

IT'S ONLY SKIN DEEP: FDA REGULATION OF SKIN CARE COSMETICS CLAIMS

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INTRODUCTION

Cosmetics have been used for thousands of years;¹ indeed, Phoenician and Egyptian women invented and used lipstick.² Cosmetics, an \$18.5 billion industry,³ remain popular today with American consumers, who spent \$3.78 billion on retail skin care products alone in 1996.⁴ Regulation of cosmetics did not obtain modern statutory authority in the United States until passage of the Food, Drug, and Cosmetic Act of 1938 (the "Act").⁵ This statute provided that certain cosmetics⁶ were consid-

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¹ See ALLEN EDWARDES & R. E. L. MASTERS, THE CRADLE OF EROTICA 297-98 (1962).

² See *id.*

³ See Jacqueline A. Greff, *Regulation of Cosmetics That Are Also Drugs*, 51 FOOD & DRUG L.J. 243, 243 (1996).

⁴ Across the major markets of Europe, facial skin care sales have grown by 25% since 1990 to \$4.4 billion. Alpha-hydroxy acids have entered the mainstream, playing a significant role in the growth of retail facial skin care sales in the US to almost \$6 billion, with the market continuing to increase by 8% a year.

Cosmeceuticals: Adding Value in a Changing Market, EUR. COSM. MARKETS, May 1, 1996, at 197, available in LEXIS, Health Library, Curnws File.

U.S. retail sales of skincare products reached \$3.78 billion in 1996, up from \$3.56 billion in 1995, according to Packaged Facts, a marketing research organization. The market is projected to show steady increases, with retail sales reaching \$3.98 billion in 1997, \$4.18 billion in 1998, \$4.37 billion in 1999, and \$4.57 billion in 2000, notes packaged facts.

Roberta Gerry, *Ironing Out Wrinkles*, CHEMICAL MARKET REPORTER, May 12, 1997, available in 1997 WL 8496970.

⁵ 21 U.S.C. §§ 321-362 (1992).

⁶ Cosmetics are defined in the Act as:

(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

21 U.S.C. § 321(l) (1992).

ered to violate the Act if they were "deemed to be adulterated"⁷ or "misbranded."⁸ The Food and Drug Administration (the "FDA") has been delegated the authority to enforce the Act.⁹

Because the FDA has focused on physical safety of cosmetics in its recent history,¹⁰ it has generally ignored unsubstantiated claims of efficacy by cosmetics manufacturers, and has not attempted to prosecute these products as *per se* misbranded under section 602 of the Act.¹¹ Instead, the FDA, emphasizing its role as guardian of consumer safety, has attempted to use its statutory powers to regulate cosmetics as drugs under the definition in section 201(g)(1) of the Act.¹² To do this, the FDA must establish that the cosmetic's "intended use" is as a drug.¹³ Once deemed a drug, the cosmetic in question becomes subject to the extensive requirements of new drug regulation, particularly pre-market approval (including investigational new drug and new drug application procedures), as well as drug labeling requirements.¹⁴ If this drug status is established in litigation, the FDA will usually obtain summary judgment against the cosmetics manufacturer, since the material in question has generally not been subjected to the rigorous new drug application and approval process.

However, the FDA's focus on physical safety, and its attempted designation of skin care cosmetics as drugs, has ignored the significant responsibility of the agency to protect the public against highly questionable efficacy claims by certain cosmetics manufacturers. The desire for the agency to enter into this area should not be considered an idle wish; the FDA is mandated by the Act to police cosmetics and act accordingly "if [the cosmetic's] labeling is false or misleading *in any particular*."¹⁵ Furthermore, because not all suits brought by the FDA in an attempt to classify a purported cosmetic as a drug have been successful, it is impor-

⁷ 21 U.S.C. § 361 (1992).

⁸ 21 U.S.C. § 362 (1992).

⁹ Formal authority rests with the Secretary of Health and Human Services, *see* 21 U.S.C. § 371(a) (1992), who has, in turn, delegated the responsibility to the FDA.

¹⁰ See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW (1990) (quoting George P. Lerrick, *Some Current Problems in the Regulation of Cosmetics Under the Federal Food, Drug, and Cosmetic Act*, 3 FOOD DRUG COSM. L.J. 570 (1948)).

¹¹ See 21 U.S.C. § 362 (1992).

¹² See 21 U.S.C. § 321(g)(1) (1992).

¹³ Under 21 U.S.C. § 321(g)(1), a "drug" is defined as (A) "articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National formulary," (B) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," (C) "articles (other than food) intended to affect the structure or any function of the body," and (D) "articles intended for use as a component of any articles specified in clause (A), (B), or (C)." Cosmetics are generally claimed to be drugs under (B) or (C) when the FDA is attempting to regulate them as such.

¹⁴ See 21 U.S.C. §§ 321-362 (1992).

¹⁵ 21 U.S.C. § 362(a) (1992) (emphasis added).

tant to have an alternate strategy to protect the public against potentially false cosmetics claims. Finally, subjecting cosmetic claims to more rigorous scrutiny under scientific peer review would result in a more informed consumer who could make purchase decisions on the basis of product quality rather than on the plethora of self-interested claims of manufacturers.

Part I of this paper reviews the nature of the problem and the FDA's litigation attempts to challenge misbranded traditional skin care cosmetics. Part II discusses the FDA's regulatory methods, and considers the efficacy and safety of various cosmeceuticals (products with both cosmetic and pharmaceutical effects) in relation to their being marketed as cosmetics or drugs, and also in relation to their respective advertisement claims. Part III discusses policy considerations and proposes a method for regulating cosmetics employing section 602 of the Act. Finally, this paper concludes by calling for enhanced FDA regulation of cosmetics (as mandated by the Act) to protect consumers from financial and physical risks.

I. TRADITIONAL FDA CHALLENGES TO SKIN CARE COSMETICS CLAIMS

The cosmetics industry has commonly made questionable claims in its advertisements¹⁶ and its labeling.¹⁷ However, the lack of substantiation of such claims has rarely been challenged as *per se* misbranding. Perhaps because of early FDA failures in the courts when challenging cosmetics as misbranded,¹⁸ the FDA reevaluated its approach, changed

¹⁶ Note that the FDA and the Federal Trade Commission ("FTC") share responsibility in regulating advertisements, with the FDA having primary jurisdiction over prescription drugs, *see* 21 U.S.C. § 352(n) (1992), and vitamins and minerals, *see* 21 U.S.C. §§ 343(a)(2), 378 (1992), while the FTC regulates advertisements of over-the-counter drugs. *See HURR & MERRILL, supra* note 10, at 599. However, since the claims in advertisements of the cosmetics discussed here also appear on the package inserts and containers of the product, they are considered labeling and fall clearly within the FDA's jurisdictional authority under 321 U.S.C. § 362(a) (1992). Furthermore, the Supreme Court has held that a food product's advertisements are considered labeling, and thus has sustained the FDA's contention that the food was a drug based on advertisement claims: "[e]very labeling is in a sense an advertisement. The advertising . . . here performs the same function as it would if it were on the article or on the containers or wrappers. As we have said, physical attachment or contiguity is unnecessary under § 201(m)(2) [21 U.S.C. § 321(m)(2)] [of the Act]." *Kordel v. United States*, 335 U.S. 345, 351 (1948). Courts have also held that concurrent FDA and FTC proceedings involving the same or similar issues are acceptable and that statutory remedies from both agencies are cumulative and not exclusive. *See Warner-Lambert v. Federal Trade Commission*, 361 F. Supp. 948 (D.D.C. 1973).

¹⁷ *See infra* notes 48 and 165 and accompanying text.

¹⁸ In the first twenty years of the Act, there were 205 cosmetics notices of judgment; seven of these were litigated. *See James C. Munch & James C. Munch, Jr., Notices of Judgment: Cosmetics*, 14 FOOD DRUG COSM. L.J. 399, 401 (1958). Of these seven, two were misbranding cases, and the FDA lost both. *See id.*

its emphasis to the cosmetic-as-drug strategy, and focused on physical safety. At least in the safety realm, there was potential for "blood on the carpet,"¹⁹ so as to bring the FDA's cases into more graphic relief for courts and juries (and Congressional committees), and perhaps spur success based partially on these images.²⁰ Related to this consideration, the FDA may have simply made a policy decision to divert its limited resources²¹ to areas that have more public exposure, even in the wake of recognition by the FDA itself that "cosmetic label claims . . . have become more and more daring."²²

The recent history of skin care cosmetics challenges by the FDA began with *United States v. An Article .aa Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled In Part: Sudden Change*.²³ In this classic case, the major issue was whether the FDA could categorize the Sudden Change skin care product as a "drug" and thus subject it to the extensive regulatory requirements for new drugs (with which the manufacturer had not complied). The *Sudden Change* court reversed the district court's ruling for the manufacturer. It held that on the basis of the product's intended use and the relevant standard of a consumer faced with such representations, Sudden Change was a drug.²⁴

The court first noted that a product's intended use was to be determined on the "basis of its label, accompanying labeling, promotional material, advertising and any other relevant source."²⁵ The court also emphasized that, regardless of the actual physical effect, a product will be deemed a drug, for purposes of the Act, if the labeling and promo-

¹⁹ Personal communication from Peter Barton Hutt, Former Chief Counsel, Food and Drug Administration; Partner, Covington & Burling, Washington, D.C., to Bryan A. Liang, June 1995.

²⁰ Indeed, the Act was itself spurred into existence by tragedy: "a tragedy occurred which was directly responsible for adding a new and important proviso to the drug control legislation [the Act]. At least 73, perhaps over 90, persons . . . died as a result of taking a drug known as 'Elixir Sulfanilamide,' [d]iethylene glycol was used as a solvent." HUTT & MERRILL, *supra* note 10, at 476 (quoting David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2 (1939)).

²¹ The FDA, in 1986, devoted less than one percent of its budget to the regulation of cosmetics. See Stephen H. McNamara, *Performance Claims for Skin Care Cosmetics or How Far May You Go in Claiming to Provide Youthfulness?*, 41 FOOD DRUG COSM. L.J. 151, 157 (1986). In 1994, the FDA has budgeted a similar percentage to cosmetics regulation (approximately five million dollars out of a total \$80 million budget). See *supra* note 19.

²² McNamara, *supra* note 21, at 151-52 (quoting Arthur Hull Hayes, M.D., Commissioner of Food and Drugs, statements to the Annual Meeting of the Cosmetics, Toiletry and Fragrance Association, Boca Raton, Florida, March 2, 1983).

²³ 288 F. Supp. 29 (E.D.N.Y. 1968), *rev'd* 409 F.2d 734 (2d Cir. 1969).

²⁴ See 409 F.2d at 742.

