

# *Fordham Environmental Law Review*

---

*Volume 23, Number 1*

2011

*Article 6*

---

## Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk

Rajiv Shah\*

Kelly E. Taylor†

\*Fordham University School of Law

†Fordham University School of Law

Copyright ©2011 by the authors. *Fordham Environmental Law Review* is produced by The Berkeley Electronic Press (bepress). <http://ir.lawnet.fordham.edu/elr>

# CONCEALING DANGER: HOW THE REGULATION OF COSMETICS IN THE UNITED STATES PUTS CONSUMERS AT RISK

*Rajiv Shah and Kelly E. Taylor\**

## INTRODUCTION

The U.S. Food and Drug Administration (FDA), under the Federal Food, Drug and Cosmetic Act,<sup>2</sup> is not permitted to review the ingredients in cosmetics before they are made available to the public and has no authority to recall dangerous products. The FDA's authority over recalls is limited to monitoring their effectiveness and issuing press releases.<sup>3</sup> Similarly, under the Toxic Substances Control Act (TSCA),<sup>4</sup> the Environmental Protection Agency (EPA) lacks the ability to compel cosmetics companies to demonstrate their products are safe.<sup>5</sup>

The cosmetics industry opposes stringent pre-market federal government oversight, instead touting its self-regulation system and

---

\* The authors would like to extend a very special thanks to Jessica Boffa, who was invaluable as an editor, and Professor Elizabeth Cooper, who mentored us throughout the writing process. This Note arose out of a partnership with WE ACT for Environmental Justice, a non-profit, community-based group located in Northern Manhattan whose mission is to build healthy communities by assuring that people of color and/or low-income communities participate meaningfully in the creation of sound and fair environmental health and protection policies and practices. WE ACT FOR ENVTL. JUSTICE, <http://www.weact.org> (last visited Dec. 11, 2011). The authors of this report served as legal interns for WE ACT through Fordham University School of Law's Urban Policy and Legislative Advocacy Clinic, Lincoln Square Legal Services, Inc.

2. Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301-399a (2010).

3. Roseann B. Termini & Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 FOOD & DRUG L. J. 257, 271-72 (2008).

4. Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692 (2010).

5. *Id.* at § 2602.

supporting only mild increases in federal oversight.<sup>6</sup> Despite claims that its products are safe, the industry's review board, the Cosmetic Ingredient Review (CIR) panel, as of 2005 had not assessed the safety of 89% of the ingredients in personal care products.<sup>7</sup> When the CIR does review ingredients, it generally focuses on the ingredients' potential to cause short-term dermatological reactions such as rashes and eye irritation, not their potential to cause long-term health problems such as cancer or reproductive harm.<sup>8</sup>

Part I of this Report lays out the factual background needed to fully understand the need for greater cosmetics regulation, as well as many recent events that have sparked greater debate over the need for regulation. Part II discusses the major federal statutes affecting the regulation of cosmetics in the United States, including the Federal Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, and the TSCA. Part III examines current proposals for reforming the Federal Food Drug and Cosmetic Act and the TSCA. Part IV focuses on the potential for enacting stronger state and local laws and regulations concerning cosmetics in New York. Part V summarizes the Report's conclusions and sets out a series of policy and regulatory recommendations.

## I. FACTUAL BACKGROUND

### *A. Recent Developments*

Cosmetics regulation is particularly ripe for reform due to a renewed focus on hazardous cosmetics in the media. 2010 saw a number of high-profile and widely-covered news stories concerning

---

6. *Statement by Lezlee Westine, President and CEO of the Personal Care Products Council, in Response to the Safe Cosmetics Act of 2010*, PERS. CARE PRODS. COUNCIL (July 21, 2010), <http://www.personalcarecouncil.org/newsroom/20100721a>.

7. *See FDA Warns Cosmetic Industry to Follow Law on Untested Ingredients*, ENVTL. WORKING GRP. (Mar. 2005), <http://www.ewg.org/node/8703>. The Environmental Working Group is a non-profit organization specializing in educating consumers in matters involving public health and the environment. *About the Environmental Working Group*, ENVTL. WORKING GRP., <http://www.ewg.org/about> (last visited Dec. 11, 2011).

8. STACY MALKAN, NOT JUST A PRETTY FACE – THE UGLY SIDE OF THE BEAUTY INDUSTRY 11-12 (2007).

the possible dangers posed by ingredients in cosmetics, as well as the cultural pressures to use cosmetics. This section will examine some of the events that have drawn increased attention to the need for greater cosmetics regulation in the United States.

### 1. Brazilian Hair Straightening Treatments

In 2007, a hair treatment from Brazil swept into American salons, promising to keep hair straight for four months, far longer than older methods, all while improving hair health. The hair straightening treatments utilize liquid keratin, a naturally occurring protein, and an extremely hot iron to hydrate and relax hair.<sup>9</sup> The treatment is now extremely popular, available throughout the world, and costs from \$250 to \$600.<sup>10</sup> While many manufacturers knew that certain formulas contained formaldehyde, a known human carcinogen, some still contended that the levels were safe.<sup>11</sup>

After receiving numerous complaints from salon workers suffering from nosebleeds, eye irritation, and breathing problems after applying Brazilian hair straightening treatments, the Oregon Occupational Safety and Health Agency (OSHA) began investigating the hair solution in early 2010.<sup>12</sup> A report by the Oregon Health and Science University's Center for Research on Occupational and Environmental Toxicology revealed potentially unsafe levels of formaldehyde in Brazilian Blowout, a brand of Brazilian hair straighteners.<sup>13</sup> Oregon OSHA also conducted tests on another brand of Brazilian straightener, Açai Professional Hair Smoothing Solution, which found levels of formaldehyde as high as 100 times those

---

9. Elizabeth Hayt, *Curls, Split! Ringlets, Be Gone!*, N.Y. TIMES, July 19, 2007, at G3.

10. *Id.*; Courtney Perkes, *State Sues Makers of Brazilian Blowout; Officials Say Hair Treatment is Unsafe*, ORANGE COUNTY REG., Nov. 17, 2010, at E3.

11. Terry Pristin, *A Safety Kink in Hair Relaxing?*, N.Y. TIMES, Nov. 4, 2010, at E3.

12. KERMIT MCCARTHY ET AL., OREGON OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION & OREGON HEALTH & SCIENCES UNIVERSITY'S CENTER FOR RESEARCH ON OCCUPATIONAL AND ENVIRONMENTAL TOXICOLOGY, KERATIN-BASED HAIR SMOOTHING PRODUCTS AND THE PRESENCE OF FORMALDEHYDE (October 29, 2010).

13. Molly Prior & Andrea Nagel, *Salon Industry Grapples with Fallout from Blowout*, WOMEN'S WEAR DAILY, Oct. 8, 2010, at 6.

deemed safe by the United States OSHA.<sup>14</sup> Oregon Congressional Representative Earl Blumenauer has asked the FDA and the Federal Trade Commission to investigate whether Brazilian Blowout and Açai Professional Smoothing Solution pose safety risks to consumers and whether the products are properly labeled.<sup>15</sup>

The impact of the investigation extends far beyond Oregon's borders: in October 2010, Canada's public health department issued a warning to consumers not to use Brazilian Blowout,<sup>16</sup> and England and Ireland have issued recalls for both Brazilian Blowout and Açai Professional Smoothing Solution.<sup>17</sup> In November 2010, California's Attorney General filed suit against GIB, the manufacturer of Brazilian Blowout, for failure to disclose unsafe levels of formaldehyde and sought an injunction barring its sale.<sup>18</sup>

The suit also alleges GIB engaged in false advertising by asserting that some of its products were "formaldehyde-free" and "salon safe."<sup>19</sup> On November 4, 2010, the Personal Care Products Council, the trade association representing the cosmetics industry, announced it was working with the FDA to review the use of formaldehyde in professional hair smoothing products.<sup>20</sup>

The Brazilian Blowout controversy attracted the attention of the United States OSHA and prompted the agency to issue a hazard alert

---

14. Jill U. Adams, *A Closer Look; Brazilian Blowout Questions Continue*, L.A. TIMES, Nov. 29, 2010, at E1.

15. Katy Muldoon, *Blumenauer Asks Feds to Investigate Hair-Care Products with Formaldehyde*, THE OREGONIAN, Oct. 6, 2010, available at [http://www.oregonlive.com/health/index.ssf/2010/10/blumenauer\\_asks\\_feds\\_to\\_invest.html](http://www.oregonlive.com/health/index.ssf/2010/10/blumenauer_asks_feds_to_invest.html).

16. Carly Weeks, *With Hair Products, It's Buyer Beware: It Took Complaints From Consumers Before Health Canada Issued Warning about Brazilian Blowout*, GLOBE & MAIL, Oct. 19, 2010, at L4.

17. *Health Briefing*, IRISH TIMES, Oct. 19, 2010, at 2.

18. Andrea Nagel, *California Sues Brazilian Blowout*, WOMEN'S WEAR DAILY, Nov. 12, 2010, available at <http://www.wwd.com/beauty-industry-news?module=tn#/article/beauty-industry-news/california-sues-brazilian-blowout-3380901>.

19. Adams, *supra* note 14.

20. *Statement by John Bailey, Chief Scientist, Personal Care Products Council: Industry Concerned About Safety of Ingredient in Professional Hair Smoothing Products*, PERS. CARE PRODS. COUNCIL (Nov. 4, 2010), available at <http://www.ctfa.org/newsroom/20101104>.

to salon owners and workers in April 2011.<sup>21</sup> OSHA's investigations found levels of formaldehyde that exceeded the safe level for salons, even among products purporting to be free of the chemical.<sup>22</sup> The agency recommended salons cease use of products containing formaldehyde due to dangers such as eye and nose irritation, skin reactions, and the link between formaldehyde and nose and lung cancers.<sup>23</sup>

## 2. "I Love My Hair"

In 2010, Sesame Street struck a chord with African-American woman and girls across the country and drew considerable attention to the debate regarding chemically straightening ethnic hair, particularly for young girls. In a segment titled "I Love My Hair," a female African-American Muppet sings about her natural hair and the variety of styles it allows her to wear.<sup>24</sup> The clip not only made an impact on TV audiences, but also became a viral success – logging over 2.8 million views on YouTube.com as of October 2011.<sup>25</sup> The show's head writer, Joseph Mazzarino, was inspired by Chris Rock's documentary on the black hair products industry, *Good Hair*, and his young Ethiopian-born daughter's preference for straight, Western hair.<sup>26</sup>

## 3. "Fierce" Fragrance Protests

Popular teen clothing store Abercrombie & Fitch received unwanted attention in 2010 for use of potentially dangerous chemicals. Teens Turning Green, a student group advocating

---

21. US Labor Department's 'OSHA issues hazard alert to hair salon owners, workers on smoothing and straightening products that could release formaldehyde, DEPT. OF LABOR (Apr. 11, 2011), [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=NEWS\\_RELEASES&p\\_id=19584](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=19584).

22. *Id.*

23. *Id.*

24. Alene Dawson, *The Hair Issue: Rewriting the Rules*, L.A. TIMES, Oct. 31, 2010, at 6.

25. *Sesame Street: Song: I Love My Hair*, YOUTUBE (Oct 12, 2010), <http://www.youtube.com/watch?v=enpFde5rgmw>.

26. Kyle Buchanan, *Sesame Street's Head Writer Explains the Show's Viral-Video Dominance*, N.Y. MAG. VULTURE BLOG (Oct. 21, 2010), [http://nymag.com/daily/entertainment/2010/10/sesame\\_streets\\_head\\_writer\\_exp.html](http://nymag.com/daily/entertainment/2010/10/sesame_streets_head_writer_exp.html).

environmentally responsible choices, alleges the chain is harming the environment and their customers' health by automatically spraying its cologne, Fierce, from store track lighting.<sup>27</sup> Following testing of the fragrance, the Campaign for Safe Cosmetics, a coalition of organizations promoting cosmetics reform, announced that Fierce contains eleven ingredients not disclosed on the label, including those known to cause allergic reactions and disrupt hormones.<sup>28</sup> Teens Turning Green staged protests at Abercrombie & Fitch stores in California and New York in October 2010, hoping to draw attention to the problem and convince the chain to cease use of the fragrance in their stores.<sup>29</sup>

### *B. Products and Chemicals of Possible Concern*

There are a number of ingredients commonly found in cosmetic products that raise serious health threats. According to a study by the Environmental Working Group,<sup>30</sup> more than half of cosmetic products contain chemicals that can act like estrogen, disrupting the body's natural hormone balance.<sup>31</sup> Endocrine-disrupting chemicals are particularly concerning because they are so widespread in the environment.<sup>32</sup> One study by the United States Department of

---

27. Grace Gold, *Abercrombie & Fitch Under Fire For Spraying Cologne Containing 'Secret Chemicals' in Stores*, STYLELIST (Oct. 28, 2010), <http://www.stylelist.com/2010/10/28/abercrombie-and-fitch-fragrance-protest-teens>.

28. *Id.*

29. See *Perfume Protest: Teens Storm 'Toxic' Abercrombie & Fitch*, TIME NEWSFEED (Oct. 10, 2010), <http://newsfeed.time.com/2010/10/04/perfume-protest-teens-strom-%E2%80%98toxic%E2%80%99-abercrombie-fitch>; Gold, *supra* note 27.

30. Jane Houlihan, *Why This Matters: Cosmetics and your Health*, ENVTL. WORKING GRP. (2011), <http://www.ewg.org/skindeep/2011/04/13/why-this-matters/> (last visited Dec. 11, 2011).'

31. See *What You Should Know About Chemicals in Your Cosmetics*, CONSUMER REPORTS SHOPSMART, Jan. 2007, at 8, available at [http://www.consumerreports.org/cro/promos/shopping/shopsmart/winter-2007/what-you-should-know-about-chemicals-in-your-cosmetics/overview/0701\\_cosmetics\\_ov.htm](http://www.consumerreports.org/cro/promos/shopping/shopsmart/winter-2007/what-you-should-know-about-chemicals-in-your-cosmetics/overview/0701_cosmetics_ov.htm).

32. Rachel Rawlins, *Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics*, 20 *FORDHAM ENVTL. L. REV.* 1, 3 (2009).

Interior revealed a high incidence of intersex smallmouth bass<sup>33</sup> in the Potomac River Basin, along with chemicals from pesticides, flame-retardants, and personal-care products that are known or suspected endocrine disruptors.<sup>34</sup> The intersex condition in fish is caused by hormone disruption, and joins a growing body of evidence suggesting similar conditions in other animals including birds, mammals, and humans.<sup>35</sup> This and other studies have established that endocrine disruptors can cause intersex in fish.<sup>36</sup> However, further study is needed to determine the precise environmental factors and mechanisms, including the presence of endocrine disruptors that contribute to intersex in these species.<sup>37</sup>

The lax regulation of cosmetic products causes serious concern not only because of the potential to harm all users, but also because of the particular danger they may pose to women of reproductive age and children.<sup>38</sup> A pregnant woman shares exposure to toxicants in the blood with her developing fetus, which may experience larger doses of the toxicant relative to its body weight.<sup>39</sup> Additionally, as toxicants may stay in the body long after initial exposure, a fetus can be harmed even though the material is no longer in the woman's body.<sup>40</sup> One study found an average of 200 different industrial chemicals or pollutants in the umbilical cord blood of ten babies.<sup>41</sup> Because children are especially susceptible to many environmental risks, exposure to chemicals from conception through adolescence

---

33. Blazer et al., *Intersex (Testicular Oocytes) in Smallmouth Bass from the Potomac River and Selected Nearby Drainages*, 19 J. AQUATIC ANIMAL HEALTH 242 (2007).

34. *Id.* at 250.

35. Emily Sohn, *More Hermaphrodite Fish in U.S. Rivers*, DISCOVERY NEWS (Sept. 15, 2009), <http://news.discovery.com/animals/more-hermaphrodite-fish-in-us.html>.

36. See Jo Ellen Hinck et al., *Widespread Occurrence of Intersex in Black Basses (Micropterus Spp.) from U.S. Rivers, 1995-2004*, 95 AQUATIC TOXICOLOGY 60, 61, 68-69 (2009).

37. *Id.* at 69.

38. Rawlins, *supra* note 32, at 2.

39. *Id.*

40. *Id.* at 2, 6.

41. *Id.*



can lead to a lifetime of functional deficits and increased disease risks.<sup>42</sup>

### 1. Phthalates: An Example of Dangerous Chemicals Found in Cosmetics

A chemical may be of particular concern because of its ubiquity, its high toxicity, or both. One such example is phthalate.<sup>43</sup> Phthalate exposure occurs by breathing in air containing phthalate vapors or through the skin.<sup>44</sup> While phthalates are most commonly associated with products such as vinyl floors, shower curtains, and plastic dinnerware, they are also used in a number of personal care products such as shampoo, nail polish, and hair spray.<sup>45</sup>

In 2000, the Centers for Disease Control and Prevention (CDC) found phthalates in a wide variety of cosmetics, many of which did not include the chemical in their ingredient lists.<sup>46</sup> CDC researchers have found widespread phthalate exposure in the United States population, with adult women showing higher levels of phthalates metabolites, the breakdown product resulting from phthalates entering the body, used in personal care products.<sup>47</sup> Young children may be especially vulnerable to exposure due to hand-to-mouth behaviors.<sup>48</sup>

Evidence continues to mount that phthalates in any form are harmful, particularly to fetuses and infants. Dibutyl phthalate (DBP), a phthalate found in a variety of personal care products, causes serious birth defects and even death in laboratory animals exposed to

---

42. *Id.*

43. *National Report on Human Exposure to Environmental Chemicals: Phthalates Fact Sheet*, CTRS. FOR DISEASE CONTROL, 1 (Nov. 2009), [http://www.cdc.gov/exposurereport/pdf/Phthalates\\_FactSheet.pdf](http://www.cdc.gov/exposurereport/pdf/Phthalates_FactSheet.pdf) (defining a Phthalate as an industrial chemical that acts as a “plasticizer,” increasing the plasticity or fluidity of a material).

44. *Id.*

45. *Id.*

46. Malkan, *supra* note 8, at 16 (citing B.C. Blount et al., *Levels of Seven Urinary Phthalates Metabolites in a Human Reference Population*, 108 ENVIRON. HEALTH PERSPECTIVES 979, 979-82 (Oct. 2000)).

47. *National Report on Human Exposure to Environmental Chemicals: Phthalates Fact Sheet*, *supra* note 43.

48. As young children have a tendency to insert their hands into their mouths, there is increased risk of ingesting harmful chemicals. *Id.*

it during development.<sup>49</sup> A 2005 study examined the effects of prenatal phthalate exposure at the environmental level and discovered “a significant relationship” between the levels of phthalates in human women’s bodies during pregnancy and adverse effects on male reproductive development.<sup>50</sup>

Phthalates may also cause early puberty in girls, premature delivery, decreased sperm quality and sperm damage, changes in testosterone production, and testicular cancer.<sup>51</sup> In the wake of such research, California and New York have banned phthalates from children’s products.<sup>52</sup> However, these bans do not include products women may use during pregnancy, or any products not marketed specifically to children that they would nevertheless surely encounter in a household.<sup>53</sup> And, while virtually all nail polish manufacturers have removed DBP from their products sold in Europe and the United States, DBP is still a component of many other cosmetics.<sup>54</sup>

## 2. Permanent Hair Relaxers

Nail polish, perfumes, and hair smoothing treatments are often the subjects of media attention regarding the possible health risks associated with chemicals in those products, but ethnic hair products receive comparatively little attention. Many users of ethnic hair

---

49. *DI-n-Butyl Phthalate*, AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, 2 (Sept. 2001), <http://www.atsdr.cdc.gov/tfacts135.pdf>.

50. Shanna H. Swan et al., *Decrease in Anogenital Distance Among Male Infants with Prenatal Phthalate Exposure*, 113 ENVTL. HEALTH PERSPECTIVES 1056, 1056 (2005).

51. Rawlins, *supra* note 32, at 4.

52. Bette Hileman, *California Bans Phthalates In Toys For Children*, CHEM. & ENG’G NEWS, Oct. 22, 2007, at 12; *see also* Bisphenol A-Free Children and Babies Act, N.Y. ENVTL. CONSERV. LAW §§ 37-0501 to -0511 (McKinney 2010).

53. Household products containing phthalates that children are likely to encounter include flooring, plastic wraps and food containers. *See* Bisphenol A-Free Children and Babies Act, N.Y. ENVTL. CONSERV. LAW § 37-5303 (limiting the definition of “child care product” to “all pacifiers and unfilled beverage containers”).

54. Following a ban of DBP in the European Union in 2004 and increased negative press coverage of chemicals in nail polish in the United States, Proctor & Gamble and Estee Lauder removed DBP from their worldwide nail polish formulas. Later that year, Revlon, L’Oreal and Unilever followed suit. Malkan, *supra* note 46, at 44, 50 (citations omitted).

products lack an awareness of the dangers they pose, further highlighting the need for a system of cosmetics regulation that is not dependent on outcry in the media concerning a few particular products.

There are immense cultural pressures from within and without the Black community to conform to Western ideals of beauty.<sup>55</sup> These standards are often reinforced in school or work through dress codes and appearance standards.<sup>56</sup> Since a federal district court upheld American Airlines' decision to prohibit an African-American flight attendant from wearing her hair in braids in order to conform to its appearance policy, many corporations have embraced their power to dictate standards of appearance that may prohibit "natural" ethnic hairstyles.<sup>57</sup> Many in the Black community use hair relaxers for much of their lives, and parents may begin using relaxers on their children at a very young age. As a child's body is not able to detoxify or eliminate chemicals as efficiently as an adult's, children are particularly susceptible to their associated harms.<sup>58</sup>

African-American women spend 80% more per capita than any other ethnic groups on cosmetics.<sup>59</sup> They spend double the amount of other ethnic groups on hair treatments.<sup>60</sup> The most ubiquitous of these treatments is the permanent relaxer. Permanent relaxers, also referred to as "perms" or "relaxers," use chemicals to straighten naturally textured or curly hair.<sup>61</sup> As new hair growth emerges, it also requires treatment to maintain a uniform hair texture. Retreatment is typically performed every six weeks, though some

---

55. See generally Angela Onwuachi-Willig, *Another Hair Piece: Exploring New Strands of Analysis under Title VII*, 98 GEO. L.J. 1079 (2010).

56. See generally *id.*

57. *Rogers v. Am. Airlines*, 527 F. Supp. 229 (S.D.N.Y. 1981); see also *Eatman v. United Parcel Serv.*, 194 F. Supp. 2d 256, 259 (S.D.N.Y. 2002) (upholding UPS' standards requiring employee to cover his Nubian locks with a company-issued hat).

58. NAT'L. ACAD. OF SCIS., PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 4 (1993).

59. Tracy Jones, *No Matter How You Cut It, African-American Hair Styling is Big*, FLA. TIMES-UNION (Nov. 7, 2010), <http://jacksonville.com/entertainment/2010-11-07/story/all-about-black-hair>.

60. *Id.*

61. INGRID BANKS, *HAIR MATTERS: BEAUTY, POWER AND BLACK WOMEN'S CONSCIOUSNESS* 172 (2000).

may use the relaxers more or less frequently depending on personal preference and hair growth speed.<sup>62</sup> Users can purchase professional relaxer applications at salons or apply them at home using kits from beauty supply stores or most drug stores.<sup>63</sup> Manufacturers also produce relaxers for children, which are widely available alongside those marketed to adults.<sup>64</sup> The children's relaxers contain the same chemical agents used in adult products, but in weaker concentrations.<sup>65</sup> In addition to permanent relaxers, beauty supply stores and drug stores carry conditioning products, designed for use following permanent relaxer treatment, to soften the texture of the treated hair.<sup>66</sup>

### 3. Possible Health Risks of Permanent Hair Relaxers

Even though permanent relaxers have been used for decades, they present a number of serious health concerns. Traditionally they contained lye, a corrosive form of sodium hydroxide, to break down hair proteins and straighten the hair shaft.<sup>67</sup> Due to concerns over the strength of sodium hydroxide and its ability to cause severe scalp burns, it is now more common to see "no lye" relaxers in consumer stores.<sup>68</sup> "No lye" relaxers use a weaker chemical agent and thus are less likely to cause injury to the scalp and hair damage, but tend to be less effective.<sup>69</sup>

---

62. Tina Ezell Hull, *Catching the Natural Wave: African American Women Learning to Love Hair's Natural Texture*, THE CHARLOTTE OBSERVER, 2, <http://documents.cms.k12.nc.us/dsweb/Get/Document-17118/Catching%20the%20Natural%20Wave.pdf> (last viewed Dec. 11, 2011).

63. *Id.* On September 25, 2010, an author of this Report visited three beauty supply stores and a drug store in midtown Manhattan along with La Vida Johnson, a graduate of the University of Pennsylvania's Fels Institute of Government, who has extensive experience with American-African salons and ethnic hair products. They examined the ethnic hair sections at four stores in Manhattan, including three independent stores and one large chain store.

64. *See id.*

65. *See id.*

66. *See id.*

67. *Black Hair History*, JAZMA HAIR INC., <http://www.jazma.com/black-hair-history> (last visited Dec. 11, 2011).

68. *See id.*

69. *Id.*

Despite this change, relaxers still contain a number of ingredients that may pose serious health risks. According to an analysis by the Environmental Working Group, 97% of hair straighteners contain petrochemical ingredients that may be contaminated with 1,4-dioxane, which the EPA has deemed a possible human carcinogen.<sup>70</sup> In addition to chemical compounds of concern, many ethnic hair products, including conditioners paired with permanent relaxers, contain hormones that pose danger. For example, placenta products advertised as hair strengthening and conditioning may contain estrogenic hormones linked to early puberty and breast cancer.<sup>71</sup>

To ensure only safe cosmetic products reach consumers, it is essential to understand the current regulatory regime. The next section of this Note analyzes the federal statutes controlling cosmetics in the United States, illustrates their inadequacies, and highlights the need for legislative and regulatory reform.

## II. COSMETICS REGULATION AT THE FEDERAL LEVEL

Three statutes largely control cosmetics regulation in the United States: the Federal Food, Drug and Cosmetic Act (FDCA),<sup>72</sup> the Fair Packaging and Labeling Act (FPLA),<sup>73</sup> and the TSCA.<sup>74</sup> This section will examine the histories and mechanics of these statutes, as well as their deficiencies that permit dangerous cosmetic products to enter the market and impede product removal.

---

70. *EWG Research Shows 22 Percent of All Cosmetics May Be Contaminated With Cancer-Causing Impurity*, ENVTL. WORKING GRP. (Feb. 8, 2007), <http://www.ewg.org/release/ewg-research-shows-22-percent-all-cosmetics-may-be-contaminated-cancer-causing-impurity>. The EPA uses guidelines to categorize an agent's potential as a human carcinogen. Human data, animal data and supporting data are used to characterize the "weight-of-evidence" to classify an agent into one of five groups. Agents in Group A are human carcinogens; Group B are probable human carcinogens; Group C are possible human carcinogens; Group D are not classifiable as to human carcinogenicity; Group E evinces non-carcinogenicity for humans. Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33992-01 (Sep. 24, 1986). The chemical 1,4-Dioxane is classified by the EPA as a Group B substance. *1,4-Dioxane (1,4-Diethyleneoxide)*, DEP'T ENVTL. PROT., <http://www.epa.gov/ttn/atw/hlthef/dioxane.html> (last updated Nov. 6, 2007).

71. Malkan, *supra* note 8, at 69.

72. See Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301-399a (2010).

73. Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451-1461 (2010).

74. See Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692 (2010).

A. *The Federal Food, Drug and Cosmetic Act*

The FDCA is the primary statute regulating cosmetics in the United States. This section begins with an examination of the historical events that led to the FDCA's inception, and then explains how it currently controls the sale of cosmetics.

1. History of the Food, Drug and Cosmetic Act

During the Progressive Era,<sup>75</sup> Congress was able to usher in unprecedented regulation of private industry, yet the cosmetics industry evaded federal oversight. The precursor to the modern FDCA, the Pure Food and Drug Act,<sup>76</sup> was passed in 1906, but regulation of cosmetics was not included. This was partially due to the minimal cosmetics market in the United States at the time.<sup>77</sup>

During the 1930s, interest in regulating cosmetics began to rise following a rash of publicity surrounding injurious cosmetics.<sup>78</sup> Koremlu, a depilatory (hair removal) cream that included a highly toxic level of thallium acetate, drew attention in 1931 after users began to suffer thallium acetate poisoning.<sup>79</sup> Poisoning effects include paralysis and nerve damage.<sup>80</sup> Unfortunately, as Koremlu was not classified as a drug under the Pure Food and Drug Act, the FDA was powerless to act; private lawsuits also proved fruitless as the manufacturer declared bankruptcy.<sup>81</sup> Shortly after the Koremlu scandal, the potential dangers of cosmetics once again made headline news after a number of women became blind following the use of the eyelash dye Lash Lure.<sup>82</sup>

---

75. The Progressive Era is generally defined as the period from 1890 to 1920. The Progressive Era reformers in Congress succeeding in passing numerous statutes aimed at increasing oversight to improve health and public welfare and to eliminate corruption. See generally LEWIS L. GOULD, REFORM AND REGULATION: AMERICAN POLITICS 1900-1916 (1978).

76. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (1906).

77. See Termini, *supra* note 3, at n.16, (citing Gary L. Yingling & Suzan Onel, *Cosmetic Regulation Revisited*, 1 FUND. OF LAW & REG. 316 (1997)).

78. GWEN KAY, DYING TO BE BEAUTIFUL: THE FIGHT FOR SAFE COSMETICS 70-72 (2005).

79. *Id.*

80. *Id.* at 70-71.

81. *Id.* at 71.

82. *Id.* at 72.

While dangerous cosmetics continued to make headlines during the 1930s,<sup>83</sup> Congress failed to enact proposed reforms of the Pure Food and Drug Act that would bring cosmetics under the Act's purview, despite support by President Franklin Delano Roosevelt.<sup>84</sup> The proposed reform not only included regulation of cosmetics, but also sought more stringent regulation of drugs. Though these reforms had the backing of the FDA and the President, it took a devastating loss of life to finally propel Congress into action. Over 100 people died in 1937 after ingesting Elixir Sulfanilamide, a new "wonder drug" purported to treat a variety of bacterial infections in adults and children.<sup>85</sup> The resulting public outcry prompted Congress to finally address the reform bills introduced in the wake of the Koremlu scandal. In 1938 President Roosevelt signed the Federal FDCA into law, not only addressing the problems which allowed for Elixir Sulfanilamide to enter the market, but finally bringing the regulation of cosmetics under the federal government's purview as well.<sup>86</sup>

## 2. Regulation under the Food, Drug and Cosmetic Act

The FDCA allocates authority to the FDA to regulate food, drugs, medical devices and cosmetics.<sup>87</sup> Under the FDCA, the FDA has the authority to regulate all food products except meats and poultry products, which the United States Department of Agriculture oversees.<sup>88</sup> The FDA may remove unsafe food from the market and can require manufacturers of food additives to show that their products will be safe.<sup>89</sup>

Before a prescription drug can be sold in the United States, its manufacturer must submit an application to the FDA containing

---

83. *Id.* at 76-78.

84. Termini, *supra* note 3, at 259.

85. Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG., June 1981, available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm>.

86. Termini, *supra* note 3, at 259.

87. See Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301-399a (2010).

88. The FDA retains authority to regulate game meats such as venison, ostrich, and snake. 21 U.S.C. § 321(f) (2010).

89. 21 U.S.C. § 348(c)(3)(A) (2010).

information on the drug and testing conducted to verify its safety.<sup>90</sup> If the FDA's Center for Drug Evaluation and Research determines that the drug's health benefits outweigh its known risks, it approves the drug.<sup>91</sup> Over-the-counter drugs must conform to FDA "monographs" which specify acceptable "ingredients, doses, formulations and labeling."<sup>92</sup>

The FDA also has the authority to regulate medical devices, including products used in the diagnosis, prevention, or treatment of disease, or that affect the structure or any function of the body.<sup>93</sup> Products classified as medical devices range from simple tongue depressors to pacemakers.<sup>94</sup> If a device is not "substantially equivalent" to an approved device, the manufacturer must submit an application to the FDA and adhere to strict agency conditions before it can market the device.<sup>95</sup>

The FDCA generally treats cosmetic products and their ingredients very differently. The FDCA defines the term "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>96</sup>

Cosmetic products falling within the definition are:

skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent

---

90. *Id.* § 355.

91. *Approved Drugs: Questions and Answers*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/UCM054420> (last updated Nov. 8, 2011).

92. *Id.*

93. 21 U.S.C. § 321(h) (2010).

94. *What Does FDA Regulate?*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last updated Aug. 19, 2010).

95. 21 U.S.C. § 360(c), (o)(1)(A)-(C) (2010).

96. *Id.* § 321(i).



waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.<sup>97</sup>

Notwithstanding the FDA's broad authority to regulate food and drugs, the agency has the authority to conduct pre-market testing only of their color additives.<sup>98</sup> The FDA began to stringently regulate and evaluate color additives following investigations during the 1950s that found several previously approved color additives in fact caused serious adverse health effects.<sup>99</sup> The FDA must now approve color additives in FDCA-regulated products if the additives will come into direct contact with the human body for a "significant period of time."<sup>100</sup> The FDA Commissioner publishes regulations listing approved and restricted additives, as well as any conditions on their use.<sup>101</sup> If evidence suggests that an ingestible additive was the causative substance in inducing cancer in humans or animals, the Commissioner may ban its use.<sup>102</sup> After a color additive is listed as approved in an FDA regulation, it must also be batch certified before it can be used in a product regulated under the FDCA.<sup>103</sup> With the exception of color additives, however, the FDA is unable to require cosmetic manufacturers to file health and safety data on

---

97. *Cosmetics Q&A: Cosmetics & Over-the-Counter Drugs*, FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/CosmeticsQA/ucm135712.htm> (last updated June 18, 2009).

98. *See, e.g., Toilet Goods Ass'n v. Finch*, 419 F.2d 21 (2d Cir. 1969) (explaining that 21 U.S.C. § 321 "scarcely show[s] that all finished cosmetics were thought to be color additives requiring premarketing clearance"). Color additives are defined as any dye, pigment or certain color-imparting substance used in food, drugs and cosmetics. 21 U.S.C. § 321(t)(1) (2010).

99. *Color Additives: FDA's Regulatory Process and Historical Perspectives*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForIndustry/ColorAdditives/RegulatoryProcessHistoricalPerspectives/default.htm> (last updated Dec. 17, 2009).

100. 21 U.S.C. § 379(e) (2010).

101. *Id.*

102. 21 C.F.R. § 70.50 (2010).

103. Batch certification is the manner in which colors additives are certified with the FDA. Color additive manufacturers submit a representative sample of their color additive batch, which is reviewed to ensure it conforms with FDA regulations. 21 U.S.C. § 379(e) (2010); 21 C.F.R. § 80.22 (2010).

ingredients.<sup>104</sup> Without this information, the FDA is not able to determine the total possible harm a cosmetic product actually poses.

In fact, the FDCA permits the FDA to take action only if there is evidence that a cosmetic is “adulterated” or “misbranded.”<sup>105</sup> Adulterated cosmetics are those that may cause injury to users due to contamination or because they contain harmful substances, while misbranded cosmetics are those that are improperly or deceptively labeled.<sup>106</sup>

Under the FDCA, a cosmetic is adulterated if:

- (a) It bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual . . . [coal-tar hair dyes with a prescribed warning are exempted].
- (b) It consists in whole or in part of any filthy, putrid, or decomposed substance.
- (c) It has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- (d) Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (e) It is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.<sup>107</sup>

The FDA’s ability to take action against misbranded products stems from its authority under the FDCA to regulate the labeling of

---

104. 21 U.S.C. § 379(e) (2010).

105. See *infra* Part II.B. (discussing the FDA’s authority over misbranded products under Fair Packaging and Labeling Act); see also *Cosmetics Q&A: FDA’s Authority*, *supra* note 97.

106. 21 U.S.C. § 379(e) (2010).

107. *Id.* § 361. The parameters for listing a color additive as unsafe, including permitted exceptions, are found at 21 U.S.C. § 379e(a).

cosmetics.<sup>108</sup> Thus, FDA regulations require that every cosmetic product display an ingredient declaration to enable consumers to make informed purchasing decisions.<sup>109</sup> Under the FDCA, a cosmetic is considered “misbranded” if:

its labeling is false or misleading in any particular;  
its label does not include all required information;  
the required information is not adequately prominent and conspicuous its container is so made, formed, or filled as to be misleading;  
it is a color additive, other than a hair dye, that does not conform to applicable regulations;  
its packaging or labeling is in violation of an applicable regulation issued pursuant to the Poison Prevention Packaging Act of 1970.<sup>110</sup>

Notwithstanding its technical ability to regulate cosmetics in this manner, the FDA in fact has limited control over the sale of adulterated or misbranded products. Most notably, the FDCA does not permit the FDA to issue recalls for products.<sup>111</sup> The FDA has also been reluctant to ban dangerous ingredients in cosmetics, restricting or prohibiting the use of only nine such ingredients.<sup>112</sup> In contrast, the European Union has banned more than 1,000 chemicals known or suspected of causing cancer, genetic abnormalities, or birth defects.<sup>113</sup>

The FDA’s inability to adequately address dangerous cosmetics is abundantly clear when examining the agency’s treatment of skin-

---

108. 21 U.S.C. § 362 (2010).

109. *See id.*

110. *Id.*; *see also* 15 U.S.C. §§ 1472-73 (2010).

111. Termini, *supra* note 3, at 271.

112. The banned ingredients are bithionol, mercury compounds, vinyl chloride, halogenated salicylanilides, zirconium complexes in aerosol cosmetics, chloroform, methylene chloride, and chlorofluorocarbon propellants. 21 C.F.R., §§ 250.250, 700.11 to .35 (2010).

113. Rawlins, *supra* note 32, at 20; *see also infra* Part III.A (discussing the European Union’s regulation of cosmetics).

lightening creams.<sup>114</sup> In 1990, the FDA banned mercury, a heavy metal with the ability to lighten skin color, from skin care products.<sup>115</sup> By that point, the dangers of mercury were well known.<sup>116</sup> While the ban by the FDA was clearly a step toward more effective regulation and an accomplishment for the agency, its effectiveness is questionable. In May 2010, an investigation by the Chicago Tribune revealed that some skin lightening creams still contained mercury, though the FDA had banned the ingredient from skin lightening creams twenty years earlier.<sup>117</sup> An FDA spokesperson responded that due to their small number of inspectors “it is likely that things get past [the FDA].”<sup>118</sup> Further, the FDA’s lack of recall authority makes it virtually impossible to demand a recall of these mercury-containing products.<sup>119</sup> It is likely that many of these mercury-containing products remain on the market today.

In 2006, the FDA proposed a ban on use of hydroquinone in over-the-counter skin-lightening products due to its carcinogenic risk and potential to cause disfigurement.<sup>120</sup> Since the FDA offered the rule for notice and comment, however, it has not taken any further action.<sup>121</sup> Indeed, the agency’s inability to effectively enforce its ban

---

114. Creams designed to lighten the skin may also be referred to as “skin whitening” or “skin bleaching.” See generally Imani Perry, *Buying White Beauty*, 12 CARDOZO J.L. & GENDER 579 (2006).

115. Leslie S. Baumann, *Mercury*, SKIN & ALLERGY NEWS, Sept. 1, 2010, at 28, available at <http://www.skinandallergynews.com/views/cosmeceutical-critique-by-leslie-s-baumann/blog/mercury/a2c3e53aa8.html>.

116. *Id.*

117. Ellen Gabler & Sam Roe, *Mercury Taints Some Skin Lighteners*, CHI. TRIB., May 19, 2010, at 1.

118. *Id.*

119. See *supra* notes 3, 111 and accompanying text; see also *infra* Part III.B (explaining that the proposed Safe Cosmetics Act of 2010 sought to give the FDA authority to issue recalls).

120. Skin Bleaching Products For Over-the-Counter Human Use, 71 Fed. Reg. 51146 (proposed Aug. 29, 2006) (codified at 21 C.F.R. § 310).

121. *Rulemaking History for OTC Skin Bleaching Drug Products*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072117.htm> (last updated Dec. 14, 2009).

on mercury calls into question the worth of a ban by the agency and highlights its lack of power.<sup>122</sup>

By contrast, the National Highway Traffic Safety Administration (NHTSA) has the authority to issue recalls under the National Traffic and Motor Vehicle Safety Act.<sup>123</sup> If a vehicle or piece of motor vehicle replacement equipment, such as tires, contains a safety-related defect or does not comply with Federal Motor Vehicle Safety Standards, the Secretary of Transportation can direct a manufacturer to issue a recall.<sup>124</sup> If a company resists issuing a recall, the Secretary can move to enforce a recall order in federal court, as well as seek penalties.<sup>125</sup> Often, the threat of a recall alone is enough to lead a manufacturer to conduct its own investigation and issue a recall voluntarily.<sup>126</sup>

The Consumer Product Safety Commission (CPSC) has the similar authority to force manufacturers to recall products that violate safety standards.<sup>127</sup> Because the CPSC's enabling statute, the Consumer Products Safety Act, specifically excludes cosmetics, the agency is not able to address unsafe cosmetics.<sup>128</sup> Yet, aside from cosmetics and a small number of products regulated by other federal agencies,

---

122. Additionally, many cosmetics manufacturers avoid testing their products' ingredients for efficacy or, at least, avoid publicizing the results of such tests to avoid having their products categorized as drugs. See Deborah E. Mason, Note, *Kiss and Make-Up: A Need for Consolidation of FDA and Cosmetic Industry Regulation Programs*, 18 HEALTH MATRIX 181, 182 (2008). These products often contain ingredients that also are available in drugs. See *id.* at 182-83. Questions about whether these products are more appropriately categorized as drugs or as cosmetics have led some commentators to call for the creation of a hybrid "cosmeceutical" category of cosmetic products that claim to or have "been found to have biologic activity." *Id.* Under this proposal, these products would be subject to an intermediate level of premarket safety tests rather than the more extensive testing required of drugs and the nonexistent testing currently in place for cosmetics. See *id.* at 197.

123. National Traffic and Motor Vehicle Safety Act, 49 U.S.C. §§ 30101-30170 (2010).

124. *Id.* § 30118.

125. *Id.* § 30121.

126. See James C. Rathner, Jr., *Total Recall*, 58 LA. B.J. 102, 104 (Aug./Sept. 2010).

127. 15 U.S.C. § 2064 (2010); see also Consumer Products Safety Act, 15 U.S.C. §§ 2051-2084 (2010).

128. *Id.* § 2052(a)(1)(H).

the CPSC has wide authority to regulate nearly any product sold to consumers for use in or around the household, or for entertainment or personal use.<sup>129</sup> The CPSC is also empowered to seek civil and criminal penalties against violators.<sup>130</sup>

Both the NHTSA and CPSC have successfully exercised their recall powers for decades. Since the NHTSA was granted this authority in 1966, the agency has recalled more than 390 million vehicles.<sup>131</sup> The CPSC credits its regulation of consumer product safety and recall efforts with contributing significantly to the 30 percent decline in the rate of deaths and injuries associated with consumer products in the past 30 years.<sup>132</sup>

Absent an independent power of recall, the FDA may attempt to remove adulterated and misbranded cosmetics from the market in conjunction with the Department of Justice (DOJ) if consumer complaints raise concerns about that product.<sup>133</sup> For example, the DOJ may go to federal court on behalf of the FDA to request a restraining order preventing further shipment of an adulterated or misbranded product, seize the product, or initiate criminal action against violators.<sup>134</sup>

If a cosmetics manufacturer attempts to import a violative product into the United States, the FDA has the power to refuse its entry into interstate commerce.<sup>135</sup> The United States Customs and Border Protection (Customs) alerts the FDA when a product under its purview arrives at a port of entry.<sup>136</sup> If the FDA suspects a product violates the FDCA, its owners are provided notice and afforded an opportunity to introduce testimony regarding the admissibility of the

---

129. *Id.* § 2052(a)(1)(i)-(ii).

130. *Id.* §§ 2069-2070.

131. *Motor Vehicle Safety Defects and Recalls Campaigns*, NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., <http://www.nhtsa.gov/Vehicle+Safety/Recalls+&+Defects/Motor+Vehicle+Safety+Defects+and+Recalls+Campaigns> (last visited Oct. 28, 2011).

132. *About CPSC*, CONSUMER PROD. SAFETY COMM'N, <http://www.cpsc.gov/about/about.html> (last updated Oct. 27, 2011).

133. *Cosmetics Q&A: FDA's Authority*, *supra* note 97.

134. *Id.*

135. FOOD & DRUG ADMIN., FDA REGULATORY PROCEDURES MANUAL, 9-2, 9-9 to 9-10, <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf> (last revised Jan. 2008).

136. *Id.*

product at an administrative hearing.<sup>137</sup> If the FDA determines a product violates the statute, Customs will issue a Notice of Refusal of Admission and destroy any shipment that is not exported within 90 days.<sup>138</sup>

In sum, although the FDA has some powers to prevent dangerous products from entering the marketplace in the United States, the agency's lack of recall capabilities is both troubling and indicative of the inadequate cosmetics regulation regime in the United States. The NHTSA's and CPSC's recall powers highlight the ability of the federal government to effectively prevent unsafe products from reaching consumers. Any future reform of federal statutes controlling cosmetic regulation should look to the NHTSA and the CPSC as models for recall capabilities.

### 3. Monitoring Mechanisms

The FDCA tasked the FDA with monitoring and enforcing the statute, but the agency is not the only body monitoring cosmetics in the United States. The cosmetics industry itself has implemented a system of self-regulation and monitoring through the Cosmetic Ingredient Review Panel. This section will review these agency and industry monitoring mechanisms and their effectiveness.

#### *a. The Office of Cosmetics and Colors*

The Office of Cosmetics and Colors, a division of the Center for Food Safety and Applied Nutrition (CFSAN), is the center within the FDA charged with ensuring that cosmetic products are not mislabeled or adulterated.<sup>139</sup> In addition to issuing regulations related to cosmetics and their labeling, the CFSAN is responsible for overseeing research programs that address possible health risks associated with chemical or biological contaminants, post-market surveillance, consumer education and industry outreach.<sup>140</sup> Despite this robust mandate, as of 2007, the Office of Cosmetics and Colors

---

137. *Id.* at 9-30.

138. *Id.* at 9-36.

139. *CFSAN - What We Do*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/WhatWeDo/default.htm> (last visited Oct. 25, 2011).

140. *Id.*

employed only 14 staff members and functioned with a budget of only \$3.5 million – a paltry sum considering the tens of billions of dollars in cosmetics sales in the United States each year.<sup>141</sup>

Although the FDA's authority is limited to monitoring cosmetic products already on the market, the Office of Cosmetics and Colors does provide industry manufacturers, distributors and packagers with "recommended draft guidances."<sup>142</sup> These voluntary guidances are designed to assist the cosmetics industry to develop systems that decrease the likelihood of selling cosmetics that are adulterated, misbranded, or both.<sup>143</sup>

*b. The Cosmetic Ingredient Review Panel*

Congress has amended the FDCA numerous times since its passage in 1938, but little has changed regarding the FDA's limited ability to regulate cosmetics. Consumer and environmental groups repeatedly have pressed for reform, and nearly succeeded in the 1970s.

In 1973, Senator Thomas Eagleton of Missouri proposed requiring cosmetics manufacturers to perform thorough toxicology tests and substantiate safety before they could sell their products to consumers.<sup>144</sup> Fearing sweeping change pressed upon it by Congress, the Personal Care Products Council (PCPC),<sup>145</sup> the cosmetics industry's powerful lobby, decided to work with the FDA to develop a system for monitoring cosmetic ingredients.<sup>146</sup> The industry lobby and the FDA agreed in 1976 to create the self-monitoring Cosmetic Ingredient Review (CIR) panel in lieu of the

---

141. Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 461 (2008).

142. See, e.g., FOOD & DRUG ADMIN., FINAL GUIDANCE FOR INDUSTRY COSMETICS PROCESSORS AND TRANSPORTERS: COSMETICS SECURITY PREVENTATIVE MEASURES GUIDANCE, (Dec. 17, 2003), *available at* 2003 WL 24014301 (F.D.A.).

143. *Id.*

144. 119 CONG. REC. S4215-16 (daily ed. Feb. 15, 1973).

145. Known at the time as the Cosmetics and Fragrance Trade Association. *About Us*, PERS. CARE PROD. COUNCIL, <http://www.ctfa.org/about-us/about-personal-care-products-council> (last visited Dec. 11, 2011).

146. See *The Eagleton Bill*, PERS. CARE PROD. COUNCIL, <http://www.personalcarecouncil.org/eagleton-bill> (last visited Dec. 11, 2011).



standardized toxicological testing proposed by Senator Eagleton.<sup>147</sup> The CIR agreement allowed for “partial product labeling,” which required the cosmetics industry to identify ingredients in its products, but created a loophole that allowed manufacturers to omit identifying “trade secret” or “fragrance” ingredients.<sup>148</sup>

The cosmetics industry funds and runs the CIR through the PCPC. The CIR Expert Panel, which assesses safety data and makes final decisions regarding the purported safety of an ingredient, has seven voting members.<sup>149</sup> The CIR’s Steering Committee chooses voting members from a list of scientists and physicians nominated by outside groups, government agencies, and the cosmetics industry.<sup>150</sup> The PCPC, the FDA, and the Consumer Federation of America serve as liaison representatives and non-voting members on the Expert Panel.<sup>151</sup> Although the CIR’s ingredient and safety reviews are designed to be open for public review, the trade secret and fragrance exceptions ensure that a significant amount of information remains unavailable to the FDA and the general public.<sup>152</sup>

### *B. Fair Packaging and Labeling Act*

In addition to the FDCA, the FDA derives authority to regulate cosmetics through the Fair Packaging and Labeling Act (FPLA).<sup>153</sup> Congress initially passed the FPLA in 1966 to help consumers make informed purchasing decisions by requiring manufacturers to provide accurate information on consumer goods packaging and labels.<sup>154</sup>

---

147. *Id.*

148. 21 C.F.R. §§ 701.3(a), 720.8 (2010); *see also* Malkan, *supra* note 8, at 103; *infra* notes 157, 161-62, 164, 166 and accompanying text (defining “trade secret” and “fragrance” and describing regulations controlling the exemptions).

149. *How Does CIR Work?*, COSMETIC INGREDIENT REV., <http://www.cir-safety.org/info.shtml> (last visited Oct. 28, 2011).

150. COSMETIC INGREDIENT REV., COSMETIC INGREDIENT REVIEW PROCEDURES 6 (Oct. 2010).

151. *Id.* at 7.

152. *See* Robert L. Elder & Jonathon T. Busch, *The Cosmetic Ingredient Review*, in *THE COSMETIC INDUSTRY: SCIENTIFIC AND REGULATION FOUNDATIONS* 203, 203-204 (Norman F. Estrin ed., 1984).

153. *See* Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451-1461 (2010).

154. 15 U.S.C. § 1451 (2010). While the Federal Trade Commission is generally charged with administering the provisions of the FPLA, the FDA retains the

The statute generally requires that all consumer commodities bear a label identifying the good, the name, place of business of the manufacturer, and the net quantity of contents.<sup>155</sup>

As the FDA began to work with the cosmetics industry to create a system of self-regulation in the mid-1970s,<sup>156</sup> the agency promulgated regulations under the FPLA requiring that ingredients in cosmetic ingredients, with the notable exception of ingredients that qualify as “trade secrets” or “fragrance,” be identified by the name established by the Commissioner of Food and Drugs.<sup>157</sup>

Though the FDCA contains provisions regarding misbranding, the FDA’s regulations promulgated under the FPLA expand the concept of misbranding to factor in safety.<sup>158</sup> A product’s safety is adequately substantiated if qualified experts can “reasonably conclude from the available toxicological and other test data, chemical composition, and other pertinent information that the product is not injurious to consumers under conditions of customary use and reasonably foreseeable conditions of misuse.”<sup>159</sup> If safety has not been adequately substantiated, the product must include the following conspicuous warning on a panel display: “Warning - The safety of this product has not been determined.”<sup>160</sup>

The FPLA regulations contain an enormous loophole that may allow manufacturers to include unsafe ingredients in products without a warning label. If a chemical qualifies as a “trade secret” or

---

authority to promulgate regulations related to food, drugs and cosmetics controlled by the FPLA. *Id.* § 1454(a).

155. *Id.* § 1453(a).

156. *See supra* Part II.A.3.b (discussing FDA’s agreement with the cosmetics industry to require only partial product labeling).

157. The Commissioner of Food and Drugs establishes name for cosmetics ingredients in order to ensure uniformity among products. The Commissioner may establish names upon request or by his or her own initiative. 21 C.F.R. §§ 701.3(c), 720.8 (2010).

158. 15 U.S.C. § 1456(a) (2010).

159. *Cosmetic Warning Statements*, FOOD & DRUG ADMIN., <http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/ucm126444.htm#clgk> (last updated July 29, 2011) (explaining the FDA’s interpretation of the requirements mandated by 21 C.F.R. § 740.10).

160. 21 C.F.R. § 740.10(a) (2010).

is part of a “fragrance” or “coloring,”<sup>161</sup> it is exempt from the FPLA’s ingredient identification requirements.<sup>162</sup> The FDA considers several factors when determining whether an ingredient qualifies as a trade secret: whether the identity of the ingredient is known outside of the manufacturer’s business; whether the identity of the ingredient is known by employees of the manufacturers; the value of the trade secret to competitors; the amount of effort or money spent to develop the ingredient, and the ease or difficulty which with others could acquire or duplicate the ingredient.<sup>163</sup>

The FDA defines the term “fragrance” as “any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.”<sup>164</sup> FDA regulations further require than an ingredient can be labeled as a “fragrance” only if it is used in a manner consistent with how consumers “commonly understand” the term.<sup>165</sup>

If the FDA categorizes an ingredient as a trade secret or a fragrance, the manufacturer may list “and other ingredients” in lieu of the names of the exempted ingredients.<sup>166</sup> The omission of ingredient names from cosmetic product labels not only makes it more difficult for consumers to make informed choices, but also may make it easier for manufacturers to include ingredients that are unsafe.

### *C. The Toxic Substances Control Act*

The Toxic Substances Control Act (TSCA)<sup>167</sup> was enacted in 1976. Congress identified the statute’s policy goals as follows:(1) to

---

161. *See supra* notes 148 and 152 and accompanying text; *see also supra* Part II.A.2(discussing regulation of color additives).

162. 15 U.S.C. § 1454(c)(3)(B) (2010); 21 C.F.R. § 701.3(a) (2010); 21 C.F.R. § 20.61 (2010).

163. 21 C.F.R. § 720.8(b) (2010).

164. *Id.* § 700.3(d).

165. *Id.* § 701.3(a).

166. *Id.* § 701.3(a).

167. 15 U.S.C. §§ 2601-2692 (2010). TSCA is the only major piece of environmental legislation enacted in the 1970s that has not been substantively revised since it was passed, according to a report by the law firm of Beveridge and Diamond, P.C. MARK N. DUVALL ET AL., BEVERIDGE & DIAMOND, P.C., PROPOSED LEGISLATION WOULD OVERHAUL TSCA (April 23, 2010), <http://www.bdlaw.com/assets/attachments/2010-04->

develop adequate data on the health and environmental effects of chemical substances and mixtures while placing the onus on manufacturers to develop this data;<sup>168</sup> (2) to establish adequate authority to regulate chemicals that present an unreasonable risk of injury to health or the environment;<sup>169</sup> and (3) to ensure that the Environmental Protection Agency's regulatory authority balances the aim of preventing unreasonable health and environmental risks with concerns that such an authority could serve as an undue burden or barrier to technological innovation.<sup>170</sup>

Notwithstanding these broad goals, TSCA specifically exempts cosmetics<sup>171</sup> TSCA's definition of a chemical substance excludes "any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food Drug and Cosmetic Act)."<sup>172</sup> Dual-use chemicals may, however, be subject to TSCA for non-cosmetic uses and to the FDCA when contained in a cosmetic.<sup>173</sup> For example, phthalates used in non-exempt products, such as toys or cleaning supplies, would be subject to the EPA's authority under TSCA.<sup>174</sup> Phthalates used in a cosmetic product, however would remain subject to the FDA's authority under the FDCA.<sup>175</sup>

Because the FDCA broadly defines the term cosmetic to include "articles intended for use as a component of" a cosmetic product,<sup>176</sup>

---

19%20Alert%20on%20Proposed%20Legislation%20to%20Overhaul%20TSCA.pdf.

168. 15 U.S.C. § 2601(b)(1) (2010).

169. *Id.* § 2601(b)(2).

170. *Id.* § 2601(b)(3).

171. *Id.* § 2602(2)(B)(vi).

172. *Id.* Under the FDCA:

- (i) The term 'cosmetic' means (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(i) (2010).

173. LYNN L. BERGESON, *TSCA: THE TOXIC SUBSTANCES CONTROL ACT* 4 (2000).

174. *See id.* (describing a similar example involving the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and TSCA).

175. *Id.*

176. 21 U.S.C. § 321(i)(2) (2010).

the raw materials, intermediates, and catalysts intended solely for use in cosmetics are excluded from TSCA regulation.<sup>177</sup> Yet this exemption for chemicals used in cosmetics may not be as broad as it seems. The EPA's authority under TSCA has the potential to play a role in cosmetics regulation. Under TSCA, the EPA must coordinate with other federal agencies in the research, development, collection, dissemination, and utilization of data,<sup>178</sup> and cooperate with other federal agencies to utilize the resources of such agencies.<sup>179</sup>

Thus, if the EPA determines that a chemical poses a risk of human injury, it may ban or otherwise restrict it from all non-exempt uses that pose such a risk.<sup>180</sup> The EPA's decision to ban or restrict the non-exempt uses of a chemical would not automatically prompt the FDA to issue a similar ban or restriction, but because TSCA requires coordination and cooperation between the EPA and other federal agencies, the FDA would likely take into account the EPA's safety determination and more carefully scrutinize the chemical's cosmetic use. This is both efficient and sensible, as, in all likelihood, the "intimate bodily exposure" encountered through routine use of cosmetics containing the chemical in question would be hazardous.<sup>181</sup>

An EPA finding that a chemical poses an unreasonable risk of human injury could pose other problems for cosmetics producers.<sup>182</sup> Some dual-use chemicals are used primarily in TSCA-regulated applications, with the cosmetics industry using only a small fraction of the aggregate production volume of a given chemical. If the EPA banned or otherwise limited these primary applications, it could become uneconomical to manufacture the chemical if the cosmetics industry requires only a relatively minute amount.<sup>183</sup> The EPA's regulatory actions could thus eliminate the production sources of

---

177. Inventory Reporting Requirements, 42 Fed. Reg. 64572, 64586 (Dec. 23, 1977).

178. 15 U.S.C. § 2609 (2010).

179. *Id.* § 2625(a).

180. *See generally id.* § 2605 (authorizing the EPA to take regulatory measures to protect against an unreasonable risk of human injury posed by chemical substances, including the ability to ban manufacture and distribution in commerce, restrict use, and impose labeling requirements).

181. Estrin, *supra* note 152, at 40; *see supra* Part II.A.2.

182. Estrin, *supra* note 152, at 40.

183. *Id.* at 40-41.

some chemicals used in cosmetics.<sup>184</sup> Finally an EPA finding that a chemical presents an unreasonable risk of harm would likely deter consumers from purchasing the product, and would trigger responses from public interest groups.<sup>185</sup>

### 1. Regulatory Mechanisms under TSCA

The TSCA statutory and regulatory schemes may be helpful when considering ways to improve cosmetics testing and regulation, but it is important to note that, notwithstanding the exemption of cosmetics from EPA review, the TSCA model is hardly perfect. Its effectiveness with respect to obtaining chemical toxicity information and policing existing chemicals has been limited at best. This section sets out the TSCA regulatory mechanisms to discern lessons for cosmetics reform.

The Senate's Commerce Committee report concerning the TSCA legislation described it as a bill "designed to fill a number of regulatory gaps," as it mandated the EPA to conduct premarket review of chemical substances and mixtures, monitor industrial chemicals for health and environmental impact, take a comprehensive look at the hazards associated with chemicals, and assign responsibility to obtain data about the health and environmental effects of chemicals to manufacturers.<sup>186</sup>

TSCA regulates two kinds of materials: "chemical substances" and "mixtures."<sup>187</sup> The statute and regulations define the term "chemical substance" quite expansively<sup>188</sup> to include "any organic or inorganic substance of a particular molecular entity, including – (i) any combination of such substances occurring in whole or in part as a

---

184. *Id.* at 41.

185. *Id.*

186. S. Rep. No. 94-698, at 1 (1976), *reprinted in* LIBR. OF CONG., LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT "157 (1976). The Senate TSCA bill was passed in lieu of the House bill. *Id.*

187. ELIZABETH BROWN ET AL., TSCA DESKBOOK: A PRACTITIONER'S GUIDE TO THE TOXIC SUBSTANCES CONTROL ACT 8 (1999). A mixture is a combination of chemical substances. *Id.*

188. *Id.* ("This same expansive approach applies to many other key jurisdictional terms in the statute, including 'chemical manufacturers' (defined to include *importers* of chemical substances) and 'chemical processors' (defined to include many activities more traditionally understood as *chemical use*).").

result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical.”<sup>189</sup>

Despite TSCA’s broad scope,<sup>190</sup> the statute intentionally excludes regulation of several categories of materials from the definition of “chemical substance,” including mixtures, pesticides, tobacco products, nuclear materials, firearms and ammunition, and food, drugs and cosmetic products.<sup>191</sup> These categories, with the exception of mixtures, are all regulated under other federal statutes such as the FDCA.<sup>192</sup>

TSCA defines mixtures as any combination of two or more chemical substances not occurring in nature that also are not the product of a chemical reaction.<sup>193</sup> Although individual “chemical substances” are subject to TSCA’s pre-manufacture notice requirements, which give the EPA 90 days to evaluate and consider whether to restrict or ban the substances, the mixtures themselves are not.<sup>194</sup> This means that the EPA is not given the opportunity to assess a new mixture before it enters production.

TSCA is a complex statute. Its key regulatory mechanisms include the following:

Review of Existing Chemicals - Section 4 authorizes the EPA to promulgate rules that require manufacturers/processors to test

---

189. 15 U.S.C. § 2602(2)(A) (2010). The EPA has interpreted the definition of a “chemical substance” to reach quite broadly, even including some microorganisms. *See* 40 C.F.R. § 710.26(c) (2010). Section 3 of TSCA includes microorganisms and their component chemicals, unless they are manufactured or distributed “for use as pesticides, foods, food additives, drugs, cosmetics, and medical devices.” Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,324 (June 26, 1986). New microorganisms are subject to TSCA’s reporting requirements for new chemicals only if they are intergeneric. *See* 40 C.F.R. § 725.3. Intergeneric microorganisms are those that are “formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera.” *Id.*

190. BROWN, *supra* note 187, at 8 (noting that Congress granted the EPA broad authority, aiming to regulate chemicals that are manufactured, imported, processed, used, or disposed of in the United States).

191. 15 U.S.C. § 2602(2)(b) (2010).

192. *See* BROWN, *supra* note 187, at 8 (citing 15 U.S.C. § 2602(2)(B)).

193. *Id.* at 9 (citing 15 U.S.C. § 2602(8)).

194. *Id.* (citing 15 U.S.C. § 2604).

chemical substances and mixtures the EPA identifies to pose an unreasonable risk to health or the environment.<sup>195</sup>

Review of New Chemicals - Section 5 regulates the manufacture and import of new chemical substances in the United States.<sup>196</sup> Manufacturers of new chemicals must submit to the EPA a pre-manufacture notice of their intent to produce a new chemical, along with any data relating to the health or environmental effects of the chemical, at least 90 days before importing or manufacturing the chemical substance.<sup>197</sup> Manufacturers of existing chemical substances seeking to use or process them for a “significant new use” are similarly required to provide 90 days notice.<sup>198</sup> The EPA may restrict or ban production and distribution activities and/or the “significant new uses” of these chemical substances if they pose an unreasonable risk to the public health or the environment.<sup>199</sup>

Inventory of Chemical Substances – Section 8(b) requires the EPA to establish and maintain an inventory of all chemicals manufactured or processed in the U.S. from 1974.<sup>200</sup> By 1980, EPA had compiled a list of about 60,000 individual chemical substances,<sup>201</sup> creating a database of existing chemical substances. Any chemical substance not on this list is considered a “new chemical substance” and must undergo TSCA’s review and approval procedures under Section 5.<sup>202</sup>

Direct Regulation of Existing Chemical Substances - Section 6 authorizes the EPA to prohibit or otherwise limit the manufacture, processing, or distribution of existing chemical substances where there is a “reasonable basis” to find that a chemical “presents or will present an unreasonable risk of injury to health or the environment.”<sup>203</sup>

---

195. 15 U.S.C. § 2603(a)(4) (2010).

196. *Id.* § 2604.

197. *Id.* § 2604(a)(1)(A).

198. *Id.* § 2604(a)(1)(B).

199. *Id.* § 2604(f); *see also* 40 CFR 721.1 (2010).

200. *Id.* § 2607(b)(1); BROWN, *supra* note 187, at 7.

201. BROWN, *supra* note 187, at 7. Currently, the EPA’s TSCA inventory contains approximately 84,000 non-confidential identities of chemical substances. The list is available at <http://www.data.gov/raw/1630> (last visited Dec. 23, 2010).

202. BROWN, *supra* note 187, at 7.

203. 15 U.S.C. § 2605(a) (2010).



Import/Export Requirements – Section 13 requires that any chemical substance or mixture imported into the United States comply with TSCA.<sup>204</sup> The Secretary of Treasury and the EPA Administrator are authorized to work together to promulgate regulations regarding the importation of chemicals.<sup>205</sup> Section 12(b) requires individuals to notify EPA when they intend to export chemicals for which the submission of data is required under Section 4 or Section 5.<sup>206</sup>

TSCA requires chemical producers to provide notice to the EPA of their intent to manufacture or import a *new* chemical and any available data pertaining to testing or associated health or environmental effects.<sup>207</sup> However, the EPA has revealed that most pre-manufacture notices do not contain any testing data, and only 15 percent contain data related to environmental or health effects.<sup>208</sup> Chemical manufacturers do not have an incentive to conduct safety testing that can involve significant expenditures of time and money.<sup>209</sup> Rather than providing data drawn from safety tests, manufacturers simply provide estimates of the potential exposures to new chemicals. Lacking sufficient data regarding a new chemical's properties and effects, the EPA relies on a modeling approach known as structure activity relationships analysis, whereby the new chemical is compared to existing analogues based on their structural similarity.<sup>210</sup>

---

204. *Id.* § 2612.

205. *Id.*

206. *Id.* § 2611(b).

207. *See supra*, notes 196-99 and accompanying text (explaining that manufacturers are required to submit a pre-manufacture notice and any available health or environmental data 90 days before manufacturing a new chemical); *see also* Rawlins, *supra* note 32, at 32.

208. *Id.* (citing Testimony before the Committee on Environment and Public Works, U.S. Senate, Chemical Regulation: Actions are needed to improve the effectiveness of EPA's chemical review program, GAO-06-1032T, at 8, April 2, 2006 (statement of John B. Stephenson, Director, Natural Resources and Environment)).

209. Testimony before the Committee on Environment and Public Works, U.S. Senate, Chemical Regulation: Actions are needed to improve the effectiveness of EPA's chemical review program, GAO-06-1032T, at 8, April 2, 2006 (statement of John B. Stephenson, Director, Natural Resources and Environment).

210. *Id.* at 8.

Chemical producers seeking to use *existing* chemicals have no obligation to submit toxicity information unless the EPA first promulgates a new test rule.<sup>211</sup> Yet the EPA can do so only if it can show by substantial evidence that the existing data on the chemical is “insufficient” and that the agency has “more than a theoretical basis” to suspect a risk associated with exposure to the chemical.<sup>212</sup> This is a difficult burden to satisfy.<sup>213</sup> It can require sizable expenditures from the agency to meet this standard, and takes from two to ten years for the EPA to finalize test rules for an existing chemical.<sup>214</sup> The EPA has required testing of fewer than 200 of the 62,000 chemicals that exist in commerce since it began reviewing them in 1979.<sup>215</sup>

## 2. An Illustration of TSCA’s Inadequacies

On its face, the language of TSCA appears to grant the EPA wide authority over chemical production. However, the agency’s ability to promulgate restrictions over chemicals has been hampered by the lack of safety data available for its assessments.<sup>216</sup> This data gap compounds the EPA’s difficulties meeting courts’ high evidentiary burden to justify restrictions on chemical manufacturers. Manufacturers submitting to the EPA a pre-manufacture notice of intent to use a “new chemical” or a “significant new use” notice must include all testing data in their possession regarding health or environmental effects, and any other relevant data of which they have knowledge.<sup>217</sup> A manufacturer must develop and include additional mandatory test data in only two situations. First, when submitting a pre-manufacture notice regarding a “new chemical substance,” the manufacturer must include data relating to environmental and health risks outlined in TSCA Section 4.<sup>218</sup> Second, chemical

---

211. *Id.* at 4; *see also supra*, note 203 and accompanying text (stating that manufacturers of an existing chemical must submit data only if the EPA finds that the chemical poses an unreasonable risk to health or the environment).

212. *Id.* at 5.

213. *Id.* at 5-6.

214. *Id.* at 6.

215. *Id.*

216. *See supra* notes 207-10 and accompanying text.

217. 15 U.S.C. § 2603(a) (2010); BROWN, *supra* note 187, at 7.

218. BROWN, *supra* note 187, at 7.

manufacturers need to submit additional test data when the substance they seek to use is included on the list of the substances that the EPA has determined may present an unreasonable risk of injury to the public health or the environment.<sup>219</sup> If a pre-manufacture notice contains insufficient information for the EPA to determine health or environmental effects of a new substance, the EPA can restrict or prohibit its manufacture.<sup>220</sup> Other than these circumstances, the scope of testing of a new substance or a significant new use of an existing substance is left up to the manufacturer, who is not required to submit even minimum data set setting forth basic chemical identity or toxicology.<sup>221</sup>

After reviewing the manufacturer's test data, the EPA may prohibit or restrict the use or production of chemicals it finds by "substantial evidence" to pose an "unreasonable risk" of human injury or environmental harm.<sup>222</sup> This balancing test permits the EPA to restrict or prohibit the use of a chemical only if the severity and likelihood of the potential injury from its use offsets the economic harm that the restriction would impose on manufacturers and consumers.<sup>223</sup> Under TSCA, any such restrictions must be the least burdensome that will also adequately protect against the risk to human health or the environment.<sup>224</sup> Determining just what exactly constitutes "harm" or "adequate safety" can be difficult, and is perhaps unjusticiable.

