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Citation

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COSMECEUTICALS OR COSMEPSEUDOCALS: EXAMINING THE FDA'S UNDER-SIGHT
OF CELEBRITY DERMATOLOGISTS IN THE COSMECEUTICALS INDUSTRY

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May 2005

This paper is submitted in satisfaction of the course requirement for Food and Drug Law

Cosmeceuticals or CosmePSEUDOcals: Examining the FDA's Under-sight of Celebrity Dermatologists in the Cosmeceuticals Industry

Abstract

This paper will examine the Food and Drug Administration's regulation of the cosmeceuticals industry by exploring the legal (and ethical) implications of the industry's employment of physicians and dermatologists who sell products which the doctors themselves have a financial stake in. By focusing on famed dermatologist, cosmeceutical entrepreneur, and bestselling author Dr. Nicholas Perricone, this paper will elucidate the legal repercussions of using doctors to market and legitimize the drug-like claims of products that are in essence, just glorified cosmetics.

Introduction; Beholders v. Shareholders In the cosmeceutical industry

While beauty may be in the eye of the beholder, the money is objectively flying into the hands of the corporate cosmeceutical shareholders, corporations, and their paid entourage of star dermatologists. The cosmetics industry used to focus on hawking hot pink lipsticks and lash-extending mascara. But now the industry has grown up. Rather than just *hiding* imperfections, the new age of cosmetics products, known as cosmeceuticals, claim to *fight* imperfections. Men and women are rushing to cosmeceuticals counters to anti-wrinkle creams, Alpha Hydroxy Acids, Botox, and the like.¹ Cosmeceuticals are generally regarded

¹See Special Report: Skin Care's Changing Face, Business Week Online, <http://images.businessweek.com/db/04/11/cosmeceutical/cosmeceutical> (last visited May 5, 2005).

as cosmetics with medicinal or drug-like benefits.² The industry promises that its products are the new fountain of youth and consumers are handing over billions of dollars in accord. But with the wide array of (high priced) cosmeceutical products to choose from, consumers must rely on outside experts to help guide their decisions.

Unfortunately, the Food and Drug Administration (FDA), the agency that administrates the requirements of the Food, Drug, and Cosmetics Act of 1906, does not actively review the inflated claims of cosmeceutical manufacturers. Recognizing this loophole in FDA regulation, cosmetics companies have employed dermatologists to legitimize their overstated claims before consumers. Consumers, in turn, rely on the recommendations of these medical professional in paying upwards of \$25 to \$400 per bottle to cosmeceutical companies.

This paper explores the legality marketing practices of cosmeceutical industry i.e. making drug-like claims about products that are merely glorified cosmetics, and using doctors to market and legitimize the drug-like claims. The first part of this paper discusses the “under-sight” of the cosmeceutical industry and the industry’s questionable use of dermatologists to promote cosmetics for profit. The second section explores the growing empire of a well-known dermatologist, cosmeceutical entrepreneur, and bestselling author Dr. Perricone, to highlight the consequences of the business relationship between the cosmeceuticals and dermatologists. Ultimately, the paper argues that because the marketing practices may confuse consumers about the nature of the cosmeceuticals they purchase, the FDA should regulate the industry.

²See Cosmeceuticals, Office of Cosmetics and Colors Fact Sheet U.S. Food and Drug Administration – Center for Food Safety and Applied Nutrition February 3, 1995; revised February 24, 2000) *available at* <http://www.cfsan.fda.gov/~dms/cos-217.html> (last visited April 30, 2005).

PART I.

A. Do You “Drugs” take “Cosmetics” to be your Lawfully Wedded Partner?: background on law regarding cosmeceuticals

Although the so-called cosmeceutical industry is booming, the FDA does not actually recognize the term cosmeceutical³ nor is there an official definition for the word. Instead, the cosmeceutical industry exists in a state of regulatory limbo: at times they are regulated as drugs, but most often they are regulated as cosmetics.⁴ And in the absence of an official definition, the industry is essentially free to massage and manipulate the definition as it pleases. Thus synonyms like “quasi-drugs,” “therapeutic cosmetics,” “cosmetic drugs,” “active skin treatment,”⁵ and “cosmetics with pharmaceutical benefits”⁶ abound in the marketing of cosmeceuticals.

The FDA has created new regulatory space for some of the latest “combination products” such as drug-devices and biologic-drugs -⁷ but it has not done so for cosmeceuticals. The agency instead regulates cosmeceuticals

³www.fda.gov.

⁴Many cosmeceuticals are created by cosmetics companies. See Carol Rados, Science Meets Beauty: Using Medicine to Improve Appearances, FDA Consumer Magazine (March-April 2004) *available at* http://www.fda.gov/fdac/features/2004/204_beauty.html (last visited May 5, 2005).

There are, however, cosmeceuticals that are created by pharmaceutical companies. The Dermagenetics line of “genetically customized” skin care products is an example. The fact that the parent company, GeneLink, Inc., is a genetic-biosciences company with a focus on biomedical projects and that Pharmaceutical companies and Hospitals are amongst its primary customers would suggest to most that this is more of a drug like product. However, as this specific line of “genetically customized” skin care products are solely being marketed as just that, skin care products, this product will likely be classified as cosmetic. For more information see Cosmeceuticals: Dermagenetics Launched at ISPA Convention, Biotech Business Week (December 20, 2004) (hereinafter Dermagenetics Article), see also, Corporate Profile, Gene Link, Inc., *available at* <http://www.genelink.com/newsite/corporate.asp> (last visited April 30, 2005).

⁵Santiago A. Centurion, MD, Cosmeceuticals (last updated February 4, 2004) *available at* <http://www.emedicine.com/derm/topic509.htm> (last visited April 30, 2005).

⁶Nora Caley, More Than Skin Deep; Company’s ‘Cosmeceuticals’ Aimed at High-End Market, Rocky Mountain News (April 19, 1998) (quoting Francine Porter, owner of Osmotics).

⁷Recognizing that technological advances are continuously merging the lines between therapeutic products FDA’s Office of Combination Products was created to regulate these “combination products.” But its jurisdiction only covers combinations of

through its traditional regulatory categories: either cosmetics, drugs, or a combination of both. If the status of a product is challenged, the agency will either determine if a product held out by a company as a cosmetic is “misbranded” or if it is in fact a drug.⁸

Drugs and cosmetics undergo very different regulatory treatments. Drugs are “(A) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . . and (B) articles (other than food) intended to affect the structure or any function of the body of man or other animals.”⁹ Before they are released to the market, they must undergo a burdensome, cost intensive regulatory process.¹⁰ In contrast, cosmetics, including “creams, lotions, powders and sprays; perfume; lipstick; [and] fingernail polish,”¹¹ are statutorily defined as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance.”¹² Unlike drugs, the FDA does not review or approve cosmetics before they reach consumers. In fact, cosmetics do not even have to be proven safe before they reach paying consumers.¹³ It is therefore less costly for cosmetics companies to market their cosmeceuticals products as cosmetics, rather than drugs, because they can avoid FDA oversight.

A cosmeceutical’s “intended use” – gleaned from the labeling, advertising, promotional materials – determines the regulatory fate of a cosmeceutical as a cosmetic or drug.¹⁴ The actual physical effect of the product

drug-device, biologic-device, drug-biologic, and drug-device-biologic. See 21 C.F.R. § 3.2(e). See also Overview of the Office of Combination Products *available at* <http://www.fda.gov/oc/combination/overview.html> (last visited April 30, 2005).

⁸See generally, See Byran A. Liang, It’s Only Skin Deep: FDA Regulation of Skin Care Cosmetics Claims, 8 Cornell J.L. & Pub. Pol’y 249, 252 (1999).

⁹21 U.S.C. § 321 (g)(1)

¹⁰See Robert Higgs, Hazardous to Our Health, 15 (The Independent Institute 1995) (a drug company must receive pre-market approval for claims made about the drug, it must demonstrate that the product is efficacious for all claimed indications, and it will be subject to clinical trial regulations).

¹¹Carol Rados, *supra* note 4.

¹²21 U.S.C. § 321 (i)

¹³Carol Rados, *supra* note 4.

¹⁴See Liang, *supra* note 8, at 252 (citing United States v. An Article . . . Consisting of 216 Individually Cartoned Bottles,

has no bearing on its intended use.¹⁵ Therefore, cosmeceuticals might indeed have skin altering properties, but so long as the manufacturers are careful in their advertising claims, they will not have to worry about FDA oversight.¹⁶

B. A Cosmetic By Any Other Name Would Smell... Fishy: a look at the misleading nature of the term “cosmeceutical”

It is the job of the FDA to “protect the unwary customer”¹⁷ against a company’s false and misleading claims. A company must consider how the “ignorant, the unthinking, and the credulous”¹⁸ consumers will understand the products’ claims. In fact, even if a product’s name impliedly (but falsely) claims that it is effective at achieving a specified outcome, may render it misbranded.¹⁹ In that light, when the industry appends “ceutical” (which deceptively implies that the FDA regulates the products in the same manner as pharmaceutical drugs) to refer to products that the FDA in actuality regards as mere cosmetics is a legally questionable practice.²⁰

In order to understand consumer perceptions of “cosmeceuticals”, I informally surveyed eleven college educated consumers about what they thought the term “cosmeceutical” meant. Their responses reveal that

More or Less, of an Article Labeled in Part: Sudden Change, 288 F.Supp. 29 (E.D.N.Y. 1968) (hereinafter referred to as “Sudden Change”).

¹⁵See *id.*

¹⁶See e.g. <http://www.cfsan.fda.gov/~dms/cos-217.html> (last visited April 30, 2005).

Donald P. Hensel, FDA Regulation and the New Anti-Aging Products, FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS, available at <http://leda.law.harvard.edu/leda/data/93/dhensel.pdf> (1995) (last visited March 23, 2005) (discussing how the caustic nature of Alpha Hydroxy Acids is overlooked by the FDA because the manufacturers to not make drug claims on the labeling).

¹⁷See Liang, *supra* note 8, at 252 – 253. (citing Sudden Change).

¹⁸See *id.*

¹⁹Peter Barton Hutt and Richard A. Merrill, Food and Drug Law: Case and Materials – Second Edition, (Foundation Press 1991), at 395 – 96 (citing United States v. 43½ Gross...” Xcello’s Prophylactics,” 65 F.Supp 534 (D.Minn. 1946)).

²⁰“Cosmeceutical,” which Dr. Perricone has registered with the Federal Government as his trademark, seems to be a deceptive name under this theory.

many consumers are unaware that the products are often times officially classified as simple “cosmetics.” The participants mistakenly defined cosmeceuticals a “medicated cosmetics,” “cosmetic prescription drugs,” and “cosmetics with drugs.”²¹ If the terminology misled these college educated consumers, it is highly likely that the average consumer, the “unthinking” consumer, *and* the “credulous” consumers are being similarly confused.²² In fact, in the past years cosmeceutical sales vastly outstripped sales of regular cosmetics products,²³ indicating that indeed consumers believe that they are purchasing significantly different than regular cosmetics. Because they often promote their products as “cosmetics,” many cosmeceutical companies avoid the strict regulatory requirements of “drugs,” while at the same time profiting from consumer perception that the products are indeed drugs or that they have some type of “pharmaceutical benefit.” Unfortunately for unsuspecting consumers, the regulators seem to overlook the fact that the term cosmeceutical in and of itself is a misleading term that should be cause for regulatory concern. In the absence of federal guidelines, consumers are forced to rely on outside sources to guide their product purchases. . .

