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Food for Sport or Faustian Bargain: Regulating Performance Enhancing Dietary Supplements

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FOOD FOR SPORT OR FAUSTIAN BARGAIN: REGULATING
PERFORMANCE ENHANCING DIETARY SUPPLEMENTS

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INTRODUCTION

In a year plagued by scandal and notable lapses in the human condition,¹ even the fairytale pursuit of baseball's home run record ended with a bittersweet note. As with the fabled alchemist who made a deal with the devil in exchange for power and worldly experience,² scores of athletes seemed to cast fate and future to the wind in a seductive courtship with performance enhancing drugs.³

A national icon and red-headed role model for America's pastime was named Time Magazine's Hero of the Year⁴, one of the 25 Most Intriguing People of 1998,⁵ and the Associated Press (hereinafter AP) Sports Story of the Year. Nonetheless, Mark McGwire's seventy home runs, which effectively shattered Roger Maris' thirty-seven year old mark, seemed destined to go down in the history books with an asterisk⁶

While this epic endeavor was hallmarked by his gracious battle against a decades old foe in the record books⁷, the taint of McGwire's use of a steroid hormone supplement⁸ weighed heavily, like the ancient mariner's albatross.⁹ The culprit, androstenedione (hereinafter andro), is a legal, dietary "food" supplement to both the Food and Drug Administration (FDA) and Major League Baseball¹⁰, despite being

¹Walter Issacson, *How We Made the Choice*, TIME, Dec. 28, 1998 at 6. References to 1998 events including Serbian brutality, the Starr Report and the questionable state of public education.

²Faust was a fictional magician and alchemist, inspired by Johann Faust, a 16th century German astrologer and magician. The character, who sold his soul to the devil in exchange for power and worldly experience, was the hero of several dramatic works, most notably by Christopher Marlowe [English dramatist and poet (1564-1593)] and Johann Wolfgang von Goethe [German poet and dramatist (1749-1832)].

³John Maher, *The Year on Drugs*, AUSTIN-AMERICAN STATESMAN, Dec. 29, 1998 at C4. Providing a recap, by month and date of more than 140 incidents occurring in organized sport and involving the use of generally illegal, performance-enhancing substances. Notable highlights include the addition of snowboarders, badminton and snooker players joining the ranks of substance abusers.

⁴Daniel Okrent, *Hero of the Year: A Mac For All Seasons-Mark McGwire's 70 Home Runs Shattered the Most Magical Record in Sports and Gave America a Much Needed Hero*, TIME, Dec. 28, 1998 at 138.

⁵The 25 Most Intriguing People of the Year, PEOPLE MAGAZINE, Dec. 28, 1998 at 50.

⁶THE NEW AMERICAN HERITAGE DICTIONARY 80 (1978). A star-shaped figure (*) used in printing to indicate an omission or reference to a footnote.

⁷Okrent, *supra* note 4, at 138.

⁸*Id.* at 142.

⁹Literary reference to a constant burden or heavy cross to bear. From Coleridge's, *Rhyme of the Ancient Mariner*, the tale of a seafarer who was thought to have sinned by killing an albatross, and then had to wear it around his neck as penance.

¹⁰Joel Stein, *Mark of Excellence: To Reach the Summit, Mc.Gwire Overcame a Failed Marriage, a Crisis of Confidence and a Pain-Racked Body. What Bred the Will to Succeed?*, TIME, Dec. 28, 1998, at 149.

banned by most other sports organizations.¹¹ The defining line between legal and illegal substance—between dietary supplement and drug is horribly skewed.

Accordingly, Part I of this Note will investigate the complexities that exist with regard to the classification and regulation of dietary supplements, looking at the history leading to the passage of the governing Dietary Health and Supplement Act of 1994 (hereinafter DSHEA). Part II will focus on supplements that consumers may use for performance enhancement purposes, and the regulation of sports products. Part III will look at the regulatory debate over dietary supplements, the andro product example and the interrelationship between drugs and sport. Part IV will briefly comment on the need to establish alternatives for regulating products which may affect physiological functions or present substantial health risks. This note will conclude in Part V, analyzing when the FDA should re-examine the distinctions between drugs and dietary supplement products and regain the authority to regulate supplements to a reasonable level of scientific honesty.

I. OVERVIEW OF DIETARY SUPPLEMENT REGULATION

A. *An Uneven Path: The Winding Road to DSHEA*

1. Historical Approaches

Rather tragic circumstances led to the 1938 passage of the Federal Food, Drug and Cosmetic Act (hereinafter FDCA), which as amended, regulates food and drug today.¹² At least seventy-three people died the year before the FDCA's passage from ingesting an "elixir" that was found to contain diethylene glycol, more commonly known as antifreeze.¹³ Prior regulatory measures, including the Pure Food and

¹¹Scott M. Reid, *An Issue of Substance: McGwire's Performance-Enhancing Drug is Outlawed by IOC, NCAA and NFL*, ORANGE COUNTY REGISTER, Aug. 22, 1998, at D1. Summarizing the approach to andro use, by sport.

ORGANIZATION	STATUS	PUNISHMENT
International Amateur Athletic Federation	Banned	Two-year suspension [1st offense]; Lifetime suspension [2nd offense]
International Olympic Committee (IOC)	Banned	Suspension; Forfeiture of Medals
Major League Baseball	Not Covered	N/A
National Basketball League [NBA]	Not Covered	N/A
National Collegiate Athletic Association [NCAA]	Banned	Suspension
National Hockey League [NHL]	Not Covered	N/A
National Football League [NFL]	Banned	Suspension

¹²Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395(1994)). See David F. Cavers, *The Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 20 (1939).

¹³Cavers, *supra* note 12. In 1937 ingestion of a product marketed as "Elixir Sulfanilimide," which was found to contain the poisonous liquid form of antifreeze, killed at least seventy-three people. The product's availability was attributed to the lack of pre-market screening of drugs for safety.

Drugs Act of 1906 (hereinafter 1906 Act), had failed to require pre-market screening of drugs for safety.¹⁴

The resulting Congressional response, the FDCA, required drug manufacturers to apply for approval for new drugs and gave the Food and Drug Administration, the authority to test products for safe consumption by humans.¹⁵ The FDCA supplied the FDA with such powerful tools as criminal prosecution, injunction and seizure.¹⁶ As a result the FDA gained the authority to determine which products were safely marketable, even absent any evidence of fraud.¹⁷

Although the FDCA altered the FDA's powers somewhat, the emphasis on fraud and contamination has not changed much since the beginning of the century.¹⁸ For years, the FDA, regulated dietary supplements as foods to ensure their wholesomeness and to promote safety by barring false and misleading labels. Regulation of the dietary supplement industry has reflected a historic struggle¹⁹ between Congress and the FDA over the checks and balances governing classifications under the FDCA.²⁰

Regulation of food and drugs in this country dates back to 1785, when the first food safety regulation was passed in Massachusetts.²¹ Upon discovering that tainted quinine had been supplied to United States troops, the government made its inaugural attempt at regulating drug quality.²² The 1906 Act²³ was the first federal statute to address the adulteration and quality of food and drugs through the interstate regulation of domestically manufactured food and drug products.²⁴ Although this act

¹⁴Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

¹⁵Pub. L. No. 75-717, 52 Stat. 1040 § 505 (codified as amended at 21 U.S.C. § 355 (1994)).

¹⁶*Id.*

¹⁷Edgar R. Cataxinos, *Regulation of Herbal Medications in the United States: Germany Provides a Model of Reform*, 1995 UTAH L. REV. 561, 564 (1995) (citing PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 44 (1980)). Under the FDCA, the government has the power to decide which drugs are marketable regardless of existence of fraud or misrepresentation. The 1906 Act protected consumers from fraud and its resulting economic harm, but did not serve to protect the public from unsafe drugs—as evidenced by the “Elixir Sulfanilimide” tragedy of 1937.

¹⁸PETER B. HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 12 (2d ed. 1991).

¹⁹Eric F. Greenberg, *Dietary Supplements Caught in Murky Regulatory Scheme*, CHI. DAILY L. BULL., Dec. 23, 1998 at 5.

²⁰Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301 et. seq. (1988).

²¹Wallace F. Janssen, *America's First Food and Drug Laws*, 30 FOOD DRUG COSM. L.J. 665, 668-69 (1975). The “Act against selling unwholesome provisions,” was a comprehensive food adulteration law passed by Massachusetts in 1785.

²²Cataxinos, *supra* note 17, at 562 (citing the Act of June 26, 1848, ch. 70, 9 Stat. 237, and Joseph L. Fink & Larry M. Simonsmeier, *Laws Governing Pharmacy*, in REMINGTON'S PHARMACEUTICAL SCIENCES 1890, 1907 (Alfonso R. Gennaro et al. eds., 17th ed. 1985)).

