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The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment

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ARTICLE

The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment

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In August 2012, a well-known baby shampoo company announced its intention to remove multiple toxic substances from nearly all of its products by 2015.[1] The announcement came on the heels of its earlier promise to remove these chemicals from just its baby products by 2013.[2]

While the long timeframe of this planned corporate action—three years—is shocking, it is even more worrisome that these

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1. CBS News Staff, *Johnson & Johnson to Phase Out Potentially Harmful Chemicals by 2015*, CBSNEWS (Aug. 15, 2012, 2:05 PM), http://www.cbsnews.com/8301-504763_162-57493890-10391704/johnson-johnson-to-phase-out-potentially-harmful-chemicals-by-2015/. Johnson & Johnson has reportedly made good on its promise to remove formaldehyde and 1,4-dioxane from its baby shampoo. Katie Thomas, *The 'No More Tear' Shampoo, Now with No Formaldehyde*, N.Y. TIMES (Jan. 17, 2014), http://www.nytimes.com/2014/01/18/business/johnson-johnson-takes-first-step-in-removal-of-questionable-chemicals-from-products.html?_r=0.

2. CBS News Staff, *supra* note 1*; see also* Associated Press, *Group: Johnson's Baby Shampoo a Cancer Risk*, CBSNEWS (Nov. 1, 2011, 2:55 AM), http://www.cbsnews.com/8301-204_162-20128253/group-johnsons-baby-shampoo-a-cancer-risk/.

substances, including formaldehyde, a known carcinogen,[3] and 1,4-dioxane, a substance linked to cancer in animal studies and classified by the U.S. Environmental Protection Agency (EPA) as a probable human carcinogen,[4] were even linked to products designed for babies in the first instance. To complicate matters further, not all of these toxic substances are even listed on product labels. Formaldehyde, for example, is released over time from the interaction of substances in the shampoo with the toxic quaternium-15, which, until recently, was present in these products and found on product labels.[5]

The other shocking part of this corporate announcement is that these products are not from some unknown manufacturer sold at the fringe of U.S. commerce. Rather, they come from a corporate giant that sells cosmetic products in widespread use every day—all over the country. The news highlights the popular consumer misconception that federal cosmetic law is protective of human health.[6] In reality, federal law simply does not prohibit the creation of carcinogens or the addition of other toxins in cosmetic products in the United States.[7] To put a bleaker face on

3. The EPA lists formaldehyde as a "probable human carcinogen" that has been shown to cause cancer in animals. *Integrated Risk Information System: Formaldehyde*, EPA, http://www.epa.gov/iris/subst/0419.htm (last visited Feb. 19, 2014); *An Introduction to Indoor Air Quality*, EPA, http://www.epa.gov/iaq/formaldehyde.html (last visited Feb. 19, 2014). Formaldehyde is also a skin, eye, and respiratory irritant. CBS News Staff, *supra* note 1.

4. *Technology Transfer Network – Air Toxics Website, 1,4-Dioxane (1,4-Diethyleneoxide)*, EPA, http://www.epa.gov/ttnatw01/hlthef/dioxane.html (last visited Feb. 19, 2014).

5. CBS News Staff, *supra* note 1. Another worrisome chemical that causes the release of formaldehyde in cosmetic products is imidazolidinyl urea. This man-made chemical has been studied by the National Cancer Institute and was nominated as early as 2003 for inclusion in the National Toxicology Program. TECHNICAL RESOURCES INTERNATIONAL, INC., IMIDAZOLIDINYL UREA 1 (2004), *available at* http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/imidazolidinylurea_508.pdf. When paired with parabens, imidazolidinyl urea is one of the most widely used cosmetic preservatives in the world. *Id.* Another commonly used substance in personal care products is DMDM hydantoin, which also causes the release of formaldehyde over time. Katie Thomas, *Johnson & Johnson to Remove Formaldehyde from Products*, N.Y. TIMES (Aug. 15, 2012), http://www.nytimes.com/2012/08/16/business/johnson-johnson-to-remove-formaldehyde-from-products.html?_r=0.

6. An August 2012 CBS News story contains this shocking statement: "[T]he U.S. Food and Drug Administration doesn't regulate cosmetic products." CBS News Staff, *supra* note 1.

7. *See id.*

U.S. cosmetics regulation, the company in question had already removed these hazardous substances from its products for sale in other regions, such as the United Kingdom and Scandinavia.[8] Worse still, consumers in the United States willing to pay more for their baby shampoo could purchase the company's "natural" baby shampoo, a product marketed and sold without a dose of 1,4-dioxane.[9]

Unfortunately, the headline from this baby shampoo giant is only the tip of the iceberg with regard to the regulation of consumer cosmetics. For the average U.S. consumer, there is an enormous "gaping hole"[10] or "missing link" in federal law that allows these questionable product formulations.

The Safe Cosmetics and Personal Care Products Act of 2013 (House Bill 1385) would require the U.S. Food and Drug Administration (FDA) to finally set rules banning carcinogens and many toxins from cosmetics in the United States.[11] The Cosmetics Safety Enhancement Act of 2012 (Enhancement Act),[12] introduced by Representative Frank Pallone, Jr. (D-NJ), and the Cosmetic Safety Amendments Act of 2012 (Amendments Act),[13] introduced by Representative Leonard Lance (R-NJ) were likewise attempts to begin to strengthen the regulation of U.S. cosmetics.

8. *Toxic Baby Shampoo: Johnson & Johnson Agrees to Global Reformulation Under Pressure from Health Groups*, THE CAMPAIGN FOR SAFE COSMETICS (Nov. 1, 2011), http://safecosmetics.org/article.php?id=888.

9. CBS News Staff, *supra* note 1. The cosmetics industry is a $60 billion per year industry, and it has lobbied against stricter regulation. Jim Avila, *FDA Regulation of Cosmetics Nears Despite Industry Objections*, ABCNEWS (Apr. 30, 2012, 9:07 PM), http://abcnews.go.com/blogs/lifestyle/2012/04/fdas-regulation-over-cosmetics-nears-despite-industry-backlash.

10. Then-U.S. Representative Edward Markey (now Massachusetts Senator), the 2011 sponsor of the Safe Cosmetics Act, said the 2011 version of the Act would close a "gaping hole" in federal law. Associated Press, *J&J Steadily Removing Toxins from Baby Products,* THE CAMPAIGN FOR SAFE COSMETICS (Nov. 16, 2011), http://safecosmetics.org/article.php?id=907.

11. *See* Safe Cosmetics and Personal Care Products Act of 2013, H.R. 1385, 113th Cong. (2013), *available at* http://www.govtrack.us/congress/bills/113/hr1385. This bill was introduced in March 2013 and has been referred to committee. *Id*.

12. *See generally* Cosmetics Safety Enhancement Act of 2012, H.R. 4262, 112th Cong. (2012).

13. *See generally* Cosmetic Safety Amendments Act of 2012, H.R. 4395, 112th Cong. (2012).

Neither of these latter bills, however, went far enough to address the fundamental weaknesses in how we regulate toxic substances in consumer products and in U.S. commerce generally, and previous versions of the House Bill 1385 stalled in committee. The Act seems unlikely in any forthcoming Congressional session to garner necessary support.[14]

This article explores these lax regulatory efforts and their connection to risk assessment, and proposes changes to our current toxics regulatory paradigm. Part I of this article explores our current regulatory approach for consumer cosmetics. Part II discusses the specific and dire concerns regarding chemicals that are suspected carcinogens and those suspected of disrupting the human endocrine system. The article argues in Part III that because the framework for our current regulation of consumer cosmetic products is not designed to be protective of human health, our regulatory paradigm must shift dramatically in the future if this is to become our true goal. Part IV of the article compares our federal efforts to regulate toxic substances in cosmetics with those in other developed countries and at the state level in the United States. This section concludes that we lag far behind in our health protective regulatory efforts relative to other jurisdictions. If we are to make the protection of human health a fundamental goal of our toxics regulatory system and specifically, our cosmetic product regulation, we must change our normative goals and operate from a more precautionary stance. In Part V, the article reviews past and current federal legislative proposals regarding cosmetic regulation, and makes suggestions on how the current proposal could be strengthened to make U.S. cosmetics safer, and have a greater potential to protect human health.

14. *See* H.R. 1385; *see also infra* note 365 and accompanying text.

I. REGULATION OF COSMETICS

A. History of the United States' Regulatory System

a. The Federal Food and Drugs Act

Although federal regulation of cosmetic products in the United States did not begin until 1938,[15] the course of early regulatory efforts regarding food, drugs, and other chemicals influenced the current regulation of cosmetics. Between 1879 and 1906, dozens of Congressional bills seeking to regulate food and drugs had failed to pass.[16] The Pure Food and Drugs Act of 1906, however, finally authorized the Bureau of Chemistry to prohibit adulterated or mislabeled food and drugs.[17] Adulterated drugs were those whose strength, quality, or purity departed from professional standards,[18] while misbranded drugs included those with misleading or false packaging or labeling.[19] "The central purpose of the food and drug legislation was to prohibit adulteration and misrepresentation. This perfectly laudable objective amounted to little more than a modest extension of the common law prohibition against fraudulent conduct."[20]

These early efforts to regulate drugs were often hindered by narrow judicial interpretations and high evidentiary burdens. In 1911, the Supreme Court of the United States, in *United States v. Johnson*, held that false statements on a drug's label indicating it was effective in curing cancer did not cause the drug to be

15. Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-399f (2012).

16. *FDA History - Part I: The 1906 Food and Drugs Act and its Enforcement*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm (last visited Feb. 19, 2014) [hereinafter *FDA History*].

17. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, § 2 (1906); *FDA History*, *supra* note 16. In 1927, the relevant operations of the Bureau of Chemistry were moved to the newly created Food, Drug, and Insecticide Administration, later known as the FDA. *Significant Dates in U.S. Food and Drug Law History*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm (last visited Feb. 19, 2014).

18. Pure Food and Drugs Act § 7.

19. *Id.* § 8.

20. Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1228 (1986).

mislabeled under the Pure Food and Drugs Act.[21] The Court noted that "the phrase [mislabeled] is aimed not at all possible false statements, but only at such as determine the identity of the article, possibly including its strength, quality and purity . . . ."[22] Congress amended the Act in the following year to do an end run around *Johnson*, by specifically prohibiting false therapeutic claims for drugs.[23]

While the amended Pure Food and Drugs Act provided some minimum regulation of drugs, it still had significant shortcomings.[24] The Amendment attempted to protect consumers by allowing prosecution for false therapeutic statements, however, the Amendment also required proof that such statements were intended to defraud consumers, and thus significantly increased the government's burden to win cases.[25]

Additionally, the Act did not require that drugs be proven safe or effective prior to distribution.[26] As a result, a number of

21. United States v. Johnson, 221 U.S. 488, 498 (1911).

22. *Id*. at 497. The *Johnson* holding that, despite labeling indicating that a drug was effective in curing cancer (when it was not so proven), the drug was not "misbranded," appeared to directly conflict with the clear language of the Pure Food and Drug Act: "[T]he term 'misbranded' . . . shall apply to all drugs, . . . the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular . . . ." *Id*. (citing Pure Food and Drugs Act § 8).

23. Sherley Amendment of 1912, 37 Stat. 416 (1912). (A drug shall be misbranded "[i]f its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.").

24. *See supra* notes 17-20 and accompanying text.

25. Marc T. Law, *How do Regulators Regulate? Enforcement of the Pure Food and Drugs Act, 1907-38*, 22(2) J.L. ECON. & ORG. 459, 472-73 (2006). The Supreme Court of the United States, in a case construing the meaning of the Sherley Amendment of 1912, held that: "it must be found that the statement contained in the package was put there to accompany the goods with actual intent to deceive,—an intent which may be derived from the facts and circumstances, but which must be established." Seven Cases v. United States, 239 U.S. 510, 517 (1916). *But see* United States v. 47 Bottles, 200 F. Supp. 1, 6 (D.N.J. 1961) (interpreting the corresponding mislabeled drug provision of the later FDCA and finding that "no fraudulent intent . . . need be shown . . .").

26. *See Johnson*, 221 U.S. at 496; *see also FDA History*, *supra* note 16 ("The basis of the [Pure Food and Drugs Act] rested on the regulation of product labeling rather than pre-market approval.").

harmful products continued to be sold and consumed.[27] The most shocking case involved Elixir Sulfanilamide.[28] Sulfanilamide drugs were used throughout the 1930s without incident, until one manufacturer produced a liquid form of the drug dissolved in a type of antifreeze.[29] Over 100 people died after using the drug, and the public pressured Congress to pass the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938, which forms the basis of all cosmetics regulation in the United States today.[30]

b. The FDCA

The FDCA of 1938[31] was intended to address many of the problems with the Pure Food and Drugs Act.[32] Congress specifically included cosmetics within the new FDCA, partly in response to the FDA's publicizing of many defective and harmful cosmetic products prior to the bill's passage.[33] The FDCA explicitly banned misbranded or adulterated cosmetics.[34] Adulterated cosmetics under the Act include:

> [1] [Cosmetics] that [bear] or [contain] any poisonous or deleterious substance which may render it injurious to users

27. *See* Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L.J. 215, 217-18 (1999).

28. *See id*. at 218.

29. *Id*.

30. *Id*.

31. *See* 21 U.S.C. §§ 301-399f.

32. *See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 12-13 (1939).

33. *See FDA History Part II: The 1938 Food, Drug, and Cosmetic Act*, FDA, http://www.fda.gov/aboutFDA/WhatWeDo/History/origin/ucm054826.htm (last visited Feb. 19, 2014) ("The FDA . . . [assembled] a collection of products that illustrated shortcomings in the [Pure Food and Drug Act]. It included . . . Lash-Lure, an eyelash dye in which a number of women suffered injuries to their eyes, including one confirmed case of permanent blindness . . . .").

34. 21 U.S.C. § 331(a). "Cosmetic" is defined 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.

Id. § 321(i).

> under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual; . . . [2] [cosmetics consisting] in whole or in part of any filthy, putrid, or decomposed substance; . . . [3] [cosmetics made or held] under insanitary conditions whereby [they] may have become contaminated with filth, or whereby [they] may have been rendered injurious to health, . . . [4] [and cosmetics with a] container composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health . . . .[35]

A cosmetic product can also be "misbranded" under the FDCA if: (1) its labeling is false or misleading; (2) its label does not contain the name and address of the manufacturer, packer, or distributor, or an accurate ingredient list; or (3) if "any word, statement, or other information required by . . . this [Act] to appear on the label . . . is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[36]

These statutory definitions of "misbranded" and "adulterated" remain in place today, although originally enacted in 1938,[37] and even as we have made vast strides in our scientific and technological knowledge in the last century.[38] The statutory nomenclature speaks of "putrid" and "filthy" products made under unsanitary conditions, evincing a lack of understanding of current corporate production, and a total lack of concern about the long-term effects of a cosmetic product on the user.[39] Instead, the FDCA was then and continues today to be mainly concerned with the immediate and short-term effects of a consumer product and its ingredients. By these standards, most cosmetic products are considered safe in the United States today, absent some meaningful proof of harm in the long-term, which is not regularly available.[40]

35. *Id*. § 361(a)-(d).