C. Is there a Dermatologist in the House?: a look at the misleading nature of dermatologist promotions

Dermatologist recommendations are the *Consumer’s Digest* of the beauty industry. The same reasons that we hold doctor recommendations in such high esteem are the very reasons that regulators should be wary

²¹Though some respondents did not extract the medical reference from the term, they did nonetheless ascribe some elevated status to the word as they thought it might mean “able to teach cosmetics,” or the “study of cosmetics.” The remaining responses were: “getting people to focus in on the medical side of cosmetics” and simply “cosmetics in the pharmacy.” Not one person said simply “cosmetics.”

²²Jacqueline A. Greff, Regulation of Cosmetics that are also Drugs, 51 Food & Drug L.J. 243 (1996).

²³See Sally Beatty, New Wrinkle – Hot at the Mall: Skin-Care Products from Physicians; Cosmeceutical Creams Tap Antiaging Market; Questions About Claims; Dr. Perricone TV Specials, *The Wall Street Journal*, A.1 (Nov. 14, 2003) (stating that “[s]ales of dermatologist and so-called clinical brands have exploded in the last year, becoming the fastest-growing segment of the department store skin-care business. While total skin-care sales in department stores grew just 2.6% in 2002, sales of dermatologist and clinical brands jumped 62% in the same period. . .”).

of an industry that uses doctors to promote cosmetics for profit. In fact, in other areas, doctors can be held legally liable for referring patients to facilities in which they have a financial stake.²⁴ Cosmeceutical customers are denied the same protections. Nevertheless, it is difficult for consumers to assess the claims of products and therefore they must rely on experts to guide their decisions.²⁵ Because the FDA insufficiently regulates these glorified cosmetics, from the consumers' perspective, these expert recommendations serve as a proxy for federal regulatory filters.

Recently, recognizing the large profits to be extracted from the rapidly growing market, a number of large cosmeceutical companies have rushed to incorporate the medically-trained into their entourage of salespersons.²⁶ A growing sect of dermatologists is bringing the industry, their own books, their products, and their own image to celebrity status.²⁷ Doctors such as Dr. Murad²⁸ and Dr. Perricone are paraded before consumers to emphasize the "ceutical" nature of products that are in actuality considered by the FDA as nothing more than cosmetics. Thus, in addition to the misleading moniker, the FDA should be more concerned with cosmeceuticals because they are being promoted by doctors whose presence could further act to confuse consumers.

In order to protect consumers, the FDA imposes strict regulations on the relationship between pharmaceutical companies, doctors, and the information exchanged between the two.²⁹ There is no such proscription on the

²⁴See generally, Sam A. Mackie, J.D., Liability of a Physician for Improper Referral of Patients to a Medical Care-Facility in Which the Physician Has a Financial Interest, 61 Am. Jur. Proof of Facts 3d 245 (2004).

²⁵Rados, Science *supra* note 4.

²⁶Beatty, *supra* note 23 (noting that L'Oreal jumped on growing trend of hiring dermatologists and "hired Dr. Tina S. Alster, who frequently give skin-care advice on daytime talk shows, as a dermatological consultant to help with product development and *department-store appearances* [emphasis added]).

²⁷Doctors such as Dr. Howard Murad, Dr. Fredric Brandt, and Dr. Nicholas Perricone. See Beatty, *supra* note 23. Dr. Perricone will be discussed in more detail, *infra* page 9.

²⁸For more information on Dr. Murad see <http://www.murad.com/>.

²⁹See Hutt, *supra* note 19, at 458 (discussing FDA's restrictions against pharmaceutical companies that in essence bribe doctors with gifts and other promotionals in order to get the doctors to recommend their products to patients).

relationship between cosmetics companies and doctors. These companies have significantly more leeway in recruiting doctors to promote their products. Of course medical professionals are prohibited from engaging in false, fraudulent, deceptive, or misleading advertising, and advertising that would lower or demoralize professional standards,³⁰ but beyond that there are no specific ethical standards to which they are bound that directly address the promotion of products and services.³¹ Thus, these doctors have tremendous latitude with respect to their marketing practices. A large part of the problem is that FDA does not have jurisdiction over the medical profession,³² instead it is a task left to the whims of state legislatures³³ – and even state standards may be too vague to effectively regulate doctors’ advertising practices.³⁴ When consumers are running to the cosmeceuticals counters in droves based solely on the assurances of these trained professionals, the FDA should be concerned. To be sure, many medical professions may hesitate to use their status to promote products for a profit.

One should not underestimate the trust that beauty consumers, and the general public more generally place in medical professionals. Indeed, doctors are legally regarded as “learned intermediaries”³⁵ who are liable for ramifications of their advice and opinions given regarding risks and benefits of products. In some sense, we trust their professional expertise and good judgment to be the final word on the products that they recommend.³⁶ Unfortunately for unsuspecting consumers, (and quite *fortune*-ately for the cosmeceutical

³⁰Laura Hunter Dietz, J.D., *et al*, Advertising and Soliciting, 61 Am. Jur. 2d Physicians, Surgeons, and Other Healers §13 (updated 2004).

³¹See MORE <http://www.ama-assn.org/ama/pub/category/2512.html>. In contrast, the legal profession has sketched out ethics standards that directly speak to the propriety of attorney advertising.

³²See Peggy Chen, Education or Promotion? Industry-Sponsored Continuing Education (CME) as a Center For the Core/Commercial Speech Debate, 58 Food & Drug L.J. 473, 473 (2003) (citing 21 U.S.C. §396 (2000) which states that the Food, Drug, and Cosmetic Act (FDCA) “[shall not] be construed to limit or interfere with the authority of a healthcare practitioner to prescribe or administer any legally marketed device to a patient for any condition of disease within a legitimate healthcare practitioner - patient relationship.”) Instead, the medical profession is regulated by the states,

³³See generally Dietz, *supra* note 30.

³⁴See e.g. *Amsel v. Brooks*, 141 Conn. 288 (1954) (holding that state’s definition of “advertise” in the context of denture sales through a licensed dentist was unconstitutional as it had no reasonable relation to public welfare).

³⁵Kimberly Castelaz, J.D. *et al*, Learned-Intermediary Doctrine; Products Provided by Physicians, 63A Am. Jur. 2d Products Liability §1200.

³⁶*Id.*

companies and doctors), learned-intermediary doctrine is likely inapplicable to physicians who promote cosmeceuticals because these products are not prescription products.³⁷ This is so despite the evidence that consumers regard the products as something akin to “cosmetic prescription drugs,” *supra* page 6.

PART II

A. Enter Dr. Nicolas Perricone – The Celebrity Dermatologist

He can make you beautiful in twenty-eight days! The cosmeceutical industry is being rocketed to a new level of fame by the promotion of Yale Medical School professor and New York Times best seller, Dr. Nicholas Perricone.³⁸ Coined the “celebrity dermatologist,”³⁹ Dr. Perricone has made his indelible mark on the cosmeceuticals field. One need only conduct a cursory study of Dr. Perricone’s career and empire to understand the distorting effect that a dermatologists recommendation can have on the sale of cosmetics products. Advising consumers about the links between beauty, neurology, and health, he has a series of New York Times Bestselling books.⁴⁰ And his celebrity status is not limited to the reading public; Dr. Perricone lectures about his theory television stations around the country.⁴¹ Indeed, in the five years since his media debut, sales of his products reached the millions. Because he is considered the “father of cosmeceuticals”⁴² this paper will

³⁷See *id.* (noting that “the learned-intermediary doctrine does not apply to nonprescription products give to a patient by a physician, since it would be illogical to treat a plaintiff differently based on the mere fortuity of attaining the product from his or her physician”).

³⁸See <http://www.drperricone.com/drnvperricone.htm> (last visited April 30, 2005).

³⁹Joel Lang, The Perricone Formula: To Become a Cosmetics King, You Can’t Let Anybody Get Under Your Skin, Hartford Courant (March 6, 2005).

⁴⁰See Liang, *supra* note 8.

⁴¹See *id.*

⁴²<http://www.nvperriconemd.com/> (hereinafter referred to as “Perricone Online”) (“The Science” link, “Drug and Cosmetic Industry” link) (last visited May 5, 2005). Interestingly enough, cosmeceuticals were in existence long before Perricone’s rise to fame. Products first arrived on the scene more than 22 years ago, when vitamin A was added to creams to help fight wrinkles. See Daniela Lamas, Cosmeceutical Controversy; Dermatologists walk a fine line with skin-care product endorsements, The Houston Chronical, p. 14 (October 8, 2003).

focus on Dr. Perricone as a case study of the problems incumbent when doctors and profit motives are mixed.

1.

Dr. Perricone - The Doctor

Most consumers would be impressed with the credentials of this “learned intermediary” and likely will make purchases based on his recommendations – a reality that the FDA should be concerned about. The doctor started his medical career in the halls of Michigan State University College of Human Medicine (where he graduated in three years) and Yale University School of Medicine.⁴³ Impressive, extensive, and available to consumers worldwide, his online biography acts to legitimize and bolster any claims that he makes about skin care products:

Dr. Perricone is an Adjunct Professor of Medicine at the Michigan State University’s College of Human Medicine. He is certified by the American Board of Dermatology, is a Fellow of the New York Academy of Sciences, and a Fellow of the American College of Nutrition. He is also a Fellow of the American Academy of Dermatology and the Society of Investigative Dermatology. Dr. Perricone has served as Assistant Clinical Professor of Dermatology at Yale School of Medicine and as Chief of Dermatology at the state of Connecticut’s Veterans Hospital.

Dr. Perricone is the recipient of the Eli Whitney Award, presented by The Connecticut Intellectual Property Law Association to an outstanding individual who has made significant contributions to science, invention, and technology. Prior recipients include National Medal of Science beneficiary, Igor Sikorsky, (founder of Sikorsky aircraft) inventor of the first practical helicopter, which established the bedrock upon which today’s helicopter industry rests, and Buckminster Fuller, inventor of the geodesic dome—the lightest, strongest, and most cost-effective structure ever devised. Dr. Perricone is also the recipient of the American College for Advancement in Medicine (ACAM) 2000 Norman E Clark, Sr. Lecture Award for his, “dedication and contributions towards advancing Complementary and Alternative Medicine.”

⁴³See Liang, *supra* note 8.

It was during this time of receiving medical training that he developed his theory that “chronic inflammation underlays symptoms of aging.” Dr. Perricone’s theory, despite medical skepticism, *infra* next paragraph, now stands as heart of his success because it is the driving force of his cosmeceuticals skin care line and books. According to the doctor, inflammation is caused by stress, dehydration, sun, sugar, and high-glycaemic carbohydrates.

But it would take a bit more research for his trusting clientele to learn about the various criticisms that have been lodged against the celebrity dermatologist by his professional peers. Because he has not published studies in peer-reviewed journals proving that the main ingredients in his products indeed erase wrinkles, it is doubtful that “he has been able to convincingly prove efficacy of his products.”⁴⁴ Instead, his peers charge that his claims are contrary to scientific research in the area and that the claims are only based on his own anecdotes.⁴⁵ Moreover, although he touts his affiliation with Yale Medical School, his website does not disclose that in 2002 Yale allowed Dr. Perricone’s appointment to expire because of the aforementioned criticism in regards to his anti-inflammatory theories.⁴⁶

B. Dr. Perricone – The Empire

Dr. Perricone’s theories are founded on shaky science. Yet and still Dr. Perricone has managed to amass a large industry and consumer following.⁴⁷ His name is ubiquitous as his products are retailed through national chains such as Nordstrom and Sephora. Moreover, the “Perricone” name reaches worldwide purchasers

⁴⁴Beatty, *supra* note 23 (quoting Dr. Leslie Baumann, director of cosmetic dermatology at the University of Miami, who conducts clinical trials for the cosmetics and pharmaceutical industry).