²³Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

²⁴Cataxinos, *supra* note 17, at 563.

created standards for drugs marketed in interstate commerce, it failed to create accountability for false claims about a drug's therapeutic effects.²⁵

In 1938, Congress expanded the FDCA "drug" definition to include non-food "articles intended to affect the structure or any function of the body of man or other animals."²⁶ Ironically, more than sixty years ago, the very products that the legislature sought to regulate were diet aids which were then referred to as anti-fat or slenderizing products.²⁷

Historically, the dietary supplement industry was unable to take advantage of the "other than food" distinction because, at the FDA's urging, courts tended to limit the definition of food to that which is ingested for "taste, aroma or nutritive value."²⁸ In 1958, dietary supplements began to be regulated as food additives and were regulated, in a more stringent manner than conventional foods.²⁹

The FDA's conscious desire to promote safe and effective use and proper labeling was evidenced in the 1970's by increased federal regulation of supplements.³⁰ Among the safety concerns at this time were those that the FDA had regarding high potency vitamins and mineral supplements, and whether their potencies should be limited to the minimum levels necessary for nutrition.³¹ As is the case today, there was tremendous industry opposition to the stricter regulations and, as a result, the Proxmire Amendment was enacted and added to the FDCA in 1976.³²

This limitation on the regulation of advertising and labeling prohibited the FDA from setting maximum levels of vitamin potencies in food, and from classifying any vitamin or a mineral as a drug simply because it exceeded a nutritionally sound potency level.³³ Congress once again fired a return shot into the dietary supplement

²⁵United States v. Johnson, 221 U.S. 488, 497-98 (1911) (holding that an "effective against cancer" claim on a drug label did not violate the 1906 Act).

²⁶21 U.S.C. § 321(g)(1)(C). Legislative history suggests that Congress expanded the definition in order to include products with physiologic effects unrelated to disease, under the FDA's regulatory purview. S. REP. NO. 361, 74th Cong., 1st Sess. 3 (1935), *reprinted in* 3 LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND AMENDMENTS 660.

²⁷S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935), *reprinted in* 3 LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND AMENDMENTS 660.

²⁸*See supra*, note 26 and accompanying text.

²⁹Stephen H. McNamara, *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 FOOD & DRUG L.J. 341(1995) (discussing food additive regulation).

³⁰Robin Elizabeth Margolis, *Vitamins, Minerals and Herbs: How Should the FDA Regulate Dietary Supplements?*, 10 HEALTHSPAN, Oct. 1993, at 21, 23 (an explanation of the history of dietary supplement regulation.)

³¹Margolis, *supra* note 30, at 23.

³²*Id.* *See* Health Research and Health Services Amendments of 1976, Pub. L. No. 94-278, 90 Stat. 401, 410-413 (codified at 21 U.S.C. § 350) (date).

³³Pub. L. No. 94-278, 90 Stat. 401, 410-413 (codified at 21 U.S.C. § 350) (date). *See also*, Margolis *supra* note 31 at 23. Noting that in the wake of the Proxmire Amendment, the FDA issued minimal regulations for dietary supplements between 1979 and 1993).

minefield, enacting the Nutrition Labeling and Education Act of 1990 (hereinafter NLEA).³⁴

2. The Nutrition Labeling and Education Act of 1990

The NLEA establishes requirements, including label content for conventional foods,³⁵ ingredient listing,³⁶ manufacturer name and address,³⁷ number of servings,³⁸ and nutrient content claims.³⁹ While food manufacturers may make health claims and nutritional support statements, only the health claims are subject to NLEA scrutiny, while the balance is not tightly regulated by the FDA.⁴⁰ Despite making claims about effect on body structure or function, dietary supplements can still escape classification as “drugs.”⁴¹ Health claims, which imply a relationship between a food substance in the food and a disease or health-related condition, are prohibited by the NLEA unless found by the FDA to have “significantly scientific agreement.”⁴²

Accordingly, absent FDA approval of the claim, health claims cannot appear on the label or labeling of food products or dietary supplements.⁴³ In essence, the NLEA applies the same standards to dietary supplements as it does to conventional foods.⁴⁴ This increased authority over food labeling exemplifies the dreaded risk aversion inherent in the operation of the FDA.⁴⁵

While the agency’s historic mission has been one of consumer protection, it is often criticized for excessive caution in granting product approval.⁴⁶ The costs

³⁴Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343 (1994)).

³⁵*Id.* (forbidding, inter alia, false or misleading information and misleading containers).

³⁶21 C.F.R. § 101.4, .5, .8, .13 (1996) (requiring containers to list a product’s ingredients).

³⁷§ 101.5.

³⁸§ 101.8.

³⁹§ 101.13.

⁴⁰*Id.* These statements of nutritional support are known as structure/function claims, which state non-disease related effects that foods have on the human body. S. REP. NO. 103-410, at 37 (1994).

⁴¹21 U.S.C. § 321(g)(1)(C) (1994). Products can still be classified as food not drugs, because part (C) of the drug definition excludes foods: “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”

⁴²21 C.F.R. § 101.14(a)(1). Disease or health-related condition includes “damage to an organ, part, structure or system of the body such that it does not function properly . . . or a state of health leading to such dysfunctioning.” § 101.14(a)(6).

⁴³McNamara, *supra* note 29, at 345. In the wake of the NLEA, the FDA promulgated rules imparting the same standards on dietary supplements as with conventional food.

⁴⁴*Id.*

⁴⁵Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J. 651, 654 (1996) (discussing the historical factors that have led to the FDA’s preference for caution).

⁴⁶*Id.* at 656. FDA review deficiencies extend beyond drugs, to medical devices and food additives as well. For example, olestra, the innovative fat substitute, received FDA approval

associated with satisfying such regulation arguably squelch any incentive there might be to bring new and innovative products to market. Presumably, consumers and manufacturers alike are the losers in this regulatory dilemma.

As a result, politics keep the tug-of-war game going between regulation for consumer protection and the need to freely move products to market. In staying true to historical course, the FDA's NLEA-authorized clamp down on dietary supplements was followed by yet another attempt to restore equilibrium to the regulatory process.⁴⁷

3. Dietary Supplement Act of 1992

Congress responded to the FDA's application of conventional food standards to dietary supplements, with the Dietary Supplement Act of 1992 (1992 Act),⁴⁸ which restricted the implementation of the NLEA with regard to dietary supplements.⁴⁹ The 1992 Act expressly called for the establishment of rules that are specific to dietary supplements,⁵⁰ with the FDA opting to respond with a proposal to revise its food labeling regulations to make dietary supplements subject to the same requirements as food—a wholesale reiteration of its stance under the NLEA.⁵¹

The FDA's monopolistic position is exemplified by the agency's absolute unwillingness to consider alternative methods for regulating dietary supplements, as Congress seemed to intend with the 1992 Act.⁵² The lack of tolerance for this “only overseer in town” attitude is evident in the well-heeled efforts at reform that followed.⁵³

in January 1996, following twenty-one years of agency scrutiny, 100,000 pages of research data and development costs in excess of \$300,000,000. See Jennifer Lawrence, *What Ever Happened to Olestra: How P&G's Hopes for Food Division's Future Got Mired in FDA Quicksand*, ADVERTISING AGE, May 2, 1994, at 16, 17. Proctor and Gamble filed an investigational new drug (IND) application with the FDA in 1975.

⁴⁷Pub. L. No. 102-571, 106 Stat. 4491 (1992).

⁴⁸Pub. L. No. 102-571, 106 Stat. 4491, 4500-05 (codified as amended at 21 U.S.C. § 343 (1994)).

⁴⁹*Id.* § 202 (a)(1), 108 Stat. at 4500. Establishing a moratorium on the FDA's application of the NLEA.

⁵⁰*Id.* § 202(a)(2)(A) (“[T]he Secretary shall issue . . . proposed regulations that are applicable to dietary supplements. . .”).

⁵¹See Food Labeling: General Requirements for Health Claims in Dietary Supplements, 58 Fed. Reg. 33,700, 33,700 (1994).

⁵²Price, *supra* note 45, at 651. The FDA's authority as sole reviewer of the safety and efficacy of products requiring pre-market approval gives rise to the monopolistic atmosphere. The scope of the agency's authority is enormous with over \$1 trillion in annual revenues generated by the products under its purview—or twenty five cents out of every dollar expended by American consumers. See PRESIDENT BILL CLINTON & VICE PRESIDENT AL GORE, NATIONAL PERFORMANCE REVIEW: REINVENTING DRUG AND MEDICAL DEVICE REGULATIONS 2 (1995); See also *The FDA Home Page* (visited April 14, 1999) <<http://www.fds.gov/bbs/topics/NEWS/NEW00414.html>>.

⁵³Price, *supra* note 45, at n.59. A random review of food and drug company political action committee (PAC) contributions during the 1993-1994 contribution cycle, revealed a total of \$2,548,804 given by 15 drug and 6 food PACs. Allocated among the 535

4. The Dietary Supplement Health and Education Act of 1994.

In 1994, Congress sought to reduce such burdens on dietary supplement manufacturers by amending the existing law. Broad, bipartisan support for such relief was evident in the absence of a detailed legislative history.⁵⁴

The legislature's loathing for the FDA's autocratic reign is evidenced in the passage of the 1994 Dietary Supplement Health and Education Act (DSHEA),⁵⁵ which dealt swiftly with the agency's apparent unwillingness to effectively address the regulation of dietary supplements. DSHEA gutted the FDA's authority to regulate dietary supplements by exempting claims about the effects of dietary supplements on humans⁵⁶ from the drug provisions of the FDCA.⁵⁷ Furthermore, the DSHEA exempted supplements from food additive definition,⁵⁸ publication,⁵⁹ and statements of nutritional support,⁶⁰ while establishing new provisions for claims and safety determination.⁶¹

Pursuant to unanimous approval by the House of Representatives on October 6, 1994 and an identical response from the Senate the next day, The Dietary Supplement Health and Education Act of 1994 (DSHEA), was given presidential approval on October 25, 1994.⁶² In its new form, the law statutorily defined dietary supplement products as foods⁶³ that are authorized to make claims regarding their effect on the structure or function of the human body, regardless of whether they are consumed for their "taste, aroma or nutritive value."⁶⁴

Herbs and dietary substances used to supplement the diet are included in the DSHEA's broad definition of "dietary supplement,"⁶⁵ as are vitamins and minerals. Historically, supplements have been marketed absent evidence of nutritional value or

Congressmen and Senators, these 21 PACs alone, averaged \$4,764 per member. See Peter Stone, *The Demolition Prescription: Industry Leaders and Lawmakers Want to Overhaul the Food and Drug Administration*, ORLANDO SENTINEL, Mar. 26, 1995, at G1. The Progress and Freedom Foundation, a Newt Gingrich backed think-tank, raised over \$400,000 from FDA-regulated entities for "Medical Innovation and Personal Health in the 21st Century", a project aimed at dismantling the FDA and creating a wholly privatized method of product approval.

⁵⁴140 Cong. Rec. H11, 173, H11, 179 (daily ed. Oct. 6, 1994).

⁵⁵Pub. L. No. 103-417, 108 Stat. 4325 (1994).

⁵⁶21 U.S.C. §§ 321(g)(1), 343(r)(6)(A) (1994).

⁵⁷21 U.S.C. §§ 301-397 (1994).

⁵⁸21 U.S.C. § 321(s) (1994).

⁵⁹21 U.S.C. § 343-2 (1994).

⁶⁰21 U.S.C. § 343(r)(6) (1994).

⁶¹21 U.S.C. §§ 342(f), §§ 350(b) (1994).

⁶²Pub. L. No. 103-417, 108 Stat. 4325.

⁶³Pub. L. No. 103-417, § 3(a)(3), 108 Stat. at 4327 (codified at 21 U.S.C. § 321(ff)(3)).

⁶⁴*Id.*

⁶⁵21 U.S.C. § 321 (ff) (1994).

known use in food or traditional medicine,⁶⁶ and the DSHEA does little to provide guidance on the expanded new meaning of “dietary.”⁶⁷ Not surprisingly, the heavily deregulated environment fostered by DSHEA is representative of an era in which the effects of deregulation are readily questioned.⁶⁸

Though supplement manufacturers cannot make prevention and disease treatment claims on product labels, the DSHEA does enable them to make statements of nutritional support claiming effects on the structure and functions of the body.⁶⁹ Similarly, claims of this nature for non-nutritional supplements are no longer regarded as drug claims subject to the pre-market approval and controlled testing gauntlet of the past.⁷⁰

These changes blur the line between food claims and drug claims, as the DSHEA limits the FDA’s ability to regulate labeling claims (“the publication exemption”); this leaves the door wide open for dietary supplement manufacturers to tout their latest and greatest potions as “preventative medicine.”⁷¹ As one might expect, DSHEA’s deregulatory nature has led to a plethora of new claims being made with regard to the miracles of supplement consumption—they help us think better, improve the immune system, reduce cholesterol levels and may be all-natural herbal replacements for prescription drugs.⁷²

⁶⁶See FDA Notice of Proposed Rulemaking, 21 C.F.R. ch.1, Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,697 (1993).

⁶⁷21 U.S.C. § 343(r)(6)(A) (1994).

⁶⁸In the past decade, deregulation has impacted industry ranging from communications and transportation to public utilities. Results have been mixed. See generally Christopher Clott and Gary S. Wilson, *Ocean Shipping Deregulation and Maritime Reports: Lesson Learned From Airline Deregulation*, 26 TRANSP. L.J. 205 (1999) (while airline deregulation has decreased fares, it has also decreased service to less profitable airports); Michael F. Finn, *The Public Interest and Bell Entry into the Long-Distance Under Section 271 of the Communications Act*, 7 COMM.LAW CONSPECTUS 173 (1997) (discussing the quid pro quo inherent in successful regulation: the Bell Companies will be allowed into Long-Distance service, but must first allow competition in local service); Christine Garcia, *A Future of Green Power: Impacts of the Electric Utility Regulation in America*, 10 LOY. CONSUMER L. REV. 225 (1998) (positive effects of deregulation include lower rates for consumers, technological advances through competition and increasing accountability for pollution-related damage to the environment).

⁶⁹21 U.S.C. § 343(r)(6)(A)(1994).

⁷⁰21 U.S.C. § 355 (1994). See *Nutrilib v. Schweiker*, 713 F.2d 335 (7th Cir. 1983) (holding that “starch blockers” constituted “drugs” under the FDCA, since the blockers were intended to affect digestion in the people who took them, and that to qualify as a “drug”, an article must also “be intended to affect the structure or any function of the body of man or other animals”).

⁷¹21 U.S.C. § 343-2 (1994). The Federal Trade Commission (FTC) may regulate advertising, including misleading claims. The FTC’s authority is different however, from the FDA’s, and does not encompass pre-market approval of drug claims. See 15 U.S.C. §§ 45, 52 & 55 (1988).

⁷²Michael Higgins, *Hard to Swallow*, A.B.A. J., June 1999 at 60 (discussion of the regulation of dietary supplements and the marketing hype that may lead manufacturers to the courthouse for a number of products and their related health claims including: selenium (heart); androstenedione (muscle development); gingerroot (digestion); fo-ti root (kidneys,

Where the FDA's prior ability to require pre-market approval of the safety of dietary supplements had previously been narrowed by court decisions,⁷³ the DSHEA resulted in full revocation of such power.⁷⁴ The passage of DSHEA and a failure to keep dangerous dietary supplements off the market were viewed as former FDA Commissioner Kessler's "greatest failures."⁷⁵ Kessler (an attorney and medical doctor) burst onto the regulatory scene in 1991, and as the new Commissioner of the U.S. Food and Drug Administration emphatically promised Congress and the American public that he "would teach the elephant to dance."⁷⁶

Instead, the mammoth agency appeared to stumble and reel from setbacks. These included legislatively mandated exemptions from strict oversight for questionable supplements such as ephedra, which has been linked to several deaths.⁷⁷ Presumably out of frustration, Kessler sounded much like a spurned dance partner in commenting at the end of his FDA tenure that "certain problems you aren't going to solve," and dietary supplements are "one of them."⁷⁸

The deregulatory effect of the Act sent a clear message from Congress to the FDA, signaling its intention to end the previously inconsistent approach to regulating supplements and to quell the agency's historic bias towards viewing such substances as drugs.⁷⁹ The enormous influence of the dietary supplement business is reflected in the DSHEA, which notes that almost half of all Americans regularly consume some form of dietary supplement,⁸⁰ produced by an industry with annual sales approaching \$4 billion annually.⁸¹ As the findings associated with the DSHEA indicate, a

liver); tribulus terrestris (sexual performance); saw palmetto (prostate); St. John's Wort (mood); ginkgo biloba, phosphatidyl serine (alertness); echinacea (immune system); lobelia (lungs); and ephedra (weight loss)).

⁷³United States v. Oakmont Inv. Co., 937 F.2d 33 (1st Cir. 1993) (holding that encapsulated oil, which was "food" in its liquid form, in two inert substances did not render oil a "food additive," presumed to be unsafe absent FDA regulations prescribing conditions assuring safe use); United States v. Vipone Ltd. Black Current Oil, 984 F.2d 814 (7th Cir. 1993) (holding that encapsulated black currant oil (BCO), with a single active ingredient, was not a "food additive" and, thus, the processor did not have a burden of proving that BCO was generally recognized as safe ("GRAS"), even if BCO was merely a component of BCO dietary capsules).

⁷⁴21 U.S.C. § 321(s)(6) (1994).

⁷⁵Marian Burros, *F.D.A. Commissioner is Resigning After 6 Stormy Years in Office*, N.Y. TIMES, Nov. 26, 1996 at A1.

⁷⁶Henry Miller, *Anti-Medicine Man: Commissioner David A. Kessler*, NAT'L REV., Oct. 9, 1995, at 48.

⁷⁷Burros, *supra* note 75 at A1. Congress passed such exemptions under significant pressure from the dietary supplement industry.

⁷⁸*Id.* at A18.

⁷⁹Greenberg, *supra* note 19, at 5.

⁸⁰Pub. L. No. 103-417, § 2(9), 108 Stat. at 4326.

⁸¹§ 2(12)(C), 108 Stat. at 4326.

connection may be made between dietary supplement use, health-care expenditure and disease prevention.⁸²

B. FDCA's Regulation of Food and Drugs

The FDCA regulates the sale of both food and drugs, setting out requirements for approval, labeling and dispensation through its statutes and regulations. As the historic treatment of dietary supplements illustrates, drugs are more stringently regulated than foods.

1. Drugs

As drugs are more highly regulated than any other type of product,⁸³ a manufacturer must first obtain FDA approval before beginning to market or advertise a product.⁸⁴ This hurdle, known as "pre-market approval," requires substantive clinical evidence demonstrating that the drug is both safe and effective for its intended use.⁸⁵

Habit-forming drugs and those that are potentially harmful or unsafe unless taken under supervision, require prescriptions.⁸⁶ Furthermore, the FDCA prescribes precise labeling requirements for drugs, including placement and content.⁸⁷

Specific health claims about drugs must also seek approval, conditioned by substantial evidence derived from controlled investigations by experts in the field.⁸⁸ A manufacturer must also establish a basis in any claim by "sufficient scientific agreement," which may necessitate a large number of experts concurring about the meaning of clinical research results.⁸⁹

A drug is deemed adulterated and subject to government enforcement actions if it contains poisonous or unsanitary ingredients, or if its manufacturing procedure is

⁸²§§ 2(2),(6)(A), 108 Stat. at 4326.

⁸³Yumiko Ono, *States Move to Restrict Fat-Burning Aid Ma Huang*, SAN DIEGO UNION-TRIBUNE, Aug. 11, 1995 at E3.

⁸⁴21 U.S.C. § 355(a) (stating that no person shall introduce any new drug into interstate commerce unless an application has been approved).

⁸⁵§ 355(b)(1) (providing that a manufacturer make "full reports of investigations").

⁸⁶§ 353(b).

⁸⁷*Id.* The information on a label attached to the immediate container of an article must also appear on the outside wrapper. § 321(k). See § 352(b)-(c) (requiring, inter alia, an accurate statement of contents, prominence, warnings if the product is a habit-forming substance, and directions for use); § 352(n) (listing guidelines for side effects and contraindications, as well as false advertising).

⁸⁸§§ 352(a), 355(d) (any such claims would be considered labeling and a drug must be approved for all of its labeled uses). To gain approval as a new drug, and to label and market its uses, the manufacturer must present "substantial evidence" that the drug has the claimed effect. § 355(d)(5),(7).

⁸⁹Regulation of Dietary Supplements: Hearing Before the Subcommittee on Health and the Environment of the Comm. on Energy and Commerce, 103d Cong. 1, 164 (1993) (testimony of David A. Kessler, Commissioner of the FDA).

contrary to good manufacturing practices.⁹⁰ Among the enforcement actions that drugs are subject to include: search and recall,⁹¹ criminal sanctions for prescription drug marketing violations,⁹² and withdrawal of drug application approval.⁹³

2. Food

Food and its subset, food additives, are statutorily defined as: “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article,”⁹⁴ and

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use.⁹⁵

While food and food additives must meet guidelines concerning adulteration, these products are subject to less regulatory scrutiny than drugs, as they do not have to meet pre-market approval.⁹⁶ Food is adulterated if the FDA can establish by a preponderance of the evidence that the food is “injurious to health” or contains poisonous, unsanitary, or other dangerous ingredients;⁹⁷ an absence, substitution or addition of constituents;⁹⁸ or unsafe color additives.⁹⁹

Food additives will be presumed unsafe absent FDA authorization for their use.¹⁰⁰ While the FDA guidelines for deeming a food additive safe are rigorous,¹⁰¹

⁹⁰21 U.S.C. § 351(a). *See* 21 C.F.R. § 211 (1996). FDA regulations for “good manufacturing practices (GMP’s) cover organization and personnel, building and facilities, equipment, control of components and drug product containers and closures, packaging and labeling control, holding and distribution, laboratory controls, records and reports, and returned and salvaged drug products. *See also* 21 U.S.C. § 351(b) (drugs are considered adulterated if they differ in strength, quality or purity from the official compendium).

⁹¹21 U.S.C. § 334.

⁹²21 U.S.C. § 333(b).

⁹³21 U.S.C. § 335(c).

⁹⁴ 21 U.S.C. § 321(f) (defining food).

⁹⁵21 U.S.C. § 321(s) (defining food additive).

⁹⁶21 U.S.C. § 342 (a)-(c) (defining when foods shall be deemed adulterated).

⁹⁷§ 342(a).

⁹⁸§ 342(b).

⁹⁹§ 342(c).

¹⁰⁰21 U.S.C. § 348(a).

¹⁰¹21 C.F.R. § 170.22 (1996) (explaining that permitted tolerance in humans will not exceed one one-hundredth of the maximum tolerable amount in experimental animals).

manufacturers may petition the FDA, and request a regulation prescribing safe use of product.¹⁰²

It should be noted however, particularly when considering sports supplements, that an additive is generally considered “safe” if there is sufficient prior usage of such additive with no safety problems or if there is a general recognition of its safety based on scientific procedures.¹⁰³

3. Dietary Supplements Under the FDCA

As defined by the DSHEA, a dietary supplement is a “product (other than tobacco) intended to supplement the diet.”¹⁰⁴ Though specifically excluded from the definition of food additives,¹⁰⁵ dietary supplement labels under the DSHEA may describe ingredients intended to affect the “structure and function in humans,” even though the supplements are not drugs.¹⁰⁶

In general, the DSHEA has established relatively lenient standards for health claims and claims of nutritional support, with manufacturers only having to substantiate that their claims are truthful and not misleading.¹⁰⁷ The DSHEA does not however, preempt the states from regulating dietary supplements and accordingly, inconsistent regulation may occur.¹⁰⁸

And so the tug-of-war between the FDA, Congress and the dietary supplement industry continues. Sports products, such as andro, are illustrative of the ongoing conflict and the need for more consistent regulation.

¹⁰²21 U.S.C. § 348(a).

¹⁰³21 C.F.R. § 170.30(a) (the FDA exempts food additives that are generally recognized as safe (“GRAS”) from the pre-petition approval requirement).

¹⁰⁴Dietary Supplement Health and Education Act § 3(a), 21 U.S.C. § 321(ff).

¹⁰⁵§ 3(b), 21 U.S.C. § 321(s)(6) (specifying that food additives do not include any ingredients described in section 321(ff) or any ingredients for use in dietary supplements).

¹⁰⁶21 U.S.C. § 321(ff)(3)(A). These products constitute dietary supplements unless the Secretary of Health and Human Services issue a regulation, after notice and comment, that the article is unlawful. Provided that the Secretary finds the classification lawful, the products may be deemed as such, even though the manufacturer never marketed them as dietary supplements. *See also* 21 U.S.C. § 321(ff)(3)(B)(ii).

¹⁰⁷21 U.S.C. § 343(r)(6)(B). Manufacturers are required to place a disclaimer on dietary supplements stating that the FDA has not evaluated the validity of the health claim. *See also* 21 U.S.C. § 343(r)(6)(C).

¹⁰⁸*See State Official See Flaws in Dietary Supplement Act*, FOOD LABELING & NUTRITION NEWS, Sept. 28, 1995 at 10 (discussing how the continual modification of dietary supplement regulation has led to much uncertainty in the industry).

II. SPORTS PRODUCTS AND THEIR CONSUMER USES

A. *Regulating Sports Products as Dietary Supplements, Conventional Foods, Food Additives or Drugs*

Sports products do not fit neatly into a single regulatory classification, given their broad range of forms and intended uses.¹⁰⁹ These products include items as innocuous as sports bars and beverages, which often combine protein or carbohydrates with vitamins, minerals, botanicals or biochemicals.¹¹⁰

Basic products such as beverages are used to replace sugar and fluids lost during exercise,¹¹¹ while bars, powders and pills may be used as snacks and meals and to provide necessary nutrients before or after exercise.¹¹² These products can also be divided into three basic categories relative to physiological effect: high-protein products with amino acids maintain and increase muscle mass;¹¹³ high carbohydrate products containing sugars, vitamins and minerals provide quick energy and improved recovery time;¹¹⁴ and high-calorie products combine increased carbohydrate, protein, amino acids and fat for muscle increase and weight gain.¹¹⁵

These products are popular because they produce significant physiological effects, though most have not been proven clinically effective for their claimed uses.¹¹⁶ In fact, some ingredients in these products can adversely impact the body and present clear danger to consumers.¹¹⁷ The rampant popularity of dietary

¹⁰⁹See Bill Brubaker, *In NFL, Supplements Complement; With Steroids Banned, Some Players Turn to Pills and Powders to Get Ahead*, WASH.POST, Jan. 22, 1995 at D 1.

¹¹⁰*Id.* See Fred Weihmuller, *Formulating a Sporting Effort*, PREPARED FOODS, Feb. 1995, at 34 (illustrating the various forms of sports products).

¹¹¹See Leigh Pressley, *A Powerful Thirst, Think First, Guzzle Later Experts Say*, GREENSBORO NEWS & RECORD, July 28, 1995 at D1.

¹¹²Weihmuller, *supra* note 110 at 38 (explaining that athletes rely on the carbohydrates found in these products to maintain and enhance athletic performance).

¹¹³*Id.* at 36, 38 (explaining the three categories of sports products and the function of protein).

¹¹⁴*Id.* at 39 (discussing the mechanism underlying carbohydrate breakdown during exercise).

¹¹⁵*Id.*

¹¹⁶*Id.* at 44. An excellent example is chromium piccolinate, a popular ingredient in sports products and a required element of carbohydrate metabolism. *Id.* While manufacturers claim that taking it in increased doses will enhance metabolism, there is no scientific evidence to support such a claim. *Id.*

¹¹⁷Mike Fish, *Sports Supplements: Big Hype, Little Help: USOC Tie to Supplier Questioned NuSkin's Image, Marketing Approach Not Exactly Golden*, ATLANTA CONST., Dec. 11, 1994 at E 16 (discussion of the FDA's increased regulation of sports products in the wake of 38 deaths between 1989 and 1992, attributable to L-tryptophan, an amino acid). Although officially banned from the market, L-tryptophan is still found in some sports products. *Id.*

supplements¹¹⁸ gives rise to the need for resolution of the regulatory conflict and the promotion of a much-needed balance between consumer safety and consumer freedom.

Under DSHEA, the regulations governing such products turn on product, rather than on function. Ironically, sports bars and beverages, which are typically safer than other supplements, are regulated more stringently based on their classification as conventional foods.¹¹⁹

Powders and pills however, are classified as dietary supplements, and thus subject to the more lenient regulatory regime established by the DSHEA.¹²⁰ It may be more desirable to regulate these items, which often contain dangerous amino acids and herbal ingredients, as food additives, which would subject them to stricter scrutiny.¹²¹

Ultimately, whether a product is classified as a drug, food, food additive or dietary supplement, turns on four critical considerations: product definition, product safety, nutritional support claims, and labeling.¹²²

1. Product Definition

For years the FDA has considered dietary supplements to be composed of essential nutrients, such as vitamins, minerals and proteins.¹²³ In the past, substances

¹¹⁸See *CEO Interview: General Nutrition Cos., Inc.(GNCI)*, WALL STREET TRANSCRIPT, Apr. 11, 1994 (listing categories of dietary supplements and noting that the industry in the United States is a \$3.7 billion dollar market).

¹¹⁹See *FDA Petitioned to Define Powders, Other Supplements as Supplements*, FOOD LABELING NEWS, Apr. 21, 1994 at 7. In 1994, the National Nutritional Foods Association petitioned the FDA for regulation of sports bars and drinks as dietary supplements, rather than as foods. The Association argued that if the intended use of the products was to add nutrients to the diet, then the foods are not used “conventionally,” and therefore their regulatory classification should be determined by use, not by form. *Id.*

¹²⁰See Dietary Supplement Health and Education Act of 1994 § 3(a), 21 U.S.C. § 321(ff) (1994) (defining dietary supplements as products containing amino acids and herbs).

¹²¹Ono, *supra* note 83 at E3 (explaining that many sports products contain herbal ingredients that can prove dangerous if not used properly). For example, ephedrine has been used for thousands of years and is an active ingredient in popular drugs, but has side effects including high blood pressure and irregular heartbeats. See Pressley, *supra* note 112 at D1 (noting that ephedrine is found in the popular herb ma huang, and that such ingredients, if not used correctly, can be harmful). *Id.*

¹²²See 21 U.S.C. §§ 321, 341-343 (1994) (discussion of definitions, health claims, safety and labeling).

¹²³Dietary supplements have been long regarded by the FDA as the type of food intended for “special dietary uses.” The Federal Food, Drug & Cosmetic Act (FDCA), § 403(j) provides that a food is “misbranded” and thus illegal unless its label bears information concerning its vitamin, mineral and dietary properties. Additionally, 21 U.S.C. § 343(j) recognizes as a type of food, product intended for “special dietary uses” based on its content. Section 403(j) provides for the issuance of mandatory label regulations.

that did not provide “taste, aroma or nutritional value” in a supplement form could not be sold as a food product and may have been subject to regulation as a drug.¹²⁴

In an attempt to provide a broad, expansive definition of dietary supplement (and ideally the integration of such products into the marketplace), The Dietary Health and Supplement Act of 1994 provides in part, that a dietary supplement means:

a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; . . . a mineral; . . . an herb or other botanical; . . . an amino acid; . . . a dietary substance for use by man to supplement the diet by increasing total dietary intake; or . . . a concentrate, metabolite, constituent, extract, or combination . . . [of any ingredient previously described].¹²⁵

The Act further expands the definition of dietary supplement to include: product which is intended for ingestion in “pill, capsule, tablet or liquid” form; is not meant to be a conventional food or singular meal or diet item; is labeled “dietary supplement” and may be approved as new drugs, certified as antibiotics or licensed as biologics, that were previously marketed as food or dietary supplements.¹²⁶ It would appear that these definitions provided by the DSHEA are for broad application to a variety of products, regardless of their nutritional value.

Despite the expanded definition, regulatory ambiguities remain.¹²⁷ For instance, does the statutorily required ‘ingestion’ necessarily mean that the ingredients “supplement the diet” or “increase total dietary intake”?¹²⁸ In the discussion at hand, to determine whether androstenedione, a naturally occurring steroid hormone and precursor to testosterone, come within the scope of the DSHEA dietary supplement definition, one could ask: (1) is andro a dietary substance, (2) is andro used to supplement the diet, and (3) does andro increase the total dietary intake? The answer to these is not readily resolved, given the regulatory guidelines at hand.

2. Product Safety

Prior to the DSHEA, the FDA had successfully argued that substances added to dietary supplements were like substances added to any other food product, and if such substances were generally not recognized as safe (GRAS), as supported by scientific documentation, they would be subject to regulation as “food additives.”¹²⁹

¹²⁴*Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983). Supporting the position that substances derived from food, but lacking food-type qualities could be classified as “drugs”, and not “foods” under the FDCA. For purposes of the FDCA, “starch blockers” which “block” the human body’s digestion of starch as an aid in weight control, constituted a “drug” based on their function, despite having been derived from raw kidney beans.

¹²⁵Pub. L. No. 103-417, § 3(a), 108 Stat. at 4327 (codified at 21 U.S.C. 321(ff) (Supp.1996)).

¹²⁶*Id.*

¹²⁷Robert G. Pinco & Paul D. Rubin, *Ambiguities of the Dietary Supplement Health and Education Act of 1994*, 51 *FOOD & DRUG L.J.* 383, 384 (1996).

¹²⁸*Id.*

¹²⁹21 U.S.C. § 321(s)(6) (new section 201(ff)(2) of the FDCA).

This was a much welcome change since, like the regulatory gauntlet set forth for drugs, the additive clearance process was formidable.¹³⁰

As a result, supplement ingredients were now more free from the risk that they might be subject to the costly and far reaching allegations of “unapproved food additive” status, with which the burden lay on the processor to demonstrate that the product was generally recognized as safe.¹³¹ With safety in mind, the DSHEA did replace the additive provisions with added safety requirements for new dietary ingredients, e.g. those that “[were] not marketed in the United States before October 15, 1994.”¹³² A product introduced after that date will be deemed unadulterated only if there is a “history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling . . . will reasonably be expected to be safe.”¹³³

3. Manufacturer Claims and Nutritional Support

Section 6 of DSHEA explicitly authorizes dietary supplement labeling to contain four types of statements of nutritional support, including nutritional deficiency; structure/function (effect); structure/function (maintenance); and general well-being.¹³⁴

In order to assert one of the above statements, a manufacturer must substantiate that the statement(s) are truthful and not misleading, and the product label must bear the statement “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”¹³⁵ As a practical matter, the DSHEA is not especially clear as to how much data is sufficient to legitimately substantiate such a statement. The level of support does not have to rise to the level of the FDA requirement for new drugs (two

¹³⁰Pinco & Rubin, *supra* note 127, at 385.

¹³¹United States v. Two Plastic Drums . . . Black Current Oil, 984 F.2d 814 (7th Cir. 1993) (ruling that black currant oil in a gelatin capsule was not subject to regulation as a food additive, and that the FDA’s allegations of food additive status constituted an “Alice-in Wonderland approach . . . to make an end-run around the statutory scheme and shift to the processors the burden of proving the safety of a substance in all circumstances”). *Id.* at 819.

¹³²21 U.S.C. § 350b(c) (new section 413(c) of the FDCA).

¹³³*Id.* at § 350b(a)(2) (new section 413(a) of the FDCA).

¹³⁴*Id.* at § 343(r)(6)(A). Supplement label statements include:

a statement that claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States (a “nutrient deficiency” statement);

a statement that describes the role of the nutrient or dietary ingredient intended to affect the structure or function in humans (a “structure/function” statement);

a statement that characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function (also a “structure/function” statement); or

a statement that describes general well-being from consumption of a nutrient or dietary ingredient (a “general well-being” statement).

¹³⁵*Id.* at § 343(r)(6)(B)-(C).

controlled clinical studies), though perhaps the standard should echo the Federal Trade Commission's measure of "competent and reliable scientific evidence."¹³⁶

As evidenced by many of the dietary supplements legally available on the market today, general recognition of safety and efficacy is not mandated by the DSHEA, nor is it required as a condition of legal sale.

4. Labeling

Products should provide the information necessary for consumers to make informed decisions as to whether to use a product or not.¹³⁷ Regulatory schemes for food, drugs and dietary supplements all require clear listings of product content, ingredients, descriptions and quantities.¹³⁸

As product labeling is an all-important conduit for consumer information, it is critical that information and warnings concerning a product's potential danger be made available. While most foods are not perilous even when consumed in large doses, it is not implausible to think that some consumers might attempt to get "faster results" by exceeding recommended dosages.

Accordingly, dietary supplements and sports products in particular should strive to present labels that clearly establish recommended dosages and post warnings with regard to dangerous side effects from overexposure.¹³⁹ Because the drug regulatory scheme is the only one that mandates this degree of information, dietary supplement manufacturers may wish to at least consider such disclosure with regard to labels.

III. REAL-LIFE APPLICATION AND RELATED ISSUES

A. *The DSHEA in Action*

Dietary supplements, such as andro are not drugs but are instead are presumed by law to be foods.¹⁴⁰ Because the FDA does not pre-approve foods or food label claims, manufacturers are simply required to provide assurance that their products and claims comport with the published regulatory requirements.¹⁴¹ Though the DSHEA legislation forbids companies from implying that a product has healing or preventative qualities with regard to a disease, a manufacturer can assert that the same product keeps a particular organ "functioning normally."¹⁴²

Companies are supposed to submit such claims to the FDA, as well as safety data on any ingredients introduced after 1994.¹⁴³ In the event that there is not sufficient

¹³⁶Greenberg, *supra* note 19, at 5.

¹³⁷Congress found a growing need for the "dissemination of information linking nutrition and long-term good health." Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(7), 108 Stat. 4325, 4326 (1994).

¹³⁸See Food Labeling; Requirements for Nutrient Content Claims, Health Claims and Statements of Nutrient Support for Dietary Supplements, 60 Fed. Reg. 67,176 (1995).

¹³⁹See Fish, *supra* note 117, at E16.

¹⁴⁰Greenberg, *supra* note 19, at 5.

¹⁴¹*Id.*

¹⁴²See Pub. L. No. 103-417, 108 Stat. at 4328.

¹⁴³Greenberg, *supra* note 19, at 5.

safety data, a manufacturer can be told to stop marketing the product and may be required to provide a disclaimer stipulating that their product claims have yet to undergo FDA evaluation.¹⁴⁴ Such advertising issues fall under the dominion of the Federal Trade Commission (FTC), which has also issued its own guidance documents.¹⁴⁵

In the event that such regulatory requirements are violated, both the FTC and the FDA are empowered to request relevant data from a manufacturer and issue an order to cease production where necessary.¹⁴⁶ In practice, enforcement is scant. Despite these requirements, a marketer need not worry too much about product disclaimers, submitting required information to the FDA or gathering data in the event that the FTC comes calling. In fact, the odds of being found in violation and actually disciplined are quite slim.

Today, there are more than 20,000 dietary supplements on the market in the United States, part of a \$15 billion industry, whose estimated annual growth rate exceeds twenty percent.¹⁴⁷ In a match up tantamount to that of David and Goliath,¹⁴⁸ the Food and Drug Administration has only five employees dedicated to the handling of tens of thousands of dietary supplements.¹⁴⁹ Not surprisingly, the supplement industry continues to grow at a pace that remains far beyond the regulatory span of control.

Given the volume of products entering the marketplace at such a rapid pace, it is not surprising that there is very little accompanying documentation regarding their efficacy and the health consequences of long-term use. The DSHEA contains a companion section, which provides that a supplement will be deemed adulterated if it contains “a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.” Despite these provisions, unsubstantiated products abound in the marketplace.¹⁵⁰

Of course, “legal” does not necessarily mean “safe,” especially since the DSHEA’s function is to effectively limit regulation of dietary supplements. It is imprudent to think that products such as andro are safe simply because there is no legally mandated data to demonstrate otherwise. For now, these potentially perilous products are classified as supplements and remain free to enter the marketplace sans evidence of safety or efficacy.

¹⁴⁴*Id.*

¹⁴⁵*Id.*

¹⁴⁶Rochelle Sharpe, *Staking Claims: One Effect of a Law on Diet Supplements is Leaner Regulation—With a Web Site, Smart Ads and Supplier, One Man Scores on a ‘Stud Pill’*, WALL STREET JOURNAL, Jan. 27, 1999 at A1. (A former securities broker turned andro distributor established a thriving mail order supplement business by marketing the product as a “stud pill” over the internet and through press releases in financial news wires.).

¹⁴⁷*Id.*

¹⁴⁸1 Samuel 17:4-51. Referencing Goliath, the giant Philistine warrior who was slain by David with a stone and a sling.

¹⁴⁹Sharpe, *supra* note 146, at A1.

¹⁵⁰21 U.S.C. § 342(f)(1)(B) (new section 402(f)(1)(B) of the FDCA).

Consumers must remain cognizant of the fact that a negative safety and/or efficacy determination *may* make it more difficult for a company to substantiate certain product statements, but it *does not* necessarily preclude the use of such statement, let alone make the product illegal.

Until andro and other untested substances are subject to more stringent regulatory controls such as pre-market approval or testing, potential users (and abusers) must be forewarned about the potential health risks associated with the product. Similarly, it would be prudent for sports authorities to regard the “unknown” with the same gravity, when determining which performance enhancing substances (if any) should be allowed by the respective organizing bodies.

B. Forms and Types of Product

1. The Supplement Debate

As examined in the previous section, the heart of this question is perhaps shrouded by the cloudy regulatory scheme that grew out of the passage of the Dietary Supplemental Health Act of 1994 (DSHEA). By definition, dietary supplements are not drugs and are presumed by law to be foods; accordingly, the FDA does not pre-approve food or food label claims.¹⁵¹

In keeping with their classification as a “food” rather a drug, andro and creatine are no longer the exclusive dominion of hardcore body building stores and underground mail order—instead, as unregulated supplements, they can be found on your neighborhood grocer or pharmacists’ shelf. Although many of the product claims are unsubstantiated, consumers are turning in droves to dietary supplements, such as ginseng for an energy boost, St. John’s Wort- to chase the blues away and ginkgo biloba to better the memory.¹⁵²

Athletes are big users and help spur the popularity of supplements that purport to boost athletic performance. In the quest for the ultimate mental or physical edge, Americans are spending billions on pills, powders, gels, energy bars and sports drinks.¹⁵³ The *Nutrition Business Journal* is forecasting a six to ten percent increase in sports product sales this year,¹⁵⁴ though little is really known, or required by law, about their efficacy and physiological consequences.

Some healthcare professionals feel that the physiological effects of supplements may vary with individual body composition and metabolism; as a result they are concerned with an industry short on research and regulation.¹⁵⁵ A desire for short-

¹⁵¹Greenberg, *supra* note 19, at 5.

¹⁵²Higgins, *supra* note 72, at 61.

¹⁵³See GNCI *supra* note 118.

¹⁵⁴Deborah Funk, *Powders, Pills, Energy Boosters: Are They Safe to Take? Experts Debate Risks Involved with Supplements*, FLA.TODAY, Dec. 29, 1998 at 5D.

¹⁵⁵*Id.* In September, the American College of Sports Medicine asked the FDA to take another look at supplements, arguing that some should be classified as drugs. Similarly, the American Dietetic Association believes that dietary supplements should be regulated like foods and that all related health claims should have a significant scientific basis. *See also*, Russ Colchamiro, *Supplement Controversy Shadows McGwire’s Home Run Record*, AM.DRUGGIST, Oct.1, 1998 (citing a sampling of pharmacists who generally agreed that supplements should be regulated, tested and approved; either by the FDA or a similar agency).

term athletic performance gains and a lack of forethought as to the long-term effects may lead some supplement users to exceed recommended doses in hopes of achieving faster, more dramatic effects.¹⁵⁶

Athletes like Mark McGwire helped to fuel such desires, while contemporaneously doing wonders for supplement sales. Night after night, millions of Americans tuned into watch this stellar physical specimen, and supplement devotee, chase a baseball dream.

2. The Androstenedione Example

While andro has been around for years, it burst back into the media spotlight in August 1998 when an Associated Press reporter spotted a bottle of the legal but controversial steroid precursor in McGwire's locker.¹⁵⁷ Ignoring his critics, the soon-to-be-crowned home run champion explained that he used the product to protect himself from muscle tears and to enable him to recover more rapidly from workouts.¹⁵⁸

From a performance perspective, the body breaks andro down into testosterone; the resultant increase in blood testosterone levels may result in greater energy, enhanced recovery and muscle growth from exercise.¹⁵⁹ On the flip side, andro's steroid qualities place it in the class of potentially hazardous, performance enhancing anabolic steroids which have been linked to coronary disease, cancer, liver dysfunction and severe mood disorders, including fits of steroid-induced rage.¹⁶⁰

Andro is not a new supplement and may have been an active component in the old East German "doping system" established for its athletes.¹⁶¹ Documents discovered after the unification of East and West Germany showed evidence of extensive experiments with androstenedione.¹⁶² East German scientists developed a mandatory nasal steroid application for all athletes competing in the 1988 Seoul Olympics.¹⁶³

¹⁵⁶Funk, *supra* note 155.

¹⁵⁷Rick Reilly, *Hey Mac, Do What Comes Naturally*, CNN-SI NEWSWIRE, Mar. 2, 1999 (visited April 5, 1999) <http://www.cnn.com/inside_game>.

¹⁵⁸Okrent, *supra* note 4, at 138.

¹⁵⁹Ross Newhan, *Baseball's Great Chase Turns Into Great Debate*, L.A. TIMES, Aug. 25, 1998 at C1. With regard to the increase in testosterone levels resulting from the consumption of andro, data is extremely scarce. Accordingly to a German Patent application for androstenedione, 50 mg. given orally to men raised blood testosterone levels from 140% to 183%, and at 100 mg. raised levels from 211% to 237%. These increases should begin to occur about fifteen minutes after consumption, and remain elevated for about three hours.

¹⁶⁰*Id.*

¹⁶¹Scott M. Reid, *An Issue of Substance*, ORANGE COUNTY REGISTER, Aug. 22, 1998, at D1.

¹⁶²*Id.* See Also, *U.S. Seeks Redress for 1976 Doping in the Olympics*, N.Y. TIMES, Oct. 25, 1998 at 33,35. Detailing the international protest regarding Olympic medals won by East Germany, currently under protest because of increasing evidence of doping by the GDR athletes.

¹⁶³Reid, *supra* note 161 at D1.

Indeed, andro's classification as a dietary supplement makes it legal, readily available and well within the rules of baseball.¹⁶⁴ The "drug" controversy arises from the fact that androstenedione is a hormonal-related testosterone precursor which carries all the components of an anabolic steroid.¹⁶⁵ Testosterone, the male hormone which andro converts into after ingestion, is a highly controlled substance requiring a triplicate prescription before dispensation.¹⁶⁶

Domestically, very little is known about andro and as a result of the health and ethical issues posed by McGwire's revelation. Major League Baseball has vowed to craft a policy on this and other performance enhancing substances.¹⁶⁷ The league commissioned two Harvard researchers to study the effects of andro in hopes of making a decision as to whether the league should ban the substance, discourage its use or allow it to be taken unchecked.¹⁶⁸

Similar questions have been raised by members of the medical community, including the Endocrine Society, the world's oldest and largest organization devoted to research on hormones, which announced its position that not enough is known about andro to declare the substance safe and/or effective.¹⁶⁹

The National Toxicology Program Interagency Committee for Chemical Evaluation and Coordination (hereinafter ICCEC) has nominated andro for testing.¹⁷⁰ This recommendation was based on the media frenzy that followed the disclosure of McGwire's use of andro, the product's steroid nature, a lack of clinical data and potential side effects. The andro issue has heightened awareness of the fact that the FDA lacks the necessary authority to appropriately regulate dietary supplements.¹⁷¹

At the consumer level, one major retailer saw fit to discontinue the sale of andro nationwide, based on the lack of suitable research demonstrating the safety of the product at various intake levels and concern about the potential impact of product

¹⁶⁴Okrent, *supra* note 4, at 138.

¹⁶⁵Newhan, *supra* note 159.

¹⁶⁶*Id.* Technically, the origin of all steroid hormones is the cholesterol molecule. Cholesterol is metabolized into a steroid hormone called pregnenolone, and in turn is eventually converted into DHEA (steroid hormone), which then converts to androstenedione (andro). Andro then converts into testosterone (the male steroid hormone), as well as estrone, which is an estrogen. This last conversion is critical, as androstenedione is chemically, only one enzymatic step away from testosterone, a strictly controlled drug.

¹⁶⁷Steve Wilstein, *Heavy Hitters Weigh in on Andro Debate*, CHI. TRIB., Jan. 3, 1999 at D1.

¹⁶⁸*Id.* According to representatives from Champion Nutrilab, Inc., the company that supplies McGwire with his supplements and has endorsement deals with many other professional players, at least 100 ball players in the major and minor leagues use andro regularly.

¹⁶⁹The Endocrine Society is a 9,000 member group of doctors and scientists dedicated to the study of hormones. *The Endocrine Society* (visited July 14, 1999) <<http://www.endo-society.org/index.htm>> 4350 East West Hwy., Suite 500, Bethesda, MD 20814-4410. Tel:(301)941-0200, Fax:(301)941-0259. E-mail: endostaff@endo-society.org.

¹⁷⁰Department of Health and Human Services, 63 Fed. Reg. 241, 245 (1998) (*See* 4 THE TAN SHEET, FDA REP., Jan. 4, 1999).

¹⁷¹*Id.*

abuse.¹⁷² Whether andro is a benign muscle enhancer or a dormant hazard lying in wait remains to be determined. It is, however, a risk that General Nutrition Stores (GNC) is not willing to take in any of its 3700 stores across the country.

Any definitive correlation found between andro usage and increased levels of testosterone may be legitimate cause for concern because harmful side effects can take years to manifest. Unlike most drugs, the adverse impact of steroids usually do not appear until long after the time of use.¹⁷³ It is this reality that has led to the banning of andro from the Olympics, the NFL and the NCAA, all of which have classified the substance as an anabolic steroid

Beyond the obvious chemical implications, one argument for andro to be classified as a drug, and treated accordingly in sports, is that use of the product will generate a positive result for testosterone on a steroid urinalysis test.¹⁷⁴ Even if andro has natural origins, it breaks down into a compound that mirrors illegal, anabolic steroids.

How can a level playing field ever be established where it is impossible to differentiate between athletes using legal and illegal performance aids? For now, that all depends on who you play for—contrast Olympic shot put champion Randy Barnes' lifetime ban from track and field by the International Amateur Athletic Federation for using andro,¹⁷⁵ with McGwire's basking in the glory of *legally* crushing Roger Maris' single season home run record. The sadly divergent directions in which Barnes and McGwire find their careers heading is reflective of the wildly inconsistent approach within sport, to the use of performance-enhancing substances.¹⁷⁶

¹⁷²Rick Morrissey & Bruce Japsen, *McGwire's Spiked Swing Raises Health Questions*, CHI. TRIB., Aug. 26, 1998.

¹⁷³*Id.*

¹⁷⁴Internet advertisement for "Andro-forte 100," describes andro as the "single best food" available to support the body's natural production of testosterone. The product description also includes a warning which states that "product usage may generate positive results on a steroid urinalysis test. <<http://www.undergroundsports.com/andro-forte.htm>> (visited April 5, 1999).

¹⁷⁵*See* Maher, *infra* note 179.

¹⁷⁶*MLB Unlikely to Rule on Andro in '99*, AP NEWSWIRE, Feb. 26, 1999. The number two official of the Major League Baseball player's association, Gene Orza "assumes" andro is safe, "because the United States government chooses not to regulate it." The concerns of steroid experts, who warn of serious health consequences for teen-agers who take the supplement to emulate McGwire will not factor into the union's decision according to Orza. The union will consider a ban on andro only if it is found to give some players a competitive advantage over others. Unlike the Olympics, NFL and tennis tour, baseball does not have a random testing program for illegal substances. *Compare, NBA Players Told to Keep Off the Grass*, PLAIN DEALER, July 9, 1999 at D2. NBA player's union advising player representatives that they will be tested for marijuana when training camps open in October. NBA players who test positive at training camp must undergo a mandatory counseling program. A second positive test brings a \$15,000.00 fine, and any third or subsequent positive test results in a five-game suspension. Contrast this with baseball's Orza on why the baseball player's association objects to testing, "[w]e don't believe that in America people are required to give evidence of wrongdoing to their employers . . . testing for illegal drugs and testing for performance-enhancing drugs are quite different."

C. *Sports and Drugs, Drugs in Sport: Winning at What Cost*

Since the time of the early Greeks, athletes have been looking for ways to get an edge on the competition.¹⁷⁷ In ancient times, as today, performance-enhancing supplements have been a major strategy.¹⁷⁸ Regrettably, as evidenced by 1998, during which an unprecedented number of drug-related incidents occurred in sports, athletes appear to be on the edge: doping and drugging to win at all costs.¹⁷⁹

From badminton to baseball, soccer to swimming and the ubiquitous problems in track and cycling, perhaps the saddest symbol of the times were the once proud Olympic rings. When the andro issue first emerged, Major League Baseball sought to consult with the venerable International Olympic Committee (IOC) to develop a strategy for managing and regulating performance enhancing substances amongst the league's players. In turn, the IOC envisioned developing its own anti-doping agency during a three day summit on drugs and sports held earlier in the year.

Following three days of debate, a global answer to the doping plague was no more clear as the beleaguered Olympic committee received a resounding "no" vote of confidence from the IOC membership, left without a new agency, and instead had to settle for a "committee" that would continue to look at anti-doping strategies.¹⁸⁰ To add insult to the indignities already brought forth by cheating on the playing fields, the world sat back and watched a soap opera-like tale of back room bribery and scandal unfold relative to the Olympic Site Selection process.¹⁸¹

It is bitterly ironic that the recent desperate measures employed by administrators and athletes alike are representative of a society on the proverbial edge—blinded by a desire to get ahead and perhaps willing, in any way, shape or form, to pay the requisite price. Be it an indictment or jail time for influence peddling, or perhaps a lifelong suspension for ingesting the "wrong" supplement—some athletes seem willing to risk even greater unknowns by experimenting with wholly untested substances, all in the name of short-term gain.

IV. TOWARDS A NEW ALTERNATIVE

A. *Re-defining the Focus*

Rather than continuing to operate under the presumption that the administrative tug-of-war between Congress and the FDA will go on in perpetuity, consideration

¹⁷⁷Instances of athletes using performance-enhancing substances dates back over 2000 years, when Charmis, the winner of the 200m sprint in the Olympic Games of 668 BC prepared for the event by ingesting a special diet of dried fig leaves. <<http://www.ausport.gov.au/drug.html>>(visited July 14,1999).

¹⁷⁸*Id.*

¹⁷⁹John Maher, *The Year on Drugs*, AUSTIN-AMERICAN STATESMAN, Dec. 29, 1998 at C4. Worldwide, more than 150 incidents were documented worldwide in which illegal drugs and sports were an issue. In addition to sports like cycling, track and baseball where such infractions are regrettably familiar, violators were found in unexpected places like snooker, badminton and snowboarding.

¹⁸⁰Paul L. Montgomery, *IOC Adopts a Watered Down Drug Declaration*, N.Y. TIMES, Feb. 5, 1999 at C1.

¹⁸¹*Id.*

should be given to the development of methods to protect consumers within the reduced scope of regulatory powers.

The existing legal system already provides an indirect way for consumers to use supplements for disease prevention and treatment purposes by the very availability of products labeled dietary supplements. The ambiguously constructed DSHEA seems to protect the accessibility of dietary supplements, even though consumers may, on their own initiative, procure these products for drug purposes. Either intentionally or by default, the DSHEA gives consumers the choice and ability to use supplements to treat disease.¹⁸² This type of use, referred to as “off label” in the health care industry, is an informal characterization of an unregulated substance or FDA approved drug for a purpose other than that which may have originally been intended.¹⁸³

Use of drugs on an off label basis, such as high blood pressure medication to combat male pattern baldness (Rogaine™), is somewhat analogous to consumer use of dietary supplements for unapproved purposes. Neither these consumers, nor the physicians who prescribe ‘extra-label’ use as part of the practice of medicine, are operating in contravention of the law.¹⁸⁴

Pre-market approval, restriction of nutritional claims and enhanced labeling requirements are among the techniques that the FDA might employ in the regulation of products such as andro. Because such products meet the statutory definition of dietary supplement, they escape FDA scrutiny as drugs.¹⁸⁵

While the DSHEA effectively dismantled the FDA’s authority to adequately police dietary supplements, more appropriate regulation might be possible if Congress encourages pre-market approval. Supplement manufacturers should have an enforceable obligation to substantiate, at the very least, a product’s safety. In turn, the FDA should be allowed to determine whether manufacturers have met this implied legal obligation and the accompanying claims set forth.

¹⁸²See Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 FED. REG. 16503, 16503-04 (1972); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996) (for a discussion of how, under the 1997 drug reform law, for the first time, a manufacturer can refer to scientific studies for off label (use other than originally intended) uses under certain conditions).

¹⁸³Merrill, *supra* note 182.

¹⁸⁴*Id.*

¹⁸⁵The term “dietary supplement”—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid; [or]

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake. . . . Food, Drug and Cosmetics Act (FDCA), § 201(ff)(1)(A)-(E), 21 U.S.C. § 321(ff)(1)(A)-(E)(1994).

V. CONCLUSION

Like the Babe, who set the big league bar with sixty home runs back in 1927, and Roger Maris who raised it by one in 1961, Mark McGwire's magical feat will undoubtedly beckon like a ballpark siren's call to the sluggers of tomorrow. For now though, McGwire deserves to bask unashamedly in the glory of his seventy run crown and a newly minted baseball record.

Unlike the scores of other public figures whose indignities we had to stomach during the past year, Big Mac did not lie *and* he did not cheat—he simply played by the rules of his game. And ideally, long before we ordain our next home run hero, the rules of the game will change for the better. After all, just because something is legal does not mean it is safe, or for that matter, effective. The mere absence of statistically demonstrable risk seems like a rather foolish basis for endorsement.

The current state of affairs surrounding the multi-million dollar sports product industry is indicative of the need for a look at reforming the FDA's attempt to regulate the dietary supplement industry. Doing so would still comport with the legislature's intent to allow for increased flexibility in the regulation of dietary supplements as opposed to drugs. The ultimate goal of enhancing consumer safety could be actualized by the FDA's being given the enhanced ability to distinguish between those dietary supplements that do require strict regulation and the many that do not.

In addition to preserving the precious sanctity of athletic competition, we should strive to shield the public safe from potential harm brought on by untested products. In the long term, the FDA should have the authority to regulate supplements to a reasonable level of scientific honesty and establish a brighter line between legitimate nutritional additives and performance enhancing drugs.

The possible side effects produced by these substances may not manifest until far into the future and accordingly; today's explosive gain in power and strength may come with dubious strings attached. Until it can be substantiated *how* a product should be classified; *how* well it works, if at all; *and* above all, if it's safe, we can hardly afford to sell our regulatory souls to an indifferent devil.

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