²⁵ *Id.* at 739.

tional claims indicate intended uses that bring it into the definition of a drug.²⁶

Next, the court indicated the appropriate consumer standard for use in evaluating the claims made by skin care cosmetics manufacturers. Rejecting what it called the district court's "reasonable woman" standard,²⁷ the *Sudden Change* court held that the relevant consumer standard is that which includes "the ignorant, the unthinking and the credulous,"²⁸ and thus the Act was intended to "protect unwary customers."²⁹ The court related its accord with previous decisions in not allowing "those who prey upon the weakness, gullibility, and superstition of human nature [to] escape the consequences of their actions."³⁰

The major claims of interest to the court were that *Sudden Change* would "lift out puffs"³¹ and give a "face lift without surgery."³² These claims were displayed on the product's leaflet insert, the box containing the product, and advertisements in newspapers, magazines, store placards, and on television. The advertisements indicated that "[the product] cannot eliminate wrinkles permanently."³³ Because these claims were deemed by the court as having physiologic—i.e., drug connotations to the court-constructed consumer, the court deemed *Sudden Change* a drug under the definition in section 201(g)(1) of the Act,³⁴ and it held for the FDA.

In a similar case, *United States v. An Article of Drug Consisting of 36 Boxes, More or Less, Each Containing One Bottle of an Article Labeled In Part "Line Away Temporary Wrinkle Smoother, Coty,"*³⁵ a circuit court affirmed a lower court's ruling that a skin care cosmetic product was a drug on the basis of its claims. Even though the leaflet packaged with each box indicated that the effect of the cosmetic (like *Sudden Change*) was only temporary, the court was disturbed by the descriptions made by the manufacturer that *Line Away* was an "amazing protein lotion" . . . made in a 'pharmaceutical laboratory' and packaged under 'biologically aseptic conditions.'³⁶ The court indicated that the emphasis on protein content suggested that *Line Away* nourished the

²⁶ See *id.*

²⁷ See *id.* at 741.

²⁸ *Id.* at 740 (quoting *Florence Mfg. Co. v. J.C. Dowd & Co.*, 178 F. 73, 75 (2d Cir. 1910)).

²⁹ *Id.* at 741 (quoting *U.S. v. Cal's Tupelo Blossum U.S. Fancy Pure Honey*, 344 F.2d 288, 289 (6th Cir. 1965)).

³⁰ *Id.*

³¹ *Id.* at 738.

³² *Id.*

³³ *Id.*

³⁴ See 21 U.S.C. § 321(g)(1) (1992).

³⁵ 284 F. Supp. 107 (D.Del. 1968), aff'd, 415 F.2d 369 (3d Cir. 1969).

³⁶ *Id.* at 372.

skin. More disturbing to the court were the claims of aseptic manufacture in a pharmaceutical laboratory, “imply[ing] that the product [was] itself a pharmaceutical.”³⁷ Furthermore, the *Line Away* court explicitly noted that “puffery” is employed simply for the purpose of selling merchandise.³⁸ Thus, describing claims of the skin care product as such did not make them *de minimis*. The court ultimately held that *Line Away* was a drug for purposes of the Act.³⁹

What appears to have triggered both courts in concluding that the skin care cosmetics in the *Sudden Change* and *Line Away* cases were drugs was the manufacturers’ use and emphasis upon specific terms that implied a physiologic effect and drug status. In *Sudden Change*, the terms “face lift” and “surgery” were used strategically by the manufacturer to imply that use of the cosmetic would result in medical results similar to plastic surgery. Similarly, in *Line Away*, use of the scientific buzzwords “biologically aseptic” while being made in a “pharmaceutical laboratory” simply led the court to believe that a consumer would imply that the cosmetic was a scientifically formulated, therapeutic drug.⁴⁰

Despite these successes, the FDA was not successful in using the cosmetic-as-drug strategy in another skin care cosmetic case. In *United States v. An Article of Drug . . . 47 Shipping Cartons, More or Less, . . . “Helene Curtis Magic Secret,”*⁴¹ the court held that the skin care product, virtually identical in composition to both *Line Away* and *Sudden Change*, did *not* constitute a drug on the basis of its intended use representations. The court, in accord with the *Sudden Change* court, adopted the standard of the “ignorant, unthinking, or credulous consumer,”⁴² and the consideration of “whether the claim . . . constitute[s] a representation that the product will affect the structure of the body in some medical- or drug-type fashion”⁴³ in ascertaining whether a cosmetic should be deemed a drug.⁴⁴ However, although the manufacturer made claims that *Magic Secret* was a “pure protein”⁴⁵ that caused an “astringent sensation,”⁴⁶ the court held that the cosmetic was not a drug on the basis of its claims, which were considered “less exaggerated”⁴⁷ than those reported in *Line Away* and *Sudden Change*.

³⁷ *Id.*

³⁸ See *id.* at 741.

³⁹ See *id.* at 742.

⁴⁰ The *Line Away* court did not reach the question of the appropriate standard.

⁴¹ 331 F. Supp. 912 (D.Md. 1971).

⁴² *Id.* at 917.

⁴³ *Id.*

⁴⁴ *Id.* (quoting *Sudden Change*, 409 F.2d at 741-42).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

Thus, the *Magic Secret* court introduced a tenuous “less exaggerated” standard to hold that the cosmetic’s claim did not place it into the feared drug category. This standard, in combination with the standards promulgated in the *Sudden Change* and *Line Away* decisions, did not significantly clarify the relevant lines over which a manufacturer cannot step (or the FDA cannot validly challenge) in order to stay within the safety of a cosmetics designation.

II. PUBLIC POLICY CONCERNs AND CONSIDERATIONS

A. MODERN REGULATORY METHODS

Almost thirty years ago, the *Sudden Change* and *Line Away* cases revealed a general gray zone in which the courts supported the FDA’s attempts to denote a cosmetics manufacturer’s claims broad enough to place the product within the statutory drug category. The *Magic Secret* court limited this ability somewhat by introducing an exaggeration consideration. Presumably, claims that represented at least a “clear” exaggeration by manufacturers on the order of *Sudden Change* or *Line Away* would place their skin care products dangerously close to drug status.

However, as demonstrated by more recent labeling and advertisements, the promise of relatively “unpuffed” claims by cosmetics manufacturers based on previous litigation has not been achieved. Indeed, fifteen years after the *Magic Secret* case was decided, a cosmetics manufacturer, among others who made similar claims, put forth the following skin care promotional claim:

[a]n unprecedented anti-aging complex . . . helps conserve internal collagen . . . stop[s] age breakdown on vulnerable areas . . . will actually diminish the length and depth of wrinkles . . . your personalized “prescription” for vibrant, health-looking skin . . . helps relieve and release puffiness . . . helps slow premature aging of the skin . . . deep moisture penetration helps improve skin texture and elasticity . . . actually helps prevent tomorrow’s lines from forming.⁴⁸

Such claims, as compared to the thirty-year-old, almost naive-sounding claims of the manufacturers in the *Sudden Change*, *Line Away*, and *Magic Secret* cases, are arguably more “exaggerated” and use more sophisticated scientific and medical terminology. To its credit, in 1987, the FDA made some attempts to warn skin care cosmetics manufacturers that claim that their products have anti-aging and anti-wrinkle properties.

⁴⁸ McNamara, *supra* note 21, at 155-56 (quoting advertisements in COSMOPOLITAN, GLAMOUR, LADIES’ HOME JOURNAL, MADEMOISELLE, and VOGUE from the first half of 1985).

No cases were brought to court; instead, in a series of regulatory letters issued by the FDA to cosmetics manufacturers, the FDA indicated that it considered “most of [the manufacturers’] anti-aging and skin physiology claims . . . to be drug claims.”⁴⁹ Thus, the FDA continued its cosmetic-as-drug strategy in an attempt to control questionable cosmetics claims by manufacturers.

This regulatory process is inefficient for both the FDA and cosmetics manufacturers and does not appear to have stemmed the tide of questionable cosmetics claims.⁵⁰ The regulatory letter process was outlined in *Est’ee Lauder, Inc. v. U.S. Food & Drug Administration*,⁵¹ where a cosmetics manufacturer attempted to obtain clarification of cosmetic claims that would deem its product a drug. The regulatory letter process was described in the case as follows, with a focus upon the interplay between the FDA and Est’ee Lauder:⁵²

1. In early 1987, the Director of the FDA Office of Compliance for the Center for Drugs and Biologics (“Director”) issued to more than 20 cosmetics manufacturers and distributors regulatory letters that indicated its objection to certain product claims during marketing of anti-aging and anti-wrinkle creams. On April 17, 1987, the Director wrote Est’ee Lauder objecting to some of its claims. The letters contained a review of current labeling for the product and claims that the Director believed to be drug claims. The Director asked that the company take “prompt” action to correct enumerated violations and warned Est’ee Lauder that the FDA was prepared to invoke sanctions such as seizures or injunctions under the Act; he then asked Est’ee Lauder to advise the FDA of the firm’s actions.

2. In response to the Director’s letter, twelve companies wrote and later met with the FDA in May and July, 1987.

3. On the basis of these meetings, the twelve companies formed a coalition and sent John M. Taylor, FDA’s Associate Commissioner for Regulatory Affairs, a proposal which attempted to devise a framework for distinguishing between cosmetic and drug categories.

4. On November 18, 1987, Taylor advised firms that he did not agree with their proposal, particularly for the skin care anti-wrinkle and anti-aging claims. He requested the firms to respond within 30 days regarding measures that they would take to correct the objectionable claims identified in the regulatory letters.

⁴⁹ HUTT & MERRILL, *supra* note 10, at 829 (quoting the FDA’s Associate Commissioner of Regulatory Affairs response to cosmetics industry coalition).

⁵⁰ See *infra* note 165 and accompanying text.

⁵¹ 727 F. Supp. 1 (D.D.C. 1989).

⁵² See *id.* at 3-4.

5. After many letters, phone conversation, and meetings, Est'ee Lauder submitted a proposal to FDA for revising its skin products' claims on December 18, 1987.

6. On March 24, 1988, Taylor responded to Est'ee Lauder's proposal, indicating his belief that the company's labeling still violated the Act.

7. Four days later, counsel for Est'ee Lauder met with another FDA official requesting guidelines for industry assistance. Est'ee Lauder followed up this meeting with a letter dated May 4, 1988, indicating that the company was eliminating older promotional materials.

8. One month later, an FDA official from the Office of Compliance wrote back to Est'ee Lauder, notifying the company that its response to the regulatory letter did not bring its products into compliance with the Act for its skin care products and since it had not submitted any examples of its revised labeling to the FDA.

9. On July 12, 1988, Est'ee Lauder submitted proposed revised labeling for the skin care products in question referred to in the April 17, 1987 regulatory letter.

10. In a letter dated September 2, 1988, the Director indicated that some of the revised labeling continued to be objectionable due to skin care claims and requested that the claims be removed. He requested that if Est'ee Lauder was not willing to make the changes identified, it should indicate such to the FDA within ten days.

11. On September 13, 1988, Est'ee Lauder stated it would contact the Director "as soon as possible."

12. On September 23, 1988, Est'ee Lauder filed suit against the FDA in U.S. District Court.

13. On June 16, 1989, the case was dismissed by the court.⁵³

The *Est'ee Lauder* case took the FDA, Est'ee Lauder and regulatory observers on an almost two-and-a-half year circular journey that accomplished nothing—neither FDA approval for Est'ee Lauder's claims, nor termination of use of offensive labeling by Est'ee Lauder for at least this time period. Further, no clarification was made as to how claims could be brought into compliance with the Act from the cosmetics manufacturer's point of view, although both parties expended significant resources in their respective efforts. Thus, the *Est'ee Lauder* case illustrates the fundamental need for additional, more efficient strategies for the FDA to police cosmetics claims, as well as provide cosmetics

⁵³ *Id.* The case was dismissed by the court because the regulatory position taken by the FDA did not constitute the agency's final position, and thus the case was not ripe for judicial review. See *id.* at 6.

manufacturers with a clear sense of what is expected of them in their labeling and advertisements.

B. MOVING INTO THE MODERN AGE: COSMETICS OR DRUGS?

Although the cosmetic industry in the United States is an \$18.5 billion industry, “[c]osmetics are the only major FDA-regulated product group that does not have its own center within the FDA.”⁵⁴ Unfortunately for American consumers, the relative lack of attention given to cosmetics regulation by the FDA⁵⁵ has resulted in more potent (i.e., more dangerous) materials being sold. These products have slipped through the cracks at the FDA because they have avoided the FDA’s stringent drug approval process and have passed directly to consumers via the retail cosmetics shelf. Indeed, as cosmetics, these products have entered the market without information as to safety precautions, adverse side-effects, or efficacy. However, the stakes are higher here; since these products can also cause physical harm in addition to economic harm, it is even more imperative that the FDA exercise some authority over assessing whether these products should be on the market. The following sections will discuss products that should either be regulated as drugs generally or as drugs at certain concentrations; as well, these should also be more heavily regulated under section 602 of the Act. In addition, to contrast the questionable retail products to be discussed, the FDA-approved drug, Renova, will be discussed to illustrate a model approval process that all drug-effect cosmetics should undergo.

1. *Topical Aminophylline*

Just as the new generation of anti-aging cosmetics have caught the attention of consumers in search of young new skin, aminophylline⁵⁶ “fat reducing” creams have caught the attention of women in search of thinner thighs.⁵⁷ Like most cosmetics, topical aminophylline creams have escaped the FDA drug approval process by being marketed simply as cosmetics without any supporting data.⁵⁸ As far as efficacy claims are

⁵⁴ Greff, *supra* note 3, at 248.

⁵⁵ In 1997, President Clinton signed into law the Food & Drug Administration Modernization Act (“FDAMA”), which amended the Food, Drug, and Cosmetic Act to streamline and rationalize the new drug and medical device approval process; however, it did not address the issues surrounding the misbranding or safety concerns of cosmetics. *See* Pub. L. No. 105-115, 111 Stat. 2296 (1997).

⁵⁶ Aminophylline is a prescription drug for asthma when taken internally. *See Thin thighs in a bottle!?: fat dissolving-creams*, THE UNIVERSITY OF CALIFORNIA, BERKELEY WELLNESS LETTER, June 1994, at 1, available in LEXIS, Health Library, Allnw File.

⁵⁷ In just over one year from the release of patented topical aminophylline cream, over 15,000 women had purchased the product. *See* Pamela A. Simon et al., *Skin reactions to topical aminophylline*, 273 JAMA 1737 (1995).

⁵⁸ *See Thin thighs in a bottle!?: fat dissolving-creams*, *supra* note 56.

concerned, few relevant, neutral studies have been published. The patent for this cosmetic was granted based upon an experiment using only five obese women who were *injected* with the drug in the thighs and who were concurrently following a 1,200 calorie-a-day diet program.⁵⁹ The experiment was considered "hardly impressive,"⁶⁰ since the product is being sold as a topical cosmetic cream and not as an intra-muscular injection. Furthermore, there is no evidence that aminophylline would work as a cream if applied to humans. Claims by the holders of the patent that eleven women who had rubbed their thighs with two-percent aminophylline cream for a period of six weeks had seen a reduction in thigh circumference by about 0.5 inches,⁶¹ were attributable, according to an academic endocrinologist, to temporary water loss.⁶²

Marketing for aminophylline-containing products is typically outlandish. For example, an advertisement for "Liposlim," an aminophylline containing "contouring gel," claims: "Liposlim is a deeply-penetrating body contouring gel. . . . Use it to lose inches off your thighs, hips, abdomen, buttocks, and chin."⁶³ Although the above product claims to work on other areas of the body besides the thigh area,⁶⁴ the patented cream⁶⁵ is normally marketed as a "thigh smoother," and not as an actual "fat reducer," so as to "avoid potentially embarrassing confrontations with the FDA."⁶⁶

There are several product sellers in the market, including Smooth Contours, Thermojetics, and Skinny Dip, that are currently licensed to use the cream. The cream costs approximately thirty to forty dollars for a two-week supply and requires constant application in order to prevent the loss of any perceived benefit.⁶⁷ Thus, a woman who uses one of these products for twenty-five years could spend as much as \$240,000 to receive a negligible benefit that could cause serious harm.⁶⁸

⁵⁹ See *id.*

⁶⁰ *Id.*

⁶¹ See E.C. Hamilton et al., *Regional Fat Loss from the Thigh Using Topical 2% Aminophylline Cream*, 1 OBESITY RES. 95S (1993).

⁶² See Katherine Griffin, *A thigh-slimming cream that works?*, HEALTH, March 1994, at 36, available in LEXIS, Health Library, Allnw File.

⁶³ ALLURE, March 1997, at 162.

⁶⁴ See *id.*

⁶⁵ According to Bray and Greenway, the aminophylline cream penetrates the skin to reach the layer of fat cells below, where it triggers a series of chemical changes. They believe the causes fat molecules inside the cells to break down into fatty acids, which then slip past the cell membrane and into the bloodstream.

Griffin, *supra* note 62, at 36.

⁶⁶ *Thin thighs in a bottle!?: fat dissolving-creams*, *supra* note 56, at 1.

⁶⁷ See *id.*

⁶⁸ See *id.* Higher levels of fatty acids in the blood stream could be extremely dangerous. See Griffin, *supra* note 62, at 36; *infra* note 73 and accompanying text (reviewing the safety problems of aminophylline).

Ironically, if aminophylline cream actually does shrink fat cells as claimed, there could be major trouble with the FDA for marketing a cosmetic product that provides a drug-like reaction.⁶⁹ The fact that aminophylline-containing products have already boasted that their product "deeply penetrates" the skin should be enough to send up a red flag to the FDA that this is a drug with unknown safety hazards. Furthermore, since the product is marketed as a harmless cosmetic, unwary consumers, who are more likely to be concerned with losing fat than with whether or not the product should rightfully be subjected to the drug approval process by the FDA, may abuse the product on the assumption that it is completely safe. As one prospective purchaser said in a fax sent to Dr. Bruce Frome, who is involved in licensing the cream, "I really don't think people care if this product has side effects. Women will do just about anything for thinner thighs."⁷⁰

Beyond the lack of efficacy data, safety issues surrounding topical aminophylline have raised concerns from some researchers who believe that there may be possible long-term danger associated with "circulating aminophylline," if it is in fact absorbed into the skin.⁷¹ Furthermore, "some researchers fear that any fat released from cells in one area may circulate in the bloodstream and ultimately be deposited elsewhere in the body—perhaps even in the coronary arteries."⁷² At least one adverse side-effect, topical dermatitis, has been reported in some users.⁷³ As stated in the Journal of the American Medical Association, "topical dermatitis is due to a type IV hypersensitivity reaction to the ethylenediamine complexed in the aminophylline molecule."⁷⁴ In addition, physicians are likely to see cases of contact dermatitis resulting from the ethylenediamine in the aminophylline molecule, and indeed, "practitioners may still report adverse skin reactions associated with these [aminophylline] creams to the FDA Medical Products Reporting Program MedWatch at (800) FDA-1088"⁷⁵ —a hotline used for adverse drug reactions—despite the fact that the creams are classified as *cosmetics* and not drugs.⁷⁶

It thus appears that aminophylline cream runs afoul of the Act, both in product claims and actual physiological effect. Moreover, the fact that

⁶⁹ Griffin, *supra* note 62, at 36.

⁷⁰ *Id.*

⁷¹ Peg Jordan, *Learn to scrutinize claims; when choosing cosmetics and fitness techniques*, AMERICAN FITNESS, Sept. 1994, at 6, available in LEXIS, Health Library, Allnws File.

⁷² *On your mind; A thigh-thinning cream?*, CONSUMER REP. ON HEALTH, Sept. 1994, at 108, available in LEXIS, Health Library, Allnws File.

⁷³ See Simon et al., *supra* note 57, at 1737.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ See *id.*

there has been great concern over topical aminophylline's safety, coupled with the lack of published data on its safety profile, is cause enough to demand FDA intervention. However, by carefully wording the product's advertisements, sellers are able to hide in the gray area between cosmetics and drugs that the FDA has yet to directly attack, although presently the FDA is "evaluating" whether thigh creams should undergo drug approval in an effort to better protect the public health.⁷⁷

2. A New Wrinkle: Cosmeceuticals

As implied by the name, the term *cosmeceutical* is a hybrid of the terms *cosmetic* and *pharmaceutical*.⁷⁸ Many cosmeceuticals are simply pharmaceuticals that have either been re-formulated for consumer use (i.e., use a lower concentration of the "active ingredient") or have long been approved for non-cosmetic use.

The cosmetic consumer is continually in search of products that will cease, and even reverse, the aging process of the skin (i.e., wrinkling).⁷⁹ Wrinkles appear as a result of the elastic fibers of the dermis (the layer of tissue beneath the epidermis) deteriorating from aging, and in most cases, as a result of damage caused by the sun's ultraviolet rays.⁸⁰ The deterioration process starts when there is an excessive production of abnormally structured elastic fibers.⁸¹ Under normal circumstances, the excessive deterioration is not noticeable until after age seventy; however, sun-damaged skin may show signs of excessive deterioration as early as age thirty.⁸²

Skin care cosmetics are essentially defined as "products which are limited to temporary improvement of the appearance or feel of the skin."⁸³ Traditional cosmetic moisturizers do nothing more than tempo-

⁷⁷ *Thigh Creams*, CFSAN, FDA, OFFICE OF COSM. FACT SHEET, Feb. 22, 1995, (visited May 7, 1998) <<http://vm.cfsan.fda.gov/~dms/cos-202.html>>.

⁷⁸ See *Still Pushing Back the Boundaries of C&T*, EUR. COSM. MARKETS, May 1995, available in LEXIS, Health Library, Allnws File.

⁷⁹ See *supra* note 4 (discussing the billion dollar market for anti-wrinkle cosmetics such as alpha hydroxy acids).

⁸⁰ In the aging process there are changes in the connective tissue that are subtle and not easily detected until a secondary manifestation appears. Such is the case in the vascular system where blood vessels are slowly altered owing to elastin degradation or modification. . . . Elastin provides a return spring system for the skin, allowing the collagen fibers to return to their original position after deformation.

Peter T. Pugliese, *Assessment of Antiaging Products*, in CLINICAL SAFETY AND EFFICACY TESTING OF COSMETICS 298-99 (William C. Waggoner, ed., 1990).

⁸¹ See Dori Stehlin, *Erasing Wrinkles: Easier Said Than Done*, FDA CONSUMER, July 1987, at 20, available in LEXIS, Health Library, Allnws File.

⁸² See *id.*

⁸³ Robert L. Goldemberg, *Believe It or Not; Cosmetics, Pharmaceuticals Often Bear Questionable Marketing Claims*, DRUG & COSM. INDUS., March 1997, at 64, available in LEXIS, Health Library, Curwens File.

rarily keep water from evaporating on the skin's surface cells. The result is that moisturized skin, even skin that already has noticeable wrinkles from aging or sun exposure, takes on a softer and smoother appearance with greater "flexibility."⁸⁴ Products that are known to have an actual physiological effect (i.e., products that alter the structure of the skin) and/or make claims akin to having an actual physiological effect (e.g., claims to make skin "function as if it were young again"⁸⁵), may be considered a drug for regulatory purposes, according to FDA guidelines.⁸⁶ There is, however, a gray area between the strictly-defined *cosmetic* and the strictly-defined *drug*. The products that fall within this gray area have been termed *cosmeceuticals*.⁸⁷

Cosmeceuticals are products that claim to have an actual physiological effect,⁸⁸ which is usually not scientifically substantiated,⁸⁹ and is temporary in nature because the claimed effect is dependent upon continued and frequent use of the product. *Cosmeceuticals* are a fairly new generation of products that have sparked FDA attention as a result of marketing "claims creep."⁹⁰ Many cosmetics manufacturers have made both aggressive and inventive claims about the physiological benefits derived from their products—claims which bring them close to, if not well within, the drug category.⁹¹ Moreover, because of the significantly different labeling requirements for cosmetics versus drugs,⁹² those cosmeceuticals that rightfully should go through the FDA's drug approval

⁸⁴ See Stehlin, *supra* note 81, at 20.

⁸⁵ *Id.*

⁸⁶ See *id.*

⁸⁷ See *Cosmeceuticals Bridging the Health / Beauty Divide*, OTC NEWS & MARKET REP., June 1, 1997, at § 104, available in 1997 WL 8740585.

⁸⁸ "Cosmetic claims are a type of pre-emptive claim which associate product usage with some desirable physiological skin change such as the elimination of wrinkles. Some cosmeceutical product claims are not adequately substantiated using scientific methodology, but depend upon testimonials from celebrities as evidence of efficacy." Thomas J. Stephens et al., *Assessment of Antiaging Products*, in CLINICAL SAFETY AND EFFICACY TESTING OF COSMETICS 3-5 (William C. Waggoner ed., 1990).

⁸⁹ "True 'antiaging' actions would require evidence for the return toward normal of the regenerative/ degenerative balance by increased collagen and elastin synthesis." Charles Fox, *Topical Bioactive Materials; part 2*, COSM. & TOILETRIES, Sept. 1994, at 83, available in LEXIS, Health Library, Arcnws File.

⁹⁰ Stephen H. McNamara, *FDA Regulation of Cosmeceuticals: U.S. Cosmetic and Drug Regulations Pertinent to the Cosmeceutical Issue*, COSM. & TOILETRIES, March 1, 1997, at 41, available in 1997 WL 10053046.

⁹¹ See *id.*

⁹²

Generally, the label on a cosmetic is required to list all ingredients in descending order of predominance, while the label on a drug is required only to list its 'active' ingredients. If an article is both a cosmetic and a drug, it must list the active ingredients first, followed by other ingredients in descending order of predominance. (The FDA also generally encourages the voluntary listing of inactive ingredients on the labels of OTC drugs.)

process⁹³ (because they do in fact have an actual physiological effect on the skin), are posing a serious threat to unwary consumers.

The FDA has done relatively little to address these claims specifically and the cosmeceutical movement in general. As a result, a competitive environment among cosmetics manufacturers has developed whereby all cosmetics manufacturers are forced to meet their competitors' increasingly grandiose product claims with similar claims of their own. For a cosmetic company to stay silent or limit its claims to what can be proven would place that company at an economic disadvantage; consumers are likely to buy the "most potent" retail skin care cosmetic product, as defined by product advertising. Thus, until the FDA does step in to regulate cosmeceuticals, it is economically beneficial for all cosmetics manufacturers to aggressively promote and market these gray area products. Moreover, until the FDA does take appropriate regulatory action, whether under section 602 or under its drug regulatory power, it is the consumer who must bear the burden of assessing the truth or falsity of these products' claims. Of course, these are the very individuals who lack expertise in the area and thus may be misled by the overstated and ever increasing fraudulent claims.

3. *Retinoids*

An example of a product that has been re-marketed for wrinkle reduction as an alternative use is Johnson & Johnson's Retin-A (a derivative of tretinoin), a product long used for the treatment of severe acne.⁹⁴ Retin-A had the side-effect of "reducing visible lines in the skin,"⁹⁵ a side-effect that would be welcomed by any skin care cosmetic consumer. To be sure, during the year that Retin-A's wrinkle-reducing side-effect was publicized, sales of the product in the United States rose by 340% from \$25 million to \$110 million.⁹⁶ Unfortunately for Johnson & Johnson, however, it violated FDA rules and promoted Retin-A for an unauthorized use, and it was consequently fined \$5 million and forced to pay another \$2.5 million in restitution for government expenses.⁹⁷ Nevertheless, the decision to promote Retin-A for a use other than what had been FDA-approved remained economically cost effective despite the \$7.5 million total fine levied against Johnson & Johnson, as the company still profited enormously from sales of the product. Thus, even when the FDA has taken action, the action still has not effectively monitored the

⁹³ Most cosmetic drugs conform to over-the-counter drug monograph requirements, thereby avoiding the drug approval process. See Greff, *supra* note 3, at 243.

⁹⁴ See *Still Pushing Back the Boundaries of C&T*, *supra* note 78.

⁹⁵ *Id.*

⁹⁶ See *Cosmeceuticals: Adding Value in a Changing Market*, *supra* note 4, at 197.

⁹⁷ See *Phantom Competitor*, COSM. INSIDERS' REP., Apr. 24, 1995, at § 8, available in LEXIS, Health Library, HCare File.

safety and use of these products, and it certainly has not deterred manufacturers from selling the product when these companies have deemed a profit might still be made.

Furthermore, other similar products have been able to make unsubstantiated claims with seeming impunity. Take, for example, Lancome's magazine advertisement for its "Renergie" skin care product: "Double performance anti-wrinkle and firming treatment *scientifically proven* in its dual ability to firm and strengthen skin while diminishing the appearance of wrinkles. Fortified with proteins and age-defiant elements. For face and throat, in a choice of silky creme or new oil-free lotion."⁹⁸

Although the advertisement claims that its product's beneficial effect has been "scientifically proven," the advertisement cites no study, provides no information substantiating the claimed efficacy and safety of the product, and lists no ingredients. Furthermore, the use of the term "age defiant" implies a cessation of the aging process—a claim that arguably constitutes a section 602 violation.

Similarly, Neutrogena boasts, in a magazine advertisement, that its Healthy Skin Anti Wrinkle Cream is "dermatologist recommended" and "clinically proven:"

Visibly reduce the appearance of fine lines and wrinkles from sun damage. In days, skin is softer, smoother. In weeks, the appearance of fine lines, wrinkles and age spots diminish. Your skin looks firmer, younger, healthier. Clinically proven formula with Retinol (the purest form of Vitamin A) works deep within the skin's surface where wrinkles develop. Contains Pro-Vitamin B5, Vitamin E and special moisturizers for softer, smoother skin.⁹⁹

Although this Neutrogena advertisement does list certain key ingredients, it does not disclose the concentration of the retinoid used, it claims a "clinically proven" result, and it blatantly implies that the product penetrates the skin by stating that it "works deep within the skin's surface."¹⁰⁰ Also, while the advertisement is designed to lead the consumer to believe that the product will actually penetrate the skin by stating that it "works deep within,"¹⁰¹ the advertisement is carefully worded to avoid being considered (technically) to have a drug effect by qualifying the degree of penetration as affecting only the "skin's surface."¹⁰²

⁹⁸ *ALLURE*, Mar. 1997, at 71 (emphasis added).

⁹⁹ *REDBOOK*, Apr. 1998, at 13.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

The FDA has demonstrated concern that the ingredients in these new cosmeceuticals (which have been shown to cause irritation), even if naturally occurring, "might be stripping the skin of its natural protective barriers."¹⁰³ Dr. Zoe Draelos, Clinical Assistant Professor of Dermatology at Wake Forest University, commented on the issue of irritation caused by anti-aging products by stating, "when skin stings and burns, it's telling you that it's injured. . . . Perhaps, instead of the anti-aging benefits, we're actually injuring the skin."¹⁰⁴ Yet even under these physical harm concerns, no regulatory action has been taken. And like most cosmetic advertisements, although cosmeceutical advertisements state that their products are "clinically proven," they fail to cite any peer-reviewed studies attesting to efficacy or safety. These factors would thus seem to indicate that the FDA should reconsider its current efforts to regulate these cosmetics.

4. *Alpha Hydroxy Acids*

Alpha hydroxy acids (AHAs)¹⁰⁵ also represent a crossover between cosmetics and drugs. The typical effects of alpha hydroxy acids have been described as follows:

Alpha hydroxy acids are basically chemical versions of facial scrubs. When applied topically, they slough off the dead cells of the skin's top layer, forcing the underlying cells to create fresh new cells to replace them. The body may also attempt to repair this minor "damage" by depositing new collagen in the underlying, dermal layer.

¹⁰³ Lisa Kintish, *Treatment Cosmetics: Beyond the Surface; Companies Develop Makeup With Added Benefits for the Skin*, SOAP-COSM.-CHEMICAL SPECIALTIES, Mar. 1997, at 26, available in LEXIS, Health Library, Curnws File; Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 FOOD & DRUG L.J. 375, 375 n.129 (1997) (citing Jacqueline A. Greff, *Regulation of Cosmetics That Are Also Drugs*, 51 FOOD & DRUG L.J. 243, 257 (1996) (quoting John E. Baily, Jr., Ph.D., Acting Dir., Office of Cosmetics & Colors, FDA, Skin Care B State of the Art: A Regulatory View of B Alpha- Hydroxy Acid, Remarks at the Annual Spring Seminar of the New York Chapter of the Society of Cosmetic Chemists, New York City, Apr. 6, 1994)).

¹⁰⁴ Fighting Time: With Its Patented Beta Hydroxy Complex, *Oil of Olay Age Defying Series Dawns On A New Age In Skin Care*, SOAP-COSM.-CHEMICAL SPECIALTIES, May 1997, at 66, available in LEXIS, Health Library, Curnws File.

¹⁰⁵ Alpha hydroxy ingredients include glycolic acid, lactic acid, malic acid, citric acid, glycolic acid plus ammonium glycolate, alpha-hydroxyethanoic acid plus ammonium alpha-hydroxyethanoate, alpha-hydroxyoctanoic acid, alpha-hydroxycaprylic acid, hydroxycaprylic acid, mixed fruit acid, tri-alpha hydroxy fruit acids, triple fruit acid, sugar cane extract, alpha hydroxy and botanical complex, L-alpha hydroxy acid, and glycomer in crosslinked fatty acids alpha nutrion (three AHAs). See *Alpha Hydroxy Acids in Cosmetics*, FDA BACKGROUNDER, FDA, July 3, 1997 (visited May 7, 1998) <<http://vm.cfsan.fda.gov/~dms/cos-aha.html>>.

The result is smoother, firmer, more evenly pigmented skin.¹⁰⁶

The AHA is an example of a drug that has long been used, at high concentrations, for controlled chemical peels in a physician's office, and that has made the transition to the over-the-counter retail cosmetic market with concentrations that are greatly reduced, yet arguably effective.^{107a} AHAs come in different concentrations and different pH levels. The concentration of the product will determine its effect on the dermal layer of the skin, and the effects range from light peeling to complete resurfacing and scarring. Dermatologists have used AHAs during in-office treatments with twenty to seventy percent concentrations, while retail AHA products utilize two to twelve percent solutions.¹⁰⁸ In addition to concentrations, the actual absorption of an AHA into the skin will depend critically on the formulation's pH level, with optimal absorption of the AHA into the skin at a pH of 3.0.¹⁰⁹

Cosmetics manufacturers have experimented with products that have a borderline drug concentration of AHAs. The marketing strategy of retail AHA cosmetics manufacturers is to keep the concentrations of their products low enough to avoid falling into a drug category and, therefore, becoming subject to drug regulations, while simultaneously keeping their concentrations high enough to have an actual effect, or at least be able to claim an effect.¹¹⁰ If, however, the concentration is in fact too low, the result is that consumers pay a exorbitant price for what is essentially a moisturizer with the same effect as petroleum jelly.¹¹¹ Most AHA product advertisements, unfortunately, do not inform the consumer as to the product's concentration or pH levels. For example, Avon's magazine advertisement for its "A New All-in-One" reads as fol-

¹⁰⁶ Mary Roach, *Heavenly Skin*, HEALTH, July 1986, at 94, available in LEXIS, Health Library, Allnw File.

¹⁰⁷ Routine use of skin-care cosmetics with alpha-hydroxy acids ("AHAs") moisturizes and smoothes the skin providing a less wrinkled skin appearance. See Donald G. Vidt & Wilma F. Bergfeld, *Cosmetic use of alpha-hydroxy acids*, 64 CLEVELAND CLINICAL J. MED. 327 (1997).

¹⁰⁸ See Roach, *supra* note 106, at 94.

¹⁰⁹ See Anne Wolven Garrett, *AHAs and More; Alpha Hydroxy Acids Discussed At Society of Cosmetic Chemists Annual Meeting; Scientifically Speaking*, DRUG & COSM. INDUS., Jan. 1997, at 8, available in LEXIS, Health Library, Curnw File.

¹¹⁰ Because an AHA containing a product's effectiveness is dependent upon its concentration and pH level, "[o]ne concern is that absent regulation, manufacturers will attempt a race to the top, increasing concentration of the acid in their products to achieve a more drastic effect." Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 FOOD & DRUG L.J. 357, 359 (1997).

¹¹¹ "Moisturizers form a seal that keeps water from evaporating from the skin's surface cells. More water in the cells means greater flexibility, softness, and smoothness. This effect can come with equal success from a \$65 bottle or exotically named cream or a plain jar of petroleum jelly." Stehlin, *supra* note 81, at 20.

lows: "Give your skin a second chance with one alpha hydroxy formula that smooths, moisturizes and protects. Now with SPF 15 and antioxidants. See younger looking skin in two weeks or your money back. Guaranteed."¹¹²

Yet, irrespective of the safety¹¹³ and efficacy issues surrounding AHAs and their varying concentrations, as of 1997, AHA products had reached one billion dollars in sales worldwide.¹¹⁴ Presently, the FDA has not taken any regulatory or legal action against cosmetics manufacturers of AHAs, although these products clearly have the potential of causing both economic and physical harm. This inaction on the part of the FDA is indefensible, in light of the fact that the FDA has itself published concerns about potential skin irritation caused by use of AHAs, and it has received at least 100 reports¹¹⁵ citing adverse effects "ranging from mild irritation and stinging to blistering and burns."¹¹⁶

In addition, although the majority of the literature assessing AHAs finds that topical AHAs are effective in some instances,¹¹⁷ a study performed by the Cosmetic Ingredient Review (CIR)¹¹⁸ found that there was

¹¹² ALLURE, Mar. 1997, at 107.

¹¹³ See Eric F. Bernstein et al., *Citric Acid Increases Viable Epidermal Thickness and Glycosaminoglycan*, 23 DERMATOLOGICAL SURGERY 689 (1997).

¹¹⁴ See Symposium: *Skin Disorders*, 102 POSTGRADUATE MED. 115 (1997), available in 1997 WL 9104705.

¹¹⁵ "Past experience suggests that for every adverse reaction report the agency receives, the manufacturer receives 50 to 100." Paula Kurtzweil, *Alpha Hydroxy Acids For Skin Care: Smooth Sailing or Rough Seas?*, FDA CONSUMER, FDA, Mar.-Apr. 1998 (visited May 7, 1998) <<http://vm.cfsan.fda.gov/~dms/fdacaha.html>>.

¹¹⁶ *Alpha Hydroxy Acids in Cosmetics*, *supra* note 105.

¹¹⁷ In one double-blind study, it was concluded that AHAs had "modest but real benefits" when applied to women with mild to moderate photoaging. See Matthew J. Siller et al., *Topical 8% Glycolic Acid and 8% Lactic Acid Creams for the Treatment of Photodamaged Skin*, 132 ARCHIVES OF DERMATOLOGY 631, 632 (1996). In a second study, "[t]est participants applied either 5% or 12% lactic acid twice a day for 3 months. Changes in skin smoothness and texture, the depth and number of lines and wrinkles, and epidermal and dermal firmness and thickness were determined." Walter P. Smith, *Epidermal and Dermal Effects of Topical Lactic Acid*, 35 J. AM. ACAD. DERMATOLOGY 388, 388 (1996). The results of the study were as follows: "Treatment with 12% lactic acid resulted in increased epidermal and dermal firmness and thickness and clinical improvement in skin smoothness and in the appearance of lines and wrinkles. No dermal changes were observed after treatment with 5% lactic acid; however, similar clinical and epidermal changes were noted." *Id.* The study concluded that "cosmetic benefits from the use of α-hydroxy acids are caused by modification of the skin surface, the epidermis and the dermis." *Id.*; see also Barbara A. Gilchrest, *A Review of Skin Aging and Its Medical Therapy*, 135 BRITISH J. DERMATOLOGY 867 (1996).

¹¹⁸ The CIR consists of a seven-member independent expert panel selected through a public nomination process from among the scientific disciplines of dermatology, pharmacology, chemistry, and toxicology. Three nonvoting members assist the panel: a consumer representative appointed by the Consumer Federation of America, an industry liaison, and an FDA contact person. The CIR reviews both published and unpublished industry data. The panel classifies ingredients as either safe, as currently used or with qualifications; unsafe; or insufficient information for a determination. CIR findings are reported to members of the industry in the annual *CIR*

insufficient evidence to ascertain a clear benefit.¹¹⁹ The study, commissioned by the FDA staff, declared that AHAs are safe at ten percent concentration and a pH of 3.5.¹²⁰ The two key issues surrounding the study, aside from actual effectiveness, was the risk of increased penetration of the skin by other chemicals following AHA application and dermal irritation resulting from AHA use.¹²¹ The CIR Panel found that “there is no need to be concerned about AHA ingredient use enhancing the penetration of other chemicals.”¹²² With regard to dermal irritation caused by AHAs, the Panel did find that “AHA ingredients can be dermal irritants,” depending on the concentration and pH of the AHA formulations.¹²³ As the Panel reported, “[a]t a given pH, increasing the concentration increases irritation;”¹²⁴ furthermore, “[a]t a given concentration, reducing the pH increases the irritation.”¹²⁵ The Panel’s primary concerns regarding irritation focused on mid-range AHA formulations that are used by salons. The Panel stated that AHAs used by salons are safe within the following parameters and guidelines:

[A]t concentrations less than or equal to 30 percent, at final formulation pH equal or greater than 3.0, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection.¹²⁶

As far as cosmetic use (i.e., retail sale) is concerned, the CIR Panel concluded that AHAs were safe at concentrations of up to ten percent and at pH levels no lower than 3.5, provided that the particular AHA-containing product was formulated to avoid increased sun sensitivity, or contained instructions calling for the daily use of appropriate sun protection.¹²⁷ Despite the Panel’s findings, however, the FDA has not formally accepted the CIR study and will only consider it in relation to its own

Compendium. Industry uses the CIR’s findings, but is not bound specifically to follow them.

Greff, *supra* note 3, at 246.

¹¹⁹ See *New Wrinkle On Age Creams*, CONSUMER REP. ON HEALTH, Feb. 1997, at 22, available in LEXIS, Health Library, Curnws File.

¹²⁰ See Cynthia C. Urbano, *CIR Declares Retail AHAs Safe at 10% Concentration and 3.5 pH Levels*, COSM. & TOILETRIES, at 11, available in LEXIS, Health Library, Curnws File.

¹²¹ See Kintish, *supra* note 103, at 26.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ See *id.*

internal evaluation.¹²⁸ In fact, the Panel's findings merely provide recommendations to the FDA that are in no way binding on the manufacturers of AHAs. The controversy surrounding AHAs as cosmeceuticals has obviously not been resolved.¹²⁹

5. *Renova*

Renova, a Johnson & Johnson product, is the first drug to ever be approved by the FDA for the treatment of fine wrinkles,¹³⁰ and the only anti-aging cosmeceutical to undergo extensive, neutral, double-blind studies producing results that parallel the manufacturer's claims.¹³¹ Renova's active ingredient, tretinoïn (a vitamin A derivative), is the same ingredient used in Retin-A, the prescription acne treatment found to have the side-effect of reducing fine wrinkles.¹³² Tretinoïn is a retinoid that has demonstrated its ability to mitigate photoaged skin on Retin-A users,¹³³ although Retin-A's original function was to treat severe acne and not photoaged skin.¹³⁴

Research demonstrates that Retinoids, as a whole, have a significant physiological effect on the skin; in fact, “[n]o other known chemicals or drugs can duplicate the diversity of anatomic and physiologic effects brought about by retinoids.”¹³⁵ Renova is a 0.05% tretinoïn emollient cream that “uses a water-in-oil emulsion instead of the drying base used in tretinoïn (Retin-A).”¹³⁶ The result is that Renova is a milder (less irritating on the skin) version of its sister product, Retin-A. The physiological effect that Renova has on the skin is that it “sloughs off dead surface cells, thickens the skin's living cells, and increases the production of collagen—the spongy tissue that lies below the skin's epidermal layer—making the skin more supple and less wrinkled.”¹³⁷ In a large-scale, six month, double-blind study, 0.05% tretinoïn emollient cream was shown to “reduce fine wrinkles and skin roughness, and it produced histologic changes such as epidermal thickening, increased granular layer

¹²⁸ See Donald A. Davis, *Not Likely! Food and Drug Administration to Study Skin Care Products Despite Industry's Findings*, DRUG & COSM. INDUS., Feb. 1997, at 20, available in LEXIS, Health Library, Curnws File.

¹²⁹ During the spring of 1997, the National Toxicology Program of the National Institute of Environmental Science accepted the FDA's proposal to study AHA safety. See Kurtzweil, *supra* note 115. The institute's results are expected by the year 2000. *See id.*

¹³⁰ See *Renova*, MED AD NEWS, Feb. 1, 1996, at 32, available in 1996 WL 9195689.

¹³¹ See Gilchrest, *supra* note 117, at 867.

¹³² See *Still Pushing Back the Boundaries of C&T*, *supra* note 78.

¹³³ *See id.*

¹³⁴ *See id.*

¹³⁵ Laura Newman, *FDA Approves Tretinoïn Emollient Cream; Tretinoïn Becomes First FDA-Approved Skin Cream for Treatment of Wrinkles*, DERMATOLOGICAL TIMES, Feb. 1, 1996, at 1, available in 1996 WL 9079730.

¹³⁶ *Id.*

¹³⁷ Roach, *supra* note 106, at 94.

thickness, stratum corneum compaction, and decreased melanin content.”¹³⁸ The same study noted even greater benefits following twelve months of use.¹³⁹

Renova is intended for mature dry skin as a nighttime facial cream application that requires comprehensive sun protection during the period of usage.¹⁴⁰ Renova will not reverse the aging process,¹⁴¹ although it has been shown to improve the appearance of photoaged skin by improving “roughness, fine wrinkling, irregular pigmentation, texture, and firmness.”¹⁴² As with any use of a tretinoin-based topical product, Renova does cause some skin irritation, especially during the first month of use.¹⁴³ While “[a] majority of patients will lose most mitigating effects . . . with discontinuance,”¹⁴⁴ it has been asserted that the loss of such mitigating effects is gradual.¹⁴⁵ Renova users who fall within the narrow margin of

¹³⁸ Barbara A. Gilchrest, *Treatment of Photodamage With Topical Tretinoin: An Overview*, 36 J. AM. ACAD. DERMATOLOGY 27 (1997).

¹³⁹ See *id.*

¹⁴⁰ See Newman, *supra* note 135, at 1.

¹⁴¹ Excluding the full one-sided magazine page devoted to listing indications and usage, warnings, precautions, and adverse reactions, as required by the FDA for the advertisement of an approved drug, Renova’s advertisement in a popular woman’s journal reads as follows:

Ask your dermatologist about Renova, from the makers of Retin-A. Renova works. Renova is unlike any other anti-aging or anti-wrinkle cream. It is a prescription cream that is proven to work. Because Renova is a prescription wrinkle cream, you won’t find it on any cosmetic shelf, you’ll need to see your doctor. And while it won’t work overnight, if you follow a total skin care program, it can work for you. How Renova and Retin-A are the same. And different. Renova is a rich emollient cream whose active ingredient is a vitamin A derivative like the one naturally occurring in your body. It’s called Tretinoin. The same active ingredient in Retin-A. But while Retin-A is formulated for acne-prone skin, Renova is a rich emollient cream developed to treat lines, wrinkles, brown spots, and surface roughness. Leaving your skin with a smoother texture and rosier glow. Renova works deep at the cellular level to increase collagen. That’s how researchers believe Renova reduces signs of aging. Like other prescription medications, Renova has been tested for safety and effectiveness. While it will not *repair* sun damaged skin or *reverse* the aging process, it is proven to *reduce* wrinkles, *fade* brown spots, and *smooth* roughness. When you use Renova, you can expect to experience some redness, itching, or flaking. This is most often mild, and most common when treatment is started. Soon your skin will become softer and smoother, with a rosier glow. When using Renova, or any other anti-wrinkle cream, you should limit exposure to the sun and always use a sunscreen. Renova is a dermal irritant. Results of use beyond 48 weeks have not been established in controlled clinical trials. Some people using Renova longer have shown evidence of atypical skin changes, the significance of which is unknown. Clinical trials in those over 50 or with moderately or heavily pigmented skin have not been conducted.

REDBOOK, Apr. 1998, at 26.

¹⁴² Newman, *supra* note 135, at 1.

¹⁴³ See *id.*

¹⁴⁴ *Id.*

¹⁴⁵ See *id.*

candidates for beneficial use will usually notice a reduction in skin roughness within the first month of usage, fading of skin discoloration within six to eight weeks, and a diminishment of fine lines and wrinkles within three to six months.¹⁴⁶

Renova may appear to be a miracle remedy, but at least one study has shown that similar results have been achieved through the ordinary use of moisturizers.¹⁴⁷ However, irrespective of Renova's effectiveness as compared to the effectiveness of ordinary retail cosmetic products, Renova has survived rigorous testing in order to be approved as a drug by the FDA, a process that no other retail anti-aging product has endured.¹⁴⁸ Although Johnson & Johnson's claims about the beneficial effects of Renova are significantly similar to those claims made by manufacturers of retail AHA products, Renova users can feel confident about the safety and efficacy of Renova, while AHA users can only hope and assume that because AHAs are sold on the retail shelf and not by prescription, they are safe and effective for cosmetic use based only upon the particular manufacturers' claims.¹⁴⁹ Furthermore, consumers that are aware of both the prescription product Renova and AHA-containing cosmetic products may erroneously presume that Renova poses significantly more risks simply because it is not available over-the-counter. This presumption, caused by the prescription/over-the-counter dichotomy, can create consumer misconception about cosmeceuticals generally because the FDA has yet to make clear bright-line rules regarding the avenue of availability for such products. The result may be that consumers will not treat retail cosmeceuticals with the same caution as they will prescription cosmeceuticals.

6. *Beta-Hydroxy Acids*

Within the past year, beta hydroxy acids (BHAs) have leaped ahead of AHAs as the hot new unregulated cosmeceutical for wrinkle reduction, with potential adverse economic and physical effects to the consumer.¹⁵⁰ Typical of most cosmetics and cosmeceuticals, the published efficacy research on BHAs (specifically, the effectiveness of salicylic

¹⁴⁶ See *Renova*, *supra* note 130, at 32.

¹⁴⁷ See *Roach*, *supra* note 106, at 94.

¹⁴⁸ See *id.*

¹⁴⁹ Note that the CIR study was only advisory in nature and not determinative of FDA policy, and furthermore cannot attest to each individual manufacturer's AHA formulation, based on concentration and pH. The study merely provided one resource from which to derive information about efficacy and safety. Because the FDA has not regulated AHAs as drugs, specific AHA formulations may not conspicuously fall within the parameters of what the CIR study concluded as being safe.

¹⁵⁰ See *Skin Care & Color Cosmetics Annual Trend Report*, DRUG & COSM. INDUS., June 1, 1997, at 38, available in 1997 WL 9344538.

acid for safely reducing wrinkles) is negligible at best.¹⁵¹ According to one study, salicylic acid (the primary ingredient in all BHA formulations) was more effective at just one-fifth the concentration of glycolic acid (an AHA formulation ingredient),¹⁵² with less potential for skin irritation than that caused by glycolic acid.¹⁵³ Because BHAs are lipid soluble, as opposed to water soluble like AHAs, BHAs concentrate their exfoliation on the top layers of the skin as opposed to “localizing below the surface, where irritation is likely to occur.”¹⁵⁴ It should be noted, however, that there is dispute over the assertion that BHAs are less irritating than AHAs.¹⁵⁵ Indeed, in 1995, Procter & Gamble had to suspend worldwide sale of two of its BHA products (containing two-percent concentrations) following numerous complaints of blurred vision and watery eyes.¹⁵⁶

Taking the lead in the new BHA trend, Oil of Olay, a Procter & Gamble product, has introduced its Daily Renewal Cream, which contains 1.5% salicylic acid in a moisturizing base, and is allegedly less irritating and equally as effective as AHA formulations.^{157a} Yet one of the major marketing points manufacturers and industry-commissioned dermatologists make about BHAs is that salicylic acid achieves deeper penetration within the skin,¹⁵⁸ and has the ability to “renew the stratum corneum.”¹⁵⁹ It seems clear that if BHAs have, as claimed, the same, if not a greater, beneficial effect than AHAs,¹⁶⁰ they too fall into the cos-

¹⁵¹ See *infra* notes 153-54.

¹⁵² See *Alpha Hydroxy Acids in Cosmetics*, *supra* note 105.

¹⁵³ See *Skin Care & Color Cosmetics Annual Trend Report*, *supra* note 150, at 38.

¹⁵⁴ *Fighting Time: With Its Patented Beta Hydroxy Complex, Oil of Olay Age Defying Series Dawns On A New Age In Skin Care*, *supra* note 104, at 66.

¹⁵⁵ See Faye Brookman, *United States of Colour; Cosmetics, SOAP PERFUMERY & COSM.*, July 1997, at 17, available in LEXIS, Health Library, Cumws File.

¹⁵⁶ See P&G Withdraws Skin Care Products, EUR. COSM. MARKETS, Apr. 1995, at 1S, available in LEXIS, Health Library, Allnws File.

¹⁵⁷ See *Symposium: Skin Disorders*, *supra* note 114, at 115.

¹⁵⁸ “SA provides more exfoliation and penetrates skin more effectively than GA. Oil of Olay Age Defying Series, Almay Time-Off Revitalizer with a 16 percent concentration claiming to deliver the benefits of hydroxy mini-peels formerly available only from dermatologists and estheticians É.” *Skin Care & Color Cosmetics Annual Trend Report*, *supra* note 150, at 38.

¹⁵⁹ *Fighting Time: With Its Patented Beta Hydroxy Complex, Oil of Olay Age Defying Series Dawns On A New Age In Skin Care*, *supra* note 104, at 66.

¹⁶⁰ In comparing the effectiveness of AHAs versus BHAs, one non-peer-reviewed article stated the following:

BHA, however, offers three advantages. It exfoliates not just on the surface but also deeper into oil-clogged pores—something AHAs can’t do. Two, it’s less irritating (studies show that women report less redness, stinging, and burning using a BHA vs. an AHA). Three, as a derivative of aspirin, it has a similar anti-inflammatory effect on the skin. That is good news since many women with older, sundamaged skin also suffer from tiny whiteheads that are a type of acne. BHA helps treat this condition.

meceutical category and should be considered a drug under FDA guidelines.

Indeed, illustrating the consumer perception of drug-like effectiveness of salicylic acid, a recent article in *Cosmopolitan* indicates that salicylic acid, vitamin-A derivatives,¹⁶¹ and AHAs are examples of the "new miracle skin creams."¹⁶² This article highlights the popular perception that the new anti-aging cosmetics are really products that have a drug-like effect without the drug regulatory hassle, for reasons never addressed by any cosmetic advertisement or any commercial non-peer-reviewed article. Moreover, the language of the article implies that today's new anti-aging cosmetics were given special FDA treatment. It quotes a dermatologist who made the following statement: "They're packing their products with effective ingredients—some formerly available only by prescription."¹⁶³ However, once again, questionable claims, lack of efficacy data, and no FDA regulation place the risk of economic and physical harm on the consumers—the parties least likely to be able to assess the products' efficacy and safety.

III. A POLICY PROPOSAL

The current regulatory letter method for policing the cosmetics industry and its product claims has arguably been ineffective, since cosmetics manufacturers continue to be more "daring" in their labeling and advertisements.¹⁶⁴ Further, more sophisticated and questionable marketing methods continue to be developed. For example, uncited allusions to "research" have become more common. Recent labeling and advertisements have included the following:

clinical tests in an independent laboratory study [no citation] . . . our research shows [no citation] . . . a replication of the lipid group discovered by [manufacturer] to be lacking in dry skin [no citation] . . . long, proven track record of renowned product research [no citation] . . . links natural extracts and enzyme technology to slow down the loss of elasticity . . . binds moisture into the skin . . . fortifying nourishing creme . . . works below the surface to encourage dry skin to react more like normal

¹⁶¹ Yun L. Wolfie, *Smooth Away Wrinkles: New Way to Revitalize Older Skin*, *PREVENTION*, Sept. 1997, at 47, available in LEXIS, Health Library, Curnws File.

¹⁶² Vitamin-A derivatives (e.g., retinols) are said to have a similar effect as tretinoin (i.e., they diminish wrinkles) without the irritation. See *Skin Care & Color Cosmetics Annual Trend Report*, *supra* note 150, at 38.

¹⁶³ Isabel Burton, *The New Miracle Skin Creams*, *COSMOPOLITAN*, Oct. 1997, at 184, available in LEXIS, Health Library, Curnws File.

¹⁶⁴ *Id.*

¹⁶⁵ See *infra* note 165 and accompanying text.

skin . . . tautness is immediately reversed and suppleness restored . . . reduces signs of aging . . . a "prescriptives" [name of a cosmetic] a.a. "M.D. Formulations" [name of a cosmetic] . . . your skin ages more slowly a.. forever young.¹⁶⁵

In addition, skin care cosmetics manufacturers have advertised using before and after pictures of skin, which are *not* actual results but are, as indicated in small print, "photos [that] simulate clinical results."¹⁶⁶ Also, advertisements in newspapers simulating newspaper articles have also been used.¹⁶⁷ Thus, claims by cosmetics manufacturers appear to have become not only more "daring," but also more creative, significantly broadening the gray area established over thirty years ago.

As evidenced by the scanty case law above, the standard for determining cosmetic-as-drug claims, when applied in litigation is not obviously clear and apparent, which is perhaps one reason why the FDA has been slow to attack the numerous cosmeceuticals that patently appear to qualify as violators of the Act. Further, as seen in *Estee Lauder*, the more recent regulatory letter process is highly inefficient, and arguably ineffective, when seen in light of more recent cosmetics claims.¹⁶⁸

Combining the current reality of the FDA's emphasis upon physical safety and no clear regulation of cosmetic industry claims for its products, consumers, if knowledgeable about the FDA, can usually assume

¹⁶⁵ VOGUE, January 1994, at 69; LES NOUVELLES ESTHETIQUES, January 1994. Note that some of the cosmetics labeling and advertisements that were deemed objectionable by the FDA in its past regulatory letter efforts included: "anti-age . . . avoids formation of wrinkles" [Regulatory Letter to Burton Wanetik, Skin Culture Institute, Inc., Ref: 34-NYK-89, 1989]; "reduc[es] the visible signs of aging" [Regulatory Letter to Robert Bocchi, Cosmetics Laboratories of America, Ref: LA-40-8, 1988]; "helps prevent the visible signs of aging" [Regulatory Letter to Ronald Perelman, Revlon, Inc., Ref: 57-NYK-88, 1988]; "able to act directly on your wrinkles and noticeably decrease their depth . . . effectiveness . . . has been scientifically measured to the accuracy of the micron . . . laboratory tests have proven their effectiveness . . . nourishes and smoothes the skin . . . [manufacturer] leads the world in applying the use of plant extracts containing DNA for the benefit of beauty products . . . proven results" [Regulatory Letter to Yves Rocher, Yves Rocher, Inc., Ref: 88-PHI-43, 1988]; "protects against cell damage . . . forms an invisible 'bulletproof vest' around cells . . . neutralizing renegade 'free radicals' . . . vastly increases cell renewal . . . proven to be a catalyst that helps correct [mineral] imbalance" [Letter to Stephen Strassler, Reviva Labs, Inc., Ref: 88-NWK-23, 1988]. Arguably, these claims are similar, if not identical, to those used today and may reflect the lack of effectiveness of the current FDA policing methodology.

¹⁶⁶ VOGUE, *supra* note 165, at 69 (emphasis added).

¹⁶⁷ See Advertisement: Alpha Hydroxy, Anti-Aging Superstar: Yet Many Women Do Not Really Know What It Is, or How It Works, WASHINGTON POST, Jan. 5, 1994, at 4. The advertisement has a dateline and uses a column format and font type identical to that of a newspaper article. The advertisement speaks about an "alpha hydroxy acid" of which "[d]ermatologists discovered an amazing new benefit . . . to reduce the appearance of wrinkles . . . [and] concluded that a substance could actually reverse the skin aging process." *Id.* No citation is given.

¹⁶⁸ See *supra* note 165.

that cosmetic products are safe.¹⁶⁹ However, some cosmetic products, such as aminophylline creams and various cosmeceuticals, conceal themselves within a yet unregulated gray area between drug and cosmetics—an area that poses serious questions regarding safety.¹⁷⁰ And even if consumers may still have some degree of confidence in the FDA to monitor the safety of cosmetics, they cannot have that same level of confidence regarding the efficacy of these products.¹⁷¹ Since the claims for these products are not effectively limited to truthfulness by the FDA, consumers base their purchase decisions on haphazard claim implications rather than product quality or components. Indeed, it was the claim implications that were seen in the *Sudden Change*, *Line Away* and *Magic Secret* cases that determined liability even though all three products in question were virtually identical in composition.¹⁷² Moreover, many consumers are enticed to a greater degree by haphazard claims emphasizing hot new buzz words that label a particular product's formulation. Phrases such as "alpha-hydroxy," "beta-hydroxy," and "enzyme technology" all have a glamorizing effect on the consumer in that they label a product's new "scientifically proven" formulation, but fail to accurately convey the efficacy or safety of the product.

A primary purpose of the Act is economic protection.¹⁷³ As recognized by the *Sudden Change* court, and through its analysis of its legislative history, the Act serves to "protect . . . the ultimate consumer's economic interest."¹⁷⁴ Furthermore:

¹⁶⁹ However, even this assumption may not be true for all cosmetic products. In 1978, the U.S. General Accounting Office reported that only about 40% of manufacturers and packers had registered their plants under a voluntary industry program that is coordinated with the FDA. *See UNITED STATES GENERAL ACCOUNTING OFFICE, COSMETICS REGULATION: INFORMATION ON VOLUNTARY ACTIONS AGREED TO BY FDA AND THE INDUSTRY, GAO/HRD-90-58*, March 1990, at 2. Further, less than 20% of manufacturers, packers, and distributors had filed ingredient listings, and, importantly, less than four percent had filed injury reports. *See id.* In 1989, with the exception of the ingredient listings, participation rates in the industry show a decrease as compared with 1977. *See id.*

¹⁷⁰ *See supra* notes 61 and 103 and accompanying text (discussing significant side effects).

¹⁷¹ Compare prescription drugs, such as Renova, of which the consumer is usually assured that there has been appropriate pre-clinical and clinical testing for safety and efficacy before a new drug application is approved and the drug allowed onto the market. *See supra* note 141, at 26.

¹⁷² The products' major ingredients were bovine albumin and distilled water. *See 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), *rev'd* 409 F.2d 734, 736 (2d Cir. 1969); *United States v. An Article of Drug Consisting of 36 Boxes, More or Less, Each Containing One Bottle of an Article Labeled In Part "LineAway Temporary Wrinkle Smoother, Coty*, 284 F. Supp. 107 (D.Del. 1968), *aff'd*, 415 F.2d 369, 372 (3d Cir. 1969); *United States v. An Article of Drug . . . 47 Shipping Cartons, More or Less, . . . "Helene Curtis Magic Secret*, 331 F. Supp. 912, 915 (D.Md. 1971).

¹⁷³ *See infra* note 175.

¹⁷⁴ *Sudden Change*, 409 F.2d at 740 (emphasis added); *see also id.* at 740 n.6.

Economic harm is clearly an important consideration and will, in some instances, justify court intervention The agency must justify its delay to the court's satisfaction. . . . [I]f an agency's failure to proceed expeditiously will result in harm or substantial nullification of a right conferred by statute, "the courts must act to make certain that what can be done is done."¹⁷⁵

Thus, economic harm should be considered in determining the FDA's discretion in avoiding active enforcement of section 602 of the Act. Since this protection is mandated by the statute, and this right may arguably be currently "nullified" by FDA inactivity, the FDA may be abusing its discretion in its non-enforcement of the Act against cosmetics manufacturers.

To protect these consumer interests, a favorable solution would use, if possible, the current infrastructure and powers of the FDA and couple them with more clear and effective standards for the cosmetics industry. The use of the FDA rulemaking power may represent the optimal method for more efficient and clear regulation in support of the FDA's enforcement of the Act.¹⁷⁶

The FDA should construct a system under which it can effectively monitor skin care cosmetics claims and also address the issue of how to regulate cosmeceuticals. The fundamental regulatory tenet of this system would be to require cosmetics manufacturers, when claims are identified as they were at the outset of the regulatory letter process in the *Estee Lauder* case, to provide clear, scientifically peer-reviewed research documentation supporting the efficacy claims of the cosmetic rather than taking the cosmetic-as-drug approach.¹⁷⁷ If the manufacturer could not provide such evidence, the offending labeling could not be used and the product would be deemed misbranded under section 602 of the Act.¹⁷⁸ An alternative would be to place the burden of regulatory compliance on cosmetics manufacturers by requiring FDA approval of a product's efficacy claims before allowing their use in labeling or advertisements.¹⁷⁹ Although the latter is preferable due to its preventive rather than corrective nature, it also represents a more expensive, labor-intensive, premarket approval-type approach that currently is used for prescription

¹⁷⁵ Cutler v. Hayes, 818 F.2d 879, 898 (1987) (quoting American Broadcasting Company v. Federal Communications Comm'n, 191 F.2d 492, 501 (1951)).

¹⁷⁶ 321 U.S.C. § 371(a) (1992).

¹⁷⁷ See *infra* note 178.

¹⁷⁸ Another alternative would be to have cosmetics manufacturers publish retractions of efficacy claims as has been done with prescription drugs.

¹⁷⁹ The *Sudden Change* court indicated that "there may be merit in the cause of those who seek to require pretesting of new cosmetics," but declined to legislate such a requirement. *Sudden Change*, 409 F.2d at 742.

drugs. A policing emphasis may be less costly to the FDA while still maintaining a great enough incentive for cosmetics manufacturers to use nondeceptive claims. However, in order to maintain adequate incentives, the probability of cosmetics manufacturers not being caught using unsubstantiated claims must be taken into account. Thus, if a manufacturer is successful in avoiding FDA scrutiny fifty percent of the time, the relative penalty must be twice that of a manufacturer who is caught 100% of the time.¹⁸⁰

Defining the relative evidence requirements would begin with a rulemaking procedure,¹⁸¹ allowing the FDA, industry, consumers, and other interested parties to participate in drafting the regulation. Ultimately, perhaps one or two peer-reviewed, published studies would be required in order to allow skin cosmetics claims to be used; in conjunction, or in the alternative, a third party, such as an independent laboratory, could be involved to assess the product and industry-submitted data.¹⁸² The standard would most likely be far lower than the double-blind, clinical studies as required for new drug approval. The essential component, however, would be that researchers, other than those with the incentive to support cosmetics manufacturers' claims, have the opportunity to accept or reject the claims using established, neutral scientific review. If the claims are substantiated, the FDA may then wish to either require citation to that scientific article on the product's labeling or create a symbol of claim approval to be affixed onto the cosmetic's labeling or advertisement. In either case, it should be clear to the consumer when the FDA has approved the product's claims, and when it has not.¹⁸³

¹⁸⁰ See A. MITCHELL POLINSKY, AN INTRODUCTION TO LAW AND ECONOMICS 78-86 (2d ed. 1989).

¹⁸¹ The regulatory powers, including procedural regulations, for the FDA are derived from 321 U.S.C. § 371 (1992). The rulemaking proceeding has had extensive support in the courts:

[R]ule-making has been increasingly substituted for adjudication as a regulatory technique, with the support and encouragement of the courts. The rule-making proceeding . . . provides the [FDA] with an opportunity first to receive a wide spectrum of views proffered by all segments affected by the proposed rule . . . and then in a legislative fashion to consider and choose from several alternatives. Furthermore, once binding regulations are promulgated, the industry and public are put on notice and may be guided accordingly rather than speculate as to the outcome of a seizure or enforcement suit.

National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688, 698 (2d Cir. 1975).

¹⁸² Claim substantiation of skin care products by private organizations has been done in the past. The National Advertising Division ("NAD") of the Council of Better Business Bureaus investigated a skin care product that claimed to "accelerate the natural skin cell renewal process" and "restore the skin's youthful ability to care for itself." McNamara, *supra* note 21, at 158. The NAD found that the product's manufacturer was able to provide valid scientific support for its claims. *See id.*

¹⁸³ See also *supra* note 178 (noting retractions of wrongful claims may be beneficial to provide consumers with appropriate information on efficacy).

This proposal uses the current regulatory infrastructure to identify questionable cosmetic claims. Thus, by using the already existing mechanism for identifying offending labeling and advertisement claims, the new proposal has not created a fundamentally new bureaucracy. In addition, by putting the burden of proof on the industry and simply treating the cosmetic as a cosmetic, the burden on the FDA to prove, if necessary in court, that the cosmetic in question is a drug under the statutory definition, is obviated. Also, the extensive costs and wasted resources that result from wrangling over advertisements and modifications thereof, as was seen in the *Estee Lauder* case, are minimized.

Further, through use of the rulemaking procedure, a standard of evidence with party input, and thus legitimacy, will be established that gives relatively clear guidance by which cosmetics claims are to be scrutinized. From the industry point of view, a standard that has been formulated with its input will reduce the relative allocation of resources necessary for negotiations with the FDA as to appropriate labeling standards, as well as decrease the uncertainty as to the agency's relevant review methods. In addition, the honest competitor in the industry that is reluctant to continually push the line of ethical marketing will be protected, and competitors will compete on the basis of quality of the product, not on the basis of unsubstantiated labeling or advertisements.¹⁸⁴

In a world of limited resources, sanctions should also be considered from an efficiency and cost-effectiveness point of view. If a cosmetics manufacturer has not corrected claims deemed inappropriate by the FDA, informal mechanisms such as publicity (particularly general media such as television), warning letters, voluntary detainment and voluntary recalls should be attempted first. Only if these solutions are not effective should the FDA exercise its formal, but expensive, powers of enforcement, including seizure, injunction, and criminal prosecution.¹⁸⁵ By the use of minimally expensive solutions with progressively more powerful, albeit expensive, alternatives, FDA enforcement costs will be expended only to the extent marginally necessary.¹⁸⁶

Finally, there are other policy rationales as to why cosmetic claims require more effective policing. First, the very labeling and advertisements that represent clearly questionable claims are subsidized by the

¹⁸⁴ Shifting some of the approximately two billion dollars spent annually on cosmetics advertising, see McNamara, *supra* note 21, at 157, to efficacy research and publication will serve the consumer by resulting in more accurate labeling and advertising and a greater range of efficacious products. Honest competitors will flourish due to competition based upon product quality.

¹⁸⁵ See also *supra* note 178.

¹⁸⁶ The FDA may wish to consider requesting Congress to implement user fees for cosmetics regulation similar to that for new prescription drugs. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1840 (1996).

federal government. Advertisement and other business expenses are deductible from corporate taxes under section 162 of the Internal Revenue Code.¹⁸⁷ Because of the implicit benefit given to cosmetics manufacturers by the government for deduction of advertising and labeling costs, the government in turn should demand a high quality of information from manufacturers in their communications to consumers. The government should not subsidize potential fraud. Second, from a statutory point of view, nowhere in the Act is there allowance for cosmetics manufacturer "puffery" by the FDA. If the product can substantiate safety and efficacy claims, it is in compliance with the Act. On the other hand, if the product is misbranded due to lack of efficacy, it is in violation of section 602 of the Act. The FDA (or the courts) should not be allowed to impose a limitation on the protection of consumers that was not intended by Congress through the Act itself. Finally, the use of scientific and medical terminology in an inappropriate fashion, implying technical certainty and/or testing to the unwary consumer, is an abuse of science and should not be used to represent the imprimatur of the scientific or medical community on these products.

CONCLUSION

The practice of claiming questionable benefits for skin care cosmetic products has continued and become more "daring" since the classic cases of thirty years ago. The current FDA system of regulating questionable cosmetics claims through a cosmetic-as-drugs strategy, however, is inefficient for both the FDA and the cosmetics industry. Furthermore, consumers, on the basis of past and current FDA actions, cannot differentiate truthful and untruthful cosmetics claims.

In addition, beyond mere cosmetics, which pose only a risk of economic loss, numerous cosmeceuticals being marketed as cosmetics also have the potential for causing physical harm. Thus, not only is there a need for the FDA to crack down on cosmetics manufacturers that are marketing products that should be regulated as drugs under the Act, but there is an even greater need for the FDA to utilize section 602 of the Act to eliminate cosmetic advertisements that mislead consumers into believing a product is effective simply because non-cited claims say so. Consumers are entitled to feel secure that they are fully informed as to the safety and efficacy of the product they are buying. At the present time, they have little foundation on which to base any such security.

By using the current FDA infrastructure to identify questionable claims and also requiring scientific, peer-reviewed proof of safety and

¹⁸⁷ Itemized Deductions for Individuals and Corporations: Trade or Business, I.R.C. § 162 (1993).

efficacy for substantiation of these claims, the difficulties consumers face with respect to both cosmetics and cosmeceuticals would be alleviated. The standard of proof would be determined through a rulemaking process so as to involve the FDA, industry, consumers, and other interested parties. In this fashion, a legitimized standard would emerge for determining efficacy of skin care products. Sanctions would be also selected on the basis of efficiency and would move progressively from informal to formal measures, so as to utilize only the marginally necessary resources for enforcement of the Act.

The cosmetics industry has come a long way in its attempts to develop, market, and sell its products. The FDA, however, has not concomitantly evolved an efficient method of protecting the public's economic and physical safety from questionable cosmetic products. By requiring substantiation of cosmetics safety and efficacy claims, the interests of the FDA, the honest cosmetics manufacturer, and the consumer are jointly advanced.