⁴⁵Krum, *supra* NOTE x. But see George W. Evans and Arnold I. Friede, The Food and Drug Administration’s Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis, 58 Food & Drug L.J. 365, 383 - 86 (arguing that courts do not necessarily regard claims made in light of competing scientific claims to be “inherently misleading”).

⁴⁶Beatty, *supra* note 8.

⁴⁷*Id.*

through his online website.⁴⁸ He even has connections with big pharmaceutical companies. Though it seems as if he meant to keep his link to pharmaceutical giant Johnson & Johnson a secret,⁴⁹ the celebrity physician is paid millions by the company to license his products.

C. Dr. Perricone - The Products

The fact that Perricone products are intentionally encased in the medicinal-looking brown jars and bottles with scientific naming, and fact that they are priced at pharmaceutical like prices contribute to a sense that these products are more than beauty products. And yet the FDA regulates these products in the same manner that they would regulate a tube of lipstick.

C.

The Perricone Skin Care Line

Make no mistake; consumers' economic interests are a stake when they purchase Perricone products. A 2-ounce vial of *Alpha Lipoic Acid Face Firming Activator with NTP Complex and DMAE* costs consumers \$95;⁵⁰ \$120 is the price tag on the Perricone *Face Lipid Replenishment*;⁵¹ and for his *Neuropeptide Facial Conformer*, consumers are charged a whopping \$570 for 2 ounces. But even his lower priced products are

⁴⁸<http://www.nvperriconemd.com/> (hereinafter referred to as "Perricone Online").

⁴⁹See Liang, *supra* note 8 (stating that "a confidentiality agreement prevented [Dr. Perricone] from naming [the large company] paying him \$150 million per year to license= his DMAE formulations").

⁵⁰Available at Perricone Online, *supra* note 42 (last visited May 6, 2005).

⁵¹*Id.*

exorbitant: *Moist Lips* and *Lip Plumper* – products akin to Chapstick-run between \$18 and \$33.⁵²

D. The Nutritional Supplements

In addition to the topical products, the Perricone arsenal also includes nutritional supplements. According to his website “N.V. Perricone Nutraceuticals® [are] Nutritional supplements that work on the cellular level, from the inside out, to help you achieve and maintain a more youthful, healthy look.” For instance, Polysaccharide Peptide Blend” described as “a daily part of the Perricone Program [that provides the body with] alpha-glucans, which help increase the energy in our cells and help the skin repair, renew, and revitalize itself” are set at \$60 per month. His Benfotiamine Capsules will cost a consumer \$40 per month. And the month long “Weight Management Program” – a cornucopia of nutritional supplements – is sold for \$195.⁵³

There is no denying Dr. Perricone’s connection to his product line. He “personally formulates every product” that he promotes.⁵⁴ This artificially exaggerates the drug-like mystique of his skin care line. Moreover, he also carries a higher potency professional line only distributed to “qualified, licensed physicians, and to medical spas with a qualified physician on staff.”⁵⁵ Since they are only distributed *to* these qualified professionals, then much like filters on prescription drugs, they are presumably only available to the general public *through* the same professionals. Based on all of this it is almost certain that the “ignorant, the unthinking, and the

⁵²For a jocular insight on Perricone product pricing see Jeannie Kever, Paying a price by the Gallon, The Houston Chronicle (April 29, 2004) (stating “the next time you’re filling up your SUV, be glad it doesn’t run on Dr. Perricone’s Neuropeptide Facial Conformer. Twenty gallons of his wrinkle-fighting cream would set you back \$729,600”).

⁵³Available at Perricone Online, *supra* note 42.

⁵⁴*Id.*

⁵⁵See <http://www.drperricone.com/professional.htm> (last visited April 30, 2005).

credulous”⁵⁶ consumers would be confused as to the nature of the Perricone products.

Dr. Perricone – The Books

E. The Labeling

Although the claims on the products’ packaging are relatively “mild,”⁵⁷ the Wall Street Journal noted that in contrast, Perricone’s books make claims that seem quite “fantastic.”⁵⁸ Indeed, in one of his book Perricone himself admits that his claims may seem “pretty lofty” he assures skeptical consumers that his claims “will make perfect sense” once they understand how his program works.⁵⁹ One can reasonably assume that the manufacturers differentiated the product claims and the book claims so that they and the M.D. could avoid the FDA’s drug regulations. Effectively, Dr. Perricone, much like many other cosmeceutical entrepreneurs is having is cake and eating it too – (or in this case having his cosmetics and selling it too): The claims on the labels that are directly affixed to his products are diluted.⁶⁰ All of the real drug claims are made in his books (and television promotionals) – a strategy which diverts FDA attention but still entices consumers to purchase his products which they likely think have drug like effects. But Perricone’s bifurcated marketing strategy seems to overlook that the FDA might very well consider the books themselves product “labeling” whose “fantastic” claims might in fact elevate the skin care line from mere “cosmetics” to more heavily regulated drugs.

⁵⁶See Liang, *supra* note 8, at 252 – 253 (citing Sudden Change).

⁵⁷For instance his *Eye Area Therapy System* only states, in relevant part: “This unique eye care combination provides you with the patented, powerful benefits of Vitamin C Ester, Alpha Lipoic Acid, and DMAE. Vitamin C Ester Eye Area Therapy cares for the delicate eye area, minimizing the appearance of fine lines and revitalizing stressed skin.

Alpha Lipoic Acid Eye Area Therapy provides energy to the skin, relieving the appearance of puffiness and dark circles.”

⁵⁸Beatty, *supra* note 23.