36. *Id*. § 362(a)-(c).

37. 21 U.S.C. §§ 361, 362.

38. WHO WILL KEEP THE PUBLIC HEALTHY? EDUCATING PUBLIC HEALTH PROFESSIONALS FOR THE 21ST CENTURY 27 (Kristine Gebbie et al. eds., 2003), *available at* http://www.nap.edu/openbook.php?isbn= 030908542X.

39. *See* 21 U.S.C. § 361(b)-(c).

40. *See* Mary O'Brien, *Our Current Toxics Use Framework, Our Stolen Future, and Our Options*, 11 J. ENVTL. L. & LITIG. 331, 346-51 (1996) (reviewing

c. Recent Changes to the FDCA

While the FDCA remains largely similar to the original statute, several recent changes deserve note. Under the FDCA, labeling requirements include specific warning labels for coal-tar hair dye,[41] in addition to the general prohibitions on false or misleading labels or packaging, exclusive of ingredient lists.[42] The Fair Packaging and Labeling Act[43] also contains provisions requiring product labels to conspicuously include information about the manufacturer, packer or distributor, and net quantity information.[44] The Special Packaging of Household Substances for Protection of Children Act, commonly known as the Poison Prevention Packaging Act of 1970,[45] allows the Consumer Product Safety Commission to set special packaging guidelines for consumer products that may have a high degree of risk to children.[46] Specific labeling and packaging requirements also attach under FDA regulations within the existing legal framework.[47] An amendment to the FDCA in 1997 also outlawed—with minor exceptions—any state or local requirements for labeling or packaging of cosmetics that are different from requirements under the Act, the Poison Prevention Packaging Act of 1970, or the Fair Packaging and Labeling Act.[48]

In July 2012, as part of an effort to extend current FDA user-fee programs and to institute new fees, Congress also added a section on "nanotechnology" to the FDCA.[49] "Nanotechnology," "nanomaterials," and "nanoparticles" all refer to new materials

THEO COLBORN ET AL., OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE, AND SURVIVAL?—A SCIENTIFIC DETECTIVE STORY (1996)).

41. 21 U.S.C. § 361(a).

42. *Id*. § 362(a).

43. Fair Packaging and Labeling Program, 15 U.S.C. §§ 1451-1461 (2012).

44. *Id*. § 1453(a)(1)-(2).

45. Special Packaging of Household Substances for Protection of Children, 15 U.S.C. §§ 1471-1477 (2012).

46. *See id*. § 1472(a)(1).

47. *See generally* 21 C.F.R. §§ 701.1-701.30 (2014) (FDA regulations for cosmetic labeling); 16 C.F.R. §§ 500.1-500.29 (2014) (Federal Trade Commission regulations under section 4 of the Fair Packaging and Labeling Act); 16 C.F.R. §§ 1700.1-1700.20 (2014) (Consumer Product Safety Commission regulations under the Poison Prevention Packaging Act of 1970).

48. 21 U.S.C. § 379s(a).

49. *See id*. § 399e.

created from the manipulation of atoms and molecules at the "nanometer scale," that is, from 1 nanometer to 100 nanometers.[50] The use of such nanoparticles in cosmetic products in recent years has increased dramatically, often because these new materials have new or enhanced properties, including "color, transparency, solubility[,] and chemical reactivity . . . ."[51] Certain nanoparticles, however, have been found to have high risks of health concerns, often because the very small size of the particles increases the likelihood of inhalation or migration beyond the surface of the skin.[52] Furthermore, their small size is believed to increase the possibility that they might interact with more sensitive cells of the body,[53] such as in the digestive tract or respiratory system.

This new section in the FDCA attempts to address these concerns by authorizing the FDA to "intensify and expand activities related to enhancing scientific knowledge regarding nanomaterials" intended for use in products regulated by the FDA, and to collect user fees to further this purpose.[54] The section notes that these new studies will address issues including "the potential toxicology of such nanomaterials, the potential benefit of new therapies derived from nanotechnology, the effects of such nanomaterials on biological systems, and the interaction of such nanomaterials with biological systems."[55]

B. Cosmetic Ingredient Review and Industry Self-Regulation

The cosmetics industry has over the last forty years also made a minimal attempt to self-regulate. The Cosmetic Ingredient Review Panel (CIR) was established in 1976 by the cosmetic industry's trade association,[56] and is also funded by that

50. Raj Silpa et al., *Nanotechnology in Cosmetics: Opportunities and Challenges*, 4 J. PHARMACY & BIOALLIED SCI. 186, 186 (2012) (noting that one nanometer is one billionth of a meter).

51. *Id*.

52. *Id*. at 188.

53. *See* Silpa et al., *supra* note 50, at 188.

54. 21 U.S.C. § 399e(a).

55. *Id*.

56. *About the Cosmetic Ingredient Review*, COSMETIC INGREDIENT REV., http://www.cir-safety.org/about (last visited Feb. 20, 2014) (The CIR was set up

association.[57] The CIR assesses the safety of ingredients used in cosmetic products.[58] Voting panel members include doctors and scientists, plus three non-voting members representing the cosmetics industry, consumer groups, and the government.[59]

The importance of the CIR's findings to FDA determinations regarding the safety of cosmetic products is revealed in references to the expert panel's evaluations in a number of the FDA's rulemaking notices.[60] The EPA[61] and the Occupational Safety and Health Administration[62] have also referenced CIR studies in their respective actions. The FDA has nonetheless noted, that CIR determinations do not serve as the sole source of evidence for rulemaking actions regarding cosmetics.[63]

While CIR review is a laudable and ambitious program of self-regulation, experts have estimated that only between 11% and 13% of ingredients used in cosmetics have actually been subject to CIR analysis.[64] Additionally, the CIR has only found

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and is funded by what was the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council, with the support of the FDA and the Consumer Federation of America.).

57. *Id.*

58. *How Does CIR Work?,* COSMETIC INGREDIENT REV., http://www.cir-safety.org/how-does-cir-work (last visited Feb. 20, 2014).

59. *Id.*

60. *See, e.g.*, 50 Fed. Reg. 39,854 (Sept. 30, 1985) (notice of proposed rulemaking regarding dental anti-cavity products); 70 Fed. Reg. 1721, (Jan. 10, 2005) (guidance for industry regarding cosmetic products containing alpha hydroxy acids); 68 Fed. Reg. 32,232 (May 29, 2003) (notice of proposed rulemaking regarding anti-plaque and anti-gingivitis products).

61. *See, e.g.*, 54 Fed. Reg. 8116 (Feb. 24, 1989) (notice of intent to cancel regulations for pesticides containing captan); 60 Fed. Reg. 54,637 (Oct. 25, 1995) (proposed rule regarding jojoba oil); 76 Fed. Reg. 56,644 (Sept. 14, 2011) (notice of final rule regarding sulfur dioxide).

62. *See, e.g.*, 52 Fed. Reg. 46,168 (Dec. 4, 1987) (final rule regarding occupational exposure to formaldehyde).

63. 58 Fed. Reg. 33,700 (June 8, 1993). The FDA noted that

> [t]hese [CIR] reviews are used primarily by industry to make self-determinations of cosmetic ingredient safety. The agency may, or may not, comment on any CIR. Even where FDA comments on a CIR, there would be little likelihood that agency rulemaking would result. In situations where such a review does serve as a stimulus for a rulemaking proceeding, the review would not be the sole reason for the proceeding.

Id.

64. *See* Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23

eleven chemicals or groups of chemicals actually unsafe for use in cosmetics since the panel first came into existence almost forty years ago.[65] Moreover, manufacturers are not even required to follow CIR's published determinations.[66] In California's recently enacted laws regulating cosmetic products,[67] the statement of legislative findings notes that "54 cosmetic products violate the CIR's own safe use recommendations to manufacturers by containing an ingredient that the CIR has found is not safe for the specific use indicated on the product's label."[68] There have also been instances where CIR determinations of a substance's safety directly conflict with other findings of significant health concerns.[69]

C. Lack of Regulation of Endocrine Disruptors in Cosmetics[70]

One significant health concern is chemicals that disrupt or have the potential to disrupt the human endocrine system. These so-called endocrine disrupting chemicals (EDCs) are synthetic compounds[71] found routinely in cosmetic products.[72] Yet, EDCs

FORDHAM ENVTL. L. REV. 203, 204 (2012); Katharine A. Van Tassel & Rose H. Goldman, *The Growing Consumer Exposure to Nanotechnology in Everyday Products: Regulating Innovative Technologies in Light of Lessons from the Past*, 44 CONN. L. REV. 481, 511 (2011).

65. *Myths on Cosmetics Safety*, EWG'S SKIN DEEP, http://www.ewg.org/skindeep/myths-on-cosmetics-safety/ (last visited Feb. 20, 2014).

66. *See* Sarah E. Schaffer, *Reading Our Lips: The History of Lipstick Regulation in Western Seats of Power*, 62 FOOD & DRUG L.J. 165, 200 (2007).

67. California's progressive and health protective cosmetics laws, known as California's Safe Cosmetics Act of 2005, are discussed in further in Part IV.D of this article. *See infra* notes 269-74 and accompanying text.

68. CAL. HEALTH & SAFETY CODE § 111793.5(a)(2) (West 2014).

69. *See, e.g.*, Thomas O. McGarity, *Resisting Regulation with Blue Ribbon Panels*, 33 FORDHAM URB. L.J. 1157, 1190 (2006).

70. This section is reprinted in part with permission and is originally found in-part at: Valerie J. Watnick, *Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point*, 2004 UTAH L. REV. 1305, 1307-10 (2004).

71. Cassandra L. Bevan et al., *The Effects of Endocrine Disrupting Compounds on the Development of the Nervous System: Use of the Frog,* Xenopus Laevis*, as a Model System,* 2 VT. J. ENVTL. L. 41, 42 (2001).

72. *See, e.g.*, Rachael Rawlins, *Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics*, 20 FORDHAM ENVTL. L. REV. 1, 3 (2009)

are believed by scientists to be one of the most significant man-made environmental problems of our time.[73] EDCs affect the functioning of the endocrine system[74] by either blocking the effect of naturally produced hormones in the endocrine system or by altering the effect of naturally occurring hormones.[75] The inherent difficulty in regulating EDCs to achieve safety, or what might be called negligible,[76] or politically acceptable risk,[77] is that the science of endocrine disruption remains relatively new.[78]

(referring to findings of "personal-care products containing known or suspected endocrine-disrupting chemicals").

73. *See generally* THEO COLBORN ET AL., OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE, AND SURVIVAL?—A SCIENTIFIC DETECTIVE STORY (1996).

74. *What Are Endocrine Disrupters?*, EPA, http://www.epa.gov/scipoly/oscpendo/pubs/edspoverview/whatare.htm (last visited Feb. 20, 2014) ("The endocrine system regulates all biological processes in the body from conception through adulthood and into old age, including the development of the brain and nervous system, [and] the growth and function of the reproductive system . . . .").

75. O'Brien, *supra* note 40, at 333. The endocrine system consists of glands, organs, and tissues that release hormones into the human circulatory system. The hormones carry messages that direct development and function in the animal's cells and organs. Hormones therefore control sexual development, both prenatally and postnatally. *Id.* at 332. Commonly known EDCs include various pesticides, polychlorinated biphenyls (PCBs), and dioxins (a byproduct of paper production). Robin Fastenau, *EPA's Investigation and Regulation of Endocrine Disruptors*, 14 J. ENVTL. L. & LITIG. 53, 54 (1999).

76. Negligible risk is commonly considered to be the one-in-a-million chance that an event will occur. While this seems like a small amount of risk, it takes on a new meaning when you or someone you love is the one suffering the harm. Additionally, these sorts of risk calculations do not account for the fact that a typical consumer faces accumulated negligible risks from multiple toxic sources every day. Watnick, *supra* note 68, at 1306 n. 8.

77. *Id*.

78. *See, e.g.,* Jonathan Chevrier et al., *Maternal Urinary Bisphenol A during Pregnancy and Maternal and Neonatal Thyroid Function in the CHAMACOS Study*, 121 ENVTL. HEALTH PERSP. 138, 138-39 (2012), *available at* http://ehp.niehs.nih.gov/wp-content/uploads/121/1/ehp.1205092.pdf; Fastenau, *supra* note 75, at 54-56 (explaining that in 1999, the EPA was entering a new phase in the regulation of toxics by becoming more concerned about the effects of chemicals that could potentially affect the human endocrine system as a result of the passage of the Food Quality Protection Act of 1996 and amendments to the Safe Drinking Water Act); *Endocrine Disruptors*, NAT'L INST. OF ENVTL. HEALTH SCI., http://www.niehs.nih.gov/health/materials/endocrine_disruptors_508.pdf#search=endocrine (last visited Feb. 20, 2014) [hereinafter *Endocrine Disruptors*]. *See* Safe Drinking Water Act, 42 U.S.C. §§ 300f-300j-26 (2012); Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended at various sections of 7 U.S.C. and 21 U.SC.). The EPA has stated that for the majority of chemicals, it does not have either effects or toxicity data with regard

EDCs are believed to work by blocking the effect of hormones or by mimicking hormones so that the organism's reactions are altered.[79] They are believed to "engage with the body's mechanism for regulating growth and development, while sabotaging its normal functions."[80] Synthetic chemicals that act like hormones may bind to hormone receptors just as natural hormones would, but then interfere with the intended bodily function.[81] Alternatively, EDCs may relay molecular messages that alter cell growth and division.[82]

While the exact mechanism by which EDCs cause harm is not fully understood,[83] the potential harm from EDCs is insidious[84] and well documented.[85] In particular, scientists have hypothesized that a link exists between EDCs and decreased

to endocrine disruption. 67 Fed. Reg. 79,611, 79,614 (Dec. 30, 2002). Even as to the risk of cancer, which has been studied for many years, at least two commentators have suggested that the use of risk analysis to draw conclusions about cancer occurrence is limited, and subject to the application of a myriad of estimates and assumptions. John S. Applegate & Celia Campbell-Mohn, *Risk Assessment: Science, Law and Policy*, 14 NAT. RES. & ENV'T 219, 220-21 (2000).

