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# The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids

LAURA A. HEYMANN \*

"Time doth transfix the flourish set on youth  
And delves the parallels in beauty's brow."  
— Shakespeare, Sonnet 60, l. 9-10

"Old age is woman's hell."  
— Ninon de L'Enclos (1620-1705)

## I. INTRODUCTION

In 1935, the *New Yorker* reported that 200 women visited Elizabeth Arden's New York salon each day to reap the benefits of the salon's "Vienna Youth Mask," "a device made of papier-mâché and lined with tin foil," which was fitted to the face and connected to an electrical current to "replenish" the cells.<sup>1</sup> There was, of course, no scientific evidence proving the mask's effectiveness. But this is not the case with alpha-hydroxy acids (AHAs), an ingredient in several dozen skin-cream formulations. No product ingredient in recent memory has caused the reaction that AHAs have. Women's magazines, word of mouth, and aggressive marketing have spread the message that AHAs are the first skin-care ingredients that achieve lasting effects by exfoliating the top layer of skin, revealing "new" skin underneath. Soon after their appearance on the mass market in 1992, AHA products rapidly became a booming business. Sales of Avon's Anew, one of the first mass-marketed AHA products, totaled \$70,000,000 in the product's first year on the market;<sup>2</sup> in 1996 sales of AHA-based products reached a half-billion dollars a year.<sup>3</sup>

In the midst of this furor, however, the question of the product's safety has, until recently, gone largely unanswered. Spurred by reports of adverse reactions to AHA-based products, the Food and Drug Administration (FDA) began focusing a more critical eye on the industry early in 1995, believing the use of AHAs in cosmetics to represent "a significant departure from traditional cosmetic ingredients and products."<sup>4</sup> Two subsequent clinical studies and a review by an industry panel have suggested not only that the product does achieve its promised results but also that it is generally safe in low concentrations despite the possible increase in sun sensitivity. FDA currently is conducting its own review of the data and plans to issue its findings

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\* Ms. Heymann currently is serving as a Clerk to the Hon. Patricia M. Wald, U.S. Court of Appeals for the D.C. Circuit. The views expressed in this article are solely those of the author. A previous version of this article won First Place in the 1997 H. Thomas Austern Memorial Writing Awards Competition sponsored by FDLI.

<sup>1</sup> MARGARET ALLEN, *SELLING DREAMS: INSIDE THE BEAUTY BUSINESS* 33 (1981).

<sup>2</sup> Patricia McLaughlin, *About Face*, PHILADELPHIA INQUIRER, Mar. 7, 1993, at 31. The product's success inspired manufacturers to introduce more than 50 AHA products to the market in 1993. Susan Sargisson, *The AHA Phenomenon*, DRUG & COSM. INDUS., Jan. 1, 1994, at 24.

<sup>3</sup> Lauren Neergaard, *FDA to Study Wrinkle Cream, Effect of Sensitivity to Sun*, COURIER -J. (Louisville, KY), Dec. 22, 1996, at 14A.

<sup>4</sup> Letter from John Bailey, Dir., Off. of Cosmetics and Colors, FDA, to Alan Andersen, Sci. Coordinator and Dir., Cosmetic Ingredient Review Expert Panel, CTFA (Nov. 30, 1995), quoted in F-D-C REP. ("The Rose Sheet"), Dec. 11, 1995, at 1, 3.

before the end of 1997. The agency also plans to meet with the cosmetics industry to discuss an appropriate response.<sup>5</sup>

One of the primary, and indeed threshold, questions facing FDA in this review is whether products containing AHAs are to be considered cosmetics or drugs under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA),<sup>6</sup> the statutory basis for the agency's regulatory power. Under most interpretations of the FDCA with regard to cosmetics, the answer to this question would be rooted not in the chemical composition or physiological effect of AHAs but rather in how the manufacturer has positioned the product and the promises made as to its effects.<sup>7</sup> The cosmetic/drug distinction has considerable implications for the cosmetics industry because of the difference in regulation between cosmetics and drugs, most notably the lack of any requirement of premarket review for cosmetic products. A decision that AHAs are to be regulated as drugs could force manufacturers to pull available products from the market and submit extensive tests as to the products' safety and effectiveness for FDA approval, clearly an undesirable result for the industry. But a decision that the products are to be treated as cosmetics means that any regulation of their safety comes completely *ex post* in the form of product liability suits<sup>8</sup> or FDA seizure proceedings, which involve considerable government resources.

This paper will review the history of the FDCA, the current state of the law, and the likely resolution of this issue as the FDCA now stands. It ultimately concludes that perhaps the biggest obstacle to the resolution of this and similar issues arising from the cosmetic/drug distinction is the lack of a statutory definition that would encompass cosmetic products that have drug-like effects. This paper suggests that, in light of industry developments, congressional reexamination of the FDCA is in order.

## II. BACKGROUND

### A. Alpha-Hydroxy Acids

AHAs have been used for many years to adjust pH levels in cosmetic products, but it is only recently that they have been touted as the elixir of youth.<sup>9</sup> The term AHA comprises a group of organic carboxylic acids in which a hydroxy group is at the alpha position, including glycolic, lactic, citric, malic, mandelic, and tartaric acids.<sup>10</sup> Each of these acids has a natural derivation but now also is produced synthetically for use in creams and lotions.<sup>11</sup> Products sold to the mass market generally contain less than ten percent AHA; products sold for use in salons typically contain twenty percent

<sup>5</sup> Neergaard, *supra* note 3, at 14A.

<sup>6</sup> Pub. L. No. 75-717, § 201(g), (h), 52 Stat. 1040, 1041 (codified as amended 21 U.S.C. § 321(g), (h) (1994)).

<sup>7</sup> This interpretation is now open to question after a recent federal court ruling that upheld the FDA's power to regulate tobacco. See *infra* text accompanying notes 82-87.

<sup>8</sup> Of course, the possibility of suit is an incentive for manufacturers to ensure the safety of their products before marketing them. See *infra* text accompanying notes 123-24.

<sup>9</sup> The first patent for AHAs was filed in 1976 by Drs. Eugene Van Scott and Ruey J. Yu, who are credited with discovery of the potential of AHAs. See Sargisson, *supra* note 2, at 24; Eugene J. Van Scott & Ruey J. Yu, *Alpha-Hydroxy Acids: Procedures for Use in Clinical Practice*, 43 CUTIS 222 (1989).

<sup>10</sup> ZOE DIANA DRAELOS, COSMETICS IN DERMATOLOGY 241 (2d ed. 1995).

<sup>11</sup> *Id.* Glycolic acid is derived from sugar cane, lactic acid is derived from fermented milk, citric acid is found in citrus fruits, malic acid is found in unripened apples, mandelic acid is an extract of bitter almonds, and tartaric acid is found in fermented grapes. *Id.*

to forty percent AHA; and products sold for medical use can contain as much as seventy percent AHA.<sup>12</sup>

Although the acids have been isolated comparatively recently, women have used substances containing AHAs as a facial preparation for centuries. Women in ancient Rome, for example, would use the sludge from wine barrels as a facial mask, and Cleopatra is said to have bathed in sour milk (a source of lactic acid) as a beauty treatment.<sup>13</sup> The Duchess of Alba applied orange pulp to her face, and Queen Elizabeth of Hungary, in the nineteenth century, would create beauty preparations from lemons and wine.<sup>14</sup> Mass marketing of AHAs also predated the twentieth century — Guerlain, the cosmetics manufacturer, marketed "cosmetic vinegars" based on fruit acids in 1830.<sup>15</sup>

Researchers have not determined definitively how AHAs work, but it is believed that they have two primary effects on the skin. First, the acids loosen the bonds in the stratum corneum (within the epidermis) that hold dead skin cells together, which encourages a faster sloughing process and the production of new skin cells. Second, the acids are believed to thicken underlying layers of the skin and increase the amount of hyaluronic acid, a gelatinous substance that holds cells together.<sup>16</sup> It is still unclear, however, exactly what effect AHAs have on deeper levels of the skin, a question that may become crucial to the issue of FDA regulation.

Despite its extensive lineage, the safety of AHAs, particularly at higher concentrations, remains uncertain. One 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.<sup>17</sup> But as the AHA concentration increases, so does the chance of adverse side effects, particularly a burning of the skin. In 1994, the FDA received more than thirty-five reports of adverse reactions to AHAs, which represented forty-four percent of such reports concerning skin-care products for the year.<sup>18</sup> These concerns, coupled with the recent increase in the number of products marketed that contain AHAs,<sup>19</sup> have spurred several clinical studies. One such study, conducted jointly by researchers from Boston's Massachusetts General Hospital and Beth Israel Hospital, concluded that AHAs had "modest but real benefits" in women with mild to moderate photoaging (sun damage).<sup>20</sup> (The researchers were careful to distinguish

<sup>12</sup> Anita Shaw, *The News in Skin Care*, SOAP-COSM.-CHEM. SPECIALTIES, Oct. 1, 1996, at 72.

<sup>13</sup> Maria Liberati, *Alpha & Beta Hydroxy Acids: The Skin-Care Revolution*, BETTER NUTRITION, Apr. 1996, at 70.

<sup>14</sup> *Id.*

<sup>15</sup> Shelley M. Colwell, *AHAs: The Reigning Ingredient*, SOAP-COSM.-CHEM. SPECIALTIES, Feb. 1, 1996, at 30 (citing Dana Glazer, Dir., Pub. Relations, Guerlain).

<sup>16</sup> Susan Brink, *The Dewrinkling of America, Alpha Hydroxy Acids in Pricey Creams Are the Latest Antiaging Elixir*, U.S. NEWS & WORLD REP., Jun. 6, 1994, at 79; Bernard Idson, *Retinoids and AHAs*, DRUG & COSM. INDUS., May 1, 1995, at 24.

<sup>17</sup> See, e.g., Colwell, *supra* note 15, at 30 (quoting Alex Znaiden, Dir., Global Skin Innovation Center, Chesebrough-Pond's) ("If you have delivered the concentration, that's going to keep your customer with you.").

<sup>18</sup> Alpha Hydroxy Acids (AHAs), U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition, Office of Cosmetics Fact Sheet (May 3, 1995). Based on the 97 complaints received by the agency since 1989, and on the agency's assumption that one report to the agency equals approximately 50 to 100 reports received by manufacturers, FDA estimated that cosmetic companies had received about 10,000 reports of adverse reactions to AHAs. F-D-C REP. ("The Rose Sheet"), Mar. 4, 1996, at 5. Industry representatives have questioned this finding, noting that the recent publicity given to AHAs likely encouraged a higher rate of adverse reaction reports. See F-D-C REP. ("The Rose Sheet"), Mar. 11, 1996, at 1-3.

<sup>19</sup> FDA's available data, which is reported voluntarily by the industry, indicated that glycolic acid was used in 90 products in 1996. F-D-C REP. ("The Rose Sheet"), Dec. 23, 1996, at 1-3.

<sup>20</sup> Matthew J. Stiller et al., *Topical 8% Glycolic Acid and 8% L-Lactic Acid Creams for the Treatment of Photodamaged Skin*, 132 ARCHIVES OF DERMATOLOGY 631, 632 (1996). The double-blind, vehicle-controlled



photoaging, or "extrinsic aging," upon which AHAs could have an effect, from intrinsic aging — resulting from a genetic decline in physiological functions — upon which AHAs have no effect.)<sup>21</sup>

A second study, published three months later, concluded that a five percent lactic acid formula caused a significant increase in superficial skin firmness; a twelve percent formula also caused increases in integral skin firmness.<sup>22</sup> The acid also caused an increase in epidermal thickness (with an increase in dermal thickness at the higher concentration), as well as improvement in the appearance of lines and wrinkles.<sup>23</sup> The study also concluded that the skin eventually would become resistant to AHA at the five percent concentration such that no additional benefits would become apparent.<sup>24</sup>

Two more recent studies have proven to be of particular interest to FDA. A study conducted by FDA's Office of Cosmetics and Colors in December 1996 concluded that although AHAs do not affect the skin's penetrability, they do "drastically alter[]" the structure of the skin, inducing as much as a four-fold increase in the thickness of the epidermis (the top layer of the skin).<sup>25</sup> In the spring of 1997, the Cosmetic Ingredient Review (CIR), an independent review panel established by the Cosmetic, Toiletry, and Fragrance Association (CTFA), completed its study of the safety of AHAs, concluding that AHAs are safe for use in retail products at concentrations of ten percent or less in a finished product formula with a pH of 3.5. The CIR also took note of the increased sun sensitivity caused by the AHA lotions and concluded that products either should be formulated to take this into account or should carry a recommendation that consumers wear sunscreen.<sup>26</sup>

Several industry journals have pointed to the weakness of this study, noting that successful implementation relies heavily on self-regulation and that the "lucrative market" for AHA-based products may have influenced the result.<sup>27</sup> FDA is conducting its own study (possibly with these concerns in mind) and is considering regulatory options, particularly in light of the agency's history of regulating anti-aging products.

## B. FDA Regulation of Anti-Aging Products

FDA historically has looked at "wrinkle creams" and other anti-aging products with a somewhat skeptical eye. The genesis of the most recent surveillance was in 1985, when FDA Commissioner Frank E. Young, in a speech to the CTFA, warned manufacturers of skin-care products to tone down their extreme claims or risk a regu-

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study was funded in part by Unilever, parent company of Chesebrough-Pond's, the manufacturer of the products used in the study. Unilever was not, however, involved in the study's design or conduct. Doug Levy, *Beauty: Age-Defying Creams Really Work but FDA Stays Cautious*, DERMATOLOGY NEWS, Jun. 15, 1996, at C1.

<sup>21</sup> Stiller et al., *supra* note 20, at 635.

<sup>22</sup> Walter P. Smith, *Epidermal and Dermal Effects of Topical Lactic Acid*, 35 J. AMER. ACAD. OF DERMATOL-OGY 388, 389 (1996).

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 390.

<sup>25</sup> F-D-C REP. ("The Rose Sheet"), Dec. 23, 1996, at 5. This study was conducted on hairless guinea pigs and thus has been criticized as an inappropriate model for human skin, which has a different absorption rate. See *id.* at 6 (describing findings of Norman Weiner, Ph.D.).

<sup>26</sup> Anita Shaw, *An AHA Update*, SOAP-COSM.-CHEM. SPECIALTIES, Mar. 1, 1997, at 30. See also Statement of the Cosmetic, Toiletry, and Fragrance Association on the Cosmetic Ingredient Review, Upholding the Safety of Alpha-Hydroxy Acids (Dec. 17, 1996).

<sup>27</sup> *Sensitive Feelings*, COSM. INSIDERS REP., Feb. 10, 1997; see also *Not Likely!*, DRUG & COSM. INDUS., Feb. 1, 1997, at 20. These editorials attacked the preliminary version of the CIR study; the panel reached the same conclusions in its final report.

latory response.<sup>28</sup> In 1987, Daniel L. Michels, Director of the Office of Compliance for FDA's Center for Drugs and Biologics, sent warning letters to more than twenty cosmetic manufacturers and distributors regarding what the agency believed to be therapeutic claims about certain anti-aging or anti-wrinkle creams.<sup>29</sup> Michels informed the companies that on the basis of these claims, the products were unapproved new drugs that would be subject to regulation if the companies failed to act.<sup>30</sup> The companies, in response, called for a new perspective on products that were the result of advances in cosmetic technology.<sup>31</sup> Another round of letters from the agency followed, stating:

[W]e consider a claim that a product will affect the body in some physiological way to be a drug claim, even if the claim is that the effect is only temporary . . . . Therefore, we consider most of the anti-aging and skin physiology claims . . . to be drug claims . . . . [W]e would consider a product that claims to improve or to maintain temporarily the appearance or the feel of the skin to be a cosmetic. For example, a product that claims to moisturize or soften the skin is a cosmetic.<sup>32</sup>

FDA eventually gave the companies a deadline of April 24, 1988, to change their claims or face the possibility of regulatory action; most complied.<sup>33</sup>

In 1992, FDA targeted Global Esthetics, the manufacturer of a product called "PeelAway," which used high levels of AHAs to cause skin peeling.<sup>34</sup> The manufacturer claimed the product would remove wrinkles, blemishes, and blotches; FDA received four reports of skin burns in consumers of the product. In a warning letter sent to the manufacturer, FDA stated that it considered PeelAway to be an unapproved new drug and that the product was misbranded and presented a "significant health hazard."<sup>35</sup>

As of this writing, FDA has taken no action against manufacturers of AHA-based products, although it has raised concerns regarding their safety.<sup>36</sup> Because any power FDA has in this regard is the result of statutory grant, further consideration of this issue requires a brief look at the FDCA.

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<sup>28</sup> Emalee G. Murphy, *Cosmeceuticals — The Regulatory Environment or the Cosmetic Wars and Other Phenomena*, 44 FOOD DRUG COSM. L.J. 41, 41 (1989).

<sup>29</sup> See *Estée Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1 (D.D.C. 1989), in which the District Court for the District of Columbia rejected a challenge by the Estée Lauder company to the regulatory authority of FDA over seven of its skin creams. The company had claimed in advertisements that its "Night Repair Cellular Recovery Complex" would "accelerate the natural repair of cells" and that the cream had "changed the science of skin care to skin repair." The company also had claimed that other products would "restructure and repair" the skin and "work inside cell layers to counteract aging forces." *Id.* at 3 n.1. Avon received a warning letter regarding its product BioAdvance, for which it had claimed, "Actually helps reverse many signs of facial aging in just 6 weeks . . ." F-D-C REP. ("The Rose Sheet"), Mar. 18, 1996, at 12, 14.

<sup>30</sup> Murphy, *supra* note 28, at 43-44.

<sup>31</sup> *Id.* at 44.

<sup>32</sup> *Id.* at 44-45 (quoting cosmetic regulatory letters from John M. Taylor, Assoc. Comm'r for Reg. Affs., to cosmetic skin care companies (Nov. 19, 1987)).

<sup>33</sup> *Id.* at 45; Thomas J. Donegan, *Fifty Years of Cosmetic Safety: A Government and Industry Partnership*, 50 FOOD & DRUG L.J. 151, 158 (1995).

<sup>34</sup> Skin Peelers, HHS News, U.S. Dept. of Health & Human Servs., Food & Drug Admin., P92-13 (May 21, 1992).

<sup>35</sup> *Id.*

<sup>36</sup> "Little is known about the overall safety of AHAs when they are used as chemical exfoliants because this is a relatively new application." AHAs, Office of Cosmetics Fact Sheet, *supra* note 18. John Bailey, Director of the agency's Office of Cosmetics and Colors, has suggested that regulation of AHAs is among the agency's current priorities. See *Countercurrents*, COSM. INSIDERS' REP., Mar. 24, 1997.

### C. *The Federal Food, Drug, and Cosmetic Act of 1938*

#### 1. *Legislative History*

FDA's power to regulate cosmetic products appeared for the first time in the FDCA. Government regulation of cosmetics had not been included in the 1906 Food and Drug Act,<sup>37</sup> a lacuna that was noted by an agency official in 1917: "While the accomplishments of the Food and Drug Act have been considerable, it must be admitted that it has its serious limitations. Especially conspicuous ones are . . . the limitations placed upon the term 'drug' by definition which render it difficult to control injurious cosmetics . . ."<sup>38</sup> Senator Copeland of New York took up the challenge in 1933, motivated by reports from the agency of cosmetic injury from such products as "Koremlu Cream," a depilatory containing thallium acetate, a highly poisonous chemical. The product, as stated by FDA in its annual report in 1933, had been represented as "entirely harmless and actually beneficial to the skin," and its widespread popularity had caused "many cases of severe injury to users before the manufacturer was forced into bankruptcy by accumulation of damage suits. The Federal Government, lacking legal authority to control cosmetics, was unable to give the consumer the protection which should have been afforded."<sup>39</sup> Copeland thus introduced S. 1994, the first of several versions of the Act, on June 6, 1933. The Senate's concern over cosmetic safety was manifest in section 5 of the bill, which prohibited adulterated cosmetics. Under the proposed legislation, a cosmetic would be deemed adulterated if it was or could be "injurious" to the user under the usual or prescribed conditions of use, or if it contained any "poisonous or deleterious ingredient" limited or prohibited by agency regulation.<sup>40</sup> The breadth of S. 1994, however, "met with violent opposition from every section of the country,"<sup>41</sup> and its substitute, S. 2000, changed the first part of section 5 to define an adulterated cosmetic as one that "bears or contains any poisonous or deleterious substance" that might render it injurious to the user under the usual or prescribed conditions of use.<sup>42</sup> The change, which substantially was maintained in later versions of the bill, thus focused FDA regulation on the composition of the cosmetic as the source of injury.

Another change in the legislation as it passed through its various versions occurred in the definition of the term "drug." In the original Senate bill, as in the FDCA as it now reads, food was excluded from the last portion of the definition of "drug": "all substances, preparations, and devices (other than food) intended to affect the structure of any function of the body." By the time the bill reached the House Commit-

<sup>37</sup> Pub. L. No. 59-384, 34 Stat. 768 (1906).

<sup>38</sup> Annual Report of the Chief of the Bureau of Chemistry, Food & Drug Admin. (1917), reprinted in *FEDERAL FOOD, DRUG AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD* 24-25 (Charles Wesley Dunn ed. 1938) [hereinafter *LEGISLATIVE RECORD*].

<sup>39</sup> Annual Report of the Food & Drug Admin. for Fiscal Year Ending June 30, 1933, reprinted in *LEGISLATIVE RECORD*, *supra* note 38, at 26. The dangers of Koremlu Cream also had been well documented in ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS 80-88 (1933).

<sup>40</sup> S. 1994, 73d Cong. § 5 (1933), reprinted in *LEGISLATIVE RECORD*, *supra* note 38, at 39.

<sup>41</sup> As a Senate report on yet another version of the bill noted, the bill was revised "for the purpose of allaying the apprehensions of honest manufacturers without sacrificing the essential requirements for consumer protection." S. REP. NO. 361, 74th Cong. (1935), reprinted in *LEGISLATIVE RECORD*, *supra* note 38, at 238.

<sup>42</sup> *LEGISLATIVE RECORD*, *supra* note 38, at 54. "[The statute] would not prevent the marketing of a face powder or cream or any other cosmetic which did not contain poisonous or deleterious ingredients, even though such cosmetics might contain ingredients to which a certain class of unfortunate people are allergic." S. REP. NO. 361, 74th Cong. (1935), quoted in PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 815 (2d ed. 1991).

tee on Interstate and Foreign Commerce on May 31, 1935, both food and cosmetics were excluded from the definition.<sup>43</sup> This version of the bill died in the House, however, and when the bill was reintroduced as S. 5 in the Senate on January 6, 1937, the cosmetics exception was no longer present.<sup>44</sup> As a result, the definitions of "drug" and "cosmetic" are not mutually exclusive, and a product that fits both definitions must comply with both sets of regulations.<sup>45</sup>

## 2. *The Regulation of Cosmetics and Drugs Under the FDCA*

The regulation of cosmetics under the FDCA differs from the regulation of drugs in one significant respect: Cosmetic manufacturers are exempt from premarket review of their products. This means that a potentially dangerous cosmetic usually is discovered only after it has reached the market and caused conspicuous harm to a consumer.

Cosmetic regulation is delineated in sections 361 to 363 of title 21 of the *United States Code*, which, in conjunction with section 331, prohibit the adulteration<sup>46</sup> or misbranding<sup>47</sup> of any cosmetic in interstate commerce. Thus, a cosmetic product can be unlawful either as a result of its substance or as a result of its labeling. A cosmetic product is unlawful if it contains a "poisonous or deleterious substance which may render it injurious" pursuant to customary use;<sup>48</sup> if it contains a "filthy, putrid, or decomposed substance";<sup>49</sup> or if it has been manufactured or packaged under unsanitary conditions.<sup>50</sup> A cosmetic also may be found unlawful if its label or container is false or misleading<sup>51</sup> or if it fails to bear required information.<sup>52</sup> The FDCA thus gives FDA the authority to regulate products on the market that are found to be particularly harmful or for which misleading claims have been made. But because the FDCA does not require cosmetic manufacturers to submit any information to the agency, regulation must be conducted entirely on the basis of information voluntarily supplied by manufacturers<sup>53</sup> or on a postmarket basis in response to consumer complaints or other alerting mechanisms.

Drug regulation, by contrast, is considerably more extensive, with much of the statutory subchapter devoted to safety.<sup>54</sup> As with cosmetics, the adulteration of drugs is prohibited, although the FDCA further provides that a drug may be considered adulterated if it is not manufactured in accord with "current good manufacturing practices" to ensure safety, quality, and purity.<sup>55</sup> A drug, like a cosmetic, is unlawful if it is

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<sup>43</sup> LEGISLATIVE RECORD, *supra* note 38, at 297.

<sup>44</sup> *Id.* at 638. No reason appears in the legislative history for the exception's appearance or subsequent disappearance.

<sup>45</sup> FOOD & DRUG ADMIN., CENTER FOR FOOD SAFETY & APPLIED NUTRITION, COSMETICS HANDBOOK (1992).

<sup>46</sup> 21 U.S.C. § 361 (FDCA § 601).

<sup>47</sup> *Id.* § 362 (FDCA § 602).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* § 361(b) (FDCA § 601(b)).

<sup>50</sup> *Id.* § 361(c) (FDCA § 601(c)).

<sup>51</sup> *Id.* § 362(a), (d) (FDCA § 602(a), (d)).

<sup>52</sup> *Id.* § 362(b), (c) (FDCA § 602(b), (c)).

<sup>53</sup> The voluntary regulations are codified at 21 C.F.R. pts. 710, 720, 730 (1996).

<sup>54</sup> Many of the burdens of approval can be alleviated if the drug conforms to an already-existing over-the-counter (OTC) drug monograph, which provides a set of regulatory standards for various OTC drugs. Premarket approval is not required for drugs that conform to these standards. William E. Gilbertson, *The Impact of the FDA's Over-the-Counter Drug Review Program on the Regulation of Cosmetics*, in *THE COSMETIC INDUSTRY* 71, 79-80 (Norman F. Estrin ed. 1984).

<sup>55</sup> 21 U.S.C. § 351(a)(2)(B) (FDCA § 501(a)(2)(B)).



misbranded, that is, if its label is false, misleading, fails to give adequate directions for use, or otherwise does not conform to the law,<sup>56</sup> or if the drug is dangerous to health when used as recommended.<sup>57</sup> Here, however, the similarity to cosmetics regulation ends. The FDCA further provides that all drug manufacturers must register with the Secretary of the Department of Health and Human Services (DHHS) and provide a list of all drugs manufactured.<sup>58</sup> Furthermore, no new drug may be placed on the market without application to and approval from the agency. The application must contain full reports of research conducted as to the safety and efficacy of the drug; a complete list of the drug's ingredients and description of its manufacturing process; and a sample of the proposed labeling for the drug.<sup>59</sup> Once the drug has been approved, the manufacturer must submit to the agency any information regarding clinical trials or any other information that suggests that the drug is a hazard to public health,<sup>60</sup> and the agency may revoke its approval upon review of this information.<sup>61</sup>

In sum, the FDCA provides for considerable premarket review of any new drug, particularly with respect to the safety and efficacy of the drug. No such review takes place for new cosmetics, nor are cosmetic manufacturers required to register with FDA, a situation that has concerned Congress enough to initiate hearings and legislation,<sup>62</sup> but not enough to amend the FDCA.<sup>63</sup>

Of course, how a product is to be regulated depends entirely on how it is defined. The FDCA defines "cosmetic" 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<sup>64</sup>

and "drug" as "(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . ." <sup>65</sup> The Supreme Court has tended to read this definition expansively and thus not confined itself to the strict medical definition of the word "drug."<sup>66</sup> "Con-

<sup>56</sup> *Id.* § 352(a), (b), (c), (f) (FDCA § 502(a), (b), (c), (f)).

<sup>57</sup> *Id.* § 352(j) (FDCA § 502(j)).

<sup>58</sup> *Id.* § 360 (FDCA § 510).

<sup>59</sup> *Id.* § 355(b) (FDCA § 505(b)). Of course, the procedure is considerably more complex than the brief summary offered here.

<sup>60</sup> *Id.* § 355(k) (FDCA § 505(k)).

<sup>61</sup> *Id.* § 355(e) (FDCA § 505(e)).

<sup>62</sup> See Jacqueline A. Greff, *Regulation of Cosmetics That Are Also Drugs*, 51 FOOD & DRUG L.J. 243, 244 n.14 (1996) (citing, e.g., H.R. 2244, 83d Cong. (1953); H.R. 4476, 84th Cong. (1955); H.R. 4015, 85th Cong. (1957); H.R. 4431, 85th Cong. (1957); H.R. 9153, 85th Cong. (1957); H.R. 1360, 86th Cong. (1959); H.R. 5661, 86th Cong. (1959); H.R. 1235, 87th Cong. (1961); H.R. 11,582, 87th Cong. (1962); H.R. 1235, 88th Cong. (1963); H.R. 5777, 88th Cong. (1963); H.R. 6788, 88th Cong. (1963); H.R. 8418, 88th Cong. (1963); H.R. 1235, 89th Cong. (1965); H.R. 1235, 90th Cong. (1967); H.R. 4486, 90th Cong. (1967)).

<sup>63</sup> "In my view, these regulatory gaps raise serious questions about the Food and Drug Administration's ability to effectively oversee the cosmetics industry in this country." *Potential Health Hazards of Cosmetic Products: Hearings Before the Subcomm. on Reg. and Bus. Opportunities of the House Comm. on Small Bus.*, 100th Cong. 2 (1989) [hereinafter *Hearings*] (statement of Rep. Wyden, Comm. Chair).

<sup>64</sup> 21 U.S.C. § 321(i) (FDCA § 201(i)).

<sup>65</sup> *Id.* § 321(g)(1) (FDCA § 201(g)(1)).

<sup>66</sup> *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 793 (1969).

gress fully intended," the Court noted in 1969, "that the Act's coverage be broad as its literal language indicates — and equally clearly, broader than any strict medical definition might otherwise allow."<sup>67</sup> This creates considerable problems for manufacturers of many cosmetic products because almost any cosmetic can be said to have *some* effect on the structure of the body, however minute.<sup>68</sup> In reality, the practical distinction has come to be that a cosmetic is a substance that engenders a temporary, superficial effect, linked closely to one's appearance, while a drug is a substance that causes a more permanent, structural change in one's health. There is no requirement, however, that a product's effects take place as a result of chemical or metabolic action for the product to be considered a drug — the agency interprets the statutory definition of "drug" simply as "a chemical or a combination of chemicals in liquid, paste, powder, or other drug dosage form that is ingested, injected, or instilled into body orifices, or rubbed or poured onto the body in order to achieve its intended medical purpose."<sup>69</sup> To date, FDA has declined to establish guidelines that would elucidate the cosmetic/drug distinction, stating that each claim has to be examined in context.<sup>70</sup>

The key to both definitions, however, is the word "intended" — a product can be classified as a drug or as a cosmetic only if it is intended to be used as one. Thus, both definitions are driven not by the chemical composition of the product but rather by the objective intent<sup>71</sup> of the manufacturer in marketing the product — until recently, whether the manufacturer promoted the product as having therapeutic or merely superficial effects.<sup>72</sup> As the Second Circuit noted in 1969, "Regardless of the actual physical effect of a product, it will be deemed a drug for purposes of the Act where the labeling and promotional claims show intended uses that bring it within the drug definition."<sup>73</sup> This focus has resulted in a rather untenable system, in that the status of a product may change according to the whims of the manufacturer, depending on the advertising claims the manufacturer has promulgated, the label, promotional material, and "any other relevant source."<sup>74</sup> A savvy manufacturer could keep its product from extensive regulation and premarket testing, regardless of the product's safety, merely by

<sup>67</sup> *Id.* at 798. As a result, the Court held that a disc used by physicians to determine the correct antibiotic to administer to patients fell within the Act's definition of "drug." *Id.* at 799-800.

<sup>68</sup> See *Compounder's Corner*, DRUG & COSM. INDUS., Mar. 1, 1997, at 64 (noting belief that the FDCA's definition of cosmetics is a "biological oxymoron").

<sup>69</sup> Reclassification of Lacrisert as an Approved New Drug, 47 Fed. Reg. 46,139, 46,140 (1982). Note, however, that the statutory definition of "device," at 21 U.S.C. § 321(h), is almost identical to that of drug save that the definition of "device" contains the restriction "which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes," suggesting that "drugs," by contrast, do act in this manner.

<sup>70</sup> Donegan, *supra* note 33, at 158.

<sup>71</sup> See 21 C.F.R. §§ 201.128, 801.4 ("The words 'intended uses' . . . refer to the objective intent of the persons legally responsible for the labeling of drugs.").

<sup>72</sup> See Donegan, *supra* note 33, at 152 (noting that labeling or advertising claims are "usually determinative" of product classification).

<sup>73</sup> *United States v. An Article . . . Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled in Part: Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969). This interpretation has been supported by the legislative history of the Act. See S. REP. NO. 361, 74th Cong., 1st Sess. (1935), reprinted in LEGISLATIVE RECORD, *supra* note 38, at 240: "The use to which the product is to be put will determine the category into which it will fall. . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put." A federal district court has rejected reliance on this statement, however, noting that "Congress' use of 'can' rather than 'will' arguably shows that Congress did not intend for manufacturer representations to provide the only evidence of intended use." *Coyne Beahm, Inc. v. U.S. Food & Drug Admin.*, 966 F. Supp. 1374, 1389 (M.D.N.C. 1997).

<sup>74</sup> See *Sudden Change*, 409 F.2d at 739.

couching any advertising claims in vague, unverifiable language.<sup>75</sup> Moreover, whether a product actually has an effect on a structure or function of the body would be irrelevant: If the manufacturer claims it does, it is considered a drug; if it does not, it is considered a cosmetic. A dangerous chemical for which only cosmetic claims were made might avoid premarket regulation, whereas a claim that a product consisting wholly of water<sup>76</sup> would "plump up skin cells" would cause the product to be regulated as a drug.<sup>77</sup>

The incongruity of such a system of regulation is best illustrated by three cases in the late 1960s and early 1970s in which courts grappled with the cosmetic/drug distinction in considering whether a "wrinkle remover" should be considered a cosmetic or a drug.<sup>78</sup> Although marketed by a different company and under a different name in each case, the product was identical — a combination of bovine albumin and water that, when applied to the face, formed a film that temporarily smoothed out wrinkles. Two of the courts found the product to be a drug; one found it to be a cosmetic. The Second Circuit held that because the manufacturer claimed that the product would give a "face lift without surgery" and would "lift out puffs," it should be deemed a drug.<sup>79</sup> Similarly, the Third Circuit held that because the manufacturer included such phrases in its advertising as "super-active," "amazing protein lotion," and "tightening the skin," it implied that the product was therapeutic rather than cosmetic in nature and thus should be regulated as a drug.<sup>80</sup> In contrast, a federal district court in Maryland held the product to be a cosmetic, finding that the claims made for the product under consideration (which included the claim that the product was a "pure protein" that caused an "astringent sensation") did not approach the level of the claims made for the other two products.<sup>81</sup>

This relatively settled equation of intent and product claims has been called into question by a federal district court ruling in North Carolina that upheld FDA's power to regulate tobacco.<sup>82</sup> The industry had claimed that a product's intended use could be established only by the claims of manufacturers and that, because cigarette manufacturers had made no advertising claims regarding nicotine's effect on the structure or function of the body, nicotine could not be regulated as a drug.<sup>83</sup> The court rejected this position, holding that the "plain meaning" of "intend" in the FDCA "does not

<sup>75</sup> Manufacturers are well aware of this power. See, for example, Michele Picozzi, *Discovering Cosmeceuticals* (visited Jan. 14, 1997) <<http://www.newhope.com/tradezone/library/hbc/pc/pc3.html>>, in which Rebecca James Gadberry, an industry consultant, suggests that manufacturers and retailers of cosmeceuticals "be careful about making claims" and "avoid phrases that could be construed as drug-like claims." See also *Compounder's Corner*, *supra* note 68, at 64 ("In practical terms, representation that the product penetrates the skin is an instant red flag to the FDA, denoting the possibility of systemic (drug) effects.").

<sup>76</sup> See, e.g., *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (mineral water that contained therapeutic claims on label classified as drug under 1906 Food and Drugs Act).

<sup>77</sup> Or, as one commentator put it, "You could make a very nice eyeshadow that cures cancer [and] as long as you said this was an eyeshadow and you didn't say that it cured cancer, you could sell it as a cosmetic." F-D-C REP. ("The Rose Sheet"), Mar. 18, 1996, at 11 (quoting Gerald McEwen, Vice Pres. for Sci., CTFA).

<sup>78</sup> *Sudden Change*, 409 F.2d at 734; *United States v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away Temporary Wrinkle Smoother, Coty"*, 415 F.2d 369 (3d Cir. 1969); *United States v. Article of Drug . . . 47 Shipping Cartons, More or Less . . . "Helene Curtis Magic Secret"*, 331 F. Supp. 912 (D. Md. 1971).

<sup>79</sup> *Sudden Change*, 409 F.2d at 742. The court did note, however, that if the manufacturer ceased any claims that the product temporarily affected the structure of the skin, the product would not be deemed a drug under the FDCA. *Id.*

<sup>80</sup> *Line Away*, 415 F.2d at 372.

<sup>81</sup> *Magic Secret*, 331 F. Supp. at 917.

<sup>82</sup> *Coyne Beahm, Inc.*, 966 F. Supp. at 1374.

<sup>83</sup> *Id.* at 1389.



indicate that intent must be proven by any particular kind of evidence."<sup>84</sup> Furthermore, the district court noted that although no court had found intent without manufacturers' claims, "no court has held that intended use can be established solely by promotional representations."<sup>85</sup> As a result, it held that FDA's reliance on the foreseeable and actual use of the product to prove intent (in other words, that consumers would be expected to and do use nicotine for its effects on the body) was a reasonable interpretation of the FDCA and thus entitled to deference.<sup>86</sup>

Whether this ruling, if upheld on appeal,<sup>87</sup> will impact FDA's regulation of cosmetics is unclear. The mystique of the cosmetics industry relies heavily on advertising, so it is unlikely that manufacturers will cease to make claims about the efficacy of their products. If this holds true, *Coyne Beahm* may not have much effect on cosmetics regulation, and things will continue as before. In the absence of such claims, however, and given the notoriety of AHAs, the court's ruling could open the door to stricter FDA regulation.

There are signs that FDA may seek this kind of expansive definition of intent for cosmetics, one that would encompass the formulation of the product as evidence of its intended use. "If an active ingredient is present in a therapeutic concentration, the product is a drug, even if that product does not claim to produce the effect that will result from the action of the therapeutically effective ingredient," said John Bailey, Director of FDA's Office of Cosmetics and Colors, in 1996. "The presence of the ingredient, even if used in nontherapeutic amount[s], must be considered when determining its regulatory status. Therefore, the mere presence of the ingredient could make the product a drug regardless of the claims that are made on the label."<sup>88</sup> For example, a product that includes the word "hormone" in its labeling or ingredient list will be deemed to convey an implied drug claim and will be regulated as a drug even if no other claims appear on the product's container.<sup>89</sup> Thus, how FDA will regulate AHAs will depend, in part, on how the agency chooses to define "intent" in light of its regulatory goals with respect to cosmetics.

### III. HOW ARE AHAS LIKELY TO BE REGULATED UNDER CURRENT INTERPRETATIONS OF THE FDCA?

Whether FDA is likely to classify AHA as a cosmetic or as a drug depends on several factors. If the agency confines itself to the interpretation of the wrinkle cream cases, the decision will be the result of an individual analysis of the claims of each manufacturer. Those products with relatively benign claims will be classified as cos-

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<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 1390.

<sup>86</sup> See *Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 845 (1984) (when Congress has not spoken on an issue, reasonable interpretation of enforcing agency is entitled to deference). But see *Action on Smoking and Health v. Harris*, 655 F.2d 236, 240-41 (D.C. Cir. 1980) (noting that sufficient evidence of consumer use requires a "substantial showing" and that courts have "accorded limited discretion to the Administration in its attempt to establish the requisite intent based primarily upon consumer use").

<sup>87</sup> The district court's decision in *Coyne Beam* was appealed to the U.S. Court of Appeals for the Fourth Circuit. No opinion from the appellate court has been issued as of this writing, although news reports appearing after oral argument in the case have suggested that the three-judge panel was unconvinced by the government's arguments. See Sandra Torrey, *Duel in a Country Courthouse, With Tobacco Regulation at Stake*, WASH. POST, Aug. 18, 1997, at F7.

<sup>88</sup> Shaw, *supra* note 12, at 72.

<sup>89</sup> Cosmetic Products Containing Certain Hormone Ingredients; Notice of Proposed Rulemaking, 58 Fed. Reg. 47,611, 47,612 (1993).



metics; those with more aggressive claims will be classified as drugs.<sup>90</sup> In the past, any anti-aging claim made for a cosmetic product has caused the product to be regulated as a drug. Examples of such a claim, FDA has noted, include claims that the product "counteracts," "retards," or "controls" the aging process.<sup>91</sup> Moreover, any claims that the product alters underlying layers of the skin or has more than a superficial effect would give FDA reason to characterize the product as a drug.

Statements of FDA officials suggest that the agency is well aware of the inadequacy of cosmetics regulation to deal with products' enhanced effects.<sup>92</sup> The agency's Center for Food Safety and Applied Nutrition (CFSAN) is hoping to develop a "regulatory strategy" over the next five to seven years for cosmetic products with pharmacological components and effects, a strategy that almost certainly will feature AHAs predominantly.<sup>93</sup> But what type of regulation will result from this reconsideration is unclear. The agency could decide that AHA products with drug claims are unapproved new drugs that must be pulled from the market. On the other end of the cost spectrum is a reenactment of the 1987 scenario: FDA could send warning letters to overzealous AHA manufacturers, advising them to tone down their claims.

If John Bailey's 1996 statements<sup>94</sup> prove prophetic, FDA's move toward using the chemical composition of a product<sup>95</sup> to determine its classification may augur considerable regulation of AHAs. Evidence of such a trend appeared in 1993, for example, when FDA issued a notice of proposed rulemaking regarding hormones in cosmetic products.<sup>96</sup> Certain hormone ingredients had been marketed as OTC drugs for many years, and their safety at specific concentration levels had been established. Relying on this research, and desiring to keep hormones in cosmetics to levels that would "not have any therapeutic effects" or would "not affect the structure of any function of the body" (i.e., have no drug effect), FDA proposed that progesterone be permitted in cosmetics up to 5 mg/oz, and pregnenolone acetate in concentrations of 0.5% or less.<sup>97</sup> Because insufficient information was available as to safe topical levels of estrogen, the

<sup>90</sup> For example, Neoteric Cosmetics' Alpha Hydrox AHA Facial Treatment, a widely available facial cream, contains the following claims on its box: "reduces the signs of aging," "[s]mooths surface imperfections caused by aging and sun damage," and "dramatically and rapidly improves surface texture, tone, firmness and elasticity of skin." FDA is likely to view an anti-aging claim as a drug claim (although this claim has been couched carefully in terms of the *signs* of aging rather than the aging process itself), but it seems likely that the other two claims include the word "surface" in order to avoid regulation as a drug.

<sup>91</sup> Food & Drug Admin., Import Alert No. 66-38 (Mar. 6, 1990). Examples of possible drug claims include claims that the product "rejuvenates," "repairs," or "restructures" the skin, or that the skin molecules would "absorb and expand" to erase wrinkles. *Id.* Note that because drugs are defined either as "intended for use in the . . . treatment or prevention of disease" or "intended to affect the structure or any function of the body," by characterizing as drugs products that claim only to control the "aging process," FDA implies that aging is a disease. The gender issues behind this characterization are too complex to be discussed here.

<sup>92</sup> John Bailey, Dir., Off. of Cosmetics & Colors, FDA, for example, has stated with respect to AHAs that the "legal scheme that applies to cosmetics . . . is clearly inadequate when applied to products that have a physiological effect beyond that which occurs with traditional cosmetic products." F-D-C REP. ("The Rose Sheet"), Dec. 11, 1995, at 1, 3. Bailey's statement also may be interpreted as a call to Congress for amendment of the FDCA.

<sup>93</sup> F-D-C REP. ("The Rose Sheet"), Mar. 11, 1996, at 5-6.

<sup>94</sup> See *supra* text accompanying note 88.

<sup>95</sup> Significantly, in April 1997 FDA recommended the toxicity of AHAs as a focus of study by the National Toxicology Program. See Announcement of Nominated Chemicals Approved and Under Consideration for Toxicological Studies by the National Toxicology Program; Request for Comments, 62 Fed. Reg. 19,348 (1997). Not surprisingly, industry representatives have deemed such a study "unnecessary" and a "waste of scarce testing resources." See *Further Movement on Testing of AHAs*, DRUG & COSM. INDUS., June 1, 1997, at 6.

<sup>96</sup> See 58 Fed. Reg. at 47,611. No final rule has yet been issued.

<sup>97</sup> *Id.* at 47,612.

agency proposed that any use of natural estrogen in cosmetic products would make those products unapproved new drugs.<sup>98</sup> If this example serves as a model for AHA regulation, future product classifications would be dependent only on the products' formulation and not on any claims made as to their efficacy.<sup>99</sup>

Whether AHAs are determined to be a drug also is dependent on the political climate. FDA, like all administrative agencies, is engaged in a constant battle for self-preservation. Thus, the agency must be at least somewhat responsive to Congress, which provides its funding and its statutory mandate. The Republican-controlled Congress has expressed displeasure with the aggressive regulatory activities of the FDA,<sup>100</sup> although whether displeasure will translate into amendment of the cosmetics provisions of the FDCA remains to be seen. *Coyne Beahm* may serve as an important bellwether: If Congress ultimately determines that the courts have gone too far (public opinion serving as an important consideration),<sup>101</sup> it may seek to amend the definitional portions of the FDCA to clarify or even to eliminate "intent."

On the other hand, Congress eventually may decide that cosmetics are different from cigarettes in a way that supports more aggressive agency regulation. The first steps toward such a decision may have occurred in 1996, when several senators called for the enactment of a national uniformity law for cosmetic regulation.<sup>102</sup> More recently, an attempt to preempt state regulation of cosmetics was thwarted by the efforts of Senator Edward Kennedy (D-MA), an outspoken critic of the industry, who has pointed to AHAs as a prime example of the potential dangers of unregulated cosmetics.<sup>103</sup> Further debate on this issue should include a discussion of international harmonization.<sup>104</sup> Because Japan and other countries recognize cosmeceuticals as a regulatory category,<sup>105</sup> effective regulation across national boundaries may require similar recognition in the United States.

<sup>98</sup> *Id.*

<sup>99</sup> See also *United States v. Articles of Food & Drug*, 444 F. Supp. 266, 271 (E.D. Wis. 1978) (finding that "representation in the labeling or in the promotion of an article . . . that it is or contains amygdalin, is a representation that the article is intended for use in the cure, mitigation, treatment and prevention of cancer in man" given publicity regarding such use).

<sup>100</sup> See, e.g., 142 CONG. REC. S8612 (daily ed. Jul. 24, 1996) (stating that FDA has been a "whipping boy" in recent times) (statement of Sen. Edward Kennedy (D-MA)); 142 CONG. REC. S11,129 (daily ed. Sept. 24, 1996) ("I am as angry as I can be that the FDA is being given jurisdiction over tobacco.") (statement of Sen. Wendell Ford (D-KY)). One trade publication has stated that "since the Republican landslide victory in the 1994 election [FDA] has been a mostly low profile organization, especially with regard to cosmetics." COSM. INSIDERS' REP., May 15, 1996.

<sup>101</sup> In other words, the public may respond strongly to any attempt to regulate personal habits. See, e.g., JOHN W. KINGDON, *AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES* 146 (1984) (describing public outrage over, and subsequent abandonment of, seat belt interlocks requirement).

<sup>102</sup> See, e.g., 142 CONG. REC. S12,053 (daily ed. Oct. 1, 1996) (statement of Sen. Orrin G. Hatch (R-UT)); 142 CONG. REC. S12,020 (daily ed. Sept. 30, 1996) (statement of Sen. Judd Gregg (R-NH)).

<sup>103</sup> See, e.g., 143 CONG. REC. S9148 (daily ed. Sept. 11, 1997) (statement of Sen. Kennedy) ("Alpha-hydroxy acids have been linked to severe redness, burning, blistering, bleeding, rash, itching, and skin discoloration. Most troubling, there is concern that alpha-hydroxy may promote skin cancer by increasing sensitivity to sun exposure. Yet these products are in the marketplace — with no warning labels and no limits on the concentrations that may be sold."). The preemption language was part of the Food and Drug Administration Modernization and Accountability Act of 1997, S. 830, 105th Cong., 1st Sess. (1997), which was approved by the Senate on Sept. 24, 1997. A House vote is pending as of this writing.

<sup>104</sup> "[T]here is a global trend of international harmonization for products such as cosmetics: The countries in the European Union, Latin America, and various Asian countries are working toward regulatory cooperation." 142 CONG. REC. S12,020 (daily ed. Sept. 30, 1996) (statement of Sen. Gregg).

<sup>105</sup> Bert J. Vermeer & Barbara A. Gilchrest, *Cosmeceuticals: A Proposal for Rational Definition, Evaluation, and Regulation*, 132 ARCHIVES OF DERMATOLOGY 337, 338-39 (1996).

Undoubtedly the industry's concerns about excessive agency regulation will be heard on Capitol Hill. On the other hand, "the perception that the government tolerates risks to the public might be more damaging than the risks themselves."<sup>106</sup> FDA retains the option of informal regulatory efforts, including educating the public as to the safety of AHAs,<sup>107</sup> but the pace of scientific development calls for a more formal solution.

#### IV. THE SHORTCOMINGS OF THE FDCA

Given that the FDCA "is to be given a liberal construction consistent with the FDCA's overriding purpose to protect the public health,"<sup>108</sup> and given the difficulty inherent in passing legislation, the optimal method of regulation is to work within the existing statutory framework. But, as the Commissioner of Food and Drugs noted before Congress in 1988, the science involved in the production of cosmetics — and the science involved in safety testing — has changed dramatically since the FDCA's enactment in 1938.<sup>109</sup> It may be time for Congress to recognize this progress and amend the FDCA.

##### A. *The Inherent Flaws in the Intent Requirement*

FDA is charged with two responsibilities: to protect the public health and to protect the public economic well-being.<sup>110</sup> The regulation of cosmetics therefore takes on two forms: ensuring the safety of cosmetic products and ensuring that consumer expectations are met. "Intended use" — as measured by advertising and labeling — is relevant only to the latter of these concerns in that consumer expectations are derived from the claims a manufacturer makes. In other words, whether a manufacturer advertises its product as "anti-aging" or merely "moisturizing," the product retains the same chemical composition and the same probability of harm.<sup>111</sup> A manufacturer will be wary of making specific claims because it seeks regulation of the product as a cosmetic and to avoid its regulation as a misbranded product. The result is likely to be increasingly vague claims that neither support a drug definition nor aid in defining consumer expectations. The industry is encouraged in this effort by the media, and particularly by women's magazines, which often feature articles on new cosmetic technology and are simultaneously beholden to the advertisers of those products.<sup>112</sup> A manufacturer no longer has to make any claim on its label beyond the fact that the

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<sup>108</sup> *Bacto-Unidisk*, 394 U.S. at 798.

<sup>109</sup> *Hearings*, *supra* note 63, at 174-75 (statement of Dr. Frank E. Young, Comm'r. of Food and Drugs).

<sup>110</sup> *See, e.g., Sudden Change*, 409 F.2d at 740 ("A primary purpose of the Act is the protection of the ultimate consumer's economic interests."); S. REP. NO. 361, 74th Cong. (1935), *reprinted in* LEGISLATIVE RECORD, *supra* note 38, at 239 (stating that the expansion of the definition of "drug" was necessary to protect the consumer from products that are "worthless at best and some of which are distinctly dangerous to health").

<sup>111</sup> As the Second Circuit noted in its wrinkle cream case, after holding the product to be a drug, It should be understood, however, that if the claimant ceases to employ these promotional claims and avoids any others which may fairly be interpreted as claiming to affect the structure of the skin in some physiological, though temporary, way, then assuming *arguendo* that no actual physical effect exists, the product will not be deemed a drug for purposes of the Act.

*Sudden Change*, 409 F.2d at 742. It is unclear what the court's decision would have been in this scenario if an actual physical effect did exist.

<sup>112</sup> *See, e.g.,* NAOMI WOLF, *THE BEAUTY MYTH* 70 (1991) ("Women are deeply affected by what their magazines tell them (or what they believe they tell them) because they are all most women have as a window on their own mass sensibility.").



product contains AHAs — the consumer likely will recognize the significance.

Furthermore, a literal interpretation of the intent requirement (one that does not rely on the chemical composition of the product) would result in classifying virtually all cosmetics as drugs because almost every cosmetic can be said to contain a claim that the product will affect the structure of the body.<sup>113</sup> Moisturizers, long considered a cosmetic product, soften and smooth the top layers of the skin. Hair conditioners temporarily coat and smooth the cuticles of the hair shaft. To apply the broad interpretation of “drug” not only “render[s] meaningless the distinction made by Congress between drugs and cosmetics”<sup>114</sup> but also gives the agency a seemingly boundless amount of discretion. FDA can pick and choose among cosmetics on the market, interpreting some claims as drug claims and others as cosmetic claims.

Finally, the statute’s reliance on “intended use” provides no clear connection to product safety. Of course, other controls exist to provide this protection: an adulterated cosmetic can be removed from the market, and potential product liability suits operate as somewhat effective constraints on unsafe cosmetics. But both of these methods require a substantial amount of time to accumulate sufficient adverse reactions to seek action, time during which increasing numbers of consumers are being harmed.<sup>115</sup> Although an FDA regulation requires that cosmetics that have not been tested adequately for safety carry a warning to that effect,<sup>116</sup> the fact that submission of information to the agency is completely voluntary hampers FDA’s efforts to enforce the regulation.<sup>117</sup> One question FDA should consider, then, is whether the primary gap between cosmetic regulation and drug regulation — the premarket review — is warranted in the field of cosmetics. On the one hand, premarket testing would prevent potentially harmful cosmetic products from ever reaching the market. On the other hand, the number of cosmetics found to be dangerous enough to pull from the market has been relatively small.<sup>118</sup> In addition, the high expenditures and time delays that premarket testing requires may force many products and small businesses from the market, especially given the short lifespan of many cosmetic products.<sup>119</sup> Moreover, because cosmetics are a luxury item, customers can take the time to find the product that works best for them and often develop a loyalty toward a particular line. Industry thus has an incentive to create good word-of-mouth by ensuring the efficacy and safety of its products.

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<sup>113</sup> As Judge Mansfield noted in dissent in *Sudden Change*, “[I]f the claim that a product will alter the appearance of the body . . . requires that the product be classified as a drug, practically all cosmetics (and indeed articles such as girdles and brassieres) would be required to be so classified.” 409 F.2d at 744 (Mansfield, J., dissenting). See also Naomi M. Kanof, *Cosmetics: Proposal for Redefinition*, 1 J. AMER. ACAD. DERMATOLOGY 67 (1979) (noting that it is not possible to “cleanse, beautify, promote the attractiveness or alter the appearance of the skin” without affecting the structure and function of the body).

<sup>114</sup> *Sudden Change*, 409 F. Supp. at 744 (Mansfield, J., dissenting).

<sup>115</sup> “Manufacturers do not have to determine the safety of their products before selling them or tell the Food and Drug Administration what products they are selling and what ingredients are used in them. Many manufacturers have not voluntarily given such information to the agency. As a result, a hazardous cosmetic can be marketed until the Food and Drug Administration obtains information to prove that the product may be injurious to users.” Report to the Congress of the United States by the Comptroller General, *Lack of Authority Hampers Attempts to Increase Cosmetic Safety* (HRD 78-139) (Aug. 8, 1978), reprinted in *Hearings*, *supra* note 63, at 605.

<sup>116</sup> 21 C.F.R. § 740.10.

<sup>117</sup> U.S. GEN. ACCT. OFF., *LACK OF AUTHORITY HAMPERS ATTEMPTS TO INCREASE COSMETIC SAFETY* (1978), reprinted in HUTT & MERRILL, *supra* note 42, at 820.

<sup>118</sup> See, e.g., Greff, *supra* note 62, at 243 (“This scheme works because cosmetics are by nature generally low risk and because of industry self-regulation.”).

<sup>119</sup> See S.L. Mayham, *Chemicals in Cosmetics*, 7 FOOD DRUG COSM. L.J. 184, 190-91 (1952) (decrying the effect increased cosmetic regulation would have on small businesses).



But companies also must remain competitive. If its competitors are jumping on the AHA bandwagon, a company must introduce its own product, preferably one at a higher concentration than those already on the market. Premarket testing would preempt the escalation wars by setting a safety level above which products would not be allowed on the market.

### B. *Proposals for Reform*

The advances that have been made in cosmetic technology, and the gradual blurring of the line between cosmetics and drugs, cannot be ignored. Cosmetic manufacturers are hesitant to incorporate new technology that might be helpful to acne sufferers, for example, or to make direct claims regarding the efficacy of their products for fear that the products will be regulated as new drugs.<sup>120</sup> FDA, for its part, must be concerned about resource allocation as well as consumer safety. Although the agency may be tempted to classify borderline products as drugs to place the burden of proof with respect to safety on the manufacturer, such a decision commits considerable resources to review of new drug applications.

It is clear that what have become known as "cosmeceuticals" — cosmetic products with drug-like effects — have existed for years. FDA refuses to recognize "cosmeceutical" as a valid term,<sup>121</sup> most likely because the term does not appear in the FDCA, despite the fact that the industry has long used the term to describe products that seek to cure rather than merely to camouflage an appearance problem.<sup>122</sup> Because cosmetic technology is likely to advance, FDA, along with Congress, must decide whether, and how, to regulate these products as a unique category.

FDA may, of course, continue to disclaim the existence of a separate cosmeceutical category and to regulate these products under the current scheme, thus allowing manufacturers to avoid drug regulations by promoting their products with vague claims. Whether cosmetics (that is, cosmeceuticals for which nontherapeutic claims were made) would undergo premarket testing is a decision that would remain for the manufacturer. Although the FDCA neither requires premarket testing of cosmetics nor prohibits the use of most ingredients, FDA "strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics."<sup>123</sup> Many cosmetic manufacturers do, in fact, conduct premarket tests on their products to avoid product liability suits and the loss of goodwill associated with an ineffective or harmful product.<sup>124</sup>

Dr. John Bailey, Director of FDA's Office of Cosmetics and Colors, has suggested that one solution to the cosmeceutical debate would be the creation of a premarket industry review system, working in parallel to the Cosmetic Ingredient Review (CIR).<sup>125</sup> The CIR is an industry review panel established in 1976 by the CTFA to review the

<sup>120</sup> See, e.g., Vermeer & Gilchrest, *supra* note 105, at 338.

<sup>121</sup> "Cosmeceutical," CFSAN, FDA, Office of Cosmetics Fact Sheet (Feb. 3, 1995).

<sup>122</sup> See, e.g., *Cosmeceuticals: New Class of Products Offers Important Benefits for Aging Customers*, CHAIN DRUG REV., Sept. 23 1996, at 92.

<sup>123</sup> COSMETICS HANDBOOK, *supra* note 45.

<sup>124</sup> "The law says it is prohibited for a company to produce a cosmetic product that could be injurious to the consumer under normal use . . . . If I am a cosmetic official, and I have that as a law, why do I need some kind of review by anybody prior to marketing? . . . If you can't have happy, healthy consumers, you are going to lose a lot of money." *Cosmeceuticals*, *supra* note 122, at 92 (quoting Gerald McEwen, Vice Pres. for Sci., CTFA).

<sup>125</sup> Joanna Ramey, *Review Board Could Give Nod to Alpha-Hydroxies by June*, WOMEN'S WEAR DAILY (WWD), Mar. 1, 1996, at 26. Bailey is a nonvoting member of the CIR. *Id.*

safety of cosmetic ingredients and to make the results of those reviews public. While this would be appropriate for many cosmetic products, it would not be appropriate for products such as AHAs. Self-regulation becomes more tenuous the greater the risk of harm; the FDCA's premarket regulation of drug manufacturers reflects a judgment that the societal costs of a harmful product are greater than the costs borne by the company through litigation. In addition, the trend toward confidential settlements may hamper the efficacy of the tort system in regulating product safety. Because the argument for drug regulation holds true for cosmeceuticals, which have a greater likelihood of causing harm than cosmetics, some form of regulation is desirable.

If cosmeceuticals are to be given special consideration, the FDCA must be amended to reflect recognition of their existence. Congress could err on the stronger end of the regulatory spectrum by requiring that all cosmeceuticals be regulated as drugs no matter what claim is made for them. In other words, the presence of an active ingredient would be deemed sufficient proof of intended use as a drug. While this would address safety concerns, it also likely would result in inordinately high resource expenditures, because proof of efficacy would be required even for those products about which relatively benign claims were made. If a product claims only to improve the appearance, the customer is in as good a position, if not better, to judge whether that claim has been satisfied. Contrary to drug claims, there is no concern that a customer will rely on the unsubstantiated claims of a cosmetic product and thus fail to seek treatment for a condition — in other words, the claims themselves present no significant health issues.

Alternatively, Congress could err on the weaker end of the spectrum by amending section 321(g)(1) of title 21 of the *United States Code* to exempt cosmetics as well as food from the definition of "drug." By making the definitions of "drug" and "cosmetic" mutually exclusive, the amended FDCA would end the current confusion over products that seem to straddle the line, as products intended for "cleansing, beautifying, promoting attractiveness, or altering the appearance"<sup>126</sup> would be considered cosmetics exclusively. This proposal would please the industry as well as those concerned with the regulatory reach of FDA and would place greater regulatory responsibility on the market and publicity outlets. Such an amendment does not, however, address the very problem to which cosmeceuticals give rise: the potential harmful effects of active ingredients in cosmetics. The amendment also lends itself to abuse, as manufacturers may clothe true drugs as cosmetics by making claims only as to superficial effects. These dangers could be avoided in part by strengthening the current framework for cosmetic regulation to require some form of premarket testing, but this would result in an ineffective use of resources because these regulations would encompass all cosmetic products, including those already generally recognized as safe.<sup>127</sup>

The optimal method of regulation lies between these two, in the creation of a new category of regulation for cosmeceuticals that would include AHAs. Cosmeceuticals would be defined as those products containing an active ingredient<sup>128</sup> for which cos-

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<sup>126</sup> 21 U.S.C. § 321(i) (FDCA § 201(i)).

<sup>127</sup> Of course, an exception could be made for these products; this would result in much the same system proposed below.

<sup>128</sup> A reliance on active ingredients as the determining factor for classification as a cosmeceutical may itself require revision of FDA's regulations. For example, 21 C.F.R. § 60.3(b)(2) defines "active ingredient" as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals." Because of the difficulties inherent in the current interpretations of "intent," see *supra* part IV.A, "intended to" should be read here to mean "known to or believed to." De minimis effects on the body should be deemed irrelevant to the classification.

metic claims are made; the focus of their premarket regulation would thus be on safety rather than on efficacy. Using its composition to classify the product would direct FDA's attention to safety concerns, and the requirement of cosmetic claims would properly leave the protection of consumer expectations to the market and FDA's regulatory power over adulterated and misbranded cosmetics.

A focus on the active ingredients of a product, and thus on the likely effects of that product, recognizes the heightened potency of cosmeceuticals. The Director of FDA's Office of Cosmetics and Colors has been an outspoken proponent of an effects test. He noted in a 1994 speech,

In the final analysis, it is well established that AHAs exert an effect on the skin . . . . If, under the prescribed conditions of use, the effect of the formulation is only superficial, then FDA would not consider the effect to be a drug effect . . . . If, under prescribed conditions of use, the effect is more than superficial . . . , I believe that these products are functioning as drugs and should be regulated as such.<sup>129</sup>

In addition, the creation of a cosmeceutical category would frustrate manufacturers' attempts to escape premarket regulation by promoting the product with vague, unprovable claims. Once a company decision has been made to reap the market benefits of an active ingredient, the manufacturer must bear the costs of that decision.<sup>130</sup>

Several different options exist for the regulation of the safety of cosmeceuticals, all of which build on the industry's already-existing incentive to conduct premarket product testing. The amended statute could require companies to submit proof that a certain level of testing had been conducted but require less extensive information than is currently required for new drugs. Alternatively, it could establish a system similar to that now existing for dietary supplements.<sup>131</sup> Under the FDCA, dietary supplement labels are permitted to claim a benefit related to a nutrient-deficiency disease as long as the manufacturer has proof that the statement is truthful and not misleading and the label contains a statement noting that the label has not been evaluated by FDA and that the product is "not intended to diagnose, treat, cure, or prevent any disease."<sup>132</sup> Similarly, cosmeceuticals could be permitted to contain active ingredients as long as the label carried a statement noting that FDA had not approved the safety of the ingredient and that the product was not intended to reverse the aging process. Another alternative would be to accept tests conducted by the CIR as sufficient proof, which would encourage the industry to combine its resources. And finally, the scheme could direct FDA to establish monographs similar to those existing for drugs that would establish permissible levels of active ingredients in cosmetics.

The optimal choice among these or additional options is best left to the political process — to discussions among the agency, the industry, the public, and Congress — as well as to discussions within the scientific community. Whatever the decision, it

<sup>129</sup> Greff, *supra* note 62, at 257 (quoting John E. Bailey, Jr., Ph.D., then Acting Dir., Off. of Cosmetics & Colors, FDA, Skin Care — State of the Art: A Regulatory View — Alpha-Hydroxy Acid, Speech at the Annual Spring Seminar of the New York Chapter of the Society of Cosmetic Chemists, New York, NY (Apr. 6, 1994)).

<sup>130</sup> Of course, the consumer ultimately will bear these costs; whether or not he or she decides to buy the product, and therefore absorb these costs, will depend on what value the consumer places on safety.

<sup>131</sup> Attorney William Pendergast has advocated this option. See, e.g., David C. Steinberg, *Cosmeceuticals: An Advanced Forum for Manufacturers*, COSMS. & TOILETRIES, JUN. 1, 1996, at 43; F-D-C REP. ("The Rose Sheet"), Mar. 18, 1996, at 9.

<sup>132</sup> See 21 U.S.C. §§ 321(g)(1), 343(r)(6) (FDCA §§ 201(g)(1), 403(r)(6)).

seems clear that many cosmetics can no longer be regarded as without risk.<sup>133</sup> As the demand for more effective treatments increases, so will the level of active ingredients in cosmetics and the level of regulation needed to ensure the public's safety.

## V. CONCLUSION

After FDA's crackdown on anti-aging creams in 1987, the *New York Times* noted that cosmetic manufacturers either had to prove drug-like claims or abandon the pseudoscientific advertising. "But that's not so terrible an imposition," it continued. "All the FDA is asking is that fantasy and reality be kept separate. The cosmetic companies need only retreat back to fantasy, and their customers will live happily as before."<sup>134</sup> This may have been an adequate response at the time, but it seems somewhat cavalier today, when cosmetics are encroaching further and further into the realm of drugs. As the Supreme Court noted in 1943,

The purposes of [the FDCA] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.<sup>135</sup>

Society as a whole, we should remember, shares the cost of inadequate safety, as well the costs of more psychic harms. FDA's decision on how AHAs should be regulated will serve as an initial point of discussion, not only on the government's role in regulating potentially harmful products, but also on the lengths we are willing to go to preserve a youthful look.

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<sup>133</sup> "Specifically, in 1938, cosmetics were differentiated from the agency's authority in food and drugs, and later devices, because it was judged and has continued to be judged by Congress that though these products are important, they did not quite present the risk that the other products do." *Hearings, supra* note 63, at 52 (statement of Dr. Frank E. Young, Comm'r of Food and Drugs).

<sup>134</sup> GERALD MCKNIGHT, *THE SKIN GAME: THE INTERNATIONAL BEAUTY BUSINESS BRUTALLY EXPOSED* 185 (1989).

<sup>135</sup> *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).