



Not Its Crowning Glory: Obstacles for FDA in Regulating Ingested Dietary Supplements Purporting to Prevent Hair Loss

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Citation	Not Its Crowning Glory: Obstacles for FDA in Regulating Ingested Dietary Supplements Purporting to Prevent Hair Loss (2005 Third Year Paper)
Citable link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852110
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Microsoft Word 10.0.6612;

Not Its Crowning Glory:
Obstacles for FDA in Regulating Ingested Dietary Supplements
Purporting to Prevent Hair Loss

A Paper Submitted in Satisfaction of the Course Requirement in
Food & Drug Law
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Winter Term, 2005

Class of 2005

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March 14, 2005

Not Its Crowning Glory:
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Abstract: Preventing hair loss is big business in the United States, amounting to over one billion dollars per year. While the industry is dominated by FDA-approved medications, like Propecia and Rogaine and hair transplant surgeries, there are also a variety of herbal remedies on the market with no proof of effectiveness. These products are allowed to exist and to claim to regrow hair or prevent future hair loss thanks to the provisions of the Dietary Supplement Health and Education Act of 1994, or DSHEA. This article examines how DSHEA allows these products to remain on the market, potentially defrauding millions of vulnerable Americans seeking to respond to baldness, and offers several possible solutions to the problem.

Patient: Doctor, doctor, can you give me something for my baldness?

Doctor: How about a few pounds of pig manure?

Patient: Will that cure my baldness?

Doctor: No, but with that on your head no one will come near enough to notice you're bald.

—Old Joke

While jokes like this one are common, for the sixty million American men and women who experience significant hair loss, baldness is no laughing matter.¹ By one estimate, thirty-five million men in America

¹Nicholas Thompson, *Hair Today, Gone Tomorrow*, BOSTON GLOBE, Feb. 12, 2002, at C3.

are going bald, and 90% of them say it bothers them.² And, while typical male-pattern baldness is not indicative of serious medical problems, recent clinical studies by the American Academy of Dermatology have demonstrated a link between hair loss and depression and other mental health problems, noting that despite half of American men experiencing substantial receding by the age of fifty, “[t]here is very little social acceptance of hair loss.”³

The prevalence of the problem, combined with people’s dismay at its affecting them, means big business for those purporting to have found a cure. In America, baldness prevention and cures, including prescription drugs, over the counter [OTC] drugs, hair transplants, dietary and herbal supplements, and other remedies, represent a \$1 billion business.⁴ In 2003 alone, Americans spent \$111 million on Propecia, the FDA-approved prescription baldness drug from Merck, up 13% from the previous year, and nearly one third of a billion dollars on hair transplant operations.⁵ Given these figures, it is understandable why major drug companies are investing heavily in finding a baldness cure, and why many dermatologists are making a living doing only hair transplant operations.⁶ It is also understandable why many other less reputable characters are trying to make money off of desperate men and women willing to try anything to avoid losing their hair. Throw in the Internet and its ability to reach embarrassed or shy consumers unwilling to discuss the issue with their doctors, and there are enormous opportunities for con artists to capitalize on this market.⁷

²See Jean Patterson, *Huge Changes in Hair Replacement; Exciting Advances Seen in the Next Decade*, ORLANDO SENTINEL, Dec. 21, 2005, at D5.

³The American Academy of Dermatology, *Unraveling the Mystery of Hair Loss: Dermatologists Can Help Provide Answers*, Mar. 23, 2003, para. 16, at <http://www.aad.org/public/News/NewsReleases/Press+Release+Archives/Hair/McMichaelHairLoss.htm>.

⁴See Thompson, *supra* note 1, at C3.

⁵Dan Hurley, *Does He or Doesn't He? It's Harder to Tell*, N.Y. TIMES, June 15, 2004, at F1.

⁶See Thompson, *supra* note 1. GlaxoSmithKline is investing in dutasteride, a sort of next generation Propecia which serves to block additional hormones believed to cause hair loss.

⁷See, e.g., Nicholas P. Terry, *Prescriptions sans Frontieres (or How I Stopped Worrying About Viagra on the Web but Grew Concerned About the Future of Healthcare Delivery)*, 4 Yale J. Health Pol’y & Ethics 183, 227 (2004) (“For many lifestyle drugs, stealth and anonymity may still be the predominant factors promoting online purchases.”).

Although there are only two drugs approved by the Food and Drug Administration for preventing hair loss, Minoxidil [available over the counter, and known most commonly by its trade name, Rogaine] and Finasteride [a prescription drug more recognizable by its trade name, Propecia], the Internet landscape and drug store shelves are overflowing with products making unsubstantiated claims to “regrow” hair. A single Google search for the words “hair loss remedy” returns links to over one million results, many of which promise amazing, and supposedly scientifically proven, results. One might think that, given the prevalence of these products, FDA is unaware of the problem.

Quite the contrary is true. FDA has been attempting to regulate the hair loss industry since twenty-five years ago, when they first proposed a rule proclaiming all products for external use purporting to regrow hair or prevent hair loss be considered new drugs requiring FDA approval and review for safety and effectiveness.⁸ The rule became final after a lengthy notice and comment period in 1990, codified at 21 C.F.R. §310.527.⁹ Despite this rule, products designed for internal use, e.g. pills and other dietary supplements, proclaiming miracle cures for hair loss abound, amounting to a significant portion of this billion dollar per year business.

This paper addresses the question of why these products continue to flourish on the Internet, in pharmacies, and in health food stores across the United States. Part of the answer surely is that this issue must, and perhaps rightfully so, be low on FDA’s list of priorities, given that the agency is fulfilling such a broad mandate with very limited resources.¹⁰ After all, there are no known or suspected cases of people potentially dying from using a hair loss remedy, as there were with ephedra.¹¹ Nevertheless, people are defrauded on

⁸Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use, 45 Fed. Reg. 73955 (Nov. 7, 1980).

⁹Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use, 54 Fed. Reg. 28772 (July 7, 1989) (to be codified at 21 C.F.R. pt. 310).

¹⁰See Sharon Smith Holston, *Drug Development: Who Knows Where the Time Goes?*, 52 FOOD DRUG L.J. 197 (1997) (noting, “As the FDA’s workload continues to grow, the agency has to find ways of doing more with less, without lowering the standards of its public health protection.”).

