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Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics

Rachael Rawlins*

*University of Texas at Austin

ARTICLES

TEETHING ON TOXINS: IN SEARCH OF REGULATORY SOLUTIONS FOR TOYS AND COSMETICS

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I. INTRODUCTION

We are exposed, without our knowledge or consent, to a multitude of chemicals every day. Chemicals are quietly leaching from consumer products. We ingest and absorb these chemicals as they leach from every day plastics and penetrate our skin through cosmetic and other products. Recent studies have begun to expose both the extent of chemical contamination in blood, urine, and breast milk, and the extent to which consumer products may be contributing to this potentially toxic soup.[1]

This article takes a close look at the current federal regulatory regime for cosmetic and child care products in particular, and chemical regulation more generally, as well as recent legislative action in the U.S. and Europe, and concludes with a discussion of possible regulatory solutions. This article focuses on toys and cosmetic products in

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* Rachael Rawlins, Faculty Fellow, Center for Sustainable Development Lecturer, The University of Texas at Austin. Rachael Rawlins is an environmental and land use attorney that has practiced law in both the public and private sector. Ms. Rawlins has been teaching the law classes in the graduate Community and Regional Planning and Historic Preservation programs since 1996. Ms. Rawlins is a member of the State Bar in both Texas and California, and is active in public service. She has served as a planning commissioner for the City of Austin, and is currently involved in a national campaign to reduce toxins in consumer products.

1. *See* Environmental Working Group, http://www.ewg.org/sites/humantoxome/ (last visited Feb. 15, 2009) (the Environmental Working Group (EWG), a non-profit research organization, has completed 6 studies finding a total of 455 industrial pollutants, pesticides and other chemicals in blood, urine and breast milk of 72 people. Many of these chemicals are known carcinogens or endocrine disruptors); *see also* Center for Disease Control, Third National Report on Human Exposure to Environmental Chemicals (July 2005), http://www.cdc.gov/exposurereport/pdf/thirdreport.pdf (identifying 148 manmade substances in the bodies of U.S. citizens).

particular because the regulatory control over these products is unbelievably weak given the sensitive populations exposed, including particularly children and women of reproductive age, and the non-essential nature of these consumer products. The mother's chemical body burden is shared with her fetus and the child may, in some cases, be exposed to larger doses relative to body weight.[2] The susceptibility to a wide range of adverse effects is increased during development, from preconception through adolescence, and developmental exposures can lead to life long functional deficits and manifestations of increased disease risks.[3] Potentially toxic exposure to these sensitive populations can not be solved by regulating only toys and cosmetics, but there are strong policy arguments for lowering the acceptable threshold for risk and creating additional protection in this regulatory context while we also work toward reforming our chemical regulatory system as a whole in the United States.

In one study, researchers found an average of 200 industrial chemicals and pollutants in umbilical cord blood from 10 babies born in August and September of 2004. The chemicals identified included perfluorochemicals used as stain and oil repellants in fast food packaging, clothes, and textiles, including the Teflon chemical PFOA, recently characterized as a likely human carcinogen, and dozens of widely used brominated flame retardants and their toxic by-products. Of the 287 chemicals detected, 180 cause cancer in humans or animals, 217 are toxic to the brain and nervous system, and 208 cause birth defects or abnormal development in animal tests.[4] The dangers of pre- or post-natal exposure to this complex mixture of carcinogens, developmental toxins, and neurotoxins have never been studied.[5] In fact, no toxicity information at all is available for 78% of the 12,860 chemicals that are used in commerce in

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2. Carl F. Cranor, *Do You Want to Bet Your Children's Health on Post-Market Harm Principles? An Argument For a Trespass or Permission Model For Regulating Toxicants*, 19 VILL. ENVTL. L. J. 251 (2008).

3. *Id.* at 258.

4. JANE HOULIHAN et al., BODY BURDEN: THE POLLUTION IN NEWBORNS 37-50 (EWG 2005), http://archive.ewg.org/reports_content/bodyburden2/pdf/bodyburden2_final-r2.pdf (The study was spearheaded by the Environmental Working Group (EWG) in collaboration with Commonweal. Researchers at two major laboratories identified the chemicals after the umbilical cord blood of these 10 children was collected by Red Cross after the cord was cut).

5. *Id.*

quantities of more than one million pounds per year, and only minimal toxicity information is available concerning the rest.[6]

Of particular and increasing concern are endocrine disrupting chemicals. Known or suspected endocrine disrupters are widespread in the environment. A study done by the U.S. Department of Interior, U.S. Geological Survey, found a high incidence of intersex (male fish exhibiting female characteristics) in smallmouth bass of the Potomac River Basin. Scientists found pesticides, flame retardants, and personal-care products containing known or suspected endocrine-disrupting chemicals in both the fish and the river. High intersex occurrence in aquatic species has also been documented at other locations in the U.S. and in Europe.[7] The overall impact of endocrine disrupting chemicals is unknown. There is evidence to suggest that endocrine disrupting chemicals may be related to increased rates of breast, prostate, and testicular cancer, among other health problems including reduced fertility, birth defects, endometriosis (a disease of the uterus), malformed reproductive organs, glandular dysfunction, and neurological disorders.[8] Today, 1 in 8 women are diagnosed with breast cancer.[9] For men, the risk of prostate cancer is 1 in 6.[10] In the United States, a woman's lifetime risk of breast cancer has nearly tripled during the past four decades, with less than 10% of cases occurring in women with a genetic predispo-

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6. *See* John C. Dernbach, *The Unfocused Regulation of Toxic and Hazardous Pollutants*, 21 HARV. ENVTL. L. REV. 1, 28 (1997) (citing STEERING COMMITTEE ON IDENTIFICATION OF TOXIC AND POTENTIAL TOXIC CHEMICALS FOR CONSIDERATION BY THE NATIONAL TOXICOLOGY PROGRAM, NATIONAL RESEARCH COUNCIL, TOXICOLOGY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 125 (1984)).

7. DOUGLAS B. CHAMBERS & THOMAS J. LEIKER, A RECONNAISSANCE FOR EMERGING CONTAMINANTS IN THE SOUTH BRANCH POTOMAC RIVER, CACAPON RIVER, AND WILLIAMS RIVER BASINS, WEST VIRGINIA, APR.-OCