly costly and time consuming, so the agency only brings a relatively small number of claims against the most egregious advertisers.¹³⁶ On average, from 1993 to 2003, the agency filed less than ten lawsuits per year.¹³⁷ However, when the FTC does initiate legal action, it is typically very successful.

In August 2008, the FTC settled charges with Airborne Health, Inc., the maker of the popular Airborne cold prevention tablets, for deceptive advertising claims.¹³⁸ Airborne purported to have many clinically proven health benefits, but the FTC alleged that Airborne had no credible evidence to support any of its claims.¹³⁹ Altogether, Airborne agreed to pay over \$30 million in consumer refunds and attorneys' fees.¹⁴⁰ In a similar lawsuit, the FTC brought a class-action suit against Walgreens because of its product Wal-Born. Wal-Born was an Airborne generic that also claimed it could fight colds. Walgreens settled the case for \$1.4 million.¹⁴¹

In another recent episode, the FTC's case for false advertising against Xenadrine EFX ended in April 2009.¹⁴² The marketers of Xenadrine EFX claimed that it was clinically proven to cause rapid and substantial weight loss.¹⁴³ Previously, the court had ordered the individual defendants and their company, RTC Research and Development, LLC, to pay \$8 million in consumer redress for making false weight loss claims.¹⁴⁴ The final order forbade all three defendants from making misleading advertising claims in the future.¹⁴⁵

The FTC has brought several other actions against dietary supplement companies that have also resulted in large settlements. A federal district court ruled on summary judgment that infomercials for Coral Calcium and Supreme Greens were

Business in Court: 2008-2009, 64 FOOD & DRUG L. J. 755, 768 (2009).

¹³⁶ *Issues Relating to Ephedra*, *supra* note 131.

¹³⁷ *Id.*

¹³⁸ Reiss ET AL., *supra* note 135 at 775.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² Press Release, Federal Trade Commission, *FTC Concludes Case Against Marketers of Xenadrine EFX; Court Ruling Requires Final Defendant to Accept Settlement Terms*, <http://ftc.gov/opa/2009/04/xenadrine.shtm> (April 24, 2009) [hereinafter *FTC Concludes Case*].

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

misleading and violated the FTC Act.¹⁴⁶ A Coral Calcium infomercial claimed that the supplement could treat cancer, Parkinson's, and heart disease and Supreme Greens claimed to be a weight loss supplement.¹⁴⁷ The defendants were not able to present scientific evidence to substantiate any of their claims, so the court granted FTC's motion for \$54 million in consumer redress to cover the full amount of consumer product sales.¹⁴⁸

In another case, National Urological Group and several other defendants were ordered to pay \$15 million for making deceptive claims in their dietary supplement advertisements.¹⁴⁹ The defendants claimed that their products Thermalean and Liproden were clinically proven to cause weight loss, and that their product Spontane-ES could treat ninety percent of men with erectile dysfunction.¹⁵⁰ The court held that the defendants had not presented "competent and reliable scientific evidence" to support their claims.¹⁵¹

In yet another development, the FTC recently brought charges against Kevin Trudeau, a longtime marketer of dietary supplements and other products.¹⁵² Over the years, Trudeau claimed that his various products could cure cancer, AIDS, severe pain, hair loss, slow reading, poor memory, debt, and obesity.¹⁵³ The FTC brought false advertising claims against Trudeau multiple times, particularly focusing on the claims that he made in infomercials.¹⁵⁴ In the most recent case, a federal district court sided with the FTC in concluding that Trudeau had misrepresented a book and thereby violated previous sanctions against him.¹⁵⁵ The court found Trudeau in contempt and ordered him to pay \$37.6 million in redress and banned him from appearing in any infomercials for the next three years.¹⁵⁶

The FTC continues to bring lawsuits against unscrupulous advertisers. The lawsuits are typically successful at obtaining large monetary judgments and sometimes sanctions

¹⁴⁶ Reiss ET AL., *supra* note 135 at 775.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 775.

¹⁵⁰ *Id.* at 776.

¹⁵¹ *Id.*

¹⁵² F.T.C. v. Trudeau, 579 F.3d 754, 756 (7th Cir. 2009).

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 779. The Seventh Circuit affirmed that Trudeau was in contempt but remanded for redetermination of sanctions.

against the defendants. However, bringing a lawsuit is an onerous and difficult task that requires significant time and resources. The FTC simply does not have enough resources to bring lawsuits against many supplement companies. Therefore, the FTC necessarily relies on other methods of regulating dietary supplement advertisers.

Internet Regulation. The Internet poses an especially difficult regulatory challenge for the FTC. It is becoming increasingly easier for an individual to set up a website and market a dietary supplement because the online process can be completed relatively quickly and requires little effort.¹⁵⁷ Indeed, a quick Google search shows that the number of dietary supplement advertisements on the web is staggering. In response to the proliferation of Internet solicitors, the FTC has been innovative in developing ways to regulate this industry. One such response has been the development of “surf days.” In the late 1990’s, the FTC worked with the FDA to organize a cadre of federal, state, and local officials to surf the Internet and look for potential violations.¹⁵⁸ The FTC identified types of deceptive practices that appeared to be common on the Internet and developed a protocol to find sites that displayed the undesired practices.¹⁵⁹ At a particular date and time, federal, state, and local officials searched the web for the undesired websites and then sent their findings to FTC officials.¹⁶⁰ FTC attorneys then identified which of those sites were most likely breaking the law and sent email messages to the sites’ proprietors informing them that their advertisements were in violation of FTC policy and that they may be subject to enforcement action.¹⁶¹

Through its surf day efforts the FTC has been able to help police both domestic and international supplement companies. In January and February 2002, the FTC worked with the FDA, the Australian Competition and Consumer Commission, and nineteen other members of the International Marketing Supervision Network to surf the internet for online marketing of

¹⁵⁷ THOMAS L. FRIEDMAN, *THE WORLD IS FLAT* 88 (2006).

¹⁵⁸ Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years After Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 *FOOD & DRUG L.J.* 567, 583 (1999).

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

health-related products.¹⁶² As a result, the FTC sent over 280 advisory letters to domestic and foreign sites that were identified as making questionable claims for health-related products or services including dietary supplements.¹⁶³

While surf days demonstrate the FTC's ingenuity and willingness to find new strategies to police the supplement industry, the efficacy of surf days is relatively unclear. Estimates of compliance with surf-day recommendations vary greatly. FTC investigators and attorneys made follow-up visits to websites issued surf day warnings approximately one month later and found that between "18 to 70 percent of the questionable sites had been eliminated or revised."¹⁶⁴ While surf days are clearly having some impact, the extent to which the warnings really deter unscrupulous behavior is still unclear.

In addition to targeting unscrupulous online supplement advertisers, the FTC has tried to protect consumers by identifying and reaching out to particularly unwary consumers. In order to do so, the FTC developed several "teaser" websites that were made to resemble supplement websites that commonly contain misleading claims.¹⁶⁵ When the potential consumer would click on a link to buy the product or service, he or she would be taken to a page that included a warning, advice on how to avoid being defrauded, and a hyper-text link to the FTC website.¹⁶⁶ By targeting unscrupulous online advertisers and attempting to educate unwary consumers, the FTC has developed an innovative, two-pronged approach to combating false supplement advertising on the Internet.

By bringing legal claims, the FTC is able to take powerful and effective enforcement action against a limited number of sinister advertisers, and through its online efforts, the FTC has a broad reach to police both international and domestic marketers. However, the agency must improve. The FTC's most glaring deficiency is that it lacks the resources to diligently police and enforce its policies against many of the potentially

¹⁶² *Dietary Supplements and Their Use for Weight-loss Purposes: Hearing Before the Subcomm. on Oversight of Government Management, Restructuring, and the District of Columbia of the S. Comm. on Governmental Affairs*, 107th Cong. (2002) (statement of Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition), available at <http://www.fda.gov/NewsEvents/Testimony/ucm115169.htm>.

¹⁶³ *Id.*

¹⁶⁴ *Surf Days*, *supra* note 132.

¹⁶⁵ Pinco & Halpern, *supra* note 158, at 583-84.

¹⁶⁶ *Id.*

unconscionable supplement companies who market their products to the public. While the FTC has attempted to police the supplement industry, it simply does not have enough resources to do a thorough job.¹⁶⁷ Therefore, with its current shortcomings, the FTC is insufficient to protect consumers from false and misleading advertising.

B. Private Sector Regulation

In addition to government regulation from the FDA and FTC, dietary supplements are also policed by the private industry. Local Better Business Bureaus and the NAD regularly seek out and take action against sinister dietary supplement companies. These self-regulatory agencies palpably augment consumer protection against deleterious supplements and false advertisements.

1. Council of Better Business Bureaus

One of the most well-known and powerful private agencies in place to protect consumers is the Council of Better Business Bureaus (“CBBB”). The CBBB is a non-profit organization that is “dedicated to fostering honest and responsive relationships between businesses and consumers, instilling consumer confidence and contributing to a trustworthy marketplace for all.”¹⁶⁸

The CBBB is a private, non-profit organization that is composed of both corporate partners and independent, local Better Business Bureaus (“BBBs”).¹⁶⁹ The CBBB has a mutually supportive relationship with both its corporate partners and its constituent local BBBs in the United States and Canada.¹⁷⁰ The CBBB’s corporate partners consist of approximately 200 organizations that are leaders in their respective industries and “share a commitment to corporate responsibility and the ideals of

¹⁶⁷ Berin Szoka, *How Financial Overhaul Could Put the FTC on Steroids & Transform Internet Regulation Overnight*, 6 THE TECHNOLOGY & LIBERATION FRONT 7, 2 (2010), available at, <http://techliberation.com/2010/03/17/how-financial-overhaul-could-put-the-ftc-on-steroids-transform-internet-regulation-overnight/>.

¹⁶⁸ Council of Better Business Bureaus, *BBB Structure*, <http://www.bbb.org/us/cbbb> (last visited Sept. 21, 2010) [hereinafter *BBB Structure*].

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

the BBB.¹⁷¹ The corporate partners are typically fairly large companies (e.g., Verizon Wireless and Nestle USA are both corporate partners).¹⁷² The CBBB is also composed of 122 independent local BBBs across North America that serve both businesses and consumers in their local communities.¹⁷³ Local agencies govern their own regions and process all complaints.¹⁷⁴

Businesses may or may not choose to become members of their local BBB.¹⁷⁵ In order to become accredited (membership is synonymous with accreditation¹⁷⁶), business are required to go through a lengthy review process, agree to abide by certain ethical standards,¹⁷⁷ and pay an annual fee.¹⁷⁸ Depending on the size of the company, accreditation can cost anywhere from several hundred dollars to several thousand dollars a year.¹⁷⁹ The majority of the BBB's funds come from these accreditation fees.¹⁸⁰ Once accredited, a company is permitted to use the BBB's seal in its advertising materials.¹⁸¹

The BBB protects the marketplace in a variety of ways. Perhaps the most well-known and effective method is through the processing of complaints. Local BBBs accept complaints about business from both consumers and other businesses.¹⁸² Complaints can be filed against both accredited and non-accredited businesses.¹⁸³ The process for filing a complaint is

¹⁷¹ *Id.*

¹⁷² Council of Better Business Bureaus, *Roster of Corporate Partners*, <http://www.bbb.org/us/corporate-partners/roster> (last visited Sept. 21, 2010).

¹⁷³ *BBB Structure*, *supra* note 168.

¹⁷⁴ Council of Better Business Bureaus, *BBB Online Complaint System*, <https://odr.bbb.org/odrweb/public/getstarted.aspx> (last visited Sept. 21, 2010) [hereinafter *BBB Online Complaint System*].

¹⁷⁵ Council of Better Business Bureaus, *About BBB Accreditation*, <http://www.bbb.org/us/bbb-accreditation-application> (last visited Sept. 21, 2010) [hereinafter *About BBB Accreditation*].

¹⁷⁶ Council of Better Business Bureaus, *Frequently Asked Questions*, <http://www.bbb.org/us/bbb-faqs/#Does%20BBB%20Accreditation> (last visited Sept. 21, 2010).

¹⁷⁷ *Id.*

¹⁷⁸ David Lazarus, *Better Business Bureau Grades Companies on a Peculiar Curve*, LOS ANGELES TIMES, Jan. 21, 2009, at 1, available at, <http://articles.latimes.com/2009/jan/21/business/fi-lazarus21> (last visited Sept. 21, 2010).

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *About BBB Accreditation*, *supra* note 175.

¹⁸² *BBB Online Complaint System*, *supra* note 174.

¹⁸³ *Id.*

relatively simple and can be done by completing an online form on the BBB's website.¹⁸⁴ Once filed, the local BBB forwards the complaint to the respective company within two business days.¹⁸⁵ The company is then asked to respond to the complaint within fourteen business days and the customer is notified of the business' response once it is received by the local BBB.¹⁸⁶ Before filing a complaint with the BBB, customers are strongly encouraged to attempt to resolve the dispute with the company itself.¹⁸⁷ In some cases, the local BBB may even offer arbitration or mediation to assist in resolving the conflict.¹⁸⁸

In addition to handling complaints, the BBB also helps encourage responsible business behavior by publishing a letter-grade rating system of businesses.¹⁸⁹ Any business may receive ratings, regardless of whether or not it is accredited by the BBB.¹⁹⁰ The letter grade system rates companies on a scale of A+ through F (a much more precise system than the previous "satisfactory" or "unsatisfactory" rating system that was employed by the BBB).¹⁹¹

The BBB considers a number of factors when rating a company.¹⁹² One of the most significant considerations involves complaints. The BBB considers how many complaints have been filed against a business, the severity of the complaints, and the business' response to the complaints, including how quickly the business responded and the efficacy of the response.¹⁹³ The BBB also takes into account the business' length of time in operation, whether or not the business has honored past commitments to mediate and comply with mediation obligations, and the existence of any known government actions against the company that are related to marketplace activities.¹⁹⁴

The BBB also considers whether or not a business is

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ Council of Better Business Bureaus, *What Are BBB Ratings?*, <http://www.bbb.org/business-reviews/ratings/index.html> (last visited Sept. 21, 2010) [hereinafter *What Are BBB Ratings*].

¹⁹⁰ Lazarus, *supra* note 178, at 1.

¹⁹¹ *Id.*

¹⁹² *What Are BBB Ratings*, *supra* note 180.

¹⁹³ *Id.*

¹⁹⁴ *Id.*

accredited when determining the business's rating.¹⁹⁵ A business receives four points, out of a possible ninety, if it is accredited by the BBB.¹⁹⁶ This preferential treatment of accredited businesses has been questioned and criticized as being "pay-for-play."¹⁹⁷ Since companies have to pay to become accredited, opponents of the rating system contend that business can simply pay extra money to receive a better ranking.¹⁹⁸ Regardless of the business' rating, however, consumers are free to read descriptions of why the company was given a particular grade.¹⁹⁹ Accordingly, a less-than-perfect letter grade might not discourage consumers from doing business with a particular organization. For example, a company's low grade might have been awarded because "complaints [were] unresolved, meaning that the company failed to properly address the complaint allegations or their response was inadequate."²⁰⁰ Conversely, a positive rating might not guarantee business if particularly dubious comments are included in the company's grade report. The BBB's letter-grade system and accompanying descriptions enable consumers to make more fully informed decisions about whether or not they feel comfortable and confident interacting with a particular business organization. Finally, the BBB also promotes honest business practices by distributing consumer and business education tips and by posting local marketplace alerts on its website.²⁰¹

2. National Advertising Division

a. NAD Purview, Policy and Structure

The National Advertising Division ("NAD") is the investigative division of the CBBB.²⁰² The NAD is charged with

¹⁹⁵ Council of Better Business Bureaus, *BBB Ratings Overview*, <http://www.bbb.org/business-reviews/ratings/overview.html> (last visited Sept. 21, 2010) [hereinafter *BBB Ratings Overview*].

¹⁹⁶ *Id.*

¹⁹⁷ Lazarus, *supra* note 178, at 3.

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *BBB Structure*, *supra* note 168; Council of Better Business Bureaus, *BBB Alerts Consumers: Watch out For Unscrupulous Online Payday Lenders*, <http://austin.bbb.org/article/bbb-alerts-consumers-watch-out-for-unscrupulous-online-payday-lenders-17902> (Mar. 3, 2010).

²⁰² Council of Better Business Bureaus, *NAD Case Reports*, <http://www.bbb.org/us/National-Advertising-Division/Reports/> (last visited Sept. 21, 2010) [hereinafter *NAD Case Reports*].

monitoring and evaluating truth and accuracy in national advertisements directed towards consumers age twelve and over.²⁰³ To be deemed national, the advertisement must be disseminated nationwide or on a broad regional basis.²⁰⁴ Complaints concerning local advertisements are handled by the local BBB.²⁰⁵

The NAD's policies are set by the National Advertising Review Counsel ("NARC"). NARC is another independent, non-profit organization whose mission is to "foster truth and accuracy in national advertising through voluntary self-regulation."²⁰⁶ NARC provides guidance and sets advertising standards for the NAD as well as a number of other self-regulatory agencies.²⁰⁷ In addition to having carefully constructed policies, the NAD also boasts top-notch legal talent to process claims and handle disputes. The NAD's staff includes four attorneys, two senior and two staff, who have experience with claims substantiation, advertising and trade regulation, and litigation and arbitration.²⁰⁸ The NAD plans to augment its staff with another attorney whose sole focus will be dietary supplement regulation.²⁰⁹

The NAD recently partnered with the Council for Responsible Nutrition in order to help regulate dietary supplements. The Council for Responsible Nutrition agreed to provide the NAD with nearly \$500,000 over three years in order to allow the NAD to increase the number of dietary supplement cases it handles.²¹⁰ The money will be provided to the NAD with no strings attached²¹¹ and the agency will most likely use the

²⁰³ *Id.*

²⁰⁴ Council of Better Business Bureaus, *About NAD*, <http://www.bbb.org/us/About-National-Advertising-Division> (last visited Sept. 21, 2010) [hereinafter *About NAD*].

²⁰⁵ *Id.*

²⁰⁶ Council of Better Business Bureaus, *Advertising Review Services*, <http://www.bbb.org/us/Advertising-Review-Services/> (last visited Sept. 21, 2010).

²⁰⁷ The NARC also sets standards for the Children's Advertising Review Unit (CARU), the National Advertising Review Board ("NARB") and the Electronic Retailing Self-Regulation Program ("ERSP"). *Id.*

²⁰⁸ Council of Better Business Bureaus, *Contact Information*, <http://www.bbb.org/us/national-advertising-division-contact/> (last visited Sept. 21, 2010); National Advertising Division, *How NAD Works*, <http://www.nadreview.org/AboutNAD.aspx> (last visited Sept. 21, 2010) [hereinafter *How NAD Works*].

²⁰⁹ Villafranco & Lustigman, *supra* note 18, at 710.

²¹⁰ *New Industry Initiative*, *supra* note 2.

²¹¹ *Id.*

funds in order to hire an additional attorney to focus exclusively on the dietary supplement industry.²¹²

The NAD's primary function is to review disputes between national advertisers and provide a low cost alternative to litigation.²¹³ In order to settle claims, the NAD boasts a "unique hybrid form of dispute resolution" that involves "working closely with in-house counsel, marketing executives, research and development departments, and outside consultants to decide whether claims have been substantiated."²¹⁴ The NAD strives to make the dispute resolution process as efficient, quick, and fair to all parties as possible. The dispute resolution process commences when a party files a complaint. Other businesses, local BBBs, individual consumers, consumer groups, and even the NAD itself can file complaints.²¹⁵ To file a complaint, the challenging company must pay a filing fee, which is contingent on the company's gross annual revenue and whether or not the company is a CBBB corporate partner.²¹⁶ CBBB corporate partners pay \$2,500 per complaint and non-CBBB corporate partners pay between \$6,000 and \$20,000 depending on the challenging company's gross annual revenue.²¹⁷ Consumers, however, do not have to pay a filing fee in order to file a complaint.²¹⁸ Once a complaint is received, the NAD will conduct an investigation and provide a written response within sixty days.²¹⁹ During the investigation, the challenged company is typically allowed to continue advertising.²²⁰ All information collected during the proceedings remains private except for the NAD's decision, the challenger's and the advertiser's positions, and a statement by the advertiser.²²¹

Compliance with the NAD's decision is completely voluntary.²²² The NAD's decision is not binding on the FTC or on the businesses that are parties to the complaint.²²³ However, if

²¹² Villafranco & Lustigman, *supra* note 18, at 710.

²¹³ *How NAD Works*, *supra* note 208.

²¹⁴ *About NAD*, *supra* note 204.

²¹⁵ *NAD Case Reports*, *supra* note 202.

²¹⁶ *How NAD Works*, *supra* note 208.

²¹⁷ *About NAD*, *supra* note 204.

²¹⁸ Telephone interview with Sheryl Harris, National Advertising Division, (Apr. 15, 2010).

²¹⁹ *About NAD*, *supra* note 204.

²²⁰ *Id.*

²²¹ *Id.*

²²² *How NAD Works*, *supra* note 208.

²²³ Villafranco & Lustigman, *supra* note 18, at 709.

an advertiser either refuses to cooperate with the NAD proceedings or fails to comply with its decision, there may be substantial negative consequences. Bad publicity might hurt a business' reputation and hinder future sales. In addition, the NAD can refer cases to the FTC, and the FTC tends to give referred cases a high priority.²²⁴ In a statement to Congress, C. Lee Peeler, President and CEO of the NARC, asserted that:

During the nearly 40 years of its existence, the advertising self-regulatory system has received strong support from the FTC. The FTC also has consistently supported self-regulation by committing to give a priority to examining referrals from the advertising self-regulatory process. Referrals to the FTC of advertisers that refused to participate in the self-regulatory process have resulted in FTC lawsuits and significant monetary penalties.²²⁵

Since the FTC firmly supports the NAD, supplement companies have a strong incentive to comply with NAD's recommendations. In his statement to Congress, Peeler estimated that "well over 90% of participants 'voluntarily comply' with NAD's decisions."²²⁶ Overall, NAD's decisions are respected by advertisers even though compliance is voluntary.

b. NAD Enforcement Action

The NAD provides a substantial boost to supplement regulation. In particular, the NAD is fairly diligent in bringing claims against unscrupulous companies. Between April 1, 2009 and April 8, 2010, a total of thirty-two complaints were brought against dietary supplement companies.²²⁷ Of those complaints,

²²⁴ *Id.* at 710.

²²⁵ *CBBB Statement to Congress on Advertising Trends and Consumer Protection: Hearing Before the Subcomm. on Consumer Prot., Prod. Safety, and Ins.*, 111th Cong. (2009) (statement of C. Lee Peeler, President and CEO, National Advertising Review Council), available at <http://www.bbb.org/us/article/cbbb-statement-to-congress-on-advertising-trends-and-consumer-protection-11635> [hereinafter *CBBB Statement to Congress*].

²²⁶ *Id.*

²²⁷ National Advertising Division, *Latest Cases*, <http://www.nadreview.org/search/search.aspx?doctype=1&casetype=1> (last visited Sept. 21, 2010).

twenty-five were filed by the NAD itself.²²⁸ Six of the complaints were filed by competitors and one complaint was filed by the Council for Responsible Nutrition.²²⁹ Not one complaint was filed by a consumer, despite the fact that consumers may file complaints without paying filing fees.²³⁰ The numbers show that in practice the NAD is still forced to identify and file the vast majority of claims itself, even though it theoretically has the help of thousands of concerned consumers and business on its side.

Although it alone assumes much of the responsibility for identifying claims, the NAD still manages to pose a formidable regulatory force in the supplement industry. In order to protect consumers from misleading claims, the NAD frequently recommends that advertisers substantially alter their advertisements. In its recommendations, the NAD thoroughly examines all aspects of a company's advertisement. For example, on February 16, 2010, the NAD issued a press release recommending that Artis Marketing discontinue several advertising claims that it was using to market its weight-loss supplement Slimforce 7.²³¹ The NAD recommended that Artis Marketing discontinue its claim that Slimforce 7 could "help to reduce your hunger cravings" because there was no evidence evaluating the product's ingredients' effects on hunger.²³² The NAD found that there was no evidence to support claims that Slimforce 7, or its ingredients, continued to support weight loss after a consumer had finished taking the supplement.²³³ Finally, among other determinations, the NAD recommended that the company discontinue its testimonials and claims suggesting that the product would result in weight loss regardless of diet and exercise.²³⁴ Artis Marketing stated that it would "take NAD's concerns into account in future advertising."²³⁵

However, while the NAD wants to protect consumers, it also understands the importance of fairness to businesses. The

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ *Id.*

²³¹ Press Release, National Advertising Division, *NAD Recommends Artis Marketing Discontinue Wide Range of Claims for "Slimforce 7" Dietary Supplement*, <http://www.nadreview.org/docView.aspx?DocumentID=7899&DocType=1News> (Feb. 16, 2010).

²³² *Id.*

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Id.*

NAD takes into account the difficulties of substantiating compelling advertising claims for novel and complex dietary supplements and consequently it does not recommend changes for all of the advertising claim complaints it receives. For example, on January 25, 2010, the NAD issued a press release stating that Lifes2Good Natural Healthcare could support certain advertising claims for its dietary supplement, Viviscal, which was marketed to prevent thinning hair.²³⁶ Lifes2Good had claimed that “Viviscal strengthens and nourishes thinning hair from within while promoting existing growth.”²³⁷ The NAD found that the claim was supported by studies conducted on both the product Viviscal and on some of Viviscal’s individual ingredients.²³⁸ The NAD also found support for Lifes2Good’s claim that Viviscal was “[r]ecommended by top celebrities and models.”²³⁹ Finally, the NAD agreed that there was evidence to support claims that the product was both safe and composed of all natural ingredients.

The NAD did, however, suggest that Lifes2Good amend its claim that “100% natural ingredients make Viviscal safe and free of harmful side effects” in order to prevent the possibility of a misleading interpretation that the product was safe because it was made of all natural ingredients.²⁴⁰ The NAD also recommended that Lifes2Good discontinue its claim that “Viviscal is doctor recommended” and suggested that the company discontinue its before-and-after photo comparison.²⁴¹ The Lifes2Good case presents a compelling example of how the NAD provides effective consumer protection while still remaining fair to dietary supplement marketers.

Through its efforts in bringing and resolving claims against unscrupulous supplement manufacturers, the NAD provides a significant boost to dietary supplement regulation. While the NAD is not without its shortcomings, the agency still plays a notable role in helping to protect consumers from false

²³⁶ National Advertising Division, *NAD Finds Lifes2Good Can Support Certain Advertising Claims for “Viviscal,” Recommends Advertiser Modify Certain Claims*, <http://www.nadreview.org/docView.aspx?DocumentID=7869&DocType=1> (Jan. 25, 2010).

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ *Id.*

and misleading supplement advertisements.

C. Joined Forces: The FTC and NAD as an Effective Unit

The NAD and the FTC essentially have a symbiotic relationship. The NAD needs the FTC in order to compel advertisers to comply with its recommendations and keep its costs as low as possible. The NAD's presence helps save the FTC valuable resources and also promotes greater compliance with the FTC's regulatory policies. The NAD most likely would not be able to succeed without the FTC. While the NAD boasts a ninety percent compliance rate,²⁴² it is the FTC's presence that compels advertisers to voluntarily comply with the NAD's recommendations. If the FTC did not exist, then companies would most likely ignore the NAD altogether.

Metabolic Research provides a perfect example of the NAD's dependency on the FTC.²⁴³ In 2009, the NAD recommended that Metabolic Research discontinue certain claims that it was making for its dietary supplement Stemulite.²⁴⁴ Metabolic Research ignored the complaint, so the NAD referred the issue to the FTC, which subsequently contacted Metabolic Research.²⁴⁵ Once the company heard from the FTC, it voluntarily agreed to comply with the NAD's previous recommendations.²⁴⁶ In 2010, the NAD again looked at several new claims made by Metabolic Research and on March 3, 2010, once again issued a press release recommending that the company amend and omit some of its claims.²⁴⁷ This time, Metabolic Research stated that it had "every intention on being compliant in all respects."²⁴⁸

While Metabolic Research initially ignored the NAD's recommendations, it immediately changed its position when it

²⁴² *CBBB Statement to Congress*, *supra* note 225.

²⁴³ Press Release, National Advertising Division, *NAD Recommends Metabolic Research Modify, Discontinue Claims for "Stemulite,"* <http://www.nadreview.org/docView.aspx?DocumentID=7925&DocType=1> (Mar. 3, 2010) [hereinafter *NAD Recommends Metabolic Research*].

²⁴⁴ *Id.*

²⁴⁵ *Id.*

²⁴⁶ *Id.*

²⁴⁷ In particular, the NAD found that the company had insufficient evidence to support claims that Stemulite increased muscle gain, endurance, wellness, and energy, and consequently the NAD recommended discontinuance of all the claims. *Id.*

²⁴⁸ *NAD Recommends Metabolic Research*, *supra* note 243.

was contacted by the FTC.²⁴⁹ The mere threat of engaging with the FTC was enough for the company to cooperate with the NAD's voluntary alternative dispute resolution process, and it seems safe to assume that many other companies would behave the same way. The FTC serves as a looming threat to advertisers because it boasts the capability of imposing severe penalties and future sanctions and, therefore, companies will keenly comply with NAD procedures in order to avoid more serious repercussions at the hands of the FTC

The NAD benefits from the FTC's presence in one other notable way. Since the FTC bears the price of bringing large and expensive lawsuits against some of the most egregious and costly advertising offenders, it prevents the NAD from having to do the same and, therefore, helps keep the NAD's costs relatively low. The NAD can therefore afford to bring more cases against unscrupulous supplement companies. Furthermore, by not having to fund expensive lawsuits, the NAD can keep the complaint filing fees as low as possible. The NAD currently receives few annual complaints from competitive businesses and consequently needs to do everything it can to encourage participation. By keeping filing costs low, the NAD can help boost business participation.

While the NAD relies on the FTC for success, the FTC also prospers from the existence of the NAD. The NAD can quickly and efficiently resolve cases that the FTC would have otherwise handled. By resolving these cases, the NAD saves the FTC valuable time and resources which the FTC can devote to other pressing concerns. In addition, the NAD's vigilance makes it more likely that supplement manufacturers will be caught and reprimanded for making false and misleading claims. The increased likelihood of being caught compels advertisers to have greater respect for, and be more likely to adhere to, the FTC's policies and advertising guidelines. The FTC and the NAD both benefit from one another and together the two agencies provide a more robust regulatory force than either agency could provide alone.

²⁴⁹ *Id.*

III. Critique of the Current Dietary Supplement Regulatory Regime

A. Criticisms of Current Dietary Supplement Regulation

There are several prominent criticisms of the United States' current dietary supplement regulatory regime. The most poignant and convincing argument is that many people are being harmed by deleterious supplements every year. During the period of 1983 to 2004, there were 230 deaths associated with dietary supplements.²⁵⁰ In 2005 alone, dietary supplements were responsible for 5,334 adverse reactions, 17,843 health care visits, and 12,314 medical outcomes.²⁵¹ Perhaps even more chilling than the sheer number of supplement-related incidents is the fact that the numbers of incidents are rising. In 1994 there were only four reported deaths caused by supplement use, whereas in 2005 there was a record twenty-seven reported deaths.²⁵² Granted, the increased number of incidents could simply be due to the fact that more people are reporting supplement-related incidents now than in the past. Indeed, the number of reported supplement-related adverse events has significantly increased in recent years due to the introduction of mandatory reporting requirements.²⁵³ However, the notion that supplement-related incidents have increased simply because individuals are more likely to report them should not assuage concerns regarding the safety of the supplement industry. Underreporting of adverse events is still rampant. The FDA estimated that only two percent of supplement-related adverse events are reported.²⁵⁴ That means that the actual number of supplement-related incidents is likely to be much higher than the numbers suggest. Furthermore, the supplement industry is rapidly expanding: 4,000 supplement products were available to consumers in 1994 whereas 75,000 supplement products were available to consumers in 2008.²⁵⁵ With such an influx of supplements hitting the market, it seems

²⁵⁰ Dan Hurley, *Diet Supplements and Safety: Some Disquieting Data*, N.Y. TIMES, Jan. 16, 2007, at 1, available at <http://www.nytimes.com/2007/01/16/health/16diet.html?pagewanted=1&r=1>.

²⁵¹ Dan Hurley, *Revisiting a Poison Control Database on Supplement Risks*, N.Y. TIMES, Feb. 6, 2007, at 1, available at <http://www.nytimes.com/2007/02/06/science/06dietcxn.html>

²⁵² Hurley, *supra*, note 250, at 1.

²⁵³ GAO, *supra* note 21, at 5.

²⁵⁴ *Id.*

²⁵⁵ *Id.* at 1.

quite likely the number of supplement-related incidents is indeed rising. Therefore, the lurid statistics demonstrating the large number of adverse supplement-related incidents should be a significant cause for concern.

Critics of the current regulatory policy blame the deluge of supplement-related incidents on the government's inability to police the supplement industry. While critics offer several reasons why government agencies are inadequate, one particularly strong criticism is that government agencies are unable to effectively enforce their policies against unscrupulous companies.²⁵⁶ Bruce Silverglade, the legal affairs director for the Center for Science in the Public Interest, claimed that "[w]hen it comes to dietary supplements, it's like the Wild West, and the bad guys know they don't have to take the sheriff seriously."²⁵⁷ Even when confronted with people dying from a dangerous substance like ephedra, the FDA has limited authority to get the product off the market.²⁵⁸ Silverglade's claim is well-founded. Surf-day follow-up studies estimated company compliance to be as low as eighteen percent.²⁵⁹ Additionally, companies seem to be relatively undaunted by the threat of FDA inspections. The FDA conducted 804 inspections of dietary supplement facilities from 2002 to 2008 and investigators identified potential problems in forty-nine percent of the facilities.²⁶⁰ Overall, companies can defy government policies because it is exceedingly unlikely that they will get caught and punished. While the FDA, the FTC, and the NAD do successfully bring a fair number of cases every year against supplement manufactures, the agencies simply do not have enough resources to pursue legal action against a large percentage of unscrupulous supplement companies. In a congressional hearing, the FTC testified that nearly forty percent of the weight loss claims that it sampled in 2001 made at least one representation that was "almost certainly false."²⁶¹ In 2008 there were 75,000 supplement products.²⁶² Forty percent of 75,000 products means that there are potentially 30,000 misleading

²⁵⁶ Center for Science in the Public Interest, *FDA Can't Protect Americans from Dangerous Dietary Supplements*, GAO Says, <http://www.cspinet.org/new/200903022.html> (March 2, 2009).

²⁵⁷ *Id.*

²⁵⁸ *Id.*

²⁵⁹ *Surf Days*, *supra* note 132.

²⁶⁰ GAO, *supra* note 21, at 18.

²⁶¹ *Issues Relating to Ephedra*, *supra* note 131.

²⁶² GAO, *supra* note 21, at 1.

products on the market. Even if all three U.S. agencies brought a total of one hundred cases a year—a very generous estimate²⁶³—unscrupulous supplement companies would still only have a one in three hundred chance of being legally pursued.

Even if a supplement company gets caught, typically the worst case scenario for the company is that it loses all of its profits and is sanctioned from creating false advertisements in the future.²⁶⁴ These punishments leave an offending company essentially no worse off than it would have been before it swindled consumers by illegally marketing supplements. Between the relatively moderate penalties and extreme unlikelihood of getting caught, many companies choose to roll the dice and market their supplements with misleading claims.

Overall, critics' complaints of the current dietary supplement regulatory regime are well founded. Deleterious supplements are getting to market and regulatory agencies are not able to sufficiently police all of the products and their advertisements.

B. Corrective Measures: Relatively Inexpensive and Minimally-Burdensome Methods of Enhancing the Regulatory Regime

While the FDA, the FTC and the NAD provide a strong regulatory system, deleterious supplements and misleading claims still harm consumers and changes in the regulatory system are necessary. Understandably, the agencies do not have a surplus of extra funds which they can use to boost their regulatory regimes. However, this article advocates several methods by which the FDA and FTC could significantly increase consumer protection against both harmful supplements and misleading claims that would be relatively inexpensive without being unduly burdensome to implement.

Bolstered Reporting Requirements to Create a More

²⁶³ The NAD brought 32 cases from April 1, 2009 to April 8, 2010, National Advertising Division, *Latest Cases*, <http://www.nadreview.org/search/search.aspx?doctype=1&casetype=1> (last visited Sept. 21, 2010); The FTC brought an average of 9 cases per year from 1993 to 2003, *Issues Relating to Ephedra*, *supra* note 131. The FDA pursued legal action against an average of about 6 companies per year from 2002 through 2008, *GAO*, *supra* note 21, at 20 (reporting that the FDA initiated legal action for 27 seizures and 6 injunctions from fiscal year 2002 through July 18, 2008). Using those figures, the agencies bring a total of approximately 47 cases per year.

²⁶⁴ *FTC Concludes Case*, *supra* note 142.

Comprehensive Database. First and foremost, the FDA needs to gather a complete set of data regarding the dietary supplement industry in the United States. The FDA cannot hope to effectively combat pernicious dietary supplements if the agency does not even fully know the extent of their presence and effects on consumers. Fortunately, the FDA can achieve a more robust database with little extra funding. To begin with, the Federal Food, Drug, and Cosmetic Act must be revised so that it requires all dietary supplement companies to register themselves with the FDA. Currently, some dietary supplement companies are exempt from registration; the loopholes in the law that allow such exemptions need to be ironed out. Specifically, the statute should require companies who manufacture products exclusively containing herbs to register themselves as supplement companies.

Furthermore, all dietary supplement companies should be required to register detailed information about their products with the FDA. Currently, companies only need to register the names and locations of their firms.²⁶⁵ At the very least, companies should be required to register the products they sell and their products' ingredients. Finally, supplement companies should be required to forward all adverse supplement-related reports they receive, not just reports regarding mild and moderate events to the FDA. Physicians should be required to report all supplement-related incidents to the FDA as well.

The impact of the enhanced reporting and registration requirements would be substantial. By requiring both businesses and physicians to report all supplement-related side effects, the FDA will have a much more complete and accurate picture of how supplements are affecting the population. Such reporting will allow the FDA to better identify pernicious trends in the supplement industry and also allow the agency to more easily take action to protect consumers. By having detailed information regarding supplement companies' products and ingredients, the FDA will be able to quickly and thoroughly take action to identify and remove particular supplements and ingredients from the market. Also, since companies will know that the FDA is aware of their product's existence, the companies will be more inclined to voluntarily remove their product from the market before the FDA gets a chance to pursue legal action.

Not only would the enhanced reporting requirements

²⁶⁵ *GAO, supra* note 21, at 20.

significantly improve the FDA's ability to police the dietary supplement industry, but these requirements would also be minimally burdensome for both the FDA and supplement companies to implement. The FDA does not need to spend money creating a new database or enhancing its enforcement regime to process the influx of new information. Rather, the FDA just needs to assimilate the information into its already-existing central database. Similarly, the enhanced reporting requirements will not put a terrible strain on businesses either. Businesses are already required to take the time to register with the FDA and to forward reports of serious adverse events they receive. Therefore, most supplement companies should already have procedures in place to carry out such duties. Simply requiring businesses to report slightly more detailed information should not be particularly costly or burdensome at all. Both the FDA and supplement companies have gone through the onerous process of initially implementing reporting and registration procedures; now, they simply need to build upon the foundations they have already put in place.

Grant Agencies Additional Enforcement Mechanisms.