79. O'Brien, *supra* note 40, at 339.

80. Sheldon Krimsky, *A Clue to Understanding the Environmental Causes of Disease*, 43 ENV'T 22, 26-27 (2001), *available at* www.tufts.edu/~skrimsky/PDF/environ.PDF.

81. *See* Krimsky, *supra* note 80, at 27.

82. *Id*.

83. JOHN WARGO, OUR CHILDREN'S TOXIC LEGACY: HOW SCIENCE AND LAW FAIL TO PROTECT US FROM PESTICIDES 12 (1998) (noting that certain chemicals may act as endocrine disrupters, but that the precise nature by which endocrine disrupters operate is not known); Noah Sachs, *Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals*, 24 COLUM. J. ENVTL. L. 289, 290, 300 (1999) (noting that because the science of endocrine disruption is relatively new, further research into the causal mechanism is required); *see also* Leticia M. Diaz, *Hormone Replacement Therapy, or Just Eat More Meat: The Technological Hare vs. the Regulatory Tortoise*, 27 B.C. ENVTL. AFF. L. REV. 391, 416 (2000).

84. *See, e.g.,* Karen Fassuliotis, Comment, *The Science of Endocrine Disruption—Will it Change the Scope of Products Liability Claims?*, 17 PACE ENVTL. L. REV. 351, 357-60 (2000) (noting that EDCs may be a factor in increasing rates of breast cancer, adverse reproductive trends, and decreased functioning of the nervous system and the immune system); Phil Zahodiakin, *Hexachlorobenzene Linked to Androgen Disruption*, PESTICIDE & TOXIC CHEM. NEWS (Feb. 17, 2003) (noting that hexachlorobenzene, a known hormone disrupter and herbicide now banned in the United States, is believed to be present in over 95% of the U.S. population, and has adverse effects on ovarian function).

85. *See infra* notes 87-88 and accompanying text.

sperm counts, breast, testicular and prostate cancers, and neurological disorders.[86] Even more unsettling is that EDCs are omni-present in everyday cosmetic products, in addition to household products,[87] food and beverage containers, household pesticides, and pesticide residues on food.[88]

Yet, the current cosmetics regulation system in the United States is silent on the issue of EDCs despite the fact that federal law has begun to recognize the danger of EDCs, and in certain areas, authorizes federal agencies to consider potential endocrine health effects.[89] The Safe Drinking Water Act, for example, designed to improve the safety of our nation's drinking water, contains a general provision, which allows the EPA to regulate where it believes a substantial population might be exposed to an EDC.[90] Likewise, the Toxic Substances Control Act allows the EPA to regulate a chemical substance or mixture that presents an "unreasonable risk of injury to health or the environment."[91] Conceivably, this statute could be used to regulate and protect consumers from EDCs in cosmetics, but the reality is that the

86. Krimsky, *supra* note 80, at 22.

87. *See generally* SANDRA STEINGRABER, LIVING DOWNSTREAM: AN ECOLOGIST'S PERSONAL INVESTIGATION OF CANCER AND THE ENVIRONMENT, 113-14, 277-78 (2010) (giving an overview of EDCs, and urging that EDCs are related to the development of cancer, noting that phthalates, a "ubiquitous class of petrochemicals" and a "leading suspect[] in this ransacking of manhood" are commonly used in cosmetics).

88. Chemicals that are suspected of having adverse effects on the endocrine system are ubiquitous. They include: tributylin, found in paint; flame retardants used in furniture, carpet, and electronic products; bisphenol-A, a chemical used in the lining of food and beverage containers; phthalates, found in plastics; pesticides; chemicals found in cosmetics; and alkyl phenols, used in detergents. Additionally, hormone disrupting chemicals are produced when paper is made, and in other combustion and industrial processes. These chemicals are found in our air, and seep into our drinking water. *Controversial Issues*, ENDOCRINE/ESTROGEN LETTER, http://www.eeletter.com/cntrvrsl/index.html (last visited Feb. 20, 2014); *see also,* Erin Gill, *Cleaning Your Home Can Make You Ill*, THE EVENING STANDARD, Nov. 25, 2003, at A26 (noting that everyday items such as electrical goods, nonstick frying pans, and sofa and foam seating contain chemicals that are under suspicion for endocrine disruption). Chemicals such as PCBs, organochlorine pesticides, and brominated flame retardants have been linked to rising rates of breast cancer, testicular cancer, and asthma. *Id*.

89. *See infra* notes 90-96 and accompanying text.

90. 42 U.S.C. § 300j-17.

91. 15 U.S.C. § 2601(b)(2) (2012).

EPA has infrequently used the Toxic Substances Control Act to protect human health since its passage in 1976.[92]

The Food Quality Protection Act of 1996 (FQPA), often called landmark legislation aimed at making our overall U.S. food system safer, and amending the FDCA, specifically called for an Estrogenic Substances Screening Program, commonly known as the Endocrine Disruptor Screening Program (EDSP), to analyze whether chemicals may have endocrine effects on humans.[93] Yet, the FQPA has not lived up to its overall promise, its promise as to potential EDCs, or its promise to protect children.[94] The EDSP called for by the 1996 Act, has had little effect on how we regulate potential EDCs in the food arena.[95] More than a decade after the passage of the FQPA, calling for an identification and assessment of EDCs in food, the EDSP had not designated a single chemical as an EDC.[96]

The FQPA requires the EPA to use Quantitative Risk Assessment (QRA) to regulate chemicals suspected EDCs. QRA is the process of characterizing the "potential adverse health effects of human exposures to environmental hazards."[97] QRA

92. Holly E. Pettit, *Shifting the Experiment to the Lab: Does EPA Have a Mandatory Duty to Require Chemical Testing for Endocrine Disruption Effects Under the Toxic Substances Control Act?*, 30 ENVTL. L. 413, 424 (2000).

93. 21 U.S.C. § 346a(p).

94. *See* Kristina Thayer & Jane Houlihan, *Pesticides, Human Health, and the Food Quality Protection Act*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 257, 291-303 (2004).

95. *See* EPA, OFFICE OF INSPECTOR GEN., REPORT NO. 11-P-0215, EPA'S ENDOCRINE DISRUPTOR SCREENING PROGRAM SHOULD ESTABLISH MANAGEMENT CONTROLS TO ENSURE MORE TIMELY RESULTS 9-19 (2011) [hereinafter REPORT NO. 11-P-0215].

96. *Id*. at iii. As of 2011, EDSP had not formulated the Program's goals and priorities, or established measures to track program results. *Id*. Additionally, the EDSP missed required deadlines to validate assays and to select chemicals for priority evaluation. *Id*.; *see also* Natural Res. Def. Council v. Whitman, No. C 99-03701 WHA, 2001 WL 1221774, at *1 (N.D. Cal. Sept. 24, 2001). The 2001 consent decree between the Natural Resources Defense Council and the EPA required the EPA to prioritize chemicals for screening and evaluation, and to do an initial "Tier I" screening of the 87,000 chemicals on the market that have the potential for endocrine effects. *Id*. at 21-22; 63 Fed. Reg. 42,852, 42,854 (Aug. 11, 1998).

97. NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 18 (1983) (commonly referred to as the "Redbook"); *see* Valerie Watnick, *Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality*

appears to be a good idea on its face—a purely objective and scientific analysis to ferret out substances that may present a risk to human health. However, the QRA process has been subject to serious criticism by scholars and policy makers,[98] urging that the many assumptions and extrapolations involved in risk assessments are keenly influenced by a decision maker's personal and political point of view.[99] Risk assessment determinations may be based on a "mixture of fact, experience (often called intuition), and personal values that cannot be disentangled easily."[100] Changing assumptions can result in a risk assessment that is either more or less protective of human health.[101] An additional major limitation cited regarding QRA is the "limited analytic resources" available to recognize and evaluate potentially dangerous substances.[102]

Yet, despite the many shortcomings of QRA, there is an argument that if a federal statute at least calls for an assessment of risk, there begins a public recognition of some potential for risk to humans.[103] In the cosmetics arena, as discussed further below, federal regulation does not even require identification of risk in any serious manner, let alone risk assessment with regard to

Protection Act's Safeguards for Children, 31 ARIZ. ST. L.J. 1315, 1332-36 (1999) (giving a thorough discussion of QRA).

98. *See, e.g.*, Junius C. McElveen, Jr. & Chris Amantea, *Legislating Risk Assessment*, 63 U. CIN. L. REV. 1553, 1579 (1995) (noting shortcomings in the risk assessment process, and concluding it overstates risk and provides no additional protection); Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 421 (1995) (addressing the "unreliability and malleability" of risk assessments); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1625 (1995) (analyzing the complex mix of policy and science in risk assessment decision making).

99. *See* Staci Jeanne Krupp, *Environmental Hazards: Assessing the Risk to Women*, 12 FORDHAM ENVTL. L.J. 111, 123-24 (2000) (arguing that risk assessments are inherently "value-laden").

100. NAT'L RESEARCH COUNCIL, *supra* note 97, at 36.

101. *See id*. at 37.

102. *See id*. at 12.

103. *See* Jeff Gimpel, Note, *The Risk Assessment and Cost Benefit Act of 1995: Regulatory Reform and the Legislation of Science*, 23 J. LEGIS. 61, 72 (1997) ("Hazard identification is the first phase in the process of assessing risk. This requires identifying the agent in the environment which may cause harm and assessing the evidence which associates exposure to the agent with the resulting harm.").

personal care and cosmetic product ingredients.[104] Cosmetics law in the United States instead allows manufacturers to simply state that existing research shows that the product or ingredient is safe to use, or to issue a statement that no determination regarding safety has been made.[105]

II. THE DANGER OF EDCS AND CARCINOGENIC SUBSTANCES IN COSMETICS, THE UNIQUE DANGER TO CHILDREN, AND THE NEED TO REGULATE TO PROTECT AGAINST THESE POTENTIAL HARMS

A. The "True Burden" of Environmental Cancers is Understated and the Specific Need to Reduce Toxic Exposure for Children

In 2010, the President's Cancer Panel issued a groundbreaking report, asserting that the "true burden of environmentally induced cancer has been grossly underestimated."[106] The report specifically encouraged consumers to eat food that is not grown with synthetic pesticides, chemical fertilizers, and growth hormones, to reduce the risk of contracting cancer.[107] The World Health Organization has likewise estimated that by 2020, the overall rate of cancer in the

104. *See supra* notes 31-69 and accompanying text.

105. *Id*.

106. LaSalle D. Leffall, Jr. & Margaret L. Kripke, *Letter to the President in* SUZANNE H. REUBEN, PRESIDENT'S CANCER PANEL, REDUCING ENVIRONMENTAL CANCER RISK: WHAT WE CAN DO NOW (2010), *available at* http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf [hereinafter *Letter to the President*].

107. SUZANNE H. REUBEN, PRESIDENT'S CANCER PANEL, REDUCING ENVIRONMENTAL CANCER RISK: WHAT WE CAN DO NOW xx (2010), *available at* http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.

developing world will increase by 73%, and in the developed world by 29%.[108]

In particular, the President's Cancer Panel's report also stressed the need to reduce toxic exposure for children.[109] This report was followed by documentation in the highly respected journal, *Pediatrics*, which concluded that exposure to organophosphate pesticides, commonly used on food in the United States,[110] may be contributing to the development of Attention Deficit Hyperactivity Disorder in children in the United States.[111]

These findings regarding the specific concerns for children came as no real surprise as the National Research Council reported, as early as 1993, that children are intrinsically more susceptible to harm from environmental toxins.[112] The National Research Council found that physiological and biochemical differences between adults and children make children more susceptible to the specific effects of pesticides in the environment.[113] Experts subsequently concluded that because they take in more air, food, and water per pound of body weight, and because their physical bodies are still developing, children are more susceptible generally to the effects of toxic substances in the environment.[114] And yet, two decades later, the vast majority of our regulation of environmental toxins, including the regulation of deleterious substances in cosmetics, does not treat children and adults differently or even begin to address these

108. WORLD HEALTH ORG. & FOOD & AGRIC. ORG., DIET, NUTRITION AND THE PREVENTION OF CHRONIC DISEASES 95 (2003), *available at* http://whqlibdoc.who.int/trs/who_trs_916.pdf.

109. REUBEN, *supra* note 107, at xix.

110. Maryse F. Bouchard et al., *Attention-Deficit/Hyperactivity Disorder and Urinary Metabolites of Organophosphate Pesticides*, 125 PEDIATRICS 1270, 1271 (2010), *available at* http://pediatrics.aappublications.org/content/early/2010/05/17/peds.2009-3058.full.pdf+html; *see Organophosphates*, PESTICIDE ACTION NETWORK, http://www.panna.org/resources/organophosphates (last visited Feb. 20, 2014) (noting that organophosphates are the most heavily used in the United States, are toxic to the human nervous system, and are thought to be related to the declining frog populations in California).

111. Bouchard et al., *supra* note 110, at 1270.

112. NAT'L RESEARCH COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 42-43 (1993).

113. *See id.* at 38, 42-43.

114. Cynthia F. Bearer, *Environmental Health Hazards: How Children Are Different from Adults*, 5 THE FUTURE OF CHILD. 11, 11, 15, 18 (1995).

widely acknowledged truths.[115] Indeed, the FQPA is the only federal statute to date to explicitly recognize the "unique vulnerabilit[y]" of children to toxins in the environment.[116]

B. The Particular Danger in Failing to Regulate EDCs in Cosmetics

EDCs are believed to have caused decreased fertility rates in wildlife, and there is strong evidence that they are having a similar effect on humans.[117] Perhaps the most infamously known case of the effects an EDC on humans involves diethylstilbestrol (DES), a synthetic hormone with anti-androgenizing or demasculinizing qualities,[118] given to pregnant women from the 1940s to the 1970s to prevent miscarriage.[119] DES did not just affect the women taking the drug; it had multigenerational effects, affecting her unborn fetus' later health as an adult.[120] Doctors learned that females born to mothers who were given DES suffered reproductive abnormalities.[121] These women were also prone to a rare type of vaginal cancer.[122] Additionally, males born to mothers to whom DES was administered also suffered reproductive abnormalities such as genital malformation and other testicular problems.[123] Our experience with DES has

115. *See Philip Landrigan*, HARV. SCH. OF PUB. HEALTH, http://www.hsph.harvard.edu/faculty/philip-landrigan/ (last visited Feb. 20, 2014). The FQPA began to address this different risk for children with regard to pesticide residues on food by requiring increased safety mechanisms for children, including the requirement that a special ten-times factor be applied in setting a pesticide tolerance or limit, unless reliable evidence suggests that the existing standard will be safe for children. 21 U.S.C. § 346a(b)(2)(C)(ii).

116. *Philip Landrigan, supra* note 115.

117. *See* COLBORN, ET AL., *supra* note 73, at 1-9; Keith J. Jones, *Endocrine Disrupters and Risk Assessment: Potential for a Big Mistake*, 17 VILL. ENVTL. L.J. 357, 366-67 (2006); *Endocrine Disruptors*, *supra* note 78.

118. Sachs, *supra* note 83, at 298.

119. *Id*., at 298-99; *see National Environmental Health Association Position on Endocrine Disrupters*, NAT'L ENVTL. HEALTH ASSOC. (July 2, 1997), http://www.neha.org/position_papers/PositionEndocrine.html [hereinafter *NEHA Position on EDCs*].

120. Sachs, *supra* note 83, at 299.

121. *Id*.

122. *Id*. The rare form of cancer that afflicts females born to mothers who took DES while pregnant is called clear-cell adenocarcinoma. *Id*.

123. *Id*. In the aftermath of the DES era, offspring of mothers who were prescribed DES filed lawsuits against the manufacturers of the drug. *Id*. These

proven that exposure to EDCs can have profound and lasting effects on the human race.

And yet, without adequate regulation, EDCs are routinely used in the formulation of cosmetic consumer products.[124] Triclosan, for example, a chemical commonly found in hand soaps touted to be antibacterial,[125] and even in toothpastes, has been shown to disrupt the human endocrine system.[126] Additionally, studies have shown that Triclosan affects human breast tissue.[127]

Another commonly found chemical in cosmetics is oxybenzone.[128] Oxybenzone, routinely used in sunscreen products because it is believed to block ultraviolet rays, is also believed to be an EDC.[129] Public interest groups have urged that despite its omnipresence in sunscreens, oxybenzone may cause hormone disruption, allergies, and may actually contribute to some skin cancers.[130]

Similarly, another common group of potential EDCs found in cosmetics is the paraben group.[131] Parabens, often used to preserve product shelf life, are used in all sorts of cosmetics, from

lawsuits have resulted in the imposition of liability on manufacturers under a market sharing theory. *Id.* at 334.

124. *See* Rawlins, *supra* note 72, at 1.

125. *Triclosan: What Consumers Should Know*, FDA, http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm (last visited Feb. 20, 2014) [hereinafter *Triclosan*]. Triclosan is also found in toothpaste, which is worrisome since we put this directly into our mouths. *Id.*

126. *See Triclosan*, *supra* note 125. The FDA has not said that the use of a soap containing Triclosan is any more beneficial to consumers than ordinary soap and water. *Id.*

127. *Triclosan and Triclocarbon*, BREAST CANCER FUND, http://www.breastcancerfund.org/clear-science/chemicals-glossary/triclosan.html (last visited Feb. 20, 2014).

128. *Is Your Sunscreen in EWG's Sunscreen Hall of Shame?*, ENVTL. WORKING GRP. (June 22, 2010), http://www.ewg.org/enviroblog/2010/06/your-sunscreen-ewgs-sunscreen-hall-shame [hereinafter *EWG's Sunscreen Hall of Shame*].

129. Tara Parker-Pope, *Sunscreen Safety is Called into Question*, N.Y. TIMES, July 22, 2008, at F5; *see EWG's Sunscreen Hall of Shame*, *supra* note 128 (estimating that the bodies of 97% of Americans today are contaminated with oxybenzone, which penetrates human skin).

130. *CDC: Americans Carry Body Burden of Toxic Sunscreen Chemical*, ENVTL. WORKING GRP. (Mar. 25, 2008), http://www.ewg.org/news/testimony-official-correspondence/cdc-americans-carry-body-burden-toxic-sunscreen-chemical.

131. *Parabens*, BREAST CANCER FUND, http://www.breastcancerfund.org/clear-science/chemicals-glossary/parabens.html (last visited Feb. 20, 2014).

shampoos to creams.[132] In discussing parabens in cosmetics, the FDA states that "[t]he [FDCA] does not authorize FDA to approve cosmetic ingredients,"[133] but comments that a study in 2004 found parabens in breast tumors.[134] The FDA goes on to note that these chemicals have also been found at unusual levels in the breast tissue of women diagnosed with breast cancer,[135] and additionally, that parabens "can act similarly to estrogen."[136] However, the FDA then notes that parabens exhibit much less intense estrogenic activity than natural estrogens, and that at this time, consumers should not be concerned about parabens in cosmetic products.[137] The FDA goes further with this line of rhetoric, and promises that it has continued to "evaluate new data in this area" and that it will consider its "legal options" under the FDCA to protect the health and welfare of consumers.[138]

What is noteworthy about these statements is that the FDA takes this position of inaction even while acknowledging that estrogenic activity in the body is associated with breast cancers.[139] This approach to paraben regulation provides an illustration of how hamstrung the FDA is in regulating cosmetic ingredients and the overall U.S. regulatory approach—chemicals are presumed safe until proven definitively guilty.[140]

132. *Id*.

133. *Parabens*, FDA, http://www.fda.gov/forconsumers/consumerupdates/ucm128042.htm (last visited Feb. 20, 2014) [hereinafter *FDA Parabens*].

134. *Id*.

135. *See id*.

136. *Id*.

137. *FDA Parabens*, *supra* note 133.

138. *Id*.

139. *Id*. In discussing paraben research, the FDA cites a study published in 2004 (Darbre, in the *Journal of Applied Toxicology*) that detected parabens in breast tumors, noting the weak estrogen-like properties of parabens, and the influence of estrogen on breast cancer. The FDA states, "[h]owever, the study left several questions unanswered. For example, the study did not show that parabens cause cancer, or that they are harmful in any way, and the study did not look at possible paraben levels in normal tissue." *Id*. The FDA in these comments assumes parabens are safe at low levels in the human body, citing an absence of definitive proof that they cause cancer.

140. *See* Tiffany O'Callaghan, *President's Panel Analyzes Environmental Cancer Impact*, TIME MAG. (May 6, 2010), http://healthland.time.com/2010/05/06/presidents-panel-analyzes-environmental-cancer-impact/.

Perhaps one should not be surprised by this approach as we have a long history of regulating in this regard. Cigarettes, for example, were used without recourse and without government warning until 1966 with the passage of the Federal Cigarette Labeling and Advertising Act of that year.[141] During the period prior to the passage of the 1966 Act, there is much evidence that the tobacco industry hid information from the public that cigarettes were causative of lung cancer.[142] Yet, the government did not even begin to require warnings on cigarette packages or otherwise warn the public of the dangers of tobacco smoking until the 1960s.[143] In essence, cigarette and tobacco use were assumed safe for many years after they were suspected of grave harm, and federal warnings were not mandated until definitive proof could be offered linking cigarette smoking and cancer.

Similarly, the government hesitated to warn that formaldehyde, a commonly used chemical in manufacturing, still a byproduct in cosmetic formulations,[144] and found today in particle board and other wood products,[145] was a danger.[146] In 1982, it refused to issue a warning and label formaldehyde, a likely human carcinogen, stating that it did not have enough information to do so.[147] It was not until 2011 that the National

141. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331-1341). The Cigarette Labeling and Advertising Act became effective on January 1, 1966. *Id.* § 11.

142. *See, e.g.*, Ingrid L. Dietsch Field, *No Ifs, Ands or Butts: Big Tobacco is Fighting for Its Life Against a New Breed of Plaintiffs Armed with Mounting Evidence*, 27 U. BALT. L. REV. 99, 120-22 (1997) (discussing evidence from whistleblowers and others revealing that tobacco companies knew for decades of the addictive and dangerous nature of smoking, and hid such dangers from the public).

143. Pub. L. No. 89-92, 79 Stat. 282, 282 (1965); Matthew Baldini, *The Cigarette Battle: Anti-Smoking Proponents Go For the Knockout*, 26 SETON HALL L. REV. 348, 348 (1995) (noting that the federal government first addressed publicly and noted the health impact of smoking in the Surgeon General's Advisory Committee report in 1964).

144. *See supra* notes 3-5 and accompanying text.

145. NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT ON CARCINOGENS: FORMALDEHYDE, 195, 200 (12th ed. 2011), *available at* http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/formaldehyde.pdf.

146. *Id.* at 201 (noting, based on an analysis of the FDA's voluntary cosmetic product information database, almost 20% of cosmetics contain formaldehyde or certain formaldehyde-releasing preservatives).

147. *See* 47 Fed. Reg. 14366 (Apr. 2, 1982) (notice of final rule banning certain uses of formaldehyde products, in which the Consumer Product Safety

Institutes of Health officially determined that formaldehyde is a known human carcinogen.[148]

These are just a few instances where the U.S. government failed to regulate a potentially toxic substance in a precautionary manner to protect human health—instances in which the government sided with industry even in the face of mounting evidence of harm.

Yet, EDCs in our current regulatory system present a particularly troublesome quagmire for a number of reasons. First, it is uniquely difficult to determine which of the more than 80,000 chemicals on the market,[149] and at what exposure level, have the potential to disrupt the human endocrine system.[150] Second, these types of chemicals have the potential for incalculable risk.[151] EDCs threaten the ability of wildlife to reproduce,[152] and scientists believe they may be affecting humans in this same vein.[153]

To complicate matters, as to the vast cornucopia of additional existing chemicals and their degradation products, scientists have not even identified all those that are EDCs.[154] The EPA has estimated that approximately 87,000 synthetic (man-made)

Commission stated that current evidence was insufficient to conclude that formaldehyde was carcinogenic to humans).

148. NAT'L TOXICOLOGY PROGRAM, *supra* note 145, at 195 (formaldehyde was listed as "reasonably anticipated to be a human carcinogen" in 1981, and its status was changed to "known to be a human carcinogen" in 2011).

149. *See Letter to the President*, *supra* note 106. *See generally* H.R. 1385, 113th Cong. (2013); *2013 News Coverage*, CAMPAIGN FOR SAFE COSMETICS, http://safecosmetics.org/section.php?id=86 (last visited Feb. 21, 2014).

150. *See* REPORT NO. 11-P-0215, *supra* note 95, at iii (noting that fourteen years after the passage of the FQPA and the Safe Drinking Water Act, the EDSP had not determined yet whether any chemical is an endocrine disruptor); Watnick, *supra* note 68, at 1314-15.

151. *See* REPORT NO. 11-P-0215, *supra* note 95, at iii.

152. *See generally* COLBORN ET AL., *supra* note 73.

153. Don Mayer, *The Precautionary Principle and International Efforts to Ban DDT*, 9 S.C. ENVTL. L.J. 135, 147-48 (2002) (noting that exposure to infinitesimal amounts of an EDC can disrupt animals' reproductive systems); Raphael J. Witorsch, *Endocrine Disruption—History, Fact, and Fantasy of Gender Bending Chemicals*, 6 FOOD & DRUG L. INST. 32, 32 (2002) (noting a 50% decrease in sperm production worldwide between 1940 and 1990); Fassuliotis, *supra* note 84, at 357-60.

154. *See* Mayer, *supra* note 153, at 147. Scientists continue to recognize an ever-increasing number of chemicals as EDCs. *See NEHA Position on EDCs*, *supra* note 119.

chemicals need to be screened[155] for their potential endocrine disrupting effects,[156] and still new chemicals are developed and marketed every day.[157]

In the regulation of cosmetic products, we have taken a brazen "non-precautionary" approach—ignoring these potential risks and avoiding regulation and required testing. It is plainly untrue that chemicals used in cosmetics are required to be thoroughly tested in the United States before they are sold.[158] Rather, we allow industry to market chemicals to adults and children before they are extensively tested, and then wait to see if human health effects occur.[159] Dr. Richard Clapp, a professor of epidemiology at Boston University School of Public Health, and one of the experts who submitted testimony contributing to the 2010 President's Cancer Panel's report, has said that with regard to the current policy, "you have to wait until the bodies are counted before you can go back and say, 'Oh, you shouldn't allow people to be exposed to that chemical.'"[160]

155. *Endocrine Disruptor Screening Program (EDSP): Endocrine Primer*, EPA, http://www.epa.gov/endo/pubs/edspoverview/primer.htm (last visited Feb. 21, 2014) (noting that the EPA has insufficient data to assess the estimated 87,000 chemicals produced today for endocrine associated effects).

156. Mayer, *supra* note 153, at 147-48.

157. *See* COLBORN ET AL., *supra* note 73, at 106 ("Virtually anyone willing to put up the $2,000 for the tests will find at least 250 chemical contaminants in his or her body fat, regardless of whether he or she lives in Gary, Indiana, or on a remote island in the South Pacific."); O'Brien, *supra* note 40, at 337 (noting that "worldwide, 100,000 synthetic chemicals are on the market," and that chemical contamination and pollution is ubiquitous). One of the reasons that synthetic chemicals are ever-present is that they often persist in the environment and accumulate in the fatty tissue of animals. *See id.* Every year, 1,000 new synthetic chemicals are put on the market, most without testing for toxic effects. *Id.*; *see also* Applegate & Campbell-Mohn, *supra* note 78, at 221 (purporting that variables used to calculate exposure and risk of toxics are based on scientists' and policymakers' judgments and assumptions, rather than on certainty).

158. *See infra* notes 159-62 and accompanying text. *See generally* CARL F. CRANOR, LEGALLY POISONED: HOW THE LAW PUTS US AT RISK FROM TOXICANTS (2011) (offering a thorough discussion of the problem with testing and lack of cosmetics regulation).

159. *Walmart Will No Longer Sell Cosmetics, Cleaners, Made with Targeted List of Toxic Chemicals*, CAMPAIGN FOR SAFE COSMETICS, http://safecosmetics.org/article.php?id=1157 (last visited Feb. 21, 2014) (noting that Walmart has decided to ban cosmetics with ten particularly toxic substances).

160. O'Callaghan, *supra* note 140.

In a letter to President Obama that prefaced the President's Cancer Panel's report, the authors point out that the nearly 80,000 chemicals on the market in the United States that are used by millions of Americans everyday are largely untested, and that exposure to potential environmental toxins is widespread.[161] The report noted that "[o]ne such ubiquitous chemical, bisphenol A (BPA), [a suspected EDC and carcinogen], is still found in many consumer products and remains unregulated in the United States, despite the growing link between BPA and several diseases, including various cancers."[162]

C. EDCs Are Difficult to Assess

Overall, the science of EDCs[163] and their effect on humans is still relatively new and in need of greater study. But the fact that harm from them may also be dependent on an inverse bell curve,[164] meaning that lower level exposures may turn out to be more harmful than higher exposures, suggests that these chemicals present a particularly troubling regulatory scenario,[165] especially when found in varying degrees in cosmetic products. These chemicals simply do not lend themselves to traditional QRA.[166] Even given all of its shortcomings as an assessment tool, QRA, by its regulatory existence, at least forces regulators (and the public) to acknowledge, and, at the minimum, consider the potential harm of a substance.[167]

With regard to EDCs, however, we are simply not scientifically equipped to make well-educated long-term estimates of risk from exposure to these chemicals, and this inability vexes

161. *See Letter to the President*, *supra* note 106.

162. *Id*.

163. The National Research Council calls EDCs "hormonally active agents," and the National Academies Press has published a book by this name. *See generally* NAT'L RESEARCH COUNCIL, HORMONALLY ACTIVE AGENTS IN THE ENVIRONMENT (1999). A new study, funded in part by the National Institute of Environmental Health Sciences, also notes that exposure to BPA during pregnancy may affect thyroid hormone levels in pregnant women and newborn boys. *See* Chevrier et al., *supra* note 78, at 3.

164. *See Endocrine Disruptors*, *supra* note 78 (noting that small amounts of EDCs may be problematic).

165. *See* Watnick, *supra* note 68, at 1322-23.

166. *See* Watnick, *supra* note 97, at 1334-35.

167. *See* Watnick, *supra* note 68, at 1317.

our ability to begin to regulate them effectively.[168] One additional factor that complicates the current regulation of EDCs is that it is not feasible to determine safe exposure levels in the complex and interrelated world in which we live—a world in which different individuals respond differently to different chemical exposures and differing amounts of these exposures.[169] Every day, people are exposed to multiple chemicals, some of them suspected of endocrine disruption.[170] The chemicals in our environments may have different effects on different people,[171] and the various chemicals encountered may have synergistic or cumulative effects depending on an individual's past exposures and the cumulative body burden.[172] The majority of our collective research has been done in isolation—testing one chemical at a time for its effects on living tissue—when in reality, chemicals often act in concert.[173] In real life, we are bombarded on a daily basis with multiple chemicals in the environment,[174] in our water, and in our food. While one or more of these may exhibit endocrine disrupting properties alone, the effects when combined with other exposures may be synergistic and/or cumulative.[175] And finally, in this complicated scenario, even if we could determine safe exposure levels to various EDCs,[176] we would then

168. *See id*. at 1321-23.

169. *See supra* notes 72-88, 163-64 and accompanying text.

170. *See* Watnick, *supra* note 97, at 1349 n. 251.

171. *Id*. at 1319 nn. 28-29 (noting that in performing risk assessment, scientists consider the different effects that a substance may have on varying individuals, often called intraspecies variation, as well as interspecies variation).

172. *See* O' Brien, *supra* note 40, at 348-54. Many suspected EDCs are also persistent organic pollutants, which are not water-soluble, are stored in fat cells, and are difficult for the human body to excrete after exposure. *See* RACHEL CARSON, SILENT SPRING, 21-27, 178-80, 189-91 (1962).

173. O'Brien, *supra* note 40, at 350-51.

174. *Toxic Substances in Our Environment*, OR. HEALTH AUTH., http://public.health.oregon.gov/HealthyEnvironments/EnvironmentalExposures/ToxicSubstances/Pages/index.aspx (last visited Feb. 21, 2014); *see* O'Brien, *supra* note 40, at 348-51.

175. Mary L. Lyndon, *The Toxicity of Low-Dose Chemical Exposures: A Status Report and a Proposal*, 52 JURIMETRICS 457, 475 (2012) (reviewing CARL F. CRANOR, LEGALLY POISONED: HOW THE LAW PUTS US AT RISK FROM TOXICANTS (2011)).

176. *See supra* notes 149-57, 163-75 and accompanying text.

have the enormously difficult task of ensuring compliance with these pre-determined "safe" exposure levels.

III. "GAPING HOLES" IN U.S. COSMETICS LEGISLATION AND PROPOSALS FOR CHANGE

A. The Current FDA Regulations on Cosmetic Products Are Too Lax and Contain "Gaping Holes"

a. Pre-approval of Cosmetic Ingredients is Lacking

The FDA does not pre-approve cosmetic products or ingredients before distribution.[177] Although FDA regulations state that "[e]ach ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing," the inclusion of a warning simply noting that "[t]he safety of this product has not been determined" is sufficient to allow a manufacturer to legally distribute the product.[178] There is, therefore, no prospective determination, as there is under the new European Union regulations[179] that a product formulation or ingredient is safe. Rather, in the absence of data, all cosmetic products and formulations are presumed safe until definitely proven otherwise. With limited exceptions, manufacturers can use any ingredient in their product as long as the ingredient and the cosmetic product are safe (or the lack of a safety determination is noted), the product is properly labeled, and does not otherwise constitute an "adulterated" or "mislabeled" product under the FDCA.[180] Additional regulations set up voluntary programs for the registration of cosmetic product manufacturers[181] and of cosmetic ingredient statements.[182]

177. *Cosmetics: FDA Authority over Cosmetics*, FDA, (Aug. 3, 2013), http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074162.htm.

178. 21 C.F.R. § 740.10(a).

179. *See infra* notes 216, 226-30 and accompanying text.

180. *Id*.

181. *See* 21 C.F.R. §§ 710.1-710.9.

182. *See id*. §§ 720.1-720.9.

Although a series of FDA regulations do prohibit or restrict the use of certain limited ingredients in cosmetic products,[183] the regulations overall rely too heavily on voluntary industry efforts and contain huge loopholes.[184] For example, existing regulations provide a process for manufacturers to request that certain cosmetic ingredients be kept confidential as proprietary data,[185] data that the makers then do not need to list on a cosmetic ingredient list.[186] Manufacturers thus do not have to disclose all of the ingredients in their products if they bury certain ingredients in proprietary information, using ingredient code words such as "fragrance" or "flavor."[187] These one-word phrases are often allowed in place of the actual list of ingredients that make up the fragrance or flavor.[188]

Moreover, there is absolutely no incentive for a manufacturer to test its product ingredients for ill health effects, including endocrine, carcinogenic, reproductive, or neurotoxic effects, even though the manufacturer is in the best position to do so.[189] Such

183. *See id*. §§ 700.11, 700.13, 700.14, 700.15, 700.16, 700.18, 700.19, 700.23, 700.27 (regulating bithionol, mercury, vinyl chloride, halogenated salicylanilides, zirconium, chloroform, methylene chloride, chlorofluorocarbons, and certain cattle materials at heightened risk of infection with bovine spongiform encephalopathy, respectively).

184. *See supra* notes 37-40, 64-69 and accompanying text; *see infra* notes 327, 331-37 and accompanying text.

185. The listed factors to determine whether an ingredient qualifies as a confidential trade secret are:

> (1) The extent to which the identity of the ingredient is known outside petitioner's business; (2) [t]he extent to which the identity of the ingredient is known by employees and others involved in petitioner's business; (3) [t]he extent of measures taken by the petitioner to guard the secrecy of the information; (4) [t]he value of the information about the identity of the claimed trade secret ingredient to the petitioner and to its competitors; (5) [t]he amount of effort or money expended by petitioner in developing the ingredient; and (6) [t]he ease or difficulty with which the identity of the ingredient could be properly acquired or duplicated by others.

21 C.F.R. § 720.8(b).

186. *Id*. § 701.3(a).

187. *Id*.

188. *See id*.

189. *See, e.g.*, Pine St. Trading Corp. v. Farrell Lines, Inc., 364 A.2d 1103, 1109 (Md. 1976) (noting that the government has the burden to prove a product is dangerous in an condemnation action); United States v. Wash. Dehydrated Food Co., 89 F.2d 606, 608 (8th Cir. 1937) (noting that the government's burden of proof is the same as under the former Pure Food and Drug Act).

testing, if conducted at the manufacturer's expense, might lead the FDA to determine that a product is adulterated or misbranded, and to therefore prohibit the sale and distribution of the product.[190] A cosmetics manufacturer is better served in terms of marketing its product most efficiently—although perhaps not most ethically—to simply state that a product lacks appropriate safety data or proof of efficacy prior to manufacturing and sale.[191] To begin to protect human health, Congress must pass legislation requiring pre-market safety testing of cosmetics ingredients and products.[192]

b. The FDA Must Have Recall Power Based on the Reasonable Belief that a Substance is Harmful

The FDA currently does not have authority to require a mandatory recall of cosmetics.[193] This lack of recall power, and the manner in which it severely hampers FDA regulatory efforts, has been the cause of much consternation among consumers, activists, and congressional staff seeking more rigorous regulation of cosmetics.[194] The FDA has no general power of recall—it may only require recall where a court action is instituted and upheld against a mislabeled or adulterated product, thereby allowing the seizure of such product.[195]

190. *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 775 (1997) (noting that "[a] manufacturer that conducts no research can generally avoid liability because plaintiffs and government research programs are unlikely to conduct scientific research on their own").

191. *See* Wagner, *supra* note 190, at 775.

192. *See supra* notes 37-40, 64-69 and accompanying text.

193. *Id*.

194. *See, e.g.*, Victoria Farren, Note, *Removing the Wrinkle in Cosmetics and Drug Regulation: A Notice Rating System and Education Proposal for Anti-Aging Cosmeceuticals*, 16 ELDER L.J. 375, 393 (2009).

195. 21 C.F.R. § 7.40(a), (c) (2014) ("(a) Recall . . . [of] consumer products that are in violation of laws administered by the [FDA] . . . is a voluntary action. . . . (c) [S]eizure . . . or other court action is indicated when a firm refuses to undertake a recall requested by the [FDA] . . . ."). Only through court action can the FDA mandatorily seize and stop the distribution of unsafe cosmetics. *See* 21 U.S.C. § 334(a); *see also* United States v. Eight Unlabeled Cases, 888 F.2d 945, 946, 949 (2d Cir. 1989) (affirming the FDA's forfeiture and condemnation action regarding an adulterated cosmetic product).

c. Cosmetics Regulation Must Account for the Long-Term Effects of Exposure

Perhaps the most worrisome failure of our toxics regulatory system in general, and with regard to cosmetics in particular, is that it makes no meaningful accounting for the long-term effects of consumer products on human health.[196] EDCs in particular have been shown to have long-lasting, intergenerational effects,[197] as well as associations with cancer in future generations many decades after exposure.[198]

d. Cosmetics Regulation Must Account for the Differences Between Adults and Children

Our regulation of cosmetics also does not address concerns specific to children. The news over toxic chemicals in baby shampoo highlights the fact that cosmetic products designed for children are not subject to rigorous regulation.[199] Children are particularly susceptible to toxins in cosmetic products, as they take in more air and water per pound of body weight,[200] and have longer future lives to carry the burden of persistent chemicals in their bodies.[201] Additionally, they have immature skin that may be more receptive to the absorption of toxins.[202] Revised health protective cosmetics regulations would take the differences between adults and children into account, and would provide for more health protective regulation in products designed for use on children and babies.

e. Consumers Have a False Sense of Security

Finally, the biggest mistake in our cosmetic regulation paradigm may be that it gives consumers a false sense of security. Many consumers likely believe that the FDA exerts strong and

196. *See supra* notes 37-40 and accompanying text.
197. *See supra* notes 70-88 and accompanying text.
198. *See supra* notes 83-88 and accompanying text.
199. *See supra* notes 1-9 and accompanying text.
200. *See supra* notes 109-116 and accompanying text.
201. CRANOR, *supra* note 158, at 102-03.
202. *Id*. at 103.

powerful authority over cosmetic manufacturers.[203] Consumers would likely be shocked to learn that the FDA barely has the power to recall a cosmetic product suspected of potential harm. Yet, consumers see federal regulation in place, and they may assume that all that is in their drugstore is safe. The very existence of federal regulation, coupled with perceived FDA oversight, and the FDA's actual lack of strong regulatory authority likely gives consumers an unwarranted and false sense of security that lulls the populace into complacency.

f. Nanoparticles Are Not Regulated

Other than the recent and somewhat limited amendment to the FDCA, that merely encourages the FDA to further scientific study of nanomaterials,[204] there are no provisions under current U.S. law or regulation that begin to fully address health concerns over nanotechnology in consumer products. As noted above, manufacturers have no financial incentive to study nanotechnology, but can continue to market and sell these formulations in the absence of information that they are harmful to human health.[205] The use of such particles should be disallowed pending safety studies, but at the very least, federal regulations must require labeling of products containing nanoparticles so that consumers can make informed decisions about whether to choose such products.

B. The Normative Goal Must Shift in How We Regulate Consumer Products to Protect Human Health and the Environment

The idea that "[w]e can and should develop and apply standards that ensure safety to human health in our toxics

203. As far back as the 1960s, the public seemed to believe that the government was protecting "us." *See* CARSON, *supra* note 172, at 181 ("To the question, 'But doesn't the government protect us from [pesticide contamination]?' the answer is, 'Only to a limited extent.'") (noting that in that time period, the activities of the FDA were severely hampered by a lack of resources, and that state laws were not protective).

204. *See supra* notes 49-55 and accompanying text.

205. *See id*.

regulatory schemes,"[206] including as they relate to cosmetics and other consumer products, does not have solid basis in the political and scientific reality of the current world.[207] Rather, our efforts are directed at regulating to achieve a level of risk that is "politically acceptable."[208] Indeed, since consumers seem unaware of the FDA's lack of authority and real oversight in the cosmetics arena, and even assume stringent federal regulation,[209] it seems obvious from a political point of view, for politicians to continue to endorse this loose cosmetics regulatory system. In place of strong federal oversight, the cosmetics industry is instead largely allowed to self-police and market most products as they see fit, absent some showing by the public of clear potential for human harm.[210]

Even if safety were the true goal of toxics regulation and the regulation of cosmetic products, the creation of safety-based standards to regulate toxins is not a practical goal.[211] There exist

206. Watnick, *supra* note 68, at 1305. Both the Clean Air Act and the Safe Drinking Water Act require the measurement of risk through the process of risk assessment and risk management. *See* Applegate & Campbell-Mohn, *supra* note 78, at 222 (noting that risk assessment has come to dominate Congress' approach to toxics regulation).

207. Watnick, *supra* note 68, at 1305-06.

208. It is fair to note that the change in emphasis in toxics regulation from safety to acceptable risk occurred fairly recently in the 1980s as the regulatory system became solidly based on risk assessment. *See supra* notes 98-102 and accompanying text. The author would assert however, that the public is unaware of this dramatic shift in regulatory emphasis. Indeed, I have argued in the past that politicians and regulators achieve regulatory obfuscation by using terminology and standards that imply safety, using QRA where mandated, and stating that risk levels are negligible:

> For example, the FQPA states that all tolerances must be "safe." 21 U.S.C. § 346a. However, "safe" means that there exists a "reasonable certainty that no harm will result from aggregate exposure" to the pesticide residues from food and other exposures, *id.* § 346a(b)(2)(A)(ii), and this is generally assumed to mean that there exists a one-in-one-million chance that an effect will occur. *Cf.* Jay Michaelson, *Rethinking Regulatory Reform: Toxics, Politics and Ethics*, 105 YALE L.J. 1891, 1899 (1996). [. . .] This negligible risk standard is designed in keeping with the assumption that our food supply is not ever one hundred percent safe. *See id.* The one-in-one-million standard might be deemed politically acceptable risk.