⁵⁹THE PERRICONE PRESCRIPTION: A PHYSICIAN’S 28-DAY PROGRAM FOR TOTAL BODY AND REJUVENATION, HarperResource at xi (2002) (hereinafter referred to as “Perricone Prescription”).

⁶⁰Of course, as argued in this paper, packaging, the pricing, the term “cosmeceutical,” and the doctor himself, should be enough to mislead consumers. But FDA, however, has not ruled as such.

As stated in the beginning of the paper, a product’s status as a drug or a cosmetic is determined by its “intended use,” which can be assessed through its labeling.⁶¹ Under the law of the Food, Drug, and Cosmetics Act, labeling includes, *inter alia*, “all labels and other written, printed, or graphic matter . . . accompanying [an] article.”⁶² Furthermore, the Supreme Court ruled that labeling is broader than the labels that are on or in the article or package that is transported⁶³ – labeling includes freestanding books.⁶⁴ Rather than a physical connectedness, the textual relationship between the product and the literature seems most important in determining whether a book is labeling a product.

There are several cases that provide guidance about what constitutes product labeling. *U.S. v. 250 Jars “Cal’s Tupelo Blossom U.S. Fancy Pure Honey”*⁶⁵ involved allegations of misbranded honey. A retail store owner placed for sale on a shelf, jars of honey and copies of an independently authored literature about honey.⁶⁶ The court found that despite being sold separately, the literature and honey were interdependent and part of an integrated distribution program.⁶⁷ Then, invoking the imagery of the “unwary customer” the court rejected the notion that the literature was not labeling simply because it referred to honey in the generic sense, rather than to the specific honey that was being sold.⁶⁸ From this case one can infer that literature sold by the author that specifically refers to products sold by the author will be particularly suspicious as product labeling.

⁶¹In general, however, “intended use” can be appraised from statements made by the company in any form or forum, *see* Hutt and Merrile, *supra* note 19, at 386 (noting that the agency has relied on statements that a company has made in submissions to the SEC).

⁶²21 U.S.C. § 321.

⁶³*See Kordel v. United States*, 335 U.S. 345, 350 (1948).

⁶⁴*See e.g., see* U.S. Undetermined Quantities of Articles of Drug, 145 F.Supp2d 692 (D.Md.S.Div. 2001) (holding that “any printed material, including books and pamphlets, which refers to or explains the usefulness of a drug product and which is used, *in any way, in its sale*, accompanies the article in the statutory sense and constitutes “labeling,” for the purposes of determining whether drug is misbranded. . .”).

⁶⁵344 F.2d 288 (C.A.Mich. 1965).

⁶⁶*U.S. v. 250 Jars Cal’s Tupelo Blossom U.S. Fancy Pure Honey*, 344 F.2d 288, 289 (6th Cir. 1965).

⁶⁷*U.S. v. 250 Jars, etc.*, 218 F.Supp. 208, 211-212 (D.C.Mich. 1963)

⁶⁸*U.S. v. 250 Jars, etc. of U.S. Fancy Pure Honey*, 218 F.Supp. 208 at 212. (the appeals court integrated, by reference, this lower court opinion into its final opinion).

Of course there are limits. The court in *U.S. v. 24 Bottles* ““Sterling Vinegar and Honey Aged in Wood Cider Blended With Finest Honey Contents 1 Pint Product of Sterling Cider Co., Inc., Sterling, Mass””⁶⁹ was faced with the question of whether books displayed in the same shop as an article “accompanied” the article. The court made clear that “labeling does not include every writing which bears some relation to the product;”⁷⁰ but rather “[t]he distinguishing characteristic of a label is that, in some manner or another, it is presented to the customer in immediate connection with his view and his purchase of the product.”⁷¹ The court did, however, intimate that books promoted in an “integrated transaction” with products may constitute labeling for the products.⁷² In effect, it is the “textual relationship” between product and book is a significant consideration.⁷³

Based on these cases, and even though his books are not necessarily in “immediate connection” with a purchaser’s view and purchase of his products,⁷⁴ Dr. Perricone’s products and books should still be of particular concern to the FDA based on these earlier cases. Indeed there is a textual relationship between the product and books that make them seem as if they are part of an integrated transaction. Moreover, because Dr. Perricone is both the author of his books and the creator of his products there is a stronger relationship between these items than there were in the other cases where the books were created independent of the products. And even more incriminatingly, the Perricone books actually direct consumers to his products.⁷⁵ The points argued above couple with the courts’ inclination to protect unsuspecting consumers against sellers’ exploitation of loopholes,⁷⁶ strongly suggests that the doctor’s bestselling series are part of the labeling for

⁶⁹338 F.2d 157 (C.A.N.Y. 1964).

⁷⁰*Id.* at 158.

⁷¹*Id.* at 159.

⁷²*U.S. v. 24 Bottles Sterling Vinegar and Honey Aged in Wood Cider Blended With Finest Honey Contents 1 Pint Product of Sterling Cider Co., Inc., Sterling, Mass.* 338 F.2d 157, 159 (C.A.N.Y. 1964).

⁷³*U.S. v. Diapulse Mfg. Corp. of America* 389 F.2d 612, *616 (C.A.Conn. 1968).

⁷⁴Though it might be argued that the online products which are sold on the same site as his books are indeed sold in the “immediate connection” of one another.

⁷⁵PAGES in PRESCRIPTION.

⁷⁶See e.g. *U.S. v. 250 Jars Cal’s Tupelo Blossom U.S. Fancy Pure Honey* 344 F.2d 288, *289 (C.A.Mich. 1965)

his skin care line.