¹¹Dan Hurley, *As Ephedra Ban Nears, Race to Sell Last Supplies*, N.Y. TIMES, April 11, 2004, at A23.

a daily basis by a cavalcade of hucksters, medicine men, and snake oil (pill) salesmen trying to capitalize on desperate customers, and FDA recognized this when it decided to regulate hair loss products as drugs.¹² FDA has engaged in some limited enforcement of the regulation, sending out several warning letters to companies making topical products in violation of the law. But, these actions confront only a tiny fraction of the products on the market, and do not touch the burgeoning market for dietary supplements claiming to stop hair loss.

One reason for this may be the Dietary Supplement Health and Education Act of 1994, or as it is more commonly known, DSHEA.¹³ This statute severely limited FDA's ability to regulate so-called dietary supplements, and it allowed dietary supplement producers to make a host of claims about their supplements' ability to affect the structure and function of the body.¹⁴ Congress enacted the statute to assure the availability of dietary supplements for those who choose to use them, and it is premised on the nutritional benefits of such supplements.¹⁵ While FDA still technically has the ability to initiate some enforcement actions against dietary supplements, the area in which they can act has been heavily circumscribed. Two commentators have claimed in a recent article that "FDA's enforcement activities against dietary supplement companies committing egregious violations of DSHEA have virtually been non-existent."¹⁶ Hair loss supplements, despite the FDA's 1990 regulation, almost certainly come under the act. I argue that if this is the case, it is a concrete example of how DSHEA frustrates FDA's mission to ensure that all drugs are safe and effective, and allows for the defrauding of millions of vulnerable Americans.

¹²See 54 Fed. Reg. 28772, *supra* note 9, noting: "One comment said the proposal was long overdue and that purchasers of these drugs are bilked of millions of dollars each year."

¹³Pub. L. 103-417, 108 Stat. 4325 (1994).

¹⁴See 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, 576 (1999).

¹⁵I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 1 (1996).

¹⁶Pinco & Halpern *supra* note 14, at 579.

I will begin by discussing the landscape of the hair loss remedy market and FDA's involvement with it, discussing approved hair loss drugs, and examining what is available on the Internet and in drug and health food stores. Then, I will briefly review the history and impact of DSHEA, focusing on how it specifically affects the hair loss industry, suggesting that the statute inhibits FDA's ability to protect consumers from rampant fraud. I will conclude by examining possible solutions.¹⁷ I will suggest that while DSHEA is an obstacle to taking hair growth pills off of the market, FDA may still be able to do it, particularly if it enforces its recent draft guidance regarding the types of claims these products can legally make on their labels. I will also suggest that market specific exceptions to DSHEA might provide the proper balance between Congress's desire to ensure the availability of safe dietary supplements, and FDA's statutory mission.

A Survey of the Hair Loss Industry

By nearly any measure, the \$1 billion dollar a year industry in hair loss prevention in this country is enormous, and certainly large enough to garner the attention of the FDA. Over sixty million Americans experience significant hair loss each year, and most of them, at some point, seek to do something about it.¹⁸ Surprisingly, among this population of hair loss sufferers are nearly thirty million women, most of whom experience an overall thinning instead of the more familiar male-pattern baldness, and for whom the process

¹⁷It is worthwhile at this point to note some issues this paper will not be discussing, though they are relevant to potential regulation of the hair loss industry. First, I will not examine in detail the growing concern about sales of prescription drugs through online pharmacies. Propecia appears, along with Viagra and other lifestyle drugs, on many websites offering prescriptions and drugs online for consumers embarrassed to talk with a doctor about such personal issues. For an excellent introduction to the problem, see generally Terry, *supra* note 7.

Additionally, this essay will not focus on the thorny issues surrounding direct-to-consumer (DTC) advertising of prescription drugs. Hair loss drugs have historically been at the center of this debate, as Upjohn's Rogaine with Minoxidil was the subject of one of the first direct to consumer ads. Propecia has also been aggressively marketed, with FDA issuing a warning letter in 1998 to Merck for being more positive than warranted by the scientific evidence. For full explanation of these incidents, and a broader examination of DTC advertising of prescription drugs, see generally Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD DRUG L.J. 489 (1999).

¹⁸Larry Hanover, *Hair replacement: what works, what doesn't*, FDA CONSUMER, April, 1997, at 7.

is more socially damaging.¹⁹ The problem, of course, is nothing new, as humankind has been engaged in an ancient losing battle with baldness. Egyptians' remedy of choice was a mixture of fats from mountain goats, lions, crocodiles, serpents, geese, and hippopotami.²⁰ Cleopatra offered a mixture partly composed of burnt mice to remedy Julius Caesar's balding pate, while a late 18th century American manufacturer hawked cocaine as a hair growth product.²¹

Unfortunately, while we have made some advances, we have not come very far. Although scientific studies have led to several promising prescription baldness drugs and improved hair transplantation procedures, pharmacies, health food stores, and the Internet remain chock full of supposed miracle cures. In this section, I will survey the hair loss product market, looking at both FDA-approved and unapproved remedies.

FDA has approved two prescription drugs to treat hair loss: minoxidil, more commonly known as Rogaine, and finasteride, more commonly known as Propecia. While neither drug is flawless, and neither drug can restore a bald head to the fullness of a person's youth, each has been shown to be somewhat effective, with Propecia actually helping five of six users.²² Both drugs came from unintended sources. Minoxidil was originally developed as a drug to reduce high blood pressure, but patients taking the drug began to grow hair, often in unintended places.²³ The drug underwent a lengthy FDA approval process, and is now approved for over the counter sale to both men and women.²⁴ Even after all this time, however, no one is

¹⁹ *Various Treatments Available for Female Hair Loss*, FDA LAW WEEKLY, Nov. 18, 2004, at 20.

²⁰ See Hanover, *supra* note 18, at 7.

²¹ See Thompson, *supra* note 1, at C3.

²² *Id.*

²³ *Id.*

²⁴ Lisa Skolnik, *As in Men, Hair Loss in Women is Hereditary*, CHICAGO TRIBUNE, Aug. 14, 2002, at C5.

quite sure what makes Minoxidil regrow hair some users.²⁵ Furthermore, it must be used twice a day, every day, or all that has been gained will be lost, which can be an expensive proposition as a year's supply of Rogaine can cost upwards of \$400.²⁶

The science behind Propecia, the second, and only other, FDA approved hair loss drug, is a bit more definite. In brief, our genes cause most hair loss, and the trait can come from either side of the family.²⁷ Hereditary hair loss is caused by the over-production of a hormone called dihydrotestosterone, or DHT, which causes the hair follicle to shrink and eventually die.²⁸ So, each individual hair eventually gets thinner and loses its capacity to grow until the follicle dies entirely. Doctors first realized this connection when they noticed that eunuchs never went bald, and the notion behind Propecia is that if you can stop the body from producing too much DHT, you can stop the hair loss process.²⁹ And, Propecia works fairly well at this, stopping hair loss in five out six patients, and apparently regrowing some hair in two out of every three users.³⁰

Despite this significant success, manipulating hormone production can be a messy business, and the drug is not without its risks. Another study in the law of unintended consequences, Propecia is descended from a prostate drug called Proscar, also made by Merck, which contains the same drug as Propecia, finasteride, just five times stronger.³¹ Patients taking Proscar to reduce enlarged prostates seemed to grow hair. Merck

²⁵Devera Pine, *Hair! From Personal Statement to Personal Problem*, F.D.A. CONSUMER, Dec. 1991, at 20.

²⁶See Skolnik, *supra* note 24, at C5.

²⁷American Academy of Dermatology, *August is Hair Loss Awareness Month*, July 28, 2003, at <http://www.aad.org/public/News/NewsReleases/Press+Release+Archives/Hair/AugustHairLossAwareness.htm>.

²⁸*Id.*

²⁹See Thompson, *supra* note 1.

³⁰*Id.*

³¹Richard L. Cupp, Jr., *The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?*, 30 SETON HALL L. REV. 233, 235 (1999).

noticed the connection and developed a weaker version as a baldness remedy.³² However, Proscar carried with it a significant risk of side effects, not all of which are eliminated by the smaller dose of finasteride present in Propecia.³³ In particular, Propecia can cause sexual side effects, which range in intensity from loss of libido to full-on impotence, in around two percent of users.³⁴ Additionally, Propecia is of no help to women, who cannot even touch the pills for fear of causing birth defects to a future child.³⁵ Furthermore, Propecia is not foolproof, and it is very expensive. A one year supply of Propecia can cost around \$600, cost prohibitive for many. And, Propecia only inhibits one of the two sources of DHT production in men, but help may be on the way as GlaxoSmithKline is developing a drug called dutasteride that attacks both sources of the hair-destroying hormone.³⁶

For those for whom the drugs do not work, there remains a burgeoning industry in hair transplants. Consumers spent nearly a third of a billion dollars in 2003 on hair transplant operations, which now cost on average about \$32,000 each.³⁷ And, as transplants grow more realistic and less painful, that number will surely rise, particularly if current research comes to fruition and doctors are eventually able to clone the hair follicle. Current transplants require actually taking growing hair follicles from the back of the head and transplanting them to bald areas. If cloning becomes feasible, doctors will be able to sprout an entire head of hair from a single functioning follicle.³⁸ For the more skittish, there remains a strong market in wigs and toupees,³⁹ and for those who don't mind a continual battle with wind, there is always the Donald

³² *Id.*

³³ *Id.*

³⁴ Robert Davis, *Hair Raising Discoveries, Bald Gene Finding Could Add to Growing Options*, USA TODAY, Feb. 3, 1998, at 1D.

³⁵ *Hair Growth Pill to Be Offered Next Month*, CHICAGO SUN-TIMES, Dec. 23, 1997, at 1.

³⁶ See Thompson, *supra* note 1.

³⁷ See Hurley, *supra* note 5, at F5.

³⁸ *Id.*

³⁹ Douglas Century, *A Little Sympathy for the Toupee... er, Hair System*, N.Y. TIMES, at Sec. 9, p. 4.

Trump-esque combover hairdo.⁴⁰

That, in a sense, is the good news. The bad news is that the market is also filled with products claiming to regrow hair with no FDA approval whatsoever. A trip to my local drug store revealed an entire shelf-section devoted to such products, from the FDA approved Minoxidil products to a series of pills claiming to grow hair. My local Vitamin Shoppe is also well-stocked with herbs claiming to have a positive effect on hair growth, such as extract of Saw Palmetto berries and Shen Min. The Internet has exacerbated the problem, as “natural” hair loss remedies are everywhere online, from the web to email, in the form of spam advertisements. The slickness of these websites, complete with video, client testimonials, and before/after pictures, makes the products appear to work extremely well, while any disclaimer that the products have not been approved by the FDA are in very fine print.⁴¹

FDA has been in the business of attempting to regulate the hair loss industry for the last twenty-five years. In the November 7, 1980 Federal Register, FDA proposed a rule covering products claiming to prevent hair loss or grow new hair.⁴² After a nearly decade-long comment period, the final rule was announced on July 7, 1989, and would become effective on January 8, 1990.⁴³ The agency was concerned about products being ineffective, and “consumers being bilked” into buying phony remedies.⁴⁴ The final rule states that “any OTC drug product that is labeled, represented, or promoted for external use as a hair grower or for hair loss prevention” be considered a new drug, and go through the new drug approval process.⁴⁵ The FDA based

⁴⁰See Rich McKay, *Hair-raising Comb-over; Hairstyle Patent Proves Worthy of Ig Nobel Prize*, Houston Chronicle, Oct. 13, 2004, at 2. The article notes that Harvard University awarded the inventors of the “comb-over” hairstyle an “Ig Nobel Prize” at a 2004 banquet, earning a “trophy of an empty cereal box and a pie-plate medal hanging from a shoestring.”

⁴¹A good example of this is the website for “Hair Genesis,” available at <http://www.hairgenesis.net>, which includes all of these features, and has such a disclaimer in almost unreadable fine print at the very bottom of the homepage.

⁴²“Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use,” 45 Fed. Reg. 73955, Nov. 7, 1980 (to be codified as 21 C.F.R. §310.527).

⁴³54 Fed. Reg., *supra* note 9, at 28772.

⁴⁴*Id.*

⁴⁵*Id.* at 28777.

this decision on a lack of evidence demonstrating that any product then on the market was effective for hair regrowth or hair loss prevention, stating that “[b]ased on evidence currently available, all labeling claims for OTC hair grower and hair loss prevention drug products for external use are either false, misleading, or unsupported by scientific data. Therefore, any OTC drug product for external use containing an ingredient offered for use as a hair grower or for hair loss prevention cannot be considered generally recognized as safe and effective for its intended use.”⁴⁶ FDA has often enforced this regulation against shampoos, tonics, or serums that claim to regrow hair, usually by sending a warning letter to producers whose products are violation.⁴⁷

The rule explicitly did not reach products intended to be ingested, although the FDA did comment on the matter in response to a comment suggesting that the rule be extended to ingestible remedies.⁴⁸ FDA stated that products intended for internal use were explicitly outside the scope of the regulation, but that such products might be regulable as new drugs if they make “drug claims.”⁴⁹ This notion, however, predates the Dietary Supplement Health and Education Act of 1994, which allows products labeled as dietary supplements to make claims that they affect the structure and function of the body without prior approval from the FDA. And, predictably, these products are almost all labeled as dietary supplements.⁵⁰ If DSHEA allows for these products to make hair regrowth claims in the guise of a dietary supplement, then it makes s significant

⁴⁶ *Id.*

⁴⁷ *See, e.g.*, Letter from Michael A. Chappell, Director of the Dallas District of the Food and Drug Administration, to Rudolph Johnson, Owner of Pride and Power, Inc. (Mar. 3, 2003), available at http://www.fda.gov/foi/warning_letters/g3870d.htm. The letter warns Mr. Johnson that his company’s product “Don’t-B-Bald Hair and Scalp Treatment Medicated” is in violation of the regulation and faces further action if the problem is not rectified.

⁴⁸ 54 Fed. Reg., *supra* note 9, at 28772.

⁴⁹ *Id.* at 28773.

⁵⁰ FDA has occasionally initiated actions against producers who make pill products and some drug claims when those products are not labeled as dietary supplements. *See* Letter from Jerome G. Woyshner, Director of the New York District of the Food and Drug Administration, to Anthony Imbriolo, President of Global Vision Products, Inc. (April 3, 2003), available at http://www.fda.gov/foi/warning_letters/g3938d.htm.

dent in 21 C.F.R. §310.527, and shows the propensity for frauds to be perpetrated on the public thanks to DSHEA.

Before turning to DSHEA's specific provisions, I will review some of the claims made by hair loss products labeled as dietary supplements. One popular product is called "NuHair," and it is readily available in drug stores and on the Internet.⁵¹ On its website, NuHair claims that it:

Integrates a revolutionary combination of Traditional Chinese Medicine with the applied science of modern technology. The result is a nutraceutical anti-thinning tablet that provides intensive nourishment for excessively thinning hair, receding hairlines, breakage around the hairline, and any area of the scalp that has poor hair density. This natural nutrient booster supplies vital botanical components to nourish the hair. NuHair supports embryotic follicular activity naturally to encourage hair regrowth.⁵²

It is clear that if NuHair were a topically applied product, it would come within the ambit of 21 C.F.R. §310.527 because it claims to encourage regrowth of hair. However, because the product is a pill, and is orally ingested, it does not fall under the regulation. Furthermore, the product box states in small letters in the bottom left-hand corner "Dietary Supplement," which brings it under the aegis of DSHEA. NuHair is only one example of such products claiming to regrow hair which are labeled as dietary supplements.⁵³ *These products are not regulable as "new drugs," and present a potential fraud perpetrated on the American public.*

⁵¹NUHAIR HOMEPAGE, available at <http://www.nuhairproducts.com/nuhair/nuhair.htm>.

⁵³Other examples abound on the Internet and in health food stores. I will provide a few here:

- HAIR GENESIS ORAL SOFT-GELS, available at <http://www.hairgenesis.net>. The website claims: Through 10 years of on-going clinical research and product usage testing, these botanicals have been shown to interfere with key hormonal processes implicated in the onset and progression of pattern hair loss in both men and women.
- NEW GENERATION 2 DIETARY SUPPLEMENT, available at <http://www.newgen2000.com/treatment/dietary-supplement.html>. The website claims: The New Generation Nutritional Supplement is designed to provide the missing nutritional elements that are known to have an effect on hair health and a reduction in baldness.
- NATRECIA, available at http://www.hairsite.com/secure/razack_natrecia.htm. The website claims: Natrecia is a completely natural, vitamin, mineral, and herbal supplement specifically developed for combating the effects of androgenic alopecia (AP) (i.e., male-pattern baldness). Its formulation is based on a significant body of research that firmly establishes the effect that certain natural agents have in combating the effects of dihydrotestosterone (DHT) in the treatment of benign prostatic hyperplasia (BPH).

How the Dietary Supplement Health and Education Act arguably creates cover for hair loss remedies marketed as “dietary supplements”:

The Dietary Supplement Health and Education Act of 1994 fundamentally altered the FDA’s regulatory relationship with the dietary supplement industry, and, therefore, the industry itself.⁵⁴ DSHEA, which significantly limited FDA’s ability to regulate the dietary supplement industry, has ushered in enormous growth in the use of these supplements.⁵⁵ In fact, about sixty percent of Americans take some form of dietary supplement, and sales of such products have nearly doubled since the passage of DSHEA.⁵⁶ And FDA’s ability to regulate this ever-growing market has been so circumscribed by the statute that, in some circles, being “DSHEA’ed” is a code for deregulation.⁵⁷

In this section, I will briefly review the history of FDA’s regulation of dietary supplements, a history which led directly to a grass roots movement resulting in the unanimous passage of DSHEA in the House and Senate.⁵⁸ Then, I will discuss how the statute limits FDA’s ability to regulate the dietary supplement industry, particularly with respect to claims such supplements might make about health benefits, such as the ability to grow hair. The statute arguably allows myriad hair growth remedies labeled as supplements to make unsubstantiated claims of effectiveness, circumventing FDA’s explicit regulation of the industry in

⁵⁴Sean Harmon, *Melatonin Mania: Can the FDA Regulate Hormonal Dietary Supplements to Protect Consumer Interests in Light of the Dietary Supplement Health and Education Act of 1994?*, 22 DAYTON L. REV. 77, 86 (1996).

⁵⁵Meghan Colloton, *Dietary Supplements: A Challenge Facing the FDA in Mad Cow Disease Prevention*, 51 AM. U. L. REV. 495, 496 (2002) (noting that “the use of dietary supplements has increased dramatically in the United States over the last decade.”).

⁵⁶Stephanie Kauflin, *Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme*, 33 SETON HALL L. REV. 411, 413 (2003).

⁵⁷Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 665, 666 (1997).

⁵⁸Laura A. W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD DRUG L.J. 623 (1999).

21 C.F.R. §310.527. Finally, I will review FDA's recent efforts to increase regulation of dietary supplements under DSHEA and discuss how these efforts, if enforced, may ameliorate the situation.

1. The History of Dietary Supplement Regulation Before DSHEA

The FDA has been engaged in a battle with the dietary supplement industry over regulations for over sixty years.⁵⁹ While it is beyond the scope of this paper to review the entire history of FDA's attempts to regulate the supplement industry, a brief overview is necessary to understanding the climate surrounding the passage of DSHEA, and its limitations of FDA's power.

The FDA promulgated their first regulations of dietary supplements in 1941, requiring minimum daily requirements on labels for some supplements.⁶⁰ These early regulations did not meet much resistance, but they were not particularly onerous either. The real fight began when FDA sought to revise these regulations in 1962. The agency was concerned that supplements were spreading "myths of nutrition," suggesting that people could not receive necessary sustenance from a normal diet.⁶¹ The new proposals would set a mandatory limit on the potency of a supplement at 150% of its recommended daily allowance.⁶² The new regulations also prohibited inclusion of ingredients "not recognized by 'competent authorities' as essential or as having significant nutritive value to humans."⁶³ These regulations sparked a public and industry backlash so enormous that the proposed rules not only were never promulgated, they never even made it to the public

⁵⁹ See Gilhooley, *supra* note 57, at 671.

⁶⁰ See Colloton, *supra* note 55, at 512.

⁶¹ See Gilhooley, *supra* note 57, at 673.

⁶² See Colloton, *supra* note 55, at 513.

⁶³ *Id.*

hearing stage.⁶⁴

FDA again attempted to pass similar rules in 1966, but public outcry was so great that the agency stayed the regulations the day before they were to become effective and launched a two-year public hearing phase.⁶⁵ Particularly offensive to the public and supplement manufacturers was FDA's proposed requirement that every dietary supplement label state that because the regular diet provided adequate nutrition, "there is no scientific basis for recommending routine use of dietary supplements."⁶⁶ Eventually, FDA dropped this requirement, but in 1973 it did issue a final rule classifying most vitamins with a potency greater than 150% of the recommended daily allowance as drugs, and prohibiting sales of supplements with combinations of vitamins and minerals, with few exceptions.⁶⁷

These regulations were supposed to take effect in 1975, but due to an "overwhelming number of constituent letters written to Congress," nearly seventy bills were introduced to limit FDA's ability to regulate potency of dietary supplements.⁶⁸ A three-year congressional debate ensued, with particularly virulent argument on both sides. Senator William Proxmire led the charge for those attempting to thwart the new regulations. His floor statement about the issue was particularly forceful: "What the FDA wants to do is strike the views of its stable of orthodox nutritionists into 'tablets,' and bring them down from Mount Sinai where they will be used to regulate the rights of millions of Americans, who believe they are getting a lousy diet, to take vitamins

⁶⁴BASS & YOUNG, *supra* note 15, at 11.

⁶⁵*Id.*

⁶⁶Colloton, *supra* note 55, at 514.

⁶⁷BASS & YOUNG, *supra* note 15, at 11.

⁶⁸Colloton, *supra* note 55, at 516.

and minerals. The real issue is whether the FDA is going to play ‘God.’”⁶⁹ In the end, Proxmire prevailed, and Congress passed an amendment to section 411 of the FDCA which, among other things, prohibited FDA from setting potency limits on vitamins and minerals, and allowing those supplements to be sold in various combinations.⁷⁰ Not only did the Proxmire Amendment hinder FDA’s attempts to regulate the dietary supplement industry, it also demonstrated both the enormous public resistance to such regulations, and Congress’ willingness to respond with legislation.

FDA responded to the Proxmire amendment by scaling back its attempts to regulate the dietary supplement industry, but the agency found creative ways to enter the fray if it felt there was a legitimate safety concern.⁷¹ FDA regulated some supplement ingredients as food additives, which require premarket approval if they are not generally recognized as safe.⁷² The approval process for a new food additive is so financially onerous and takes so long that this was usually enough to remove the substance from the market.⁷³ This approach was reasonably effective, but it required FDA to proceed on a case-by-case basis, rather than issuing a regulation covering the entire market for dietary supplements.

In 1990, Congress passed the Nutrition Labeling and Enforcement Act (NLEA) which set standards for health claims made by foods. The statute did not set such standards for dietary supplements, but directed FDA to craft them.⁷⁴ Although the drafters of the statute clearly intended for dietary supplements to face more

⁶⁹BASS & YOUNG, *supra* note 15, at 12 (quoting 121 Cong. Rec. 39979 (1975) (statement of Senator William Proxmire)).

⁷⁰Colloton, *supra* note 55, at 517.

⁷¹Gilhooley, *supra* note 57, at 676.

⁷²Colloton, *supra* note 55, at 518.

⁷³*Id.* According to Colloton, the approval process for a food additive not generally recognized as safe can cost up to \$2 million and take up to six years.

⁷⁴*Id.* at 520.

lenient standards than food in general, FDA responded by applying the same strict guidelines which applied to food to supplements.⁷⁵ And, perhaps to underscore the strictness of the regulations, the only supplement claim FDA deemed to possibly meet these standards was calcium's ability to prevent osteoporosis.⁷⁶

FDA's action again sparked a backlash from the supplement industry and the public, and Congress quickly enacted the Dietary Supplements Act of 1992, staying the effect of FDA's regulations under NLEA until December 1993.⁷⁷ In the interim, 38 people died and 1500 others experienced adverse health effects from use of L-tryptophan, an amino acid supplement used by bodybuilders.⁷⁸ As a result, FDA again attempted to issue broad regulations, in the form of an advance notice of rulemaking, of the supplement industry similar in many ways to those it proposed in the 1960s.⁷⁹ The proposed rules again sparked a backlash by consumers and the industry, galvanizing support for legislation to reign in FDA.⁸⁰ One colorful stunt by the industry was a "National Blackout Day," in which health food stores covered with black drapes the products that would supposedly be affected by FDA's proposed rules. The stunt contributed to the growing outcry over FDA's proposed regulations, and eventually to the passage of DSHEA.⁸¹

2. The passage of DSHEA and its limitations on FDA's ability to regulate dietary supplements.

In short, Congress responded to calls for greater access to dietary supplements by unanimously passing the Dietary Supplement Health and Education Act of 1994, which was signed into law by President Clinton on

⁷⁵*Id.* at 521.

⁷⁶BASS & YOUNG, *supra* note 15, at 15.

⁷⁷Colloton, *supra* note 55, at 522.

⁷⁸Gilhooley, *supra* note 57, at 677.

⁷⁹*Id.*

⁸⁰*Id.* at 678.

⁸¹Kaiser, at 1258.

October 25, 1994.⁸² Congressman Bill Richardson called the bill's passage "a great victory for the more than 100 million Americans who use these products."⁸³ The bill, which is premised on "the role of nutrition and benefits of dietary supplements in health promotion," flatly contradicts the FDA's efforts to regulate supplements more like drugs and less like foods.⁸⁴ Yet, the act also clearly removes supplements from regulation as food additives, which FDA had done in a reasonably successful, albeit piecemeal, fashion since the 1970s.⁸⁵ In all, as one article recently asserted, DSHEA "directly thwarted" FDA's attempts to increase restrictions on dietary supplements.⁸⁶

DSHEA defines dietary supplements essentially as products containing vitamins, minerals, herbs, or other botanicals, amino acids, or any other "dietary substance for use by man to supplement the diet by increasing the total dietary intake," including combinations of any of these ingredients.⁸⁷ A dietary supplement must also be intended for ingestion and labeled as a supplement.⁸⁸ This redefinition makes it clear that a dietary supplement can be placed on the market without the preclearance that would be required of a new drug or a food additive.⁸⁹ This change constitutes a significant liberalization of the law.

FDA still has the ability, in some circumstances, to take a supplement off of the market if it is dangerous, and they can do so immediately if the product presents an imminent hazard to public health or safety.⁹⁰ However, FDA has to overcome a major hurdle in order to get a supplement off of the market for being unsafe, because the statute clarifies that the burden of proof is on the government to show that a supplement is

⁸²*Id.* at 1260-61.

⁸³BASS & YOUNG, *supra* note 15, at 30.

⁸⁴*Id.* at 1.

⁸⁵*Id.* at 33. *See also*, 21 U.S.C.A. 321(s)(6).

⁸⁶Harmon, *supra* note 54, at 78.

⁸⁷21 U.S.C. §321(ff).

⁸⁸*Id.*

⁸⁹Pinco & Halpern *supra* note 14, at 569.

⁹⁰21 U.S.C. §342(f)(1)(C).

adulterated.⁹¹ The result is that many of the avenues FDA once pursued in regulating dietary supplements, for instance as a drug or food additive, have been explicitly eliminated.

Perhaps even more significant to the issue of hair loss supplements, because such products are usually worthless but not dangerous, is DSHEA's provision allowing supplements to make claims that they alter the structure or function of the body (so-called structure function claims). Furthermore, supplement makers may make these claims without premarket approval by FDA or treatment as a new drug.⁹² These provisions represent the drafters' intention to increase consumer access to accurate information regarding dietary supplements.⁹³ I will examine them here, and then explain how they allow market entry for hair loss remedies which are useless.

DSHEA allows supplement makers to make "statements of nutritional support," including descriptions of "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, or general well-being from consumption of a nutrient or dietary ingredient."⁹⁴ However, the ability to make such structure function claims is not completely unlimited. The claims must be substantiated, although this term is not defined, and the products' labels must include a disclaimer explaining that the claims have not been evaluated by the FDA, and that the product is not intended to prevent, treat, or cure any disease.⁹⁵ Additionally, the supplement maker must notify FDA within thirty days of when the product is

⁹¹21 U.S.C. §342(f)(1).

⁹²Pinco & Halpern, *supra* note 14, at 569.

⁹³*Id.*

⁹⁴21 U.S.C. §343(r)(6). *See also* Gilhooley, *supra* note 57, at 684.

⁹⁵21 U.S.C. §343(r)(6).

first marketed to notify them that the claim will be made.⁹⁶ The most important thing about the statute is that post-DSHEA dietary supplements can make these claims without premarket approval from FDA, while over-the-counter drugs must go through the arduous preclearance process.⁹⁷ It is the manufacturer's responsibility to ensure product labeling is truthful and not misleading.⁹⁸

The result, naturally, has been an explosion of nutritional and structure functions claims on dietary supplements, relating to a wide array of health problems, from insomnia to prostate health.⁹⁹ The hair loss industry has certainly not failed to take advantage of these new provisions. A cursory glance at products available on the web and at pharmacies will see the tell tale signs of DSHEA-compliant labels—including the words “dietary supplement” and the scripted FDA disclaimer. NuHair is not the only example of a product that bills itself as a “hair regrowth tablet,” and gets away with it because it bills itself as a dietary supplement.¹⁰⁰ The “oral soft-gels” available as part of the aforementioned “Hair Genesis” system, which claims on the same web-page that it is the “safest and most effective hair loss treatment remedy available,” and also that (in fine print, of course) “the information provided on the website is intended for informational purposes only,” and that the claims made on the website have not been evaluated by FDA.¹⁰¹

One reason for the explosion of health claims under DSHEA is a lack of definition in the statute for “substantiation” required to make a health claim on a supplement label.¹⁰² As Pinco and Halpern state, “It is not

⁹⁶Pinco & Halpern, *supra* note 14, at 576.

⁹⁷Gilhooley *supra* note 57, at 685.

⁹⁸DIETARY SUPPLEMENTS OVERVIEW, FOOD AND DRUG ADMINISTRATION, Dec. 10, 2004, available at <http://www.cfsan.fda.gov/~dms/supplmnt.html>.