Watnick, *supra* note 68, at 1306 n. 8.

209. *See* Wagner, *supra* note 190, at 774.

210. *See supra* notes 56-69 and accompanying text.

211. *See* Watnick, *supra* note 68, at 1307.

over 80,000 chemicals on the market today, the vast majority of which have not been tested for endocrine or other toxic effects.[212]

If we are to regulate these chemicals from a more health protective stance, our thinking on how we regulate synthetic substances—and especially those marketed for everyday consumer use—must change. Toward such ends, the precautionary principle mandates that when a substance is suspected of harm to human health, the substance is heavily regulated and restricted, until evidence is available to indicate that the product is not a danger to human health.[213] Under a new norm in line with the precautionary principle, products and synthetic chemicals would not be given the benefit of the doubt—they would not be "presumed innocent until proven guilty," as under the current system. This type of approach would be more consistent with those adopted in Europe and Canada, and more health protective.

IV. FOREIGN AND STATE-LEVEL COSMETICS REGULATION

A. European Cosmetics Regulation

The European Union (EU)[214] began regulating cosmetics in 1976 through the Cosmetics Directive.[215] Overall, the Cosmetics Directive is far more protective of human health than U.S. regulation. While the EU's labeling requirements are largely in line with U.S. requirements,[216] new EU regulations now go so far as to require some prospective safety findings, and also prohibit certain ingredients in cosmetics.

The original EU Cosmetics Directive requires that cosmetic products "must not cause damage to human health when applied

212. *See Letter to the President*, *supra* note 106.

213. *See* John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 13, 13 (2002).

214. *Frequently Asked Questions (FAQ),* COUNCIL OF THE EUROPEAN UNION, http://www.consilium.europa.eu/contacts/faq?lang=en&faqid=79264 (last visited Feb. 21, 2014) (noting that the EU was known as the European Community until 1993).

215. *See generally* Council Directive 76/768, 1976 O.J. (L 262) 12 (EC) [hereinafter EU Cosmetics Directive].

216. *Id*. art. 6.

under normal or reasonably foreseeable conditions of use, taking account . . . the product's presentation, its labeling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer . . . ."[217] The Cosmetics Directive further states that the inclusion of a warning label does not exempt a manufacturer or product from any requirements under the Cosmetics Directive.[218] The Cosmetics Directive includes listings of prohibited ingredients, restricted ingredients, as well as permitted colorants, preservatives, and ultraviolet filters.[219] Prohibited ingredients include those that are "carcinogenic, mutagenic or toxic for reproduction" pursuant to the EU's Dangerous Substances Directive.[220] The Cosmetics Directive also requires cosmetics manufacturers to make the following information available for government regulators: (1) the composition of the product; (2) the "physico-chemical and microbiological specifications" of all ingredients and the final product; (3) the method of manufacture of the product; (4) information regarding the assessment of the product's safety for human health; (5) data on adverse health effects from the use of the product; (6) proof of the product's effectiveness; and (7) information on any animal testing relating to the product.[221] A country in the EU may ban or restrict the

217. *Id*. art. 2.

218. *Compare* EU Cosmetics Directive, *supra* note 215 *with* 21 C.F.R. § 740.10(a) (providing that a warning label allows the distribution of a product even if it has not yet been substantiated as safe).

219. EU Cosmetics Directive, *supra* note 215, art. 4; JAN VERNON & TOBE A. NWAOGU, RISK & POL'Y ANALYSTS LTD., COMPARATIVE STUDY ON COSMETICS LEGISLATION IN THE EU AND OTHER PRINCIPAL MARKETS WITH SPECIAL ATTENTION TO SO-CALLED BORDERLINE PRODUCTS 20 (2004), *available at* http://www.pedz.uni-mannheim.de/daten/edz-h/gdb/04/j457_-_final_report_-_cosmetics.pdf (noting over 400 items on the prohibited list).

220. EU Cosmetics Directive, *supra* note 215, art. 4b.

221. *Id*. art. 7a (noting that with respect to information relating to the product's safety, the manufacturer "shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure," taking particular account of "the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended").

distribution of a product upon receiving information that such product represents a health hazard.[222]

In 2009, the European Parliament and Council further strengthened the health protectiveness of the Cosmetics Directive.[223] The new regulation, effective July 11, 2013, with some provisions in effect earlier,[224] called the New Cosmetics Regulation, provides that manufacturers—or importers, as applicable—must take immediate corrective measures to rectify non-conformity with the regulation, including withdrawing or recalling affected products, and immediately informing national regulators when a product presents a health risk.[225]

The real meat of the New Cosmetics Regulation is that prior to marketing a cosmetic product, a manufacturer must assess the safety of the product, and establish a cosmetic product safety report.[226] Information must be provided to the European Commission, including the presence of any nanomaterials—and their expected exposure conditions—and substances classified as "carcinogenic, mutagenic, or toxic for reproduction."[227] Under the New Cosmetics Regulation, manufacturers—or importers—shall maintain a product information file containing safety information on each product for a period of ten years following the date that

222. *Id*. art. 12. The Cosmetics Directive also contains a ban on products that involved testing on animals, *id*. art 4a, and requires that an inventory of ingredients used in cosmetics be compiled and published. *Id*. art. 5a.

223. *See generally* Regulation 1223/2009, of the European Parliament and of the Council of 30 Nov. 2009 on cosmetic products, 2009 O.J. (L 352) 59 [hereinafter EU Cosmetics Regulation].

224. EU Cosmetics Regulation, *supra* note 223, art. 40.

225. *Id*. art. 5.2. Distributors face obligations similar to importers and manufacturers of cosmetics. *Id*. art. 6. Manufacturers must always comply with good manufacturing practices. *Id*. art. 8. Compliance is presumed when processes comply with harmonized standards, as referenced in the EU's official journal. *Id*. art. 8.2.

226. *See id*. art. 10.1, 13.1.

227. *Id*. art. 13.1(f), (g). The New Cosmetics Regulation defines "nanomaterial" as "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm." *Id*. art. 2.1(k). The definition of "nanomaterials" will be adjusted in accordance with technical and scientific developments in the nanotechnology field. *Id*. art. 2.3.

the last batch of product was placed on the market, and shall make this information available to national regulators.[228]

This requirement of prospective safety information markedly contrasts with current U.S. regulations, pursuant to which a product is presumed safe unless information exists to suggest otherwise. Additionally, the New Cosmetics Regulation calls for identification of EDCs in cosmetic products on an expedited basis. While the New Cosmetics Regulation continues the categorization of materials with permitted, restricted, and prohibited designations,[229] it provides for the amendment of an existing categorization when substances are identified as EDCs.[230]

The New Cosmetics Regulation also takes a proactive approach concerning nanomaterials in cosmetics.[231] It states that "[f]or every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured."[232] The regulation requires manufacturers to identify: (1) the "size of particles, physical and chemical properties" of the nanomaterials; (2) an estimated amount of nanomaterials in cosmetics to be marketed per year; (3) the toxicological profile of the nanomaterial; (4) safety data of the nanomaterial; and (5) "reasonably foreseeable exposure conditions."[233] Where there is a potential risk to human health regarding nanomaterials, including when there is insufficient data available, the European Commission may add such materials to the restricted or prohibited ingredient lists.[234] Additionally, the regulation calls for the European Commission to make available to the public, by January 11, 2014, a list of all nanomaterials used in cosmetic products placed on the market.[235]

228. *Id*. art. 11 (requiring the product information file to contain information similar to that required under the Article 7a of the Cosmetics Directive). *See* EU Cosmetics Directive, *supra* note 215, art. 7a.

229. EU Cosmetics Regulation, *supra* note 223, art. 14.1(a)-(b). The New Cosmetics Regulation also continues the ban on animal testing, and contains similar product labeling requirements as in the Cosmetics Directive. *Id*. art. 18.1, 19.1.

230. *Id*. art. 15.4.

231. *Id*. art. 16.1.

232. *Id*.

233. *Id*. art. 16.3.

234. *Id*. art. 16.6.

235. EU Cosmetics Regulation, *supra* note 223, art. 16.10(a).

Moreover the manufacturer, importer and/or distributor are also required to report "serious undesirable effects" to the relevant national regulator.[236] When there is serious doubt concerning the safety of a substance contained in cosmetics, national regulators may request from manufacturers or importers a list of all their products containing such substance.[237]

Regulators may likewise require the manufacturer to withdraw or recall products for failure to comply with the New Cosmetics Regulation.[238] Such withdrawal or recall may be enforced if necessary to prevent serious health risk or if the manufacturer does not do so voluntarily.[239]

Overall, while not entirely of the long-term view, the EU's cosmetic regulations take a prospective and cautionary stance toward protecting human health.[240] In calling for disclosure of ingredient usage, such as the usage of nanomaterials[241] or suspected endocrine disrupting chemicals[242] in cosmetics, requiring prospective safety information, and providing the government with the ability to recall and force the withdrawal of products where there is doubt concerning the safety of a product,[243] the EU's New Cosmetics Regulation is decidedly more health protective than existing U.S. regulations. In all of the aforementioned ways, the New Cosmetics Regulation contrasts

236. *Id*. art. 23.1. "Undesirable effect" is defined as "an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product," while "serious undesirable effect" is "an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death." *Id*. art. 2.1(o)-(p).

237. *Id*. art. 24.

238. EU Cosmetics Regulation, *supra* note 223, art. 25.1.

239. *Id*. art. 25.5(a)-(b).

240. *See id*. art. 23. New Zealand cosmetic regulations are loosely based on the EU regulations, calling for the classification of product ingredients. *See Cosmetic Products Regulations Updated,* ENVTL. PROT. AUTH., (June 29, 2012), http://www.epa.govt.nz/news/erma-media-releases/Pages/Cosmetic-Products-regulations-updated.aspx_(N.Z.). *See generally* HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996, ENVTL. PROT. AUTH. (2012) (N.Z.), *available at* http://www.epa.govt.nz/Publications/Cosmetic%20Products%20Group%20Standard.pdf.

241. EU Cosmetics Regulation, *supra* note 223, art. 16.10(a).

242. *Id*. art. 15.4.

243. *See id*. art. 25.1.

markedly with the lack of such provisions and FDA authority in the United States.[244]

B. Canadian Cosmetics Regulation

Under the Canadian Food and Drugs Act,[245] prohibited cosmetics are those: (1) containing "any substance that may cause injury to the health of the user . . . [or] any filthy or decomposed substance," or (2) which were "manufactured, prepared, preserved, packaged or stored under unsanitary conditions."[246] While these regulations at first glance seem similar to U.S. cosmetics regulation, the Canadian regulations actually take a more health protective stance. Canadian regulations[247] prohibit the sale of cosmetics containing an estrogenic substance.[248] Health Canada, the Canadian federal regulator with authority over cosmetics, also prepares and updates a Cosmetics Ingredient Hotlist, which notes ingredients that are either prohibited or restricted from use in cosmetic products.[249]

Importantly, the Canadian regulations allow the government to request that a manufacturer submit evidence of a cosmetic product's safety, and to require the halting of sales if such information is not provided or is incomplete.[250] The Canadian regulations also require manufacturers and importers to promptly file with the government information about the manufacture and composition of a cosmetic product within ten days of first selling the product.[251] As expected, the Canadian cosmetic regulations contain general labeling requirements, but additionally, the Canadian regulations also prohibit, without evidence, labeling claims about: "(a) the ability of the cosmetic or any of its ingredients to influence the chemistry of the skin, hair or teeth; or (b) the formulation, manufacture or performance of

244. *See supra* notes 177-205 and accompanying text.
245. *See generally* Food and Drugs Act, R.S.C. 1985, c. F-27 (Can.).
246. *Id*. § 16.
247. *See generally* Cosmetic Regulations, C.R.C., c. 869 (Can.).
248. *Id*. § 15(b).
249. *List of Prohibited and Restricted Cosmetic Ingredients ("Hotlist")*, HEALTH CANADA, http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/index-eng.php (last visited Feb. 21, 2014).
250. C.R.C., c. 869, § 29 (Can.).
251. *Id*. § 30.

the cosmetic that would imply that the user . . . will not suffer injury to their health."[252]

C. Regulation of Cosmetics in Japan

Cosmetic products in Japan are regulated under the Pharmaceutical Affairs Law, which was first enacted in 1943.[253] Prior to 2001, manufacturers and importers had to obtain pre-market approval for every ingredient used in a cosmetic product from the Ministry of Health, Labor and Welfare.[254] Following a deregulation of the cosmetics industry, making the Japanese system a mirror of the U.S. system,[255] manufacturers and importers now merely need to notify the government of the product's brand name prior to distribution.[256] The revised Japanese cosmetics regulatory system still requires pre-approval for the use of certain types of ingredients (e.g. colorants, preservatives, and ultraviolet filters),[257] and other chemicals not subject to pre-approval may be disallowed or only allowed on the condition that they are sold with safe use instructions or warning labels after government review.[258]

D. State Regulation of Cosmetics—California

In 1986, Californian voters supported ballot proposal Proposition 65, under the Safe Drinking Water and Toxic Enforcement Act, to regulate chemicals in drinking water and toxic substances in the general environment.[259] Although Proposition 65 is not directed specifically at cosmetic products, it

252. *Id*. § 21.1. Health Canada can request that such evidence by submitted to it by the manufacturer. *Id*. § 21.2.

253. VERNON & NWAOGU, *supra* note 219, at 27-28; *see* Giovanni Pisacane, *Cosmetics Market Regulation in Asian Countries*, 4 HOUSEHOLD & PERSONAL CARE TODAY 21 (2009), *available at* http://www.greatwaylimited.com/admin/upload/Cosmetic%20market%20regulation%20in%20Asian%20Countries.pdf.

254. VERNON & NWAOGU, *supra* note 219, at 29.

255. *See id.*

256. *Id*.

257. Janet Winter Blaschke, *Globalization of Cosmetic Regulations*, 60 FOOD & DRUG L.J. 413, 414-15 (2005).

258. *See id*. at 415.

259. *See Proposition 65*, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, http://www.oehha.org/prop65. html (last visited Feb. 21, 2014).

regulates certain chemicals found in cosmetics. Proposition 65 is, to the author's knowledge, the most stringent health protective toxic substances regulation in the United States.

Proposition 65 prohibits the discharge of chemicals known to cause cancer or reproductive toxicity into the water,[260] and requires that products containing these chemicals contain a warning label.[261] Consumer products, including cosmetics, which contain materials included on the list of hazardous chemicals in Proposition 65, are required to include one of the following warnings: "WARNING: This product contains a chemical known to the State of California to cause cancer" or "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."[262]

Proposition 65 also requires California to publish an annual list of chemicals that cause cancer or reproductive toxicity.[263] Pursuant to Proposition 65, California thus established the Carcinogenic Identification Committee and the Developmental and Reproductive Toxicant Identification Committee,[264] both to determine whether chemicals have been found to cause cancer or reproductive toxicity,[265] and also to identify federal and international bodies whose findings may be considered as authoritative.[266]

Proposition 65 has thus required stricter, more health protective regulation of cosmetics in California. California's Office of Environmental Health Hazard Assessment, which administers the Proposition 65 provisions, for example, lists toluene, found often in nail care products, on the annual list of hazardous chemicals for which labels are required to warn that the chemical "causes birth defects or other reproductive harm."[267]

260. CAL. HEALTH & SAFETY CODE § 25249.5 (West 2014).
261. *Id*. § 25249.6.
262. CAL. CODE REGS. tit. 27, § 25603.2 (2014).
263. CAL. HEALTH & SAFETY CODE § 25249.8(a).
264. CAL. CODE REGS. tit. 27, § 25302.
265. *Id*. § 25305.
266. *Id*. § 25306. The EPA and the FDA are among the regulatory and other bodies that have been identified as authoritative. *Id*. § 25306(l)-(m).
267. PROPOSITION 65 IN PLAIN LANGUAGE!, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT 4 (2013), *available at* http://www.oehha.org/prop65/pdf/P65Plain.

In 2005, the California Legislature furthered the health protective initiative of Proposition 65 by enacting the California Safe Cosmetics Act (CSCA).[268] Under the CSCA, California's Department of Public Health runs the California Safe Cosmetics Program.[269] The Safe Cosmetics Program compiles a list of all chemicals known or suspected of causing cancer, birth defects, or reproductive harm, and maintains a publicly available database containing ingredient information.[270]

Central to the CSCA is also the requirement that cosmetics manufacturers report to the State Department of Public Health any products containing "any ingredient that is a chemical identified as causing cancer[271] or reproductive toxicity."[272] The CSCA specifically requires that ingredients listed as "fragrance," "flavoring," "other ingredient," or ingredients otherwise treated as a trade secret under federal regulations, must be identified and listed.[273]

With respect to cosmetics marketed as containing "organic" products, regulations under California's Organic Products Act of

pdf. The Proposition 65 list now contains approximately 800 substances. *Id*. at 1.

268. Amity Hartman, *FDA's Minimal Regulation of Cosmetics and the Daring Claims of Cosmetic Companies That Cause Consumers Economic Harm*, 36 W. ST. U. L. REV. 53, 68-69 (2008); *see* CAL. HEALTH & SAFETY CODE §§ 111791-111793.5.

269. *California Safe Cosmetics Program*, CAL. DEP'T OF PUB. HEALTH, http://www.cdph.ca.gov/programs/cosmetics/Pages/default.aspx (last visited Feb. 21, 2014) [hereinafter *California Safe Cosmetics Program*].

270. *California Safe Cosmetics Program*, *supra* note 269.

271. The CSCA defines "[c]hemical identified as causing cancer or reproductive toxicity" as a substance: (1) "known or reasonably anticipated to be a human carcinogen in a National Toxicology Report on carcinogens"; (2) evaluated to be a carcinogen by the International Agency for Research on Cancer; (3) identified as a known or likely carcinogen by the EPA; or (4) a "substance identified as having some or clear evidence of adverse developmental, male reproductive, or female reproductive toxicity effects in a report by an expert panel of the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction." CAL. HEALTH & SAFETY CODE § 111791.5(b)(1)-(4).

272. *Id*. § 111792(a); Hartman, *supra* note 268, at 69. Manufacturers with less than $1 million of cosmetics sales within and outside of California would not be subject to the requirement to report the use of materials that cause cancer or have reproductive toxicity. CAL. HEALTH & SAFETY CODE § 111792(d).

273. CAL. HEALTH & SAFETY CODE § 111792(a)(1)-(2).

2003[274] have been promulgated requiring that cosmetic products with labels stating "organic" must have "at least 70% organically produced ingredients."[275] In contrast, neither federal law nor FDA regulations police the meanings of the terms "natural" or "organic" with respect to cosmetic products.[276]

V. PROSPECTIVE U.S. REGULATION

A. Federal Proposals: Mistakes from the Past

Current proposals to improve the safety of U.S. cosmetics regulation generally do not go far enough to effect changes in the overall regulatory paradigm.[277] They continue to operate from the stance that a chemical or product formulation is safe until proven otherwise.[278] Several new proposals for federal law in recent years have, however, attempted to strengthen U.S. cosmetics regulation within the existing toxics regulation paradigm. The Safe Cosmetics and Personal Care Products Act, introduced by Congresswoman Jan Schakowsky (D-Ill.) and currently in committee, goes furthest, requiring prospective safety information, prior to the marketing of a cosmetic product.[279]

The proposed Enhancement Act, introduced in 2012,[280] would have amended the FDCA to require the registration of cosmetic products and cosmetic manufacturing facilities.[281] A facility's registration would have been subject to suspension for violations of the FDCA if such violations could have resulted in serious adverse health consequences or death to humans or animals.[282]

274. *See id*. §§ 110810-110959.
275. Hartman, *supra* note 268, at 70 (internal quotation marks omitted).
276. *See id*.
277. *See infra* notes 279-364 and accompanying text.
278. *Id*.
279. *See* H.R. 1385, 113th Cong. (2013); *infra* notes 319-364 and accompanying text.
280. *See* H.R. 4262, 112th Cong. (2012). Rep. Frank Pallone, Jr. (D-N.J.) introduced the Enhancement Act, and the bill was referred to the House Committee on Energy and Commerce on March 26, 2012. *Id*.
281. *Id*. § 2(c).
282. *Id*.

The Enhancement Act boldly called for cosmetic manufacturers to establish a file of scientific evidence demonstrating a product's safety before introducing the cosmetic product into commerce.[283] It defined "safe" as "evidence in the file established [pursuant to the Enhancement Act] demonstrat[ing] that there is a reasonable certainty that no harm will result from the use of the cosmetic product under the intended conditions of use for such cosmetic product."[284]

Manufacturers, packers and distributers would have also been required to submit to the FDA, within fifteen business days of receipt, reports of any serious adverse event which they received regarding the use of their cosmetics in the United States, and to have maintained records of all information about serious adverse effects for a period of six years.[285] For this purpose, the Enhancement Act defined "serious" as: "(A) resulting in—(i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a disability, disfigurement, or incapacity; or (v) a congenital anomaly or birth defect; or (B) requiring, based on reasonable medical judgment, a medical or surgical intervention to prevent [any of the previously listed outcomes]."[286] Cosmetics manufacturers would have needed to make available to the FDA all records regarding cosmetic products that are misbranded or adulterated under the FDCA.[287]

The Enhancement Act also called for the Secretary of Health and Human Services, (the Secretary), to promulgate new regulations establishing "good manufacturing practices for cosmetics,"[288] and products not made in accordance with good manufacturing practices would have been designated as "adulterated" under the FDCA.[289] In addition, the bill would have allowed manufacturers to voluntarily recall a cosmetic product that was likely adulterated where the use of the product

283. *Id*. § 3(b).

284. *Id*. The Enhancement Act would also have required the payment of $500 by each registering facility for annual registration fees, beginning in 2013. *Id*. § 2(d). This fees provision was scheduled to sunset, with no fees authorized after 2017. *Id*.

285. H.R. 4262 § 4(c), 112th Cong. (2012).

286. *Id.* § 4(c).

287. *Id*. § 5(a).

288. *Id*. § 6(b).

289. *See id*. §§ 2(b), 6(a).

would cause serious adverse health consequences or death to humans, and it would have allowed the FDA to order a mandatory recall if a voluntary recall is not obtained.[290]

While a law introduced along the lines of this bill would have been an improvement over current law, given the inclusion of FDA authority to issue a recall, and the limited requirements that manufacturers show product safety before it goes to market, the Enhancement Act was lacking in its failure to attack the issue of trade secrets and proprietary information in consumer cosmetic products.[291] Additionally, the efficacy of the somewhat ambiguous language requiring "good manufacturing practices" is questionable, given the FDA's history of deferring to industry in terms of adopting any new manufacturing rules.[292]

The Amendments Act, another federal legislative proposal, introduced by Rep. Leonard Lance (R-N.J.) in 2012,[293] also required the registration of cosmetics manufacturers and of cosmetic products.[294]

Only manufacturers performing the final steps of the manufacturing process would have been required to register, and the registration would have consisted of the company's name,

290. *Id*. § 7(b).

291. The Enhancement Act is silent on the matter of trade secrets or proprietary information. Furthermore, serious adverse event reports would be classified as medical files that are not subject to public disclosure. H.R. 4262 § 4(c), 112th Cong. (2012).

292. *See, e.g.*, Schaffer, *supra* note 66, at 200-01. Schaffer describes the history of good manufacturing practices for eye makeup as follows:

> In 1977, FDA announced that it intended to institute Good Manufacturing Practices for eye makeup preservatives as a first step towards Good Manufacturing Practices for all types of cosmetics. Rather than protesting against such imposition of Good Manufacturing Practices, the [Cosmetic, Toiletry and Fragrance Association] merely filed a petition stating what the industry would prefer to see in Good Manufacturing Practices. FDA then incorporated the cosmetics industry's petition into the Good Manufacturing Practice guidelines featured in the FDA 'Investigations Operations Manual.' Since then, FDA has removed the guidelines and so ended federal cosmetics Good Manufacturing Practices altogether.

Id.

293. *See* H.R. 4395, 112th Cong. (2012).

294. *Id*. §§ 3-4.

address, and other contact information.[295] The FDA could have thus suspended a manufacturer's registration for violations of the FDCA, where such violation presented a "significant risk of serious adverse health consequences or death to humans."[296] The bill called for exceptions to product registration, where manufacturers had previously filed voluntary cosmetic ingredient statements that contained what the FDA has determined to be confidential trade secrets.[297] This allowance for the continuation of the "trade secret formulation" severely weakened the bill.

As under the Enhancement Act, the Amendments Act would have required the filing of unexpected, adverse event reports with the FDA within fifteen business days,[298] but it did not require the filing of a report for an adverse event that was listed on the current labeling.[299] The Amendments Act also specifically stated that adverse effect reports do not "constitute an admission that the cosmetic involved, caused or contributed to the adverse event."[300] The Amendments Act explicitly stated that, "a cosmetic shall be deemed to be safe if it does not present a risk of significant illness or injury to humans under the conditions of use recommended or suggested in the labeling."[301]

The Amendments Act would also have required the Secretary to issue rules establishing good manufacturing processes for cosmetic products.[302] In contrast to the Enhancement Act, under the Amendments Act, cosmetic products made in ways that did not follow good manufacturing processes would not have been automatically considered to be adulterated.

295. *Id*. § 3.

296. *Id*. Note that, unlike the Enhancement Act, this provision does not address health consequences or death to animals. H.R. 4262 § 2(c), 112th Cong. (2012).

297. H.R. 4395 § 4, 112th Cong. (2012). Note that the actual text of the Amendments Act regarding these exceptions is inaccurate in its cross-references to existing regulations. It refers to cosmetic ingredient statements filed under 21 C.F.R. § 710, although such statements are authorized under 21 C.F.R. § 720.8(b). Section 710 actually concerns the voluntary registration of cosmetic product establishments (manufacturers and packers).

298. H.R. 4395 § 5, 112th Cong. (2012).

299. *See id*.

300. *Id*.

301. *Id*. § 12.

302. *Id*. § 6.

The Secretary would also have been permitted, or required in response to a petition, to establish tolerance levels for nonfunctional constituents in cosmetics.[303] In this manner, this bill introduced the questionable QRA process that governs so much of toxics regulation.[304] A "nonfunctional constituent" in a cosmetic is defined as "any substance that is an ancillary part of an ingredient or the manufacturing process, has not been added as a separate substance, and serves no cosmetic function in the cosmetic."[305] The law would thus have required that the tolerance level be set at a level that is "necessary for the protection of the public health using generally recognized principles of scientific risk assessment," and required risk assessors to consider what is "reasonably achievable through good manufacturing practices," and ensure that such tolerance level is consistent with that established by authoritative scientific or regulatory organizations.[306] As noted elsewhere in this article, while signaling recognition of potential risk, this proposed reliance upon the highly subjective QRA process with respect to cosmetics—many containing EDCs—would be extremely problematic.[307] This is especially true with the bill's limitation in setting any tolerance to that which is "reasonably achievable," opening the door to a potential weakening of the safety standard.[308]

Another extremely significant problem with the Amendments Act was that findings in a final report by the CIR Expert Panel, privately organized and funded by the cosmetics industry,[309] regarding the safety of a cosmetic product would have been deemed recommendations to the Secretary, and would have been accepted unless the Secretary specifically determined otherwise.[310] The bill stated that the CIR Expert Panel could determine whether a cosmetic ingredient:

303. *Id*. § 7.
304. *See* Watnick, *supra* note 68, at 1316-26.
305. H.R. 4395 § 7, 112th Cong. (2012).
306. H.R. 4395 § 7, 112th Cong. (2012).
307. *See supra* notes 97-104 and accompanying text.
308. *Id.*
309. *About the Cosmetic Ingredient Review*, COSMETIC INGREDIENT REV., http://www.cir-safety.org/ about (last visited Feb. 21, 2014).
310. H.R. 4395 § 8, 112th Cong. (2012).

> (1) is safe for use in cosmetic products without the need for specified conditions of use; (2) is safe for use in cosmetic products under specified conditions for use; (3) is not safe for use in a cosmetic product under any conditions of use; [or] (4) requires more information in order to make a determination whether the ingredient is safe for use in a cosmetic product under any conditions or use. . . .[311]

Thus, the Secretary could ban cosmetic ingredients that fall under determinations (3) and (4), or (2) if there were noncompliance with applicable conditions. This reliance on an industry organization, where the Secretary does not generally have the resources to "determine otherwise" also weakened this bill considerably.[312]

The Amendments Act also permitted—or required, in response to a petition—the Secretary to evaluate the safety of any ingredient in a cosmetic product, and establish conditions for the safe use of such ingredient.[313] Again, this presumed that the Secretary had the resources and political will to identify and then test suspicious ingredients or products—a specious presumption at best.

The proposed Amendments Act would also have authorized the creation of a National Cosmetic Regulatory Databank, which would have included: cosmetic manufacturing registrations; cosmetic ingredient statements; adverse event reports; and other information deemed appropriate.[314] The Secretary would also have been given access to company records to determine whether a cosmetic product was adulterated and presented a threat of serious adverse health consequences or death to humans.[315] This access to records was, however, significantly limited by the condition that the provision "[did] not extend to cosmetic product formulas," and other potentially proprietary data.[316]

Another provision in the Amendments Act would have prohibited states or localities from establishing laws regarding

311. *Id*.
312. *See supra* notes 37-40, 64-69 and accompanying text.
313. H.R. 4395 § 9, 112th Cong. (2012).
314. *See id.* § 10.
315. *Id.* § 11.
316. *Id.*

cosmetics that differ from the requirements of the FDCA, or from rules promulgated by the Secretary.[317] The Amendments Act did provide that imported cosmetics would have to have cosmetic establishment registration numbers and cosmetic ingredient statement numbers—numbers that are now only voluntarily provided by importers.[318]

B. The Safe Cosmetics and Personal Care Products Act of 2013

The Safe Cosmetics and Personal Care Products Act of 2013 (SCA),[319] the strongest of the three recent federal proposals, and the one that is currently in the House of Representatives that would amend the FDCA, was first introduced under a slightly different name in the House of Representatives during 2011.[320] The SCA was a revised version of the 2010 Safe Cosmetics Act, which did not survive committee.[321] The SCA provides for the mandatory registration of cosmetic products manufacturers.[322] Registration would include all cosmetic products made, gross sales from such products, and the source and name of ingredients received from other entities.[323] Under the SCA, the Secretary would compile a list of all registered establishments and make such list available to the public.[324] Registered establishments would also need to pay an annual registration fee, as set by the Secretary, which would vary based on the establishment's gross

317. *Id*. § 14.

318. *See id*. § 15; *see Voluntary Cosmetic Registration Program (VCRP)*, FDA, http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/#Registering_establishments (last visited Feb. 28, 2014).

319. *See* H.R. 1385, 113th Cong. (2013).

320. *See* Tobias J. Gillett, Note, *Lessons from Nutritional Labeling on the 20th Anniversary of the NLEA: Applying the History of Food Labeling to the Future of Household Chemical Labeling*, 37 WASH. U. J.L. & POL'Y 267, 294 (2011).

321. *Id*. at 294 n. 181.

322. H.R. 1385 § 612(a). Microbusinesses, defined as businesses with less than $2 million in annual sales receipts for cosmetic products, would be exempt from registration under the SCA. *Id*. §§ 611(7), 612(a)(1).

323. *See id*. § 612(b).

324. *Id*. § 612(d).

receipts or sales, and would only be imposed on companies with annual gross receipts or sales in excess of $10 million.[325]

The SCA would also change the reporting of cosmetic ingredients. "Ingredient" would be specifically defined to include the components of a "fragrance, flavor or preservative,"[326] thus eliminating the "trade secret" loophole.[327] Additionally, the ingredient list would be required to incorporate any contaminants that are present at more than the lower of: (1) "one part-per-billion by weight of product formulation;" or (2) "one percent of the restriction on the concentration for such contaminant for such use, as determined [on the list of restricted ingredients]."[328] The SCA would also authorize the Secretary to require ingredients to be specifically labeled as "nano-scale" if particles are 100 nanometers or smaller in at least one dimension, or require other scale-specific ingredient information if such ingredients pose scale-specific hazards.[329] Web pages selling cosmetics would similarly be required to present complete ingredients lists.[330]

The SCA also calls for the Secretary to establish safety standards for cosmetics and ingredients that provide a reasonable certainty of no harm from exposure and protect consumers "from any known or anticipated adverse health effects . . . ."[331] "Reasonable certainty of no harm" is defined as no harm caused to members of the general public or any vulnerable population[332] from aggregate exposure, taking into account low-dose exposures, additive effects from repeated exposure over time, and cumulative exposure from all sources including from cosmetic and environmental sources.[333] Safety standards would be intended to meet either of two tests: (1) likely exposure will not result in

325. *Id*. § 612(e).
326. *Id*. § 611(5)(E).
327. *Id*. § 613(f); *see supra* notes 183-88 and accompanying text.
328. H.R. 1385 § 613(c), 113th Cong. (2013).
329. *Id*. § 613(d).
330. *Id*. § 613(e).
331. *Id*. § 614(a)(1).
332. "Vulnerable populations" under the SCA would include "pregnant women, infants, children, the elderly, and highly exposed populations, including workers employed by hair salons, nail salons, beauty salons, spas, other establishments that provide cosmetic treatment services for humans, and cosmetic manufacturing plants." *Id*. § 611(13).
333. *Id*. § 611(9).

"more than a one-in-a-million risk for any adverse health effect in any vulnerable population at the lower 95th percentile confidence interval;" or (2) exposure will produce no adverse health effects with a margin of safety of at least 1000, and considering cumulative exposure from all sources.[334] The SCA would also require the Secretary to establish good manufacturing practices for cosmetics manufacturers.[335] The inclusion of this one-in-a-million standard is generally considered to be a negligible risk standard.[336] Moreover, the addition of the vulnerable population as the benchmark, as well as recognition of the potential long-term effects of consumer cosmetic products, makes the standard considerably more health protective than other ostensibly health-based standards.[337]

Manufacturers would thus be required under the SCA to provide to the FDA all information regarding safety of their cosmetics and ingredients.[338] This safety data would include information functions and uses, information on physical, chemical, and toxicological properties, exposure and rate information, and the results of all safety tests.[339] The FDA would also be required to establish a publicly available database of all non-confidential safety information provided.[340] The FDA would use this information, as well as information from other authoritative sources, to evaluate the safety of cosmetics and their ingredients, specifically considering the potential harms of nanomaterials.[341]

The SCA would also establish lists of prohibited, restricted, and "safe without limits" ingredients for use in cosmetic products, in a manner akin to the EU cosmetics regulations.[342] To determine the placement of substances on any of the lists, the FDA would take into account whether the substance: (1) reacts

334. H.R. 1385 § 614(a)(2)(A)-(B), 113th Cong. (2013).
335. *Id*. § 614(b)(1).
336. Watnick, *supra* note 97, at 1337.
337. Our past failure to consider vulnerable populations such as children and pregnant woman has been the author's long-time criticism of U.S. toxics regulatory frameworks. Watnick, *supra* note 97, at 1320-24.
338. H.R. 1385 § 615(a)(1)(A)-(B), 113th Cong. (2013).
339. *Id*. § 615(a)(2)(A)-(D).
340. *Id*. § 615(b)(1).
341. *Id*. § 615(c)(1)-(2).
342. *Id*. § 616(a)(1)(A)-(B).

with other substances; (2) is found in the body; (3) is found in drinking water or air; (4) is a "known or suspected neurological or immunological toxicant, respiratory asthmagen, carcinogen, teratogen, or endocrine disruptor, or [has] other toxicity concerns (including reproductive or developmental toxicity)"; or (5) is known to persist in the environment or living tissue.[343] Under the SCA, manufacturers would thus be required to eliminate or restrict the use of ingredients on the prohibited or restricted lists within one year of listing.[344] A further priority assessment list would be established for items that cannot be otherwise listed for lack of information, and for which a safety determination is a priority.[345] If, within five years of placement on the priority assessment list, there is insufficient information to list the substance on the prohibited, restricted, or "safe without limits" lists, such ingredient would be prohibited from use in cosmetic products.[346]

Cosmetic products made of only ingredients in the "safe without limits" use or the restricted list—where such use is in compliance with the restrictions on the use—would be presumed to meet safety standards.[347] However, manufacturers might be required to establish a product's safety if it "contains penetration enhancers, sensitizers, estrogenic chemicals, or other similar ingredients," or contains ingredients that interact to form harmful byproducts.[348] This latter requirement seems aimed at protecting against interactions in products as seen in the baby shampoo news headlines.[349]

The FDA would be mandated under the SCA to establish a list of: (1) cosmetic ingredients that may contain contaminants; (2) ingredient combinations that may create contaminants; (3)

343. *Id*. § 616(a)(2)(A)-(E). The SCA defines "reproductive or developmental toxicity" as contributing to "biologically adverse effects on the development of humans or animals, including effects on the female or male reproductive system, the endocrine system, fertility, pregnancy, pregnancy outcomes, or modifications in other functions of the body that are dependent on the integrity of the reproductive system as well [as] normal fetal development. *Id*. § 611(10).

344. H.R. 1385 § 616(b)(4)(A)-(B), 113th Cong. (2013).

345. *Id*. § 616(d)(1)(A)-(B).

346. *Id*. § 616(d)(6)(A).

347. *Id*. § 617(b)(1)(A)-(C).

348. *Id*. § 617(b)(2)(A)-(B).

349. *See supra* notes 3-5 and accompanying text.

contaminants that may leech from product packaging; or (4) any other cosmetic contaminant.[350] The FDA then would establish testing procedures for the listed contaminants.[351] The FDA would be required to respond within six months to reasonable petitions to add items to the prohibited, restricted, or priority assessment lists, remove items from the "safe without limits" list, or add items to the list of contaminants.[352] In this way, the FDA would, for the first time, have to promptly respond to consumer concerns regarding cosmetic formulations.

Also under the SCA, brand owners would be required to report adverse health effects to the FDA.[353] Such reports would be made accessible to the public, with redactions for personally identifiable information.[354] Another provision of the SCA specifically provides that any non-confidential information submitted to the FDA would be made available to the public, including: (1) the name, identity, and structure of substances, contaminants, or impurities; (2) information regarding "the function, exposure, toxicity data, health hazards, and environmental hazards for a cosmetic;" (3) the function of ingredients in a cosmetic; and (4) cosmetic fragrance, flavor, and colorants.[355] The concentration of ingredients, however, in a finished product would be considered confidential business information, and would not be made available to the public.[356] Entities would be permitted to petition for information to remain confidential by showing that the release would have a serious negative impact on its commercial interests, although the FDA could choose to not prevent the disclosure of: (1) the name, identity, and structure of an ingredient, contaminant, or impurity; or (2) the health and safety data related to the ingredient, contaminant, or impurity.[357] And finally, any cosmetic brand owner, manufacturer, packager, retailer, or distributor with reason to believe that a cosmetic is "adulterated

350. H.R. 1385 § 618(a)(1)-(4), 113th Cong. (2013).
351. *Id*. § 618(c).
352. *Id*. § 621(a)(1)-(4).
353. H.R. 1385 § 622(a), 113th Cong. (2013).
354. *See id*. § 622(d)(1)-(2).
355. *Id*. § 623(a)(1)-(4).
356. *Id*. § 623(b).
357. *Id*. § 623(c)(1)-(2).

or misbranded in a manner that presents a reasonable probability" of causing severe adverse health effects or death would have to notify the Secretary.[358]

Under the SCA, the FDA would thus have the clear authority to issue a voluntary recall and give notice of this recall if it believed a cosmetic was adulterated, misbranded, or otherwise in violation of the FDCA (as amended).[359] And, if this voluntary recall were not observed, to order that the product sales cease, and to ultimately order a mandatory recall.[360]

The SCA would also mandate that the FDA establish alternative testing procedures to minimize the testing of ingredients and cosmetics on animals.[361] Under the SCA, the FDA would also conduct annual tests of random cosmetic samples, testing for "negative reactions, pathogen hazards, contaminants, leaching of packaging additives, mislabeling, or other relevant issues of concern . . . ."[362]

The SCA would likewise significantly broaden the definitions of adulterated and misbranded cosmetics to include cosmetics that: (1) do not meet established safety standards; (2) contain ingredients on the prohibited list or the restricted list, in excess of the limits established by such list; (3) do not properly list or package their products; or (4) do not pay fees and report severe adverse effects.[363]

Overall, the SCA would significantly strengthen U.S. cosmetics law by: (1) requiring the registration of cosmetic manufacturers; (2) creating a prohibited and "safe without limits" list of ingredients; (3) doing away with the trade secret and proprietary information loopholes; and (4) requiring manufacturers to share safety testing and provide adverse health

358. *Id*. § 620(a)(1).

359. H.R. 1385 § 620(b), 113th Cong. (2013). If there was reason to believe that a cosmetic might cause serious adverse health effects or death, is misbranded, or is manufactured by an unregistered facility, the FDA could issue an order stopping distribution of the product or an order to mandatorily recall the cosmetic under the SCA. The FDA might also provide information regarding any recall to the general public and to state and local officials. *Id*. § 620(c)–(d), (f).

360. *See* H.R. 1385 § 620(c), 113th Cong. (2013).

361. *See id*. § 624(a)(1).

362. *Id*. § 625.

363. *See id*. §§ 601, 602.

effects information. Furthermore, the addition of clear FDA recall authority under the bill would be a significant and quite telling step forward in our effort to regulate U.S. cosmetics to protect human health and the environment. Given the failure of earlier versions of this bill to survive committee, the political feasibility of such a measure seems questionable absent a monumental shift in public awareness and pressure.[364]

VI. CONCLUSION

Current U.S. cosmetics law and regulations contain abundant loopholes and weaknesses, such that they do not adequately protect human health. The current regulatory framework does not call for a consideration of the special susceptibility of children, pregnant or breastfeeding women, other vulnerable populations, the potential for danger from EDCs, or the potential for long-term or synergistic harm from synthetic chemicals. It also provides no meaningful recall process for the FDA in the cosmetics arena.

A new regulatory structure should give the FDA recall power, and require pre-approval of cosmetic formulations and ingredients based on up-to-date safety data before a product goes to market, as has been required in other jurisdictions. If we are to become more health protective in our regulation of consumer products, the U.S. regulatory paradigm, for cosmetics in particular and for all consumer products, must shift to a more precautionary approach. Models for more health protective legislation are found in many jurisdictions in the developed world, including Europe, Canada, and Japan, and at home, in California. Proposed U.S. legislation to strengthen existing law would offer improvements within the existing paradigm, but at least two of the most recent federal proposals do not go nearly far enough to make human health a priority, and the third proposal, the SCA, has not been politically feasible when introduced in varying forms in prior Congressional sessions. Consumer awareness and resulting public pressure would go a long way

364. *See supra* notes 5, 159 and accompanying text (noting that planned and existing corporate changes by Johnson & Johnson and by Walmart were largely attributed to public pressure).

toward strengthening U.S. cosmetic products regulation to make it more health protective.