F. The Drug Claims

Based on the legal definition of “drugs claims” there is almost no question that Dr. Perricone’s books assert very strong drug claims. Generally claims that a product has physiological effects will be suspect as drug claims.⁷⁷ Among the claims that have rendered products drugs are that use “scientific buzzwords” [such as] ‘biologically aseptic’ while being made in a ‘pharmaceutical laboratory’ and claims that the product provides a “face lift without surgery.”⁷⁸ Even claims that would seem to most as obvious exaggerations, for instance that a commonplace household cooking sweetener honey is a “panacea for various diseases and ailments” have been held by the courts to be problematic.⁷⁹ “Less exaggerated” claims, however, will not promote a product from a cosmetic to a drug.⁸⁰

The genealogy of the title of Perricone’s first book reveals that despite his cosmetics claims, the Perricone philosophy and product line are truly intended to fit into the medical realm. Dr. Perricone intended his first book for other medical professionals and accordingly, he originally entitled his first book “Antioxidants as Natural Anti-Inflammatories for Improvement of Cellular Function.” Though the substance of the book remained untouched, his publishers later renamed it to its current more pop-friendly, consumer-enticing title, The Wrinkle Cure.⁸¹ In The Wrinkle Cure Dr. Perricone enlightens readers as the causes of certain dermatological problems, and then recommends a program of topical solutions and foods that can help

⁷⁷Liang, *supra* note 8, at 253.

⁷⁸*Id.* (quoting *United States v. An Article... Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled in Part:: Sudden Change*, 288 F.Supp. 29 (E.D.N.Y. 1968)).

⁷⁹*U.S. v. 250 Jars Cal’s Tupelo Blossom U.S. Fancy Pure Honey*, 344 F.2d 288, 289 (6th Cir. 1965).

⁸⁰*United States v. An Article of Drug... 47 Shipping Cartons, More or Less, ... “Helen Curtis Magic Secret,”* 331 F.Supp. 912 (D.Md. 1971).

⁸¹See Liang, *supra* note 8.

alleviate those problems.⁸²

Beyond the “Cure” promised in the title of his first book, the title of his next Bestseller, The Perricone Prescription,⁸³ further establishes the pharmaceutical nature of his empire. In this bestseller, Dr. Perricone emphasized how changes in eating habits can effect dramatic changes in physical appearance and well-being. Accordingly, he prescribes a specific program to reduce the cellular inflammation that he claims is related to skin aging and other degenerative *diseases*.⁸⁴ From these two books alone, it is clear that Dr. Perricone intends his products as “prescriptions” to “cure” what his theory describes as the “degenerative disease” of inflammation and aging.

In his most recent bestselling book, The Perricone Promise,⁸⁵ Dr. Perricone continues breaking down his theory to his audience of beauty-hungry consumers.⁸⁶ In this book, the doctor reveals a “groundbreaking program that helps reverse the aging process – inside and out. . . . Dr. Perricone’s revolutionary program utilizes the biggest breakthrough in anti-aging medicine in years, protein-like substances called peptides and neuropeptides. These powerful compounds revitalize skin and hair, promote heart health, help decrease the risk of certain forms of cancer, strengthen the immune system. . . .”⁸⁷ Thusly, even though the claims on the labels physically affixed to the skin care products are mild, the claims on made in the Perricone books – books that consumers are likely to readily associate with his skin care product line, should concern the FDA.

The Perricone website provides even more fuel for the argument that Perricone products are intended as

⁸²See generally Nicholas Perricone, M.D., The Wrinkle Cure, Warner Books (2000).

⁸³THE PERRICONE PRESCRIPTION, *supra* note 58.

⁸⁴*Id.*

⁸⁵Nicholas Perricone, M.D., THE PERRICONE PROMISE : Look Younger, Live Longer in Three Easy Steps, Warner Books (2004) (hereinafter referred to as “Perricone Promise”)

⁸⁶Consumers such as myself.

⁸⁷Perricone Promise, *supra* note 84, at front cover flap.

drugs.⁸⁸ On one page consumers can “Consult [the] Doctor” through a chart that prescribes various items in his skin care line to remedy various ailments (such as “dry, dehydrate” skin and “loss of tone, sagging”).⁸⁹

In contrast to the “less exaggerated” claims that past muster in the courts, Dr. Perricone’s assertions have been described by him and others as “fantastic” and “lofty.” Moreover, if the court were concerned that claims that a well-known, household grocery item would confuse consumers to actually believing that it could cure various diseases and ailments then they would be even more concerned about the less-familiar Perricone cosmeceuticals promoted in literature by a famous, well established physician who indeed offers his products as an alternative to surgery that will cure degenerative diseases. Perricone cosmeceuticals are drugs and should be regulated as such.

G. A Drug in Cosmetic’s Clothing

In light of the totality of circumstances – the clinical packaging, the clinical monikers, the appendage “ceutical,” the “Cure,” the “Prescription,” the drug-like pricing, the association with and endorsement by a renowned Yale Medical School dermatologist, – it would be a wonder if consumers realized that they were purchasing products that have in actuality been regarded by the FDA as nothing more than cosmetics – akin to a tube of lipstick or a bottle of nail polish.

Moreover, if his products are indeed drugs, Dr. Perricone might be forced to prove the efficacy of his claims under the FDA’s new drug approval process.⁹⁰ Seeing as he has not published in any peer-reviewed journals

⁸⁸Please note that the status of websites as labeling or advertising is unresolved. See Evans and Friede, *supra* note 45 at 373. See *id.* at 378 -80, for an argument that websites are akin to labeling and therefore should be regulated by the FDA.

⁸⁹See <http://www.drperricone.com/consultthedoctor.htm> (last visited April 30, 2005).

⁹⁰Evans and Friede, *supra* note 45, at 375.

and the veracity of his claims as been strongly questioned within the medical field a drug designation might shatter his empire.

H. Dr. Perricone – The Defenses

Admittedly, the case that Perricone products are drugs might not be as clear-cut as implied in the sections above. First, the disclaimers in his books and online might negate the drug-like nature of the claims in these publications. Second, the First Amendment might protect his books and claims from regulatory scrutiny. Finally, the public may actually benefit from the information that he disseminates in his books and online publications.