---

219. *Id.*; see *supra* notes 195-206 and accompanying text (summarizing the key regulatory mechanisms of TSCA); see also 15 U.S.C. § 2603(a) (2010).

220. 15 U.S.C. § 2603(a) (2010).

221. *Id.* A minimum data set for existing chemicals includes chemical identity, biological fate and transport data, volumes, toxicological other information. Safe Cosmetics Act of 2010, H.R. 5786, 111<sup>th</sup> Congress (2010).

222. 26 U.S.C. § 2604(f) (2010); see *supra* note 203 and accompanying text; see also Rawlins, *supra* note 32, at 32-33.

223. Rawlins, *supra* note 32, at 33-34.

224. 15 U.S.C. § 2605(a) (2010); see also *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 472-76 (2001) (discussing the difficulties of determining what constitutes "adequate" protection of human health and the environment); Rawlins, *supra* note 32, at 34.

The EPA's unsuccessful attempt to ban asbestos, a well-known carcinogen,<sup>225</sup> illustrates the difficulty of conducting TSCA's balancing test. In 1991, in *Corrosion Proof Fittings v. Environmental Protection Agency*,<sup>226</sup> the Fifth Circuit struck down an EPA regulation prohibiting almost all manufacturing and use of asbestos.<sup>227</sup> Manufacturing industry advocates brought suit against the EPA, arguing that the regulation was not based on "substantial evidence."<sup>228</sup> The court ruled in favor of the petitioners, finding that the EPA had considered insufficient data and had performed flawed calculations when promulgating the regulation.<sup>229</sup>

The court held that the costs and benefits of the regulation had to be discounted over time to avoid an arbitrary calculation.<sup>230</sup> Because the agency analyzed the cost of the regulation using the time a person was exposed to asbestos, not the time of his or her injury, the court found the EPA had not measured costs and benefits properly.<sup>231</sup> In

---

225. See Rawlins, *supra* note 32, at 34; see also *Asbestos*, AM. CANCER SOC'Y, <http://www.cancer.org/Cancer/CancerCauses/OtherCarcinogens/IntheWorkplace/asbestos> (last revised Nov. 8, 2010).

226. *Corrosion Proof Fittings v. Env'tl. Prot. Agency*, 947 F.2d 1201 (5th Cir. 1991).

227. Rawlins, *supra* note 32, at 34 (citing Andrew Hanan, Note & Comment, *Pushing the Environmental Regulatory Focus a Step Back: Controlling the Introduction of New Chemicals Under the Toxic Substances Control Act*, 18 AM. J. L. & MED. 395, 415 (1992) (providing a detailed analysis of *Corrosion Proof Fittings* decision)).

228. *Corrosion Proof Fittings*, 947 F.2d at 1207.

229. *Id.* at 1227.

230. *Id.* at 1218. The Court of Appeals reasoned that "[w]hen the EPA does discount costs or benefits, however, it cannot choose an unreasonable time upon which to base its discount calculation. Instead of using the time of injury as the appropriate time from which to discount, as one might expect, the EPA instead used the time of exposure." *Id.*

231. *Id.* at 1218-19. The court explained,

We do not today determine what an appropriate period for the EPA's calculations would be, as this is a matter better left for agency discretion. . . . We do note, however, that the choice of a thirteen-year period is so short as to make the unquantified period so unreasonably large that any EPA reliance upon it must be displaced.

*Id.* at 1219. The court stated that when the EPA does discount costs or benefits, it cannot choose an unreasonable time upon which to base its discount calculation. Instead of using the time of injury as the appropriate time from which to discount, as one might expect, the EPA instead used the time of exposure. *Id.* at 1218-1219.

addition the court found that the EPA improperly concluded that the number of lives saved by the regulation were unquantifiable.<sup>232</sup> The Court of Appeals found the EPA's approach improper<sup>233</sup> and relied on both of these miscalculations to strike down the regulation.

The court went on to criticize the EPA for failing to consider less restrictive alternatives to the regulation it had proposed.<sup>234</sup> While the EPA did determine that the use of fibers in lieu of asbestos was less harmful, the court found this to be inadequate justification for a wholesale asbestos ban.<sup>235</sup> The court noted that it would be many years before experimental toxicological data would be available to forecast the health effects of substitutes.<sup>236</sup> Therefore, the confirmation of any hazards would take even longer and the risks associated with the substitutes were likely to change as the industry created new substitutes.<sup>237</sup> Although the EPA did not have a duty to explore all of the possible less restrictive alternatives, the court held that the agency must fully evaluate the significant risks posed by the substitutes before it could impose a ban on asbestos.<sup>238</sup>

The EPA's inability to implement an asbestos ban illustrates the 5th Circuit's high, and perhaps impractical, evidentiary burden.<sup>239</sup> A reasonable scientific expert may have concluded "substantial evidence" existed to show that asbestos posed an "unreasonable

---

According to the American Cancer Society, illness from asbestos can take anywhere from 10-20 years after the exposure. *See Asbestos, supra* note 225.'

232. *See Corrosion Proof Fittings*, 947 F.2d at 1218-19.

233. *Id.* at 1219 ("While TSCA contemplates a useful place for unquantified benefits beyond the EPA's calculation, unquantified benefits never were intended as a trump card allowing the EPA to justify any cost calculus, no matter how high.").

234. *Id.* at 1229. The court faulted the EPA for failing to consider the less restrictive alternative of requiring improvements in workplace conditions before banning the use of asbestos. It noted that when a product is potentially dangerous the proper course of action is to consider each regulatory option concerning the product, beginning with the least burdensome, and the costs and benefits of regulation under each option. *Id.* at 1217. ("The EPA cannot simply skip several rungs, as it did in this case, for in doing so, it may skip a less-burdensome alternative mandated by TSCA.").

235. *Id.* at 1221.

236. *See id.* at 1224.

237. *Id.* at 1224-25.

238. *Id.* at 1225.

239. *Id.*

risk,” yet, the court nevertheless struck the regulation because the EPA had not calculated the level of risk with sufficient precision.<sup>240</sup> It may be impracticable to employ such precision.<sup>241</sup> Indeed, the EPA has stated that the legal burden to demonstrate an “unreasonable risk” is so high that it has been discouraged from issuing regulations under TSCA.<sup>242</sup> The EPA has issued regulations to prohibit or restrict the production or use of only five existing chemicals or chemical groups since the statute was enacted in 1976.<sup>243</sup> Thus, even if TSCA covered cosmetics, implementing robust regulations is so difficult that it would be highly unlikely that any of their contents would be banned or significantly restricted.

Given the weaknesses of TSCA and the FDCA, it is not surprising that advocates have sought to amend these statutes. The next section explores these efforts and their potential impacts on improving the cosmetics regulation.

### III. PROPOSED REFORM OF THE FDCA AND TSCA

Though the regulatory framework for cosmetics has remained largely unchanged for decades, a reform movement is gathering steam.<sup>244</sup> This section will examine recent proposals for reforming the FDCA and the TSCA, highlighting the significant differences between the proposed legislation and the currently controlling statutes. As an introduction, this section will discuss two recent

---

240. Rawlins, *supra* note 32, at 35. (citing Andrew Hanan, Note & Comment, *Pushing the Environmental Regulatory Focus a Step Back: Controlling the Introduction of New Chemicals Under the Toxic Substances Control Act*, 18 AM. J. L. & MED. 395, 414 (1992)).

241. *Id.*

242. *Id.* (citing Testimony before the Comm. on Env't and Pub. Works, U.S. Senate, Chemical Regulation: Actions are needed to improve the effectiveness of EPA's chemical review program, GAO-06-1032T, and summary of findings (April 2, 2006 statement of John B. Stephenson, Director, Natural Resources and Environment, EPA)).

243. *Id.* The five chemicals restricted are PCBs, chlorofluorocarbons, dioxin, hexavalent chromium and asbestos only in products not historically containing asbestos as of 1999. LOWELL CENTER FOR SUSTAINABLE PRODUCTION, THE PROMISE AND LIMITS OF THE UNITED STATES TOXIC SUBSTANCES CONTROL ACT 3 (October 10, 2003).

244. *See supra* Part I.A. (discussing recent developments in the movement for reform of cosmetics regulation).

reform measures in Europe, the New Cosmetic Product Regulation and the Registration, Evaluation and Authorization of Chemicals Regulation (REACH), which can serve as models for reform in the United States.

*A. A Model for Reform: Regulation in Europe*

The European Union (EU) provides a model for cosmetic regulation reform. The EU has promulgated laws that follow the environmental justice movement's precautionary principle,<sup>245</sup> placing the burden on chemical companies to prove the safety of their products, and in the interim, banning ingredients that may be harmful.<sup>246</sup>

In 1976, the EU passed its first major piece of cosmetics legislation with the Cosmetics Directive, which identified an extensive list of banned chemicals and instituted specific testing and data requirements for cosmetic ingredients.<sup>247</sup> As a directive, as opposed to a regulation, the Cosmetics Directive was non-self-executing, allowing member states flexibility in applying its provisions.<sup>248</sup> The goal of the Directive was to require manufacturers to create a full technical file that included information on a product's formulation, the manufacturing process, proof of safety, claims included on product packaging, and a record of consumer health-related claims.<sup>249</sup> Despite its progressive and ambitious approach to cosmetics oversight, the Cosmetics Directive's nature as a non-self-executing directive, as opposed to a binding regulation, limited its effectiveness.<sup>250</sup>

---

245. Deborah Katz, *The Mismatch Between the Biosafety Protocol and the Precautionary Principle*, 13 *GEO. INT'L ENVTL. L. REV.* 949, 950-51 (2001) (defining the precautionary principle).

246. Cosmetics Directive, Council Directive 76/768/EEC, 1976 O.J. (L 262) 12...

247. *Id.*

248. *Review of Cosmetics Directive*, EUROPEAN COMMISSION CONSUMER AFFAIRS, (2010), [http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm) (last update Nov. 8, 2011).

249. Roseann B. Termini & Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 *FOOD & DRUG L.J.* 257, 269 (2008).

250. EUROPEAN COMMISSION CONSUMER AFFAIRS, *REVIEW OF COSMETICS DIRECTIVE* (2010), available at [http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm).

To ensure uniformity in the application of provisions, the EU recast the Cosmetics Directive as the New Cosmetic Product Regulation in 2009.<sup>251</sup> The New Cosmetic Product Regulation is self-executing and does not allow for diverging application by member states.<sup>252</sup> The Regulation only allows variety in regard to penalties; member states are tasked with prescribing their own “effective, proportionate and dissuasive” penalties for violating the Regulation.<sup>253</sup> The Regulation will not take effect until the repeal of the Cosmetic Directive occurs on July 11, 2013.<sup>254</sup> The Cosmetic Directive still applies in the interim.<sup>255</sup>

The EU has additional authority to regulate the safety of cosmetics under the Registration, Evaluation and Authorization of Chemicals Regulation (REACH).<sup>256</sup> REACH is similar to the TSCA, in that though it does not specifically apply to cosmetics, it does apply to chemicals that may be used in cosmetics. REACH requires chemical manufacturers to publically register substances with the European Chemicals Agency (ECHA) to increase transparency and improve protection of human health and the environment.<sup>257</sup> If a substance contains properties of “very high concern,” an applicant must demonstrate that there is not a safer alternative and that the risks associated with its use are “adequately controlled” or that “the socio-economic benefits of their use outweigh the risks.”<sup>258</sup> The ECHA may withdraw authorization of the original substance if a safe

---

251. EUROPEAN COMMISSION CONSUMER AFFAIRS, *supra* note 236.

252. Regulation 1223/2009 of the 1223/2009, 2009, O.J. (L.352) 59. European Parliament and of the Council of 30 November 1223/2009, 2009 on Cosmetic Products, O.J. (L.352) 59. O.J. (L. 342) 2.

253. *Id.* at 37.

254. *Id.* at 38, 40.

255. *Id.* at 38.

256. Registration 1907/2006 of the European Parliament and of the Council of 18 Dec. 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 2007 O.J. (L) 13.

257. EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, REACH IN BRIEF 4 (Oct. 2007), [http://ec.europa.eu/environment/chemicals/reach/pdf/2007\\_02\\_reach\\_in\\_brief.pdf](http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf).

258. EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *supra* note 257, at 5.



substitute becomes available.<sup>259</sup> As a regulation, Member States of the EU are required to enforce REACH provisions and penalties.<sup>260</sup>

### *B. The Proposed Safe Cosmetics Act of 2010*

The strong cosmetics reform movement in Europe has not gone unnoticed around the in the United States. This section will examine a bill that attempted to secure sweeping reform of the FDCA and modernization of cosmetics regulation in the United States: the Safe Cosmetics Act of 2010.

On July 21 2010, Representative Jan Schakowsky of Illinois and 22 co-sponsors, all members of the Democratic Party, introduced the Safe Cosmetics Act of 2010 in the House of Representatives.<sup>261</sup> The bill was immediately referred to the House Committee on Energy and Commerce and the Committee on Education and Labor, where it languished until the end of 111<sup>th</sup> Congress on January 3, 2011.<sup>262</sup> Representative Schakowsky re-introduced the Safe Cosmetics Act in June 2011, but as of October 2011, it had not moved out of committee.<sup>263</sup>

The bill sought to amend the Food Drug and Cosmetic Act (FDCA) to require:

- (1) annual registration of any establishment engaged in manufacturing, packaging, or distributing cosmetics for use in the United States;
- (2) new fees imposed on manufacturers to provide for oversight and enforcement of cosmetics regulations;
- (3) ingredient labeling and disclosure of information on ingredients; and

---

259. EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *supra* note 257, at 5.

260. *REACH Enforcement*, EUROPEAN COMMISSION (May 20, 2010), [http://ec.europa.eu/environment/chemicals/reach/enforcement\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/enforcement_en.htm).

261. While cosmetics regulation is not a traditionally partisan issue, it has not received notable support from the Republican Party. No Republican has sponsored or co-sponsored any of the bills calling for increased cosmetic regulation in 111<sup>th</sup> Congress. Safe Cosmetics Act of 2010, H.R. 5786, 111<sup>th</sup> Congress (2010); *see supra* note 260; *see infra* note 271.

262. *Id.*

263. Safe Cosmetics Act of 2011, H.R. 2359, 111<sup>th</sup> Congress (2011).

(4) adverse event reporting.<sup>264</sup>

The bill also would have imposed new requirements on the FDA and the Department of Labor. For example, under the proposed statute, the Secretary of the FDA would be required to:

- (1) establish a list of prohibited or restricted ingredients and a list of ingredients that are safe without limits for use in cosmetics;
- (2) develop a priority assessment list of ingredients that cannot be included on either of the other two lists because of a lack of authoritative information on the safety of the ingredient(s); and
- (3) establish minimum data requirements and test protocols to be used by manufacturers to assess the safety of cosmetic ingredients.<sup>265</sup>

Additionally, the bill was drafted to permit the FDA to issue recalls, regulate nanotechnology,<sup>266</sup> and encourage alternatives to animal testing.<sup>267</sup> The FDA would be able to request that a distributor of a misbranded or adulterated cosmetic voluntarily recall the product and provide notice to those affected.<sup>268</sup> The FDA could also order a mandatory recall after an informal hearing or even issue emergency recall orders if the Commissioner perceived an “imminent threat of serious adverse health consequences or death to humans.”<sup>269</sup>

To promote collaboration among federal agencies, the bill called for the establishment of the Interagency Council on Cosmetic Safety,

---

264. *Id.*

265. *Id.*

266. Nanotechnology involves the manipulation of nanoscale materials - those measured in nanometers, one-billionth of a meter. Nanoscale materials are of concern to the FDA as they may have altered magnetic, electrical, chemical or biological activity. In turn, these differences may create safety issues different from larger or smaller counterpart materials. FDA NANOTECHNOLOGY TASK FORCE, NANOTECHNOLOGY (July 25, 2007), <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Nanotechnology/ucm110856.pdf>.

267. H.R. 5786, § 616.

268. *Id.* § 616(b).

269. *Id.* § 616(d)-(e).

which would be composed of representatives from several federal agencies, including the National Institute on Environmental Health Sciences, the Centers for Disease Control and Prevention, the OSHA and the EPA.<sup>270</sup>

The introduction of the Safe Cosmetics Act of 2010 was met with opposition from both large and small cosmetics manufacturers. The Indie Beauty Network, a trade organization representing over 500 small, independent cosmetics and soaps companies, strongly opposed the bill, contending that the bill's registration, disclosure and safety testing requirements would be onerous to small businesses.<sup>271</sup> They argued that amending the bill to include a small business exception that would relax fees and requirements would benefit the nation's economy and prevent small cosmetics manufacturers from going out of business.<sup>272</sup>

The Personal Care Products Council (PCPC), the leading trade organization representing the cosmetics industry, also opposed the bill. The PCPC argued the Safe Cosmetics Act was based on non-credible science and created mandates the FDA would be unable to achieve.<sup>273</sup> Instead, the PCPC proposed its own measures to address cosmetics oversight and supported passage of another bill seeking to reform the FDA, the FDA Globalization Act of 2009.<sup>274</sup> This Act would not have permitted the FDA to issue recalls of violative

---

270. *Id.* The proposed legislation also sought to improve safety and health in cosmetics-related workplaces. The Secretary of Labor would have been required to promulgate an occupational safety and health standard for use in cosmetics distribution workplaces and salons. See *id.* at \_\_\_.

271. *About IBN, INDEPENDENT BEAUTY NETWORK*, <http://indiebeautynetwork.com/channel-ibnyou> (last updated May 23, 2009); Donna Maria, *Indie Beauty Network Opposes H.R. 5786 Safe Cosmetics Act of 2010, INDEPENDENT BEAUTY NETWORK* (July 29, 2010), <http://www.indiebusinessblog.com/indie-beauty-network-opposes-h-r-5786-safe-cosmetics-act-of-2010/>.

272. See *Indie Beauty Network Opposes H.R. 5786 Safe Cosmetics Act of 2010*, *supra* note 271.

273. Statement by Lezlee Westine President and CEO of the Personal Care Products Council in Response to the Safe Cosmetics Act of 2010 Introduced Today in Congress by Representatives Jan Schakowsky (D-IL), Edward Markey (D-MA) and Tammy Baldwin (D-WI) (July 21, 2010) (on file with author).

274. *Id.*; see also Food and Drug Administration Globalization Act of 2009, H.R. 759, 111th Cong. (2009).

cosmetics.<sup>275</sup> The FDA Globalization Act, like the Safe Cosmetics Act of 2010, remained stalled in committee until the end of the 111<sup>th</sup> Congress.<sup>276</sup>

*C. The Toxic Chemicals Safety Act and the Safe Chemicals Act of 2011*

The Safe Cosmetics Act of 2010 is similar to two additional bills introduced in Congress at the same time. Democratic Representative Jan Schakowsky's Toxic Chemicals Safety Act (TCSA)<sup>277</sup> and New Jersey Democratic Senator Frank Lautenberg's Safe Chemicals Act of 2011<sup>278</sup> each sought to amend TSCA. The TCSA's and SCA's safety standards are somewhat different, but both seek to implement health-based standards for the EPA to use when assessing chemicals' safety.<sup>279</sup>

TCSA would have required that, accounting for its aggregate and cumulative exposure, a chemical "not [be] reasonably anticipated to present a risk of injury to health or the environment."<sup>280</sup> In addition, the EPA would have been charged with protecting "the public exposure from adverse effects, including effects on the environment."<sup>281</sup> The Safe Chemicals Act would require the EPA to use the best available science to review any existing safety data regarding the impact of cumulative exposure to a chemical.<sup>282</sup> Under

---

275. H.R. 759, 111th Cong.

276. *Id.* As of April 2011, the bill has not been re-introduced. THOMAS, LIBRARY OF CONGRESS, <http://thomas.loc.gov/> (last visited May 9, 2011).

277. The Toxic Chemicals Safety Act, H.R. 5820, 110th Cong. (July 22, 2010), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_bills&docid=f:h5820ih.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h5820ih.txt.pdf) (last visited Feb. 16, 2012). This bill was introduced on July 22, 2010 by representatives Rush, Waxman, Castor, Degette, Schakowsky, and Sarbanes. It died at the end of the 2010 congressional session on Dec. 31, 2010. *Id.*

278. See The Safe Chemicals Act of 2011, S. 847, 112th Cong. (April 14, 2011). Senator Lautenberg had introduced similar legislation in 2010. See The Safe Chemicals Act of 2010, S. 3209, 110th Cong. (April 15, 2010).

279. Linda-Jo Schierow, Cong. Research Serv., R41335, Proposed Amendments to the Toxic Substances Control Act Senate and House Bills Compared with Current Law (2010), available at <http://www.fas.org/spp/crs/misc/R41335.pdf>.

280. *Id.* (citing H.R. 5820).

281. *Id.*

282. S. 847, 111th Cong.

the Safe Chemicals Act, “a chemical substance meets the safety standard only if the Administrator finds that there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance.”<sup>283</sup>

While both TCSA and the Safe Chemicals Act would require that the EPA compile minimum data sets for all existing chemicals within five years of enactment, a key difference between the bills is that they structure their priority lists for expedited safety standard determinations differently.<sup>284</sup> TCSA would have required the EPA to create a single priority list containing no fewer than 300 chemical substances.<sup>285</sup> Rather than using a single list, the Safe Chemicals Act would create a three-tiered system of “priority classes,” into which all chemicals would be grouped.<sup>286</sup> Within one year of enactment, the Safe Chemicals Act would require the EPA administrator to assign from 20 to 30 chemicals into “priority class 1” which would contain those chemicals that require immediate risk management.<sup>287</sup> The Administrator would assign chemicals with “more-than-a-theoretical concern” regarding whether they satisfy the Safe Chemicals Act safety standard into priority class 2.<sup>288</sup> Priority class 3 would contain those “chemical substances that the Administrator determines require no immediate action.”<sup>289</sup>

Both bills would have amended TSCA significantly, attempting to shore up areas where the current statute has been minimally effective. The Environmental Defense Fund provides an excellent chart,

---

283. *Id.*

284. *Id.*; The Toxic Chemicals Safety Act, H.R. 5820, 110th Cong. (July 22, 2010). *See also infra*, note 221, for a definition of the term “minimum data set.”

285. H.R. 5820, 110th Cong..

286. The Safe Chemicals Act of 2011, S. 847, 112th Cong. (April 14, 2011).

287. *Id.*

288. *Id.*

289. Additionally, TCSA specified 19 chemicals as “chemicals of highest concern,” while the Safe Chemicals Act would leave the identification of such chemicals to the EPA’s discretion. H.R. 5820, Safe Chemicals Act of 2011, S. Res. 847, 112th Cong. (2011); Toxic Chemicals Safety Act, H.R. Res. 5820, 110th Cong. (2010).

adapted here, comparing the current TSCA with the proposed amendments under TSCA and the Safe Chemicals Act of 2011:<sup>290</sup>

|                    | <b>Currently under TSCA</b>   | <b>Under proposed TSCA/Safe Chem. Act</b>   |
|--------------------|---|---|
| <b>Safety Data</b> | In a data call-in, EPA requires a manufacturer to submit information about a chemical, including the amount of a chemical it is processing and all environmental safety and health studies concerning the chemical. EPA rarely exercises its authority to issue a data call-in on existing chemicals; even more rarely requires such chemicals to be tested; and EPA does not require manufacturers to submit a Minimum Data Set (MDS), used to assess safety, for new chemicals. | Up-front data call-ins for all chemicals would be required. Manufacturers must develop and make public a Minimum Data Set (MDS) on all new and existing chemicals sufficient to determine safety. |

290. Richard Denison, *TSCA Vs. Toxic Chemicals Safety Act of 2010* (Sept. 8, 2010), <http://notaguineapig.org/page.cfm?tagID=58972> (text amended for the purposes of this report).

|                             | <b>Currently under TSCA</b>   | <b>Under proposed TCSA/Safe Chem. Act</b>   |
|-----------------------------|---|---|
| <b>Burden of Proof</b>      | EPA is required to prove harm before it can regulate a chemical.  | Industry would bear the legal burden of proving chemicals are safe before being marketed.   |
| <b>Assessment of Safety</b> | No mandate exists to assess the safety of existing chemicals. New chemicals undergo a severely time-limited and highly data-constrained review typically insufficient to assess safety. | Both new and existing chemicals would be subject to safety determinations as a condition of entering or remaining on the market, using “the best available science,” which would be determined in consultation with the National Academy of Sciences. |

|                            | <b>Currently under TSCA</b>   | <b>Under proposed TCSA/Safe Chem. Act</b>  |
|----------------------------|---|--|
| <b>Scope of Assessment</b> | When the EPA undertakes a chemical assessment there is no requirement to assess the risks from all sources of exposure to a chemical, or to assess the risks to vulnerable populations. The statute provides no on how to determine whether a chemical presents an “unreasonable risk.” | The safety standard would require EPA to account for aggregate and cumulative exposures to all uses and sources of a chemical, and to ensure protection of vulnerable populations that may be especially susceptible to chemical effects (e.g., children, a developing fetus) or subject to disproportionately high exposure (e.g., communities living near contaminated sites or chemical production facilities). |
| <b>Regulatory Action</b>   | EPA has not been able to regulate even chemical substances of the highest concern, such as asbestos, under TSCA’s “unreasonable risk” cost-benefit standard. Assessments often drag on indefinitely without conclusion or decision.   | Chemicals would be assessed under a health-based standard, requiring manufacturers to prove they are safe. Deadlines for decisions would be specified and EPA would have authority to restrict production and use, or place conditions on, any stage of the lifecycle of a chemical needed to ensure safety.   |



|  | <b>Currently under TSCA</b>  | <b>Under proposed TCSEA/Safe Chem. Act</b>  |
|--|--|---|
| <b>Chemicals and Exposures of High Concern</b> | The statute provides no criteria to clarify how EPA should identify and prioritize chemicals or exposures of greatest concern, leaving such decisions to case-by-case judgments by the agency.   | EPA would be required to develop and apply criteria to identify toxic chemicals that persist and build up in the environment and people, and then promptly mandate controls to reduce use of and exposure to such chemicals. The EPA would specifically identify and address “hot spots,” where people are subject to disproportionately high exposure.     |
| <b>Information Access</b>                      | Companies are free to claim, often without providing any justification, that most information they submit to EPA is confidential business information (CBI), denying access to the public, state, and local governments. EPA is not required to review such claims, and the claims never expire. | All confidential business information (CBI) claims would have to be justified up front. EPA would be required to review such claims and only approved claims would stand. Approved claims would expire after a period of time. Other federal government agencies, as well as state and local governments, would have access to CBI for regulatory purposes. |

|                                | <b>Currently under TSCA</b>   | <b>Under proposed TCSA/Safe Chem. Act</b>   |
|--------------------------------|---|---|
| <b>Rulemaking Requirements</b> | To require testing of a chemical of concern or take other actions, EPA must promulgate regulations that can take many years and resources to develop. This long process is the result of the overly high burden of proving that a chemical poses an “unreasonable risk” and that there is no superior alternative chemical that does not pose such a risk. Yet, EPA must show potential for a chemical to cause harm in order to require testing to establish that it poses an unreasonable risk, a “catch-22.” | In addition to the Minimum Data Set requirement, EPA would have authority to issue an order (rather than develop a regulation) to require reporting of existing data or additional testing, and need not first show evidence of harm. |

Among the most important proposed changes in TCSA and the Safe Chemicals Act is shifting the burden to the chemical industry to prove that chemicals are safe.<sup>291</sup> No longer would the EPA have the burden to show that a chemical posed an unreasonable risk of injury to health or environment before it could regulate its use.<sup>292</sup>

---

291. See Toxic Chemicals Safety Act, H.R. Res. 5820, 110th Cong. (2010), Safe Chemicals Act of 2010, S. Res. 3209, 111th Cong. (2010).

292. See *id.*

*D. Comparing the Toxic Chemicals Safety Act and the Safe Cosmetics Act of 2010.*

The Toxic Chemicals Safety Act (TCSA), the Safe Chemicals Act of 2011, and the Safe Cosmetics Act of 2010 (SCA) would make parallel changes to the ways in which the EPA and the FDA, respectively, review and regulate chemicals.<sup>293</sup> These bills would encourage a similar scope of reform; each bill embraces the precautionary principle,<sup>294</sup> shifting the burden to manufacturers to prove that a chemical is safe. The bills can be viewed collectively as a response to the dramatic increase of scientific data linking negative health consequences to chemical exposure.<sup>295</sup> Notable similarities include:

TCSA and the Safe Cosmetics Act sought to make similar changes to the safety standard used by the respective agencies. TCSA would have changed the TSCA requirement that the EPA show that an existing chemical poses an “unreasonable risk of injury” before issuing restrictions on a chemical to a standard where the agency would take into account the aggregate exposure of a chemical for all intended uses in establishing that there is a “reasonable certainty that no harm” will result to public health.<sup>296</sup> Similarly, the safety standard under the Safe Cosmetics Act of 2010 would have required the FDA to determine “that there is a reasonable certainty that no harm will result from aggregate exposure to the ingredient or cosmetic” before approving a product for sale.<sup>297</sup>

---

293. See Mark N. Duvall & Graham C. St. Michel, *Press Release, Cosmetics Safety Bill Would Incorporate TSCA Bill Provisions*, BEVERIDGE AND DIAMOND, P.C. (Aug. 2, 2010), <http://www.bdlaw.com/news-935.html> (last visited Nov. 20, 2010).

294. See Katz, *supra* note 245, at 950-51 (defining the precautionary principle).

295. See Frank R. Lautenberg, *Safe Chemicals Act of 2011*, <http://lautenberg.senate.gov/assets/SafeChem-Summary.pdf> (last visited Nov. 10, 2011) (describing how TSCA has not been amended since its adoption “despite huge changes in chemical production and use and our state of knowledge about how chemicals can harm health and the environment”).

296. See Toxic Chemicals Safety Act of 2010 H.R. Res. 5820, 110th Cong. (2010).

297. Safe Cosmetics Act of 2010, H.R. Res. 5786, 111th Cong. (2010).

Both bills would create a public database of health and safety studies on the internet.<sup>298</sup>

Under both bills, the FDA and EPA would have to establish a priority list of chemicals that have precedence for safety assessments.<sup>299</sup> TCSA identifies 14 specific chemicals for inclusion on this list, including BPA and seven phthalates.<sup>300</sup> In addition, both bills would require that the priority list contain at least 300 chemicals at any given time.<sup>301</sup>

Under both bills, a manufacturer would have had the burden to prove that a chemical or cosmetic product meets the “reasonable certainty of no harm” safety standard.<sup>302</sup> This represents a marked change from current law, which requires the FDA or EPA to prove that a product or chemical is harmful. To meet this burden, both bills require that manufacturers submit a Minimum Data Set (MDS).<sup>303</sup> While the Safe Cosmetics Act would leave the establishment of these criteria up to the FDA, TCSA II would require the EPA to establish an MDS that includes information on “(i) chemical identity; (ii) substance characteristics; (iii) biological and environmental fate and transport; (iv) toxicological properties; (v) volume manufactured, processed, or imported; (vi) intended uses; and (vii) exposures from all stages of the chemical substance or mixture’s lifecycle that are known or reasonably foreseeable to the party submitting the data set.”<sup>304</sup>

Differences among the bills would include:

Unlike TCSA, the Safe Cosmetics Act of 2010 actually establishes a baseline definition of a “reasonable certainty of no harm” as either a one-in-a-million risk of harm or no risk of harm.<sup>305</sup>

The Safe Cosmetics Act of 2010 would eliminate trade secret protection for cosmetics ingredients.<sup>306</sup> Although TCSA would still

---

298. Toxic Chemicals Safety Act, H.R. 5820, 111th Cong. (2010); Safe Chemicals Act of 2010; S. Res. 3209 111th Cong. (2010).

299. *Id.*

300. H.R. 5820, 111th Cong.

301. *Id.*; S. 3209, 111th Cong.

302. *Id.*

303. *Id.*

304. *Id.*

305. *Id.*

306. Safe Chemicals Act of 2010; S. Res. 3209 111th Cong. (2010).

allow manufacturers to designate information as confidential,<sup>307</sup> they would be required to submit a justification for each claim of confidentiality and a certification that the information is not otherwise available to the public.<sup>308</sup> Importantly, a confidential designation would not preclude the EPA from evaluating chemicals claimed as trade secrets for safety.<sup>309</sup>

Unlike TCSA, the Safe Cosmetics Act of 2010 would require CEOs to certify, after making a good faith inquiry, that a chemical meets the safety standard (that there is “a reasonable certainty of no harm”) or that there is insufficient data to determine whether a cosmetic or its ingredients meet the safety standard.<sup>310</sup>

Both TCSA and the Safe Cosmetics Act of 2010 sought to implement a more robust system than the current legislative scheme to assess chemicals for safety by phasing out the most hazardous substances and increasing the transparency and availability of information about chemicals.<sup>311</sup> Representative Jan Schakowsky has reintroduced the Safe Cosmetics Act.<sup>312</sup> The Senate has not yet taken any action on the Safe Chemicals Act of 2011.<sup>313</sup>

#### IV. COSMETICS REGULATION AT THE STATE LEVEL

Cosmetics regulation reform at the federal level would create comprehensive change, protecting consumers throughout the country. The 111<sup>th</sup> Congress’s inability to pass cosmetics regulation reform forward will likely inhibit efforts to overhaul the FDCA and TSCA,<sup>314</sup> there is great opportunity to pursue improved regulation of

---

307. Toxic Chemicals Safety Act, H.R. 5820, 111th Cong. (2010).

308. *Id.*

309. *See id.*; Safe Cosmetics Act of 2010, H.R. Res. 5786, 111th Cong. (2010), Toxic Chemicals Safety Act, H.R. Res. 5820 111th Cong. (2010).

310. *Id.*

311. *The Safe Cosmetics Act of 2010: What it Means for Cosmetics Companies*, THE CAMPAIGN FOR SAFE COSMETICS, <http://www.safecosmetics.org/article.php?id=695#tsca> (last visited Dec. 27, 2010).

312. Safe Cosmetics Act of 2011, H.R. Res. 2359, 112th Cong. (2011), <http://www.gpo.gov/fdsys/pkg/BILLS-112hr2359ih/pdf/BILLS-112hr2359ih.pdf>.

313. Safe Chemicals Act of 2011, S. Res. 847, 112th Cong. (2011); *see supra* note 278.

314. *See infra* Part V (discussing current political challenges to cosmetics regulation reform).

cosmetics at the state and local levels. This section will focus on the New York State and New York City legislative and executive bodies and their ability to achieve cosmetics reform. As an introduction, the Report will discuss cosmetics reform in other states.

*A. The California Safe Cosmetics Act and Efforts in Other States*

Just as the European Union provides an excellent model for reform on the federal level, California's ability to institute a more stringent system for review of cosmetics at the state level could be highly instructive for reformers at the state level. Governor Arnold Schwarzenegger signed the California Safe Cosmetics Act into law on October 8, 2005.<sup>315</sup> The Act requires cosmetics manufacturers to report products that contain ingredients known or "reasonably anticipated" to be human carcinogens to California's Division of Environmental and Occupational Disease Control (Division), a program within the state's Department of Public Health.<sup>316</sup> In stark contrast to current federal regulations, the California Cosmetics Act does not contain a loophole for "trade secret" or "fragrance" ingredients. Manufacturers must still include ingredients that fall into these categories in the ingredient lists they submit to the Division.<sup>317</sup> Additionally, the Division can conduct investigations into cosmetic products containing any ingredient of concern, and can require manufacturers to submit any relevant health effects data and studies, as well as information on the , sales, product use, and ingredients' chemical concentrations.<sup>318</sup>

If the Division finds a product to be in violation of the California Safe Cosmetics Act, the manufacturer may face monetary fines or even jail time.<sup>319</sup> A person convicted of violating any section of the Act could be subject to imprisonment for up to one year in county jail and fines of up to \$1,000.<sup>320</sup> If the conviction is a result of removing, selling or disposing of an embargoed cosmetic, or if the violation

---

315. Cal. Health & Safety Code § 111791 (2006); S. 484th Leg., Reg. Sess. (Cal. 2005).

316. Cal. Health & Safety Code § 111791.5(b)(4) (2006).

317. *Id.* § 111792(a) (2006).

318. *Id.* § 111792.5 (2006).

319. *Id.* § 111825 (2006).

320. *Id.* § 111825(a) (2006).

occurred after a previous conviction under the Act, the fine can increase to \$10,000.<sup>321</sup>

Since the Act took effect in 2007, the California Safe Cosmetics Program (CSCP), the California Attorney General's Office, and the California Department of Public Health have collaborated to ensure compliance with the Act. The Division added five chemicals to the CSCP Chemical List in 2010, which triggered mandatory reporting of manufacturers who used one of them in a cosmetic product.<sup>322</sup> On April 28, 2010, the California Attorney General's Office and the Department of Public Health sent a joint letter to over 7,000 manufacturers in violation of the Act for not providing notice disclosing the presence of listed chemicals in their products.<sup>323</sup> The CSCP has also worked to make the required reporting easier for cosmetics manufacturers, and in 2011 re-launched their online reporting system with "significant improvements."<sup>324</sup>

The California Safe Cosmetics Act also attempts to facilitate the FDA's regulation of cosmetics.<sup>325</sup> If the Division determines that a product contains an ingredient that the Cosmetic Ingredient Review panel has found is not safe for that specific use, it refers the findings to the FDA for possible federal enforcement.<sup>326</sup> As of yet, however, California's more aggressive approach has not spurred any new reforms at the federal level.<sup>327</sup>

---

321. *Id.* § 111825(b)-(c) (2006).

322. Bisphenol A (BPA), metam potassium, bromochloroacetic acid, cumene, and diclofop-methyl were added to the CSCP Chemical List. *Updated 2010 CSCP Chemical List* (2010), CALIFORNIA SAFE COSMETICS PROGRAM, <http://www.cdph.ca.gov/programs/cosmetics/Pages/New.aspx#chemlist> (last visited Feb. 16, 2011).

323. *Id.*

324. *Changes to Colors, Scents, Flavors, Kits and Collections reporting* (Dec. 30, 2010), CALIFORNIA SAFE COSMETICS PROGRAM, <http://www.cdph.ca.gov/programs/cosmetics/Pages/New.aspx#colors> (last visited Jun. 2, 2011); CALIFORNIA SAFE COSMETICS PROGRAM, INSTRUCTIONS FOR THE CALIFORNIA SAFE COSMETICS PROGRAM REPORTING SYSTEM (Dec. 30, 2010), <http://www.cdph.ca.gov/programs/cosmetics/Documents/ReportingInstructions.pdf>.

325. Cal. Health & Safety Code § 111792.5(c) (2006).

326. *Id.* § 111793.5(c) (2006).

327. *See supra* Part III.B. (discussing lack of reform of cosmetics regulation at the federal level).

The CSCP is an important step forward in the fight for safe cosmetics. Not only has the state moved to bring thousands of manufacturers into compliance with the Act, but it also is now pursuing violators in court; in April 2011, the state filed a preliminary injunction against the manufacturer of Brazilian Blowout.<sup>328</sup> The cosmetics industry lobbied heavily against the Act,<sup>329</sup> yet the success of the program nullifies many arguments pressed by opponents and should help to encourage the passage of similar statutes in other states. The ability of California, the most populous state in the country,<sup>330</sup> to raise awareness of dangerous products and to remove them from the market should serve as encouragement that a similar system could be implemented in New York State.

Following the successful passage of the California Safe Cosmetics Act, other states have attempted to enact similar legislation. Although no state legislature has yet succeeded, it is informative to examine two bills introduced since 2005.

In 2007, legislators in Washington State introduced the Washington Safe Cosmetics Act.<sup>331</sup> The Act would require manufacturers with over \$1 million in sales to disclose health data and all ingredients known or suspected to cause cancer or reproductive damage, including “trade secret” ingredients, and would allow the state to investigate products suspected of containing dangerous ingredients.<sup>332</sup> The bill did not emerge from committee and has not been reintroduced since 2008.<sup>333</sup>

---

328. See *supra* Part I.A. (discussing recent events surrounding the discovery of formaldehyde in Brazilian Blowout); see also Andrea Nagel, *California to Rule on Brazilian Blowout*, WOMEN’S WEAR DAILY (Apr. 13, 2011), available at <http://www.wwd.com/beauty-industry-news/calif-to-rule-on-brazilian-blowout-3581574>.

329. According to state records, Proctor & Gamble paid Sacramento lobbyists more than \$260,000 and the Cosmetics and Fragrance Trade Association spent half a million dollars in 2005 opposing the California Safe Cosmetics Act and other environmental health legislation in California. Malkan, *supra* note 8, at 90.

330. *California – 2010 Demographic Profile*, U.S. CENSUS BUREAU (Sept. 1, 2011), <http://www.census.gov/popfinder/>.

331. Lisa Stiffler, *State Mulls Cosmetic Safety Bill Based on California Measure*, SEATTLE POST INTELLIGENCER, Feb. 20, 2007, at B1.

332. *Id.*

333. Washington Safe Cosmetics Act, H.B. 2166, 60th Leg., Reg. Sess. (2007-2008).



State legislators introduced the Colorado Safe Personal Care Products Act in 2010.<sup>334</sup> The Act proposed more aggressive consequences than the California Safe Cosmetics Act for products containing potentially dangerous chemicals. Under the bill, if a product contains a chemical identified by an “authoritative body” to cause cancer or reproductive toxicity, its sale would be banned.<sup>335</sup> The proposed Colorado bill would adopt the findings of the Environmental Protection Agency, the FDA, the National Institute for Occupational Safety and Health, or the International Agency for Research on Cancer to determine if a chemical causes cancer or reproductive toxicity.<sup>336</sup> In March 2010, the Judiciary Committee voted the Act down.<sup>337</sup>

### *B. New York State Legislation*

In February 2011, Democrat Michelle Titus introduced the Safe Cosmetics Act of 2011 in the New York Assembly.<sup>338</sup> The bill requires cosmetics manufacturers to compile an accurate list of their cosmetic products that contain any chemical ingredient identified by any of four scientific sources to cause cancer or express reproductive toxicity.<sup>339</sup> These sources are: (1) the United States National Toxicology Report,<sup>340</sup> (2) the International Agency for Research on Cancer,<sup>341</sup> (3) the EPA’s carcinogenicity list,<sup>342</sup> and (4) the National

---

334. Colorado Safe Personal Care Products Act, H.B. 10-1248, 67th Gen. Assemb., 2nd Reg. Sess. (2010).

335. *Id.*

336. *Id.*

337. Alicia Ault, *Safe Cosmetics Bill Defeated*, SKIN AND ALLERGY NEWS, April 1, 2010, at 30.

338. Safe Cosmetics Act of 2011, A. 5059, 233rd Leg., Reg. Sess. (N.Y. 2011) (sponsored by Titus, Democrat, 31st District, Queens).

339. *Id.*

340. *Id.* The United States National Toxicology report identifies known carcinogens and materials reasonably anticipated to cause cancer. *Id.*

341. Under the proposed Act, cosmetics manufacturers would be required to list a substance that receives a carcinogenicity designation of group 1, 2A, or 2B by the International Agency for Research on Cancer. *Id.*

342. *Id.* The Safe Cosmetics Act requires that manufacturers list any substance that receives a carcinogenicity designation of group A, B1, or B2 on the EPA’s carcinogenicity list; *see also supra* note 70 (describing in greater detail the EPA’s standards of carcinogenicity).

Toxicology Program's Center for the Evaluation of Risks to Human Reproduction.<sup>343</sup> The bill would designate the state Department of Health as the "authoritative body" to review cosmetic products that contain chemicals identified as causing cancer or reproductive toxicity.<sup>344</sup>

The Safe Cosmetics Act would also empower the New York State Department of Health to investigate cosmetic products that contain chemicals identified as causing cancer or expressing reproductive toxicity or other ingredients "of concern" to the Department.<sup>345</sup> During the course of an investigation, the Department could review available health effects, data and studies, worksite health hazard evaluations, and epidemiological studies to determine the health effects of exposures to chemicals. The Department would be able to require manufacturers to submit relevant health data, chemical concentration information, and sales data.<sup>346</sup> If the Department determines that an ingredient in a cosmetic product is potentially toxic, it would refer the results of its investigation to the State's Occupational Safety and Health Hazard Abatement Board.<sup>347</sup> Within 180 days, the Board would be required to develop and present one or more proposed occupational health standards to the State's Department of Labor, unless the Board affirmatively determines that a standard is not necessary.<sup>348</sup>

To ensure the public disclosure of some of the most harmful chemicals, separate legislation proposed in the Assembly in 2009 would have required the labeling of cosmetic products containing D4 or D5 siloxanes, phthalates, triclosan, parabens, or synthetic chemical

---

343. Manufacturers must report any substance that has been determined, by clear evidence, to present a risk of adverse developmental or reproductive toxicity effects by experts at the Center for the Evaluation of Risks to Human Reproduction. Safe Cosmetics Act of 2011, A. 5059, 233rd Leg., Reg. Sess. (N.Y. 2011) (sponsored by Titus, Democrat, 31st District, Queens).

344. The Department of Health's review "may include, but not be limited to, a review of health effects, data and studies, worksite health evaluations, epidemiological studies to determine the health effects of exposures to chemicals." *Id.*

345. *Id.* § 2252(1).

346. *Id.* § 2252(4).

347. *Id.* § 2253(1).

348. *Id.* § 2253(2).

musks.<sup>349</sup> A third bill proposed in 2009 would have directed the state's Department of Health to promulgate regulations concerning the use of chemicals in nail salons.<sup>350</sup> The bill would have required salons to display signs in a prominent place identifying the chemicals that are used and describing the potential health and safety hazards associated with them.<sup>351</sup> These bills died with the end of the legislative session on December 31, 2010.<sup>352</sup>

Despite the failure of legislation regarding chemical disclosure in prior sessions, there is reason to believe the Safe Cosmetics Act of 2011 may progress out of the Assembly's Health Committee this year. As 2011 is a non-election year, state legislators may have more time and resources to focus on legislative efforts. In addition, given the recent media attention to the issue of cosmetics safety,<sup>353</sup> the time for an advocacy campaign pursuing legislative reform at the state level may be ripe.

### *C. New York City Government*

#### 1. New York City Council

The New York City Council derives its authority to govern from the New York State Constitution and the New York City Charter.<sup>354</sup> The state constitution, as amended in 1963, contains a "Bill of Rights for Local Governments," also known as the "home rule" provision,

---

349. A. 6892, 232nd Leg., Reg. Sess. (N.Y. 2009) (sponsored by Meng). On January 6, 2010, this bill was referred to the Consumer Affairs and Protection Committee, where it died with the end of the last session.

350. A. 2104, 232nd Leg., Reg. Sess. (N.Y. 2009) (sponsored by Benjamin); S. 3323, 232nd Leg., Reg. Sess. (N.Y. 2009) (by Stewart-Cousins). The bill was referred to the Economic Development Committee in the Assembly in January, 2010. The Senate version of the bill was referred to the Consumer Protection Committee in March, 2009, where it died with the end of the last session.

351. *Id.*

352. See New York State Rules of Assembly § 2(f) (2010); Rules of the Senate of the State of New York, Rule IV § 8 (2010).

353. See *supra* notes 9-26 and accompanying text.

354. N.Y. Const. art. IX, § 1; N.Y. City Charter (2009), available at <http://www.nyc.gov/html/charter/downloads/pdf/citycharter2009.pdf> (last visited Feb. 16, 2011).

which is further supported by several state statutes.<sup>355</sup> Under the “home rule” provision, local governments may exercise powers enumerated to them by state statutes, as well as adopt laws within ten specific subject areas.<sup>356</sup> The subject area most relevant to the regulation of cosmetics is “the government, protection, order, conduct, safety, health and well-being of persons or property” within the local jurisdiction.<sup>357</sup>

The New York City Charter vests the legislative power of the city in the Council.<sup>358</sup> The City Council has the power to adopt local laws it deems appropriate, so long as they are not inconsistent with the City Charter, the United States or New York State Constitutions, or state or federal laws.<sup>359</sup> The current iteration of the New York City Council has thirty-seven committees and five subcommittees.<sup>360</sup> If a bill involving the regulation of cosmetics were introduced, it most

---

355. N.Y. Const. art. IX, § 1; N.Y. Mun. Home Rule Law § 51 (McKinney 2010); N.Y. Stat. Local Govt’s Law § 20 (McKinney 2010). Local governments are permitted to have a legislative body with the power to pass laws pursuant to the state’s constitution. N.Y. Const. art. IX, § 1(a), (b), § 2(b).

356. N.Y. Const. art. IX, § 2(c).

357. N.Y. Const. art. IX, § 2(c)(10). The remaining nine subject areas are: powers, duties, qualifications, number, mode of selection and removal, terms of office, compensation, hours of work, protection, welfare and safety of its officers and employees; in the case of a city, town or village, the membership and composition of its legislative body; transaction of its business; incurring of its obligations, except that local laws relating to financing by the issuance of evidences of indebtedness by such local government shall be consistent with laws enacted by the legislature; presentation, ascertainment and discharge of claims against it; acquisition, care, management and use of its highways, roads, streets, avenues and property; acquisition of its transit facilities and the ownership and operation thereof; levy, collection and administration of local taxes authorized by the legislature and of assessments for local improvements; and wages or salaries, the hours of work or labor, and the protection, welfare and safety of persons employed by any contractor or sub-contractor performing work, labor or services for it. N.Y. Const. art. IX, § 2(c)(1)-(9).

358. N.Y. City Charter, § 21.

359. N.Y. City Charter, § 28.

360. *Committees*, NEW YORK CITY COUNCIL, <http://legistar.council.nyc.gov/Departments.aspx> (last visited October 9, 2010).

likely would be referred for consideration to the committees on Environmental Protection, Health, or Women's Issues.<sup>361</sup>

The New York City Council has not considered legislation directly pertaining to cosmetics regulation since at least 1998.<sup>362</sup> The most relevant legislation since that time was bills that involved the regulation of nail salons.<sup>363</sup> Although the Committee on Health considered these bills, none became law.<sup>364</sup>

The New York City Council has previously signaled its willingness to try to improve public health through bans of smoking in public places<sup>365</sup> and parks,<sup>366</sup> and has expanded its housing program to target health violations such as mold, asthma, insects, and mice.<sup>367</sup> The City Council may thus be amenable to considering legislation to protect consumers from dangerous ingredients in cosmetics.

## 2. Mayor's Office

Although the New York City Charter vests the City Council with legislative power over the city,<sup>368</sup> it also grants the Mayor a number of general powers.<sup>369</sup> With over eight million residents,<sup>370</sup> the population of New York City is larger than that of all but eleven

---

361. Cosmetic regulation could fall under the purview of numerous committees, due to public health and environment implications, as well as the disparate impact on women, who typically have a greater exposure to cosmetics.

362. The New York City Council website only makes available the text of bills considered since 1998. NEW YORK CITY COUNCIL, LEGISLATIVE RESEARCH CENTER, <http://legistar.council.nyc.gov/Legislation.aspx> (last visited Dec. 21, 2011).

363. Int. 1096-2009, N.Y.C. Council, Session 2010-2013 (2009); Int. 0245-2010, N.Y.C. Council, Session 2010-2013 (2010).

364. New York City Council Int. 1096-2009, Int. 0245-2010.

365. New York City, N.Y., Local Law No. 47 Int. 256-A (2002).

366. New York City, N.Y., Local Law No. 11 Int. 0332-A (2011).

367. New York City, N.Y., Local Law No. 29 Int. 436-A (2010).

368. N.Y. City Charter, § 21.

369. *Id.* § 8.

370. UNITED STATES CENSUS BUREAU, POPULATION DIVISION, TABLE 1: ANNUAL ESTIMATES OF THE POPULATION FOR INCORPORATED PLACES OVER 100,000, RANKED BY JULY 1, 2009 POPULATION: APRIL 1, 2000 TO JULY 1, 2009, available at <http://www.census.gov/popest/cities/SUB-EST2009.html> (last visited Apr. 11, 2011).

states.<sup>371</sup> The government of New York City contains a number of specialized departments and agencies that befit the complexities that come with serving such a large population. The City Charter empowers the Mayor to reorganize, create or disband these agencies,<sup>372</sup> and generally to establish policy and procedures to “achieve effective and efficient functioning of management of city government.”<sup>373</sup> Mayor Michael Bloomberg has aggressively tested the limits of the powers of the New York City Mayor. During his second term in office, Bloomberg embarked upon a campaign to improve public health by banning most artificial trans-fats in prepared food and requiring restaurants to post calorie information on menus.<sup>374</sup> Bloomberg’s use of mayoral agencies to enact a calorie posting requirement, and his subsequent legal victories affirming his actions’ validity, illustrate the potential for using alternatives to legislation to alert consumers of the possible dangers lurking in cosmetics.

In December 2006, the New York City Board of Health (Board), under the authority of the City’s Department of Health and Mental Hygiene (DOHMH), instituted a regulation requiring any restaurant that voluntarily published calorie information to include that information on their menus and menu boards.<sup>375</sup> The New York State Restaurant Association (NYSRA) brought suit against the Board, arguing that the regulation was preempted by the Nutrition Labeling and Education Act of 1990 (NLEA), a section of the

---

371. U. S. CENSUS BUREAU, 2010 CENSUS ESTIMATES (2011), *available at* <http://www.census.gov/popest/eval-estimates/eval-est2010.html> (last visited Apr. 11, 2011).

372. N.Y. City Charter, § 8(a). Each January, the Mayor must submit a management report to the City Council concerning the performance of each city agency relative to established performance goals. *Id.* § 12.

373. The structure of the executive branch of the New York City government is similar to the federal government’s use of administrative agencies to promulgate regulations and rules in specialized areas to ensure an efficiently functioning nation. *Id.* § 11(a).

374. Thomas J. Lueck, *Public Speaks on Plan to Limit Trans Fats, Mostly in Favor*, N.Y. TIMES, Oct. 31, 2006, at B2.

375. See Ray Rivera, *City Council May Rewrite Calorie Rules*, N.Y. TIMES, February 26, 2007, at B1; N.Y. City Health Code § 81.50.

Federal FDCA.<sup>376</sup> Under the Supremacy Clause of the United States Constitution,<sup>377</sup> federal law preempts any conflicting state law.<sup>378</sup> However, “because the States are independent sovereigns in our federal system, [courts] have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”<sup>379</sup> Particularly “[i]n areas of traditional state regulation, [courts] assume that a federal statute has not supplanted state law unless Congress has made such an intention ‘clear and manifest.’”<sup>380</sup>

Congress passed the NLEA “to clarify and to strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods.”<sup>381</sup> When NYRSA challenged the Board’s regulation, the federal district court found that because the regulation involved health, specifically combating rising obesity, “the presumption against preemption applies, indeed, [it] stands at its strongest.”<sup>382</sup> The court further noted that public health

---

376. *New York State Restaurant Ass’n v. New York City Bd. of Health (NYSRA I)*, 509 F.Supp.2d 351, 354 (S.D.N.Y. 2007).

377. U.S. Const. art. VI, cl. 2.

378. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608 (1992) (“Article VI of the Constitution provides that the laws of the United States ‘shall be the supreme Law of the Land...any Thing in the Constitution or Laws of any state to the Contrary notwithstanding...it has been settled that state law that conflicts with federal law is without effect.’”) (internal citations and quotation marks omitted).

379. *NYSRA I*, 509 F.Supp.2d at 355, (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240 (1996)).

380. *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005) (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995)). Where “Congress has legislated ... in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Medtronic, Inc.*, 518 U.S. at 485 (citations and internal quotation marks omitted).

381. H.R. Rep. No. 101-538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337.

382. *NYSRA I*, 509 F.Supp.2d at 355, (citing *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2007)).

is prime example of a power traditionally reserved to the states.<sup>383</sup> Notwithstanding this general finding, the court ruled that because the Board's regulation applied only to restaurants that had voluntarily provided calorie information, it imposed obligations that conflict with than the federal regulations implementing NLEA and therefore was pre-empted.<sup>384</sup>

The court left the door open for a future regulation to meet preemption standards. The court noted in dicta that the city would be able to enact mandatory calorie disclosures of all restaurants under a provision in NLEA's separate misbranding section.<sup>385</sup> Under a mandatory disclosure regulation, the court stated, opponents could not successfully argue "that mandated disclosures are more properly considered the regulation of voluntary claims" under NLEA.<sup>386</sup>

On January 22, 2008, the Board repealed the original calorie disclosure regulation and issued a modified version.<sup>387</sup> The new version of Regulation 81.50 requires all chain restaurants with fifteen or more establishments nationally to display calorie information on menus and menu boards.<sup>388</sup> NYSRA again challenged the rule, arguing that even as amended, it was preempted by FDA regulations.<sup>389</sup> The city argued that NLEA did not preempt the new regulation "because [NLEA] explicitly leaves to state and local governments the power to impose mandatory nutrition labeling by restaurants."<sup>390</sup>

---

383. *Id.* (citing *Med. Soc'y of the State of N.Y. v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992)) ("The regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state.").

384. *NYSRA I*, 509 F.Supp. 2d 351 at 361-63.

385. *Id.*; 21 U.S.C.A. § 343 (West 2010).

386. *Id.* § 363.

387. See DEP'T OF HEALTH AND MENTAL HYGIENE BD. OF HEALTH, NOTICE OF ADOPTION OF A RESOLUTION TO REPEAL AND REENACT § 81.50 OF THE NEW YORK CITY HEALTH CODE (Jan. 22, 2008).

388. New York City Health Code § 81.50; Sewell Chan, "Court Upholds the City's Rule Requiring Some Restaurants to Post Calorie Counts," N.Y. TIMES, February 18, 2009, at A24.

389. See Chan, *supra* note 388.

390. *New York State Restaurant Ass'n v. New York City Bd. of Health (NYSRA II)*, 556 F.3d 114, 122 (2d Cir. 2009).



The Second Circuit Court of Appeals rejected NYSRA's challenge and affirmed the district court's ruling upholding the regulation.<sup>391</sup> The main issue for the court was whether the regulation's mandatory quantitative calorie disclosures are "claims" (such as statements like "low in fat" or "high in fiber"), which are preempted, or are "nutrition information," which are not preempted.<sup>392</sup> Adopting a test the FDA set forth in an *amicus* brief, the court determined that federal law did not preempt the regulation.<sup>393</sup> The court also used a rational basis test to reject NYSRA's claim that the regulation infringed upon their members' First Amendment rights by compelling commercial speech.<sup>394</sup> The court found that New York City "plainly demonstrated a reasonable relationship between the purpose (of the regulation) and the means employed to achieve that purpose,"<sup>395</sup> citing the city's campaign to fight obesity.<sup>396</sup>

### 3. Applicability to Cosmetics Regulation Reform

New York City's successful implementation of a calorie disclosure requirement may yield meaningful lessons should the City seek to require cosmetics ingredient disclosure. The starting point for this analysis is the whether the FDCA would preempt such an effort. Although the cosmetics chapter of the FDCA does contain a section on misbranding,<sup>397</sup> it does not contain comprehensive sections likely to preempt city action in this area.

The FDCA forbids a state or local government from establishing a requirement for labeling or packaging "that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics" under the Act itself.<sup>398</sup> This bar against establishing label requirements that contradict the FDCA applies to two other federal statutes, the Fair Packaging and Labeling Act (FPLA) and the Poison Prevention Packaging Act, because the FDCA controls in all matters

---

391. *NYSRA II*, 556 F.3d 114 at 117-118.

392. *Id.* at 123.

393. *Id.* at 130-31.

394. *Id.* 133-34.

395. *Id.* 134.

396. *Id.*

397. 21 U.S.C.A. § 362.

398. *Id.* § 379s(a).

regarding the regulation of cosmetics, even though other statutes may seem applicable on their face.<sup>399</sup> However, the FDA may provide a state or locality with an exemption from this FDCA provision if the state or local government's action: 1) protects an important public interest that would otherwise be unprotected; 2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under the FDCA; or 3) would not unduly burden interstate commerce.<sup>400</sup>

The FPLA also provides guidance regarding preemption. The statute contains a provision articulating Congress's "express intent" to supersede all state and local laws pertaining to packages' net quantity labeling that are "less stringent than or require information different from the requirements of [the Act] or regulations promulgated pursuant thereto."<sup>401</sup> Therefore, it would appear that more stringent requirements, such as those requiring the disclosure of ingredients in fragrance or trade secret chemicals, would be permitted.

A hypothetical regulation concerning cosmetics proposed by the Department of Health and Mental Hygiene (DOHMH) would fall under the FDA's exemption test.<sup>402</sup> While the DOHMH has not yet proposed regulations concerning cosmetics, this Note imagines such a regulation that would require disclosure of ingredients that are possible or known carcinogens, and would require warning labels on cosmetics containing dangerous ingredients.<sup>403</sup> Under the first prong FDA's exemption standard, the FDA would determine if the regulation protected an important public interest that would otherwise not be protected.<sup>404</sup> The federal government provides little protection for consumers from dangerous cosmetics due to the FDA's minimal oversight over cosmetics and the FDCA's loopholes.<sup>405</sup> This hypothetical City regulation would provide New York consumers with protection that is unavailable through the federal government.

---

399. *Id.*

400. *Id.* § 379s(b).

401. 15 U.S.C.A. § 1461.

402. *See supra* Part IV.B.2 (discussing the FDA's exemption test).

403. This hypothetical regulation is largely based upon the requirements of California and the EU's cosmetics regulation statutes.

404. 21 U.S.C.A. § 379s(b).

405. *See supra* Part II (discussing federal regulations controlling cosmetics).

Additionally, in the absence of the passage of the Safe Cosmetics of 2011 by the New York Legislature, the state is likewise unable to provide consumer protection.<sup>406</sup>

The second prong of the FDA's test requires that the regulation not cause a cosmetic to violate or contradict any requirements of the FDCA.<sup>407</sup> Under the hypothetical regulation, no provision of the FDCA would be violated or in any way comprised. The regulation would merely enhance the requirements under the FDCA and in no way would subvert its purpose of protecting public health.<sup>408</sup>

Finally, the FDA would examine the regulation's impact on interstate commerce.<sup>409</sup> While New York City's population of over 8 million<sup>410</sup> and its corresponding purchasing power would certainly have an impact on interstate commerce, the regulation would not impose the "undue burden" that is prohibited by the FDA.<sup>411</sup> Perhaps the best evidence in support of the regulation under this prong is the California Safe Cosmetics Act.<sup>412</sup> The FDA did not challenge California's system of cosmetics regulation, which affects a far greater number of products<sup>413</sup> and therefore has a greater impact on interstate commerce, than a regulation affecting only New York City.

---

406. See *supra* Part IV.B. (discussing the New York Safe Cosmetics Act of 2011).

407. For an example of a regulation causing a violation of a federal statute, see *supra* Part IV.C.2 (discussing *NYRSA I*); 21 U.S.C.A. § 379s(b).

408. As New York City did not preemptively seek permission from the FDA before implementing calorie labeling information, it is clearly not a requirement, but support from the agency would certainly help to bolster the City's case in any legal or political challenges to such a cosmetics regulation, as demonstrated in *New York State Restaurant Ass'n v. New York City Bd. of Health (NYSRA II)*, 556 F.3d 114, 122 (2d Cir. 2009).

409. 21 U.S.C.A. § 379s(b).

410. *New York City – 2010 Demographic Profile*, U.S. CENSUS BUREAU, <http://www.census.gov/popfinder/> (last visited Dec. 21, 2011).

411. FDA exempt a requirement for labeling or packaging that "would not unduly burden interstate commerce." 21 U.S.C.A. § 379s(b).

412. See *supra* Part IV.A. (discussing the California Safe Cosmetics Act).

413. The California Safe Cosmetics Act requires mandatory reporting of cosmetics that contain any of the 791 ingredients included on the Act's Chemical List, whereas the FDCA does not contain any similar provision. CAL. DEP'T. PUBLIC HEALTH, 2010 CSCP CHEMICAL LIST (Dec. 1, 2010), <http://www.cdph.ca.gov/programs/cosmetics/Documents/chemlist.pdf>; see *supra*, Part II.A.2 (discussing the limits of the FDCA).

It therefore seems likely that the FDA would grant this hypothetical regulation an exemption under the FDCA.

Although the legality of such a regulatory mandate would be analyzed under this federal rubric, the *NYRSA* cases, which assess the legality of mandatory calorie disclosure under the Nutrition Labeling and Education Act (NLEA), also provide a number of illuminating legal principals. First, in *NYRSA I*, the district court found that when health is concerned, the presumption against preemption “stands at its strongest.”<sup>414</sup> There is ample evidence that many cosmetics contain ingredients known to cause cancers or reproductive toxicity,<sup>415</sup> and informing consumers of this certainly benefits public health. It would likely be difficult for an opponent to overcome this presumption and establish that a regulation requiring disclosure would not concern health.

Second, critics of cosmetics labeling regulations would almost certainly raise First Amendment claims, similar to those the courts evaluated in *NYRSA I* and *II*. If a court applied a rational basis test, as it did in the *NYRSA* cases,<sup>416</sup> the city could cite the need to inform consumers and reduce instances of cancer, thereby creating a rational relationship between the purpose of regulation and the means employed. This should be more than sufficient to overcome a First Amendment challenge.

## V. CONCLUSION AND RECOMMENDATIONS

### A. Legislative and Regulatory Reform

The history of cosmetic regulation is riddled with hard-fought battles, and there is no indication that a new campaign for reform will be met with any less opposition.<sup>417</sup> The results of the 2010 Congressional elections may further reduce the likelihood of passage

---

414. See *New York State Restaurant Ass’n v. New York City Bd. of Health (NYRSA I)*, 509 F.Supp.2d 351, 355 (S.D.N.Y. 2007), (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)); see *supra* Part IV.C.2 (discussing the presumption against preemption in health regulations).

415. See *supra* Part I.B. (discussing certain chemicals used in cosmetics and their impact on the human body).

416. See *supra* Part IV.C.2 (discussing the decisions in *NYRSA I* and *NYRSA II*).

417. See *supra* Part II.A.1 (discussing the history of the passage of the Food, Drug and Cosmetic Act).

of TSCA and FDCA reform.<sup>418</sup> Though the Democratic Party maintained control of the Senate, their considerable losses in the House of Representatives make the possibility of a bill passing without some intervening event that puts tremendous pressure on legislators seem highly unlikely.<sup>419</sup>

If political circumstances preclude the possibility of success at the federal level, New York's proponents of cosmetics regulation reform activists can pursue passage of a bill in the State Legislature. Although Republicans regained control of the New York State Senate and now hold 32 of 62 seats,<sup>420</sup> Democrats still maintain a strong majority in the New York Assembly, and the possibility of building support in the State Legislature should not be completely dismissed.<sup>421</sup> Proposed legislation promoting safe cosmetics already exists in the Senate and Assembly, but thus far has not gained traction.<sup>422</sup>

In the absence of reform at the state level, local government may wish to act to better protect consumers from possibly dangerous cosmetics. The New York City Council could introduce legislation requiring warning labels or disclosure of the chemicals contained in cosmetics. Regulations could also be effective. The New York City Mayor's Office and the Department of Health and Mental Hygiene arguably has the power to pass regulations aimed at allowing consumers to make more informed decisions when purchasing cosmetics.

---

418. While the issue of cosmetics regulation is not necessarily a partisan debate, all sponsors and co-sponsors of legislation intended to reform the FDCA and TSCA are members of the Democratic Party. See EUROPEAN COMMISSION ENVIRONMENT DIRECTORATE GENERAL, *supra* note 259.

419. *Id.*

420. *Senators*, NEW YORK STATE SENATE, <http://www.nysenate.gov/senators>.

421. As with federal legislation, all sponsors, co-sponsors and multi-sponsors of cosmetics regulation reform bills in New York State are members of the Democratic Party. See *supra* Part IV.B (discussing the Safe Cosmetics Act of 2011).

422. See *supra* Part IV.B (discussing the Safe Cosmetics Act of 2009 and the Safe Cosmetics Act of 2011).

### B. Community Education

Community education is an essential component of a campaign to reform cosmetics regulation. Public awareness of the deficiencies in the current statutory scheme is essential for developing a base of support to enact reform legislation. In addition to educating the public at large about the current regulatory structure and proposed reforms, community education programs could focus on users of ethnic cosmetics, and at the same time garner helpful feedback on attitudes toward products' use. Past consumer organizing campaigns, such as those to eliminate phthalates from nail polish, were successful in pressuring cosmetics companies to change formulas and discontinue use of dangerous ingredients.<sup>423</sup> A community education program could go further to encourage manufacturers to take the lead and offer healthier products. Demonstrating the demand for safer products could facilitate a dialogue between cosmetics consumers and manufacturers, perhaps ultimately leading to the voluntarily termination of dangerous ingredient use.

A boycott of particular products or companies could prove successful if more moderate means fail. Ultimately, the cosmetics industry is compromised of for-profit corporations that are primarily concerned with sales and profits. If reformers are not able to effect change through cooperation or legislation, the use of boycotts and media outreach campaigns could be an extremely effective technique.<sup>424</sup> Even if sales are not significantly affected, boycotts could lead to increased media attention and community education, as well as increased pressure on manufacturers and legislators.

Overhauling the cosmetics regulation regime in the United States will not be easy or quick. Nonetheless, the adoption of the precautionary principal<sup>425</sup> is essential to protecting and educating consumers. For decades, the cosmetics industry has been allowed to decide for itself what is safe while consumers, who are often uninformed or misinformed, bear the risk of using possibly harmful

---

423. See *supra* Part I.C (discussing removal of dibutyl phthalate from nail polish in the United States and Europe).

424. See *supra* text accompanying note 54 (discussing the decision of cosmetic manufacturers to remove DBP from nail polish).

425. See Katz, *supra* note 245 (discussing the precautionary principle).

products. It is unacceptable that the federal government wait until harm occurs before taking action, particularly when California and Europe operate successful cosmetic regulation programs. Until Congress is willing to reform the FDCA and the TSCA, states and local governments should take it upon themselves to require increased oversight of cosmetics.