

**REMOVING THE WRINKLE IN COSMETICS
AND DRUG REGULATION: A NOTICE
RATING SYSTEM AND EDUCATION
PROPOSAL FOR ANTI-AGING
COSMECEUTICALS**

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Anti-aging skincare products often make unrealistic anti-aging claims that mislead consumers, particularly older consumers. Because of the different premarket testing standards for cosmetics and drugs, companies often classify and market their anti-aging skincare products as cosmetics to the FDA in order to avoid more rigorous standards, yet simultaneously emphasize the drug-like qualities of the products to consumers, suggesting that these products are equivalent to drugs. The FDA allows these products, known as “cosmeceuticals,” to be classified as cosmetics despite their drug-like appearances and qualities, such as high-tech anti-aging skincare products that use nanotechnology, stem cell research, or DNA. The weakness of the present classification system in handling cosmeceuticals, which fall into the gray area between clearly defined cosmetics and drugs, creates unknown health risks and confuses and misleads consumers about the actual physiological effects of these products. To resolve these two problems, the Federal Food and Drug Administration need not extensively amend its regulations of the cosmetic and drug categories. Rather, the FDA should institute a notice system paired with consumer education, as well as more carefully regulate product claims.

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This Note is dedicated to the author’s mother and sister, “the two most beautiful women I know, with and without their cosmetics.”

I. Introduction

In 2005, Debra Scheufler, a forty-seven-year-old San Diego woman, filed a class action lawsuit against Estée Lauder and two department stores for false advertising in regards to anti-aging skincare cosmetics.¹ Scheufler had spent an estimated \$1000 on anti-aging skincare cosmetic products, including Estée Lauder's Crème de la Mer product, which retailed at \$120 per ounce at the time and was "touted by the website as a 'miracle' whose skin-enhancing ability 'defies the laws of nature.'"² "It didn't remove wrinkles or do anything to improve my skin," complained a disillusioned Scheufler, adding, "In fact, it clogged my pores and made my skin rougher."³ Scheufler is not alone in her confusion as an anti-aging skincare cosmetics consumer or in her decision to file suit against a cosmetics company over anti-aging skincare product claims.⁴

Hot on the heels of the increasing elderly population is the booming industry of anti-aging skincare products. One market research survey estimated sales of all skincare products in the United States racked up \$5.8 billion in 2006 alone, with \$7 billion projected by 2010.⁵ Among this growth, anti-aging skincare products lead the pack with double-digit growth rates and are hailed as "the fastest growing market segment across the globe."⁶ While baby boomers make up the core consumer market for anti-aging skincare products in the United

1. See NBC San Diego, *Woman Sues Estée Lauder for Not Making Her Look Younger*, NBCSANDIEGO.COM, Jan. 4, 2005 (on file with the Elder Law Journal at the University of Illinois); Sid Kirchheimer, *Scam Alert: Anti-Aging Snake Oil*, AARP BULL. TODAY, Nov. 2005, http://bulletin.aarp.org/yourmoney/scamalert/articles/scam_alert_anti-aging.html.

2. Kirchheimer, *supra* note 1.

3. *Id.*

4. See Simon Pitman, *Israel Lobby Group Files Class Action Against Cosmetic Players*, COSMETICSDSIGN.COM, June 20, 2007, <http://www.cosmeticsdesign.com/Products-Markets/Israel-lobby-group-files-class-action-against-cosmetics-players>.

5. Backchannelmedia, *Very Few Wrinkles in U.S. Skincare's Expected Growth to \$7 Billion by 2010!*, BACKCHANNELMEDIA, Jan. 3, 2007, <http://news.backchannelmedia.com/articles/7662/Very-Few-Wrinkles-in-US-Skincare-Expected-Growth-to-7-Billion-by-2010> [hereinafter *Very Few Wrinkles*].

6. Tom Branna, *Actives Speak Louder than Words*, HAPPY, June 13, 2006, <http://www.happy.com/articles/2006/06/actives-speak-louder-than-words> (comment made by Tom Goode, an executive from RITA Corporation). RITA provides chemical ingredients and research services to the cosmetics and personal care industries. See RITA CORP., GENERAL PRODUCT LISTING 1 (2006), available at http://www.ritacorp.com/files/Domestic_GPL.pdf.

States,⁷ this market is also expanding globally among aging populations in Japan and Western Europe.⁸

A trip to a department store or a browse through the Web sites of major cosmetics manufacturers reveals entire anti-aging skincare product lines.⁹ These cosmetics typically come with a price tag that is higher per volume than other cosmetic products by the same manufacturer.¹⁰ For example, Clinique's Repairwear Deep Wrinkle Concentrate for Face and Eye product can be purchased on Clinique's Web site for just over \$50 for one ounce.¹¹ In comparison to Clinique's other high-end special cosmetics, Super Defense Moisturizer, a lotion, and Redness Solutions, a cream to reduce rosacea, each retail around \$40 for 1.7 ounces, while Clinique's regular moisturizer, Dramatically Different Moisturizing Lotion, is \$11.50 for 1.7 ounces.¹² A sampling of other anti-aging products on the market include Estée Lauder's Perfectionist [CP+] product, advertised as a product to "dramatically reduce[] the appearance of lines, wrinkles and age spots."¹³ This "triumph over wrinkles" retails online for just over \$50 for one fluid ounce.¹⁴ Lancôme's High Resolution with Fibrelastine product, a self-proclaimed "intensive anti-wrinkle treatment," retails online at \$74 for

7. Natasha Singer, *Anti-Aging Makeup: Multitasker in a Jar*, N.Y. TIMES, Aug. 18, 2005, at G3.

8. See Branna, *supra* note 6.

9. Tex. Coop. Extension, Tex. A&M Univ. Sys., *Can Creams & Cosmetics Really Improve Aging Skin?*, in HEALTH HINTS 1, 1 (Janet M. Pollard & Carol A. Rice eds., 2005) [hereinafter *Creams & Cosmetics*].

10. See Clinique, Skin Care, Moisturizers, http://www.clinique.com/templates/products/multiproduct.tpl?category_id=category4918 (last visited Oct. 17, 2008) [hereinafter Clinique.com, Moisturizers].

11. Clinique, Repairwear Deep Wrinkle Concentrate for Face and Eyes, http://www.clinique.com/templates/products/sp_nonshaded.tpl?category_id=category4914&product_id=prod13047 (last visited Oct. 17, 2008).

12. Clinique.com, Moisturizers, *supra* note 10.

13. Estée Lauder, Perfectionist [CP+] with Poly-Collagen Peptides (on file with the Elder Law Journal at the University of Illinois).

14. See *id.* The Web site promotes the product as:

[y]our triumph over wrinkles. Not a single injection necessary. Estée Lauder Research boldly advances our most comprehensive anti-wrinkle treatment ever to prove just how far a skincare formula can go. The result? An anti-aging phenomenon with patent-pending triple enzyme technology and our exclusive Poly-Collagen Peptides. Perfectionist [CP+] "repairs" and corrects the look of lines, wrinkles and age spots faster than we ever have before.

Id.

1.7 fluid ounces.¹⁵ At Nordstrom's Web site, Yves Saint Laurent's "Age Expert" Age Defying Crème product, one ounce, can be purchased for \$88.¹⁶ Beyond the so-called prestige brands,¹⁷ local drug stores and supermarkets carry mass-market brands of anti-aging skincare products.¹⁸ Revlon has an Age Defying product line, including treatment, moisturizer, foundation, and concealer.¹⁹ Neutrogena offers an Anti-Oxidant Age Reverse product line including cleanser, lotion, eye cream, night cream, and serum.²⁰ Across the board in all price levels, anti-aging skincare products are widely available in the mass market.²¹

To meet the explosive demand for anti-aging skincare products, cosmetic companies are mixing new ingredients and new technology in a race to discover the secret to a youthful face.²² According to one source, the overall number of new cosmetic ingredients has more than doubled in the past twelve years.²³ Most new ingredients are referred

15. Lancôme, High Résolution with Fibrelastine, <http://www.lancome-usa.com/skincare/anti-aging/high-resolution-with-fibrelastine.htm> (last visited Oct. 17, 2008).

16. Nordstrom.com, Yves Saint Laurent "Age Expert" Age Defying Crème SPF 15, <http://shop.nordstrom.com/S/2822063> (last visited Oct. 17, 2008).

The cosmetic alternative to DHEA, Age Expert contains the ganoderic fraction—an exclusive active ingredient with a structure similar to the famous "hormone of youthfulness," capable of providing the epidermis with a reinvigorated look. It compensates for the signs of aging linked to hormonal imbalance, such as dull complexion, sagging skin and dehydration. Skin feels denser, softer and more radiant. The face looks visibly younger and is protected from environmental aggressions.

Id.

17. See Navin M. Geria, *Are High-Priced Cosmetics Really Worth the Price?*, HAPPI, Oct. 1, 2006, at 38 ("[P]restige brands include La Mer, Natura Bisse, Kanebo, La Prairie and ReVive."); *Creams & Cosmetics*, *supra* note 9, at 1.

18. See, e.g., Walgreens, Skin Care, <http://www.walgreens.com/beauty/skincare.jsp?CATID=304240> (last visited Oct. 17, 2008).

19. Revlon, Age Defying, <http://www.revlon.com/ProductCatalog/ProductLine.aspx?CollectionID=1> (last visited Oct. 17, 2008).

20. Neutrogena, Anti-Aging, <http://www.neutrogena.com/antiaging.asp?mainVal=antiaging&subVal=antiaging> (last visited Oct. 17, 2008).

21. See Tom Branna, *A New Era in Skin Care?*, HAPPI, Feb. 1, 2007, <http://www.happi.com/articles/2007/02/editors-page>. Procter & Gamble owns brands such as Olay, for mass market shoppers, and SK-II, for so-called prestige channels. See *id.*

22. See Vispi Kanga, *Novel Active Cosmetic Ingredient: Do Those Anti-Aging Cosmetics in Your Medicine Cabinet Do More Than Beautify the Skin?*, HAPPI, June 1, 2004, <http://www.happi.com/articles/2004/06/novel-active-cosmetic-ingredients>.

23. Branna, *supra* note 21 (stating that the number of cosmetic ingredients increased from 6200 in 1994 to 13,500 in 2006, a twelve-year span).

to by their scientific or chemical names, such as alpha-hydroxy acids (AHAs), beta-hydroxy acids, peptides, and retinoids.²⁴ Recent anti-aging skincare products also include some exotic natural ingredients, such as fermented sea kelp with specially cultivated algae, red arctic tocol cranberry, and “rare caviar extracts found only in the waters of the Caspian Sea from the roe of the beluga sturgeon during the natural birthing process.”²⁵ There is also “pietra,” created by a specific type of yeast, allegedly “accidentally discovered at a sake brewery when a monk noticed exceptional skin smoothness of a worker who had excessive wrinkles elsewhere on his body.”²⁶ New technologies applied to anti-aging skincare products include nanotechnology,²⁷ stem cell research,²⁸ and DNA technology.²⁹ The result of such an increase in ingredients with scientific names and new technology is a generation of cosmetics with an increasingly drug-like appearance and quality, often referred to as “cosmeceuticals.”³⁰ While cosmeceuticals may be any type of cosmetic, this Note will focus on anti-aging skincare cosmeceuticals.

Behind each new anti-aging skincare product is a truckload of anti-aging product claims. More than merely hiding wrinkles, diminishing age spots, and making skin appear firmer,³¹ products are now promising to prevent wrinkles and deliver “age-defying” results.³² One Estée Lauder advertisement for Re-Nutriv Ultimate Youth Crème suggests, “Imagine if you could postpone aging indefinitely.”³³ A Philosophy-brand face cream for preventing wrinkles is even named “Hope in a Jar.”³⁴ These marketing phrases and product claims suc-

24. Harvard Health Publ., *Skin Care and Repair*, AARP.ORG, Apr. 6, 2007, http://www.aarp.org/health/conditions/articles/harvard_skin-care-and-repair_0.html [hereinafter *Skin Care and Repair*].

25. See Geria, *supra* note 17, at 38.

26. See *id.*

27. See Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 706 (2006).

28. Judith Newman, *Stem-Cell Creams, DNA-Based Workouts, \$50,000 Check-ups*, VOGUE, Jan. 2007, at 193.

29. Branna, *supra* note 6 (discussing DNA as a possible skin repair tool).

30. See Bryan Liang & Kurt M. Hartman, *It's Only Skin Deep: FDA Regulation of Skin Care Cosmetics Claims*, 8 CORNELL J.L. & PUB. POL'Y 249, 261 (1999).

31. Branna, *supra* note 6 (providing study figures showing the global market for cosmetics and toiletries).

32. See NBC San Diego, *supra* note 1.

33. Estée Lauder, Re-Nutriv: Ultimate Youth Crème, http://esteelauder.com/templates/products/multiproduct.tmp?CATEGORY_ID=CATEGORY20223 (last visited Oct. 17, 2008).

34. Larissa Dubecki, *Peddling the Beauty Myth*, THE AGE, Oct. 14, 2006, at 3.