I. Disclaimers

The point may seem obvious, but the presence of a disclaimer, might make it more difficult to place these Perricone products in the “drug” box. One such disclaimer reads: “This book is written as a source of information only. The information contained in this book should by no means be considered a substitute for the advice of a qualified medical professional, who should always be consulted before beginning any new diet, exercise or other health program. . . The author and the publisher expressly disclaim responsibility for any adverse effects arising from the use or application of the information contained herein. . .” Online, his disclaimer states that “[t]hese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”⁹¹ However, this defense might prove weak under the shadow of *Pasadena Research Laboratories v. U.S.*, where the court condemned

⁹¹Perricone Online, *supra* note 42.

disclaimers as “scientific double-talk.”⁹²

J. First Amendment Rights

Though for the sake of regulation and consumer protection the books should be considered labeling as argued above, Dr. Perricone and his books might still arguably be protected by the First Amendment right to freedom of speech. The world of first amendment protected speech can be divided into three general categories: 1) low level protection of commercial speech;⁹³ 2) high level protection of non-commercial speech and 3) non-protection of fighting words, obscenity, threats, etc. Perricone’s books are clearly not “fighting words;” therefore they will likely be subject to *some* sort of protection. The question is how much?

In assessing commerciality, courts will determine whether “1) the speech at issue is conceded to be an advertisement; 2) the speech refers to a particular product; and 3) the speaker has an economic motive.”⁹⁴ If Perricone’s books were actually labels that were physically affixed to the products in his skin care line, one could be comfortable arguing that they were commercial speech as they were attached to products that were being sold commercially. But the idea that these books are “labeling” as we commonly understand the term is merely the magic of the FDA’s broad regulatory definitions. Perricone’s books are, in actuality, freestanding publications; and it is a longstanding practice that the First Amendment protects published materials.⁹⁵ In that sense, it might seem obvious that the bestsellers are protected speech that should be exempt from regulatory oversight.

⁹²169 F.2d. 375, 383 (9th Cir. 1948).

⁹³See *Commercial Advertising and Virginia State Bd. of Pharm. v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976) (overruling an earlier decision that exempted commercial speech from the protection of the First Amendment, the Supreme Court here held that commercial speech is low value speech that receives First Amendment protection).

⁹⁴Evans and Friede, *supra* note 5, at 383.

⁹⁵See *Chneck v. U.S.*, 249 U.S. 47 (1919) (holding that published materials are protected under the First Amendment as long as they present no clear and present danger to the public).

The status of the books, however, seems more unclear than not, especially in light of recent Supreme Court cases grappling with the difficult question of the intersection between commercial speech, non-commercial speech, and issues of public importance.⁹⁶ Similarly here there are two strong competing interests: First the FDA broad mandate to protect consumers against rogue cosmetics (and their infirmed labels) and second, the constitutional guarantee of the right to free speech. Ultimately, Dr. Perricone’s best line of defense against the FDA’s duty to protect consumers might be to argue that his books are protected speech because they are traditional publications rather than mere commercial speech since he does not refer to them as advertisements and makes no reference to any *particular* products in his product line.⁹⁷

K.

Public Good

One final policy argument aid Dr. Perricone’s defense. Even if his products are in fact drugs, they should not receive the burdensome drug regulation because there are arguable benefits to his “direct to consumer”

⁹⁶See *Nike v. Kasky*, 539 U.S. 654 (2003) (presents what was at the time a novel First Amendment questions because the speech at issue represented a blending of commercial speech, noncommercial speech, and debate on an issue of public importance. Commercial enterprise Nike was accused of abusive labor practices which it responded to in various newspapers and publications.).

⁹⁷Although Perricone does make passing reference to his own products, his books do not specifically relate to his products. Instead the books detail a holistic nutrition and cosmetic regime that works “synergistically” with his products. In the text of the books there are no direct mentions of specific products of in his product line. He does however provide the addresses of online websites where consumers can purchase cosmeceuticals that would generally fit into the regimen that he advocates. The sticky issue is that even though he seems to be directing readers to an array of other online cosmeceutical products, in fact for all of the sites that consumers are directed to only sell his line of products. So, *de facto*, his books refer to his particular products.

In another twist, at the back of the Perricone Promise is a special promotional where the doctor directs consumers to his website to purchase a certain amount of his products in order to receive two of his eye therapy products for free. It is not clear where this type of product placement would fall in the realm of commercial speech jurisprudence.

advertising approach. It is an argument that is broadly applicable to more than just Dr. Perricone's products. As the argument goes, disseminating information empowers consumers to make decisions about their healthcare and their health care regimes, especially when they might have more information about their conditions than do doctors. He could in fact argue that direct to consumer information is vital for the vitality of our American consumership.⁹⁸

Conclusion

As they have done with the pharmaceutical industry,⁹⁹ the FDA may have to expand its jurisdiction to check the practices of these physicians that consumers – the consumers that the FDA is charged with protecting – are relying on to guide their cosmetic purchasing choices. Or perhaps it is just a matter of creating a new regulatory category that would provide clear guidance to cosmeceuticals companies about exactly how to and to cosmeceuticals purchasers about what they can expect from the products. No matter the strategy that the FDA ultimately employs, it is clear that the cosmetics industry's parading of dermatologists to sell their products to credulous consumers should be a matter of concern for us all.

⁹⁸For the counter to this argument see Jeffrey P. Kahn, Ph.D., M.P.H, The Double-Edged Sword of Drug Marketing, Ethics Matters (August 9, 1999) *available at* <http://www.cnn.com/HEALTH/bioethics/9908/drug.marketing/> (last visited May 8, 2005) (arguing that even though there is value in drug advertising the downsides include a proliferation of false or misleading information, and an upheaval of the traditional doctor-patient relationship).

⁹⁹See Chen, *supra* note 32, at 473 – 74.