Second, another relatively easy and inexpensive way to boost the effectiveness of the regulatory regime is to give the FDA and FTC a broader range of enforcement powers. Currently, both agencies can essentially only pursue onerous and expensive legal battles to punish unscrupulous supplement companies. While such battles are powerful enforcement mechanisms, it is simply too costly to bring legal action against most violators. Consequently, supplement companies do not fear actually being caught and punished so they willfully violate government policy in hopes of earning a profit.

One enforcement power the FDA and FTC should be given is the ability to administer fines. Implementing fines would not cost the government agencies very much time or money but would give them substantially more enforcement power. Depending on the severity of the fines, which could be increased incrementally for repeat offenders, companies would be severely punished for marketing deleterious products and using misleading advertisements, and they would be strongly deterred from engaging in future unscrupulous conduct. Furthermore, the fines would not simply have an impact on the companies who were caught. The fines would have a significant impact on compliance rates throughout the entire industry. By having the ability to dole out fines to offenders, the FDA and FTC would be

able to punish far more unscrupulous companies than at present. Each crooked company in the industry would have a greater likelihood of being caught, and with this greater risk in mind, many more companies would most likely decide that marketing pernicious and ineffective products would not be worth the gamble.

Furthermore, the FDA should be given the ability to issue mandatory recalls. If the FDA identifies a product to be potentially harmful, it should not be forced to negotiate with a supplement company to recall the product or to go through the arduous process of instituting a legal ban. Such a drawn-out process leaves consumers exposed to products for long periods of time even, after the FDA signals them to be deleterious. Instead, it is in the best interest of consumers for the FDA to be able to quickly and unilaterally remove a product from the market. By having mandatory recall authority, the FDA could provide expeditious consumer protection by removing a product from the market immediately when the agency determines the supplement to be harmful.

Together, the ability to administer fines and issue mandatory recalls would give the FDA and FTC the ability to take effective action against many more unscrupulous companies. Giving the agencies these additional enforcement powers would cost little, would strongly deter supplement companies from marketing deleterious and ineffective products, and would help ensure consumer safety.

Promote Consumer Understanding. Finally, the FDA and FTC need to work together to improve consumer understanding about the supplement industry. Currently, consumers do not understand the structure of supplement industry regulation, and this lack of knowledge is responsible for significant negative consequences.

Consumers' general ignorance about supplement industry regulation is dangerous because it can lead to a false sense of security. If consumers think supplements are approved by the FDA—an incorrect belief that a majority of consumers hold²⁶⁶—then they will be less likely to conduct thorough personal research about the supplements they are taking. Also, by believing that a supplement has been approved as “safe” by the government, consumers might be more likely to take powerful supplements casually and copiously and disregard potentially serious side-

²⁶⁶ *Id.* at 8.

effects. Consumer misunderstanding could potentially be responsible for a large number of supplement-related injuries.²⁶⁷

For example, consider parents' willingness to give supplements to their children. Major medical groups and government agencies do not typically recommend supplements for children who are otherwise healthy.²⁶⁸ However, a study by the National Maternal and Infant Health Survey, published in 1997, found that fifty-four percent of parents give their preschool children supplements at least three days a week.²⁶⁹ That statistic might explain why injuries to children under six account for nearly three-quarters of dietary supplement exposure reports.²⁷⁰ It seems likely that parents do not even know about the government's admonitions against giving supplements to children. Many parents most likely do not fully understand the risks involved with giving supplements to their children because they erroneously believe that supplements have been preapproved by the FDA. This misinformed belief that government agencies approve supplements before they reach the market appears to be making consumers more relaxed and less cautious, which in turn leads to increased health risks.

While consumer ignorance will be a tough problem to address, together the FDA and FTC can take several steps to improve general understanding. At the least, consumers need to understand that the FDA and FTC do not approve supplements before they reach the market. Fortunately, there are several relatively easy and inexpensive ways that the government can go about educating consumers. First, the FTC could require all supplement companies to put the DSHEA disclaimer—that the supplement has not been evaluated by the FDA and that the product is “not intended to diagnose, treat, cure or prevent any disease”²⁷¹—on their advertisements. While the FTC's Business Guide currently recommends the DSHEA disclaimer to be included in some advertisements,²⁷² the FTC could simply require the disclaimer on all advertisements. Such a requirement would expose consumers to the disclaimer more often so they would be more likely to read it and absorb the information. Second, both the FDA and FTC could require the DSHEA disclaimer to be

²⁶⁷ Hurley, *supra* note 250, at 2.

²⁶⁸ *Id.*

²⁶⁹ *Id.*

²⁷⁰ *Id.*

²⁷¹ *FTC Advertising Guide*, *supra* note 95.

²⁷² *Id.*

more prominently pictured on both labels and advertisements. Currently, disclaimers are often posted in very fine print on portions of labels or advertisements that are not readily apparent. Instead, the FDA and FTC could require large, bold disclaimers in prominent locations. Such bold disclaimer requirements are not unheard of: cigarette companies are already required to put bold surgeon general warnings on their cigarette packages and advertisements.²⁷³ Since supplements are harming so many consumers, it might be wise to put a similarly bold disclaimer on supplement labels and advertisements.

IV. Conclusion

Policing the dietary supplement industry is an incredibly immense and onerous task. Together, the FDA, FTC and NAD are constantly devising an array of innovative new strategies to combat unscrupulous supplement companies and establish a safe and honorable industry. While the public and private agencies provide a robust regulatory force, it is currently insufficient to protect consumers from deleterious products and misleading advertisements. Fortunately, the FDA and FTC can take several relatively inexpensive and minimally burdensome measures to help augment consumer protection. However, for the time being, consumers should still use caution when buying supplements and should be aware of the current regulatory regime's shortcomings.

²⁷³ 15 U.S.C. § 1331 (1965).