⁹⁹*Id.*

¹⁰⁰See NUHAIR HAIR REGROWTH TABLETS FOR MEN, *supra* note 52.

¹⁰¹HAIR GENESIS OVERVIEW, *supra* note 53

¹⁰²Pinco & Halpern, *supra* note 14, at 576.

entirely clear how much data a company needs in order to substantiate a structure/function statement.”¹⁰³ Hair loss websites, like Hair Genesis, often offer “clinical studies” to back up their claims of effectiveness, but since there are no clear standards defining what sorts of studies actually substantiate these claims, such studies must be taken with a grain of salt.¹⁰⁴ Unfortunately, despite the required disclaimer that appears on these products’ websites, they still have a veneer of scientific proof attached to them, usually “backed up” by a series of user testimonials and photographs of questionable legitimacy.

FDA has recognized this problem, and has recently attempted to define the substantiation required by DSHEA. Its actions may represent a fruitful avenue to reduce fraud in a way that is consistent with both the language and the spirit of the statute.

3. FDA’s recent attempts to re-enter the fray in regulating dietary supplement structure function claims:

The exponential growth of the dietary supplement industry since the passage of DSHEA, and the concomitant explosion of claims made on supplement labels, has prompted FDA to announce major new initiatives to provide guidance to the dietary supplement industry on November 4, 2004.¹⁰⁵ Among these initiatives is a “draft guidance”¹⁰⁶ attempting to define the level of substantiation necessary to make a structure function claim while also maintaining “flexibility in the precise amount and type of evidence that constitutes adequate substantiation.”¹⁰⁷ The press release announcing the initiative indicated FDA’s hope to coordinate

¹⁰³*Id.*

¹⁰⁴HAIR GENESIS OVERVIEW, *supra* note 53. The studies cited on this website claim to be, among other things, independently verified, peer-reviewed, placebo-controlled, Institutional Review Board monitored, randomized, and double-blind.

¹⁰⁵FDA ANNOUNCES MAJOR INITIATIVES FOR DIETARY SUPPLEMENTS, Nov. 4, 2004, *available at* <http://www.fda.gov/bbs/topics/news/2004/NEW01130.html>.

¹⁰⁶Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 69 Fed. Reg. 64962, (Nov. 9, 2004).

¹⁰⁷*Id.*

with FTC's efforts to stamp out fraud in dietary supplement labeling, and FTC Chairman Deborah Platt Majoras added, "The guidance FDA has issued today sends a clear and strong reminder to marketers that claims about the benefits of dietary supplements, wherever they appear, must be truthful and substantiated by high quality scientific evidence."¹⁰⁸

Obviously, the proposal is only a draft guidance, which means that the industry is not legally obligated to follow it, and response may well be the type of significant backlash from the supplement industry and consumers that the FDA has faced over the last five decades, but if implemented, the draft guidance would be a major step forward. In essence, the guidance attempts to provide a very general framework as to how a structure function claim might be substantiated: "Although there is no formula as to how many or what type of studies are needed to substantiate a claim, FDA intends to apply a standard of 'competent and reliable scientific evidence.'"¹⁰⁹ While the guidelines do not get much more specific than that, FDA does indicate that they will look at the meaning of the claim asserted, the relationship of the evidence to the claim, the quality of that evidence, and the totality of the evidence to decide whether the claim has been substantiated.¹¹⁰ The implication of this wide-ranging, case-by-case, method of analysis, is that FDA is asserting its power to clarify the substantiation requirement in DSHEA to look more closely at structure function claims made by dietary supplements. If enforced as written, the guidance represents a much more active approach in regulating dietary supplement claims than previously practiced under DSHEA.

Possible Ways FDA Might Prevent So-Called Dietary Supplements from Claiming to Regrow Hair

¹⁰⁸ *Id.*

¹⁰⁹ FACT SHEET ON FDA'S DRAFT GUIDANCE FOR INDUSTRY: SUBSTANTIATION FOR DIETARY SUPPLEMENT CLAIMS (hereinafter known as FACT SHEET), Nov. 4, 2004, available at <http://www.cfsan.fda.gov/~dms/dsclmfs.html>.

¹¹⁰ *Id.*

Dietary supplements purporting to regrow hair in balding men and women provide a textbook case of how DSHEA allows products to make strong claims about how they impact the structure and function of the body with little substantiation and no approval from the FDA. While these products do not appear to present any immediate health risks to the general public, they do represent a possibility of fraud.¹¹¹ And, there is additional reason to be concerned because consumers losing their hair constitute a particularly vulnerable population, seeking any solution to their impending baldness, particularly women.¹¹² FDA should attempt to find ways consistent with DSHEA to keep products that provide false hope to balding men and women off of the market.

One promising avenue is the new draft guidance for how FDA will enforce the requirement that dietary supplement structure function claims be substantiated. Many of the products available on the web assert that clinical studies support their claims to regrow lost hair, but these studies are of varying worth, and without FDA oversight, consumers have no means of differentiating between them. Yet, FDA's draft guidance offers an excellent opportunity for the agency to take some of these products off of the shelves without running afoul of DSHEA. This is precisely because of the DSHEA's mandate that the manufacturer have substantiation that the claims are truthful and not misleading.¹¹³ By explicitly focusing on the relationship between the specific claim to the evidence, the quality of that evidence, and the totality of the evidence supporting the claim, FDA will be able to ensure that hair loss products do not overstate their effectiveness or hide behind bogus studies.¹¹⁴ Furthermore, the coordination of standards with the FTC could have the benefits of both

¹¹¹Indeed, there are not yet any known cases of a consumer dying from ingesting a hair loss supplement. However, some of these supplements contain a significant number of herbs. It is not unimaginable that one of these combinations could provoke an adverse reaction in a user. For instance, the Natrecia product contains: Saw Palmetto Berries Extract 400 mg; Beta Sitosterol 200 mg; Rye Pollen Extract 100 mg; Pumpkin Seed Extract 100 mg; Lycopene 50 mg; Zinc 20 mg; Copper 1 mg; Vitamin B6 (pyridoxal-5-phosphate) 10 mg; Phosphorus (as phosphate) 100 mg; Calcium 125 mg. *See NATRECIA, supra* note 53.

¹¹²*See* Eileen Dempsey, *Heartache of Hair Loss*, COLUMBUS DISPATCH, Mar 25, 2002, at 1C.

¹¹³21 U.S.C. §343(r)(6)(B).

¹¹⁴*See* FACT SHEET, *supra* note 109.

reducing the FTC's enforcement load and sending a consistent message to the supplement industry from the federal government.¹¹⁵

The FDA, of course, may have to contend with the backlash which has always accompanied attempts to more closely regulate the dietary supplement industry. It is certainly possible that perceived overreaching by FDA in regulation of substance function claims will spark additional efforts to persuade Congress to intercede, even if the guidance complies fully with the language of §343(r)(6)(B). FDA so far has restricted action under the new guidance to warning letters sent to manufacturers of weight loss products.¹¹⁶ If there is little backlash to these actions, it would not be a significant step further to start cracking down on products like Natrecia or NuHair. But, if FDA begins to make attacks on other health claims made by supplements focused on supplementing the diet or helping the heart, they may experience the sort of widespread discontent that has accompanied their regulatory efforts since the 1960s.

One could also make an argument that FDA could deal with these products as new drugs under DSHEA even if they are labeled as dietary supplements. Even though 21 C.F.R. §310.527 is not written to apply to internally ingested products, the accompanying comment and text of the regulation indicate that FDA treats a claim by a product to regrow hair as a health claim. The final text of the rule states that any over the counter product for external use that claims to regrow hair must be treated as a new drug.¹¹⁷ It is not a long leap to the conclusion that a claim by any product to regrow hair is a health claim which

¹¹⁵See FDA ANNOUNCES MAJOR INITIATIVES FOR DIETARY SUPPLEMENTS, Nov. 4, 2004, *available at* <http://www.fda.gov/bbs/topics/news/2004/NEW01130.html>.

¹¹⁶*Id.*

¹¹⁷See 54 Fed. Reg., *supra* note 9, at 28777.

must be preapproved through the new drug process, especially when the accompanying comment to the final rule states that FDA retains the authority to take action against internally ingested products making these claims.¹¹⁸ Furthermore, FDA has said in other materials that “claims such as restoration of hair growth, hair loss prevention, and treatment of dandruff” are classified as drugs and not cosmetics because of the claims the products make.¹¹⁹

The key question is whether FDA could do this consistent with DSHEA, but they probably could if one considers hair loss prevention or hair regrowth a health claim as opposed to a structure function claim. Distinguishing structure function from health claims, however, is extremely tricky.¹²⁰ A health claim, which requires premarket approval before a product can assert it, is defined as “any claim... that expressly or by implication,... characterizes the relationship of any substance to a disease or health-related condition.”¹²¹ Given the previous characterizations of hair loss prevention claims as health claims requiring preapproval in 21 C.F.R. §310.527, it would be difficult for the industry to claim complete lack of notice were this interpretation applied to ingested dietary supplements for hair loss. Characterizing these claims as health claims rather than structure function claims would allow FDA to keep these products from making these claims until there is “significant scientific agreement” about them.¹²² One objection, of course, to this approach is that it violates the spirit of DSHEA, which explicitly allows structure function claims to be made on dietary supplement labels. FDA, however, might try this approach with respect to a fringe product like hair loss remedies to test the level of backlash it might face from both Congress and the public.

¹¹⁸ See 54 Fed. Reg., *supra* note 9, at 28772.

¹¹⁹ See WARNING LETTERS ADDRESS HAIR CARE PRODUCTS, available at <http://www.cfsan.fda.gov/~dms/cos-hres.html>.

¹²⁰ See Pinco & Halpern, *supra* note 14, at 577.

¹²¹ See *id.* at 572, quoting 21 C.F.R. §101.14(a)(1).

¹²² 21 C.F.R. §101.14(c).

One advantage of approaches targeting claims these products make, as opposed to taking them off the market entirely, is that it ensures people the freedom to continue taking a safe, if ineffective, product if they so choose. These approaches, therefore, takes steps toward preventing fraud while also avoiding being caught on the horns of the argument Senator Proxmire expressed so vehemently in 1975.¹²³ As such, if there are true believers, or people who for whatever reason believe they are responding to a particular supplement, they may continue to use the product if they so choose.

Finally, one other possible solution, if neither of these approaches work, is for Congress to make product-class exceptions under DSHEA. Given the extensive support for the freedom to use dietary supplements in general (remember, DSHEA passed the Senate and the House *unanimously*), any appearance that FDA is attempting to extend its regulatory reach across the board might spark a response. This response, however, may be from groups who fear that their vitamins and minerals might be taken away from them, and FDA might not be as motivated to go after these products. One approach might be for FDA to highlight some particular types of products which make uniformly unsupported claims while calling themselves dietary supplements—such as hair loss or weight loss products. Congress might be more willing to carve out exceptions to DSHEA to prevent consumer fraud for these sorts of questionable products, while still ensuring that consumers have access to more traditional and germane nutritional supplements like Vitamin C, calcium, and the like.

This approach, however, would necessitate Congress re-entering the fray on an issue they may have considered settled. Congress might also balk at setting a precedent that might encourage FDA to come calling every time

¹²³See BASS & YOUNG, *supra* note 15, at 12.

it found a class of supplements it wanted to regulate—thus potentially posing a threat to those consumers who have campaigned so vigorously in the past for their freedom of choice in taking supplements.

Conclusion

Given the vulnerability of consumers worried about losing their hair, it presents a significant risk of fraud if ingestible hair loss products are able to provide false hope through unproven claims. If DSHEA is interpreted to allow these sorts of claims simply because a product bears the label dietary supplement, then the law creates a license to commit fraud. However, there seem to be several opportunities available within the statute for the FDA to reverse course if it chooses to act.

The new draft guidance explaining FDA's point of view regarding the substantiation requirement for structure function claims allowed under 21 U.S.C. §343(r)(6) provides an excellent framework for evaluating claims on hair loss products, and eventually removing those that are unconfirmable, and perhaps leading to more studies that will push us closer to a real remedy. In time, however, we will be able to see if FDA is able to put real teeth in the requirement, and can enforce it without facing the significant backlash that has accompanied their past attempts to regulate the dietary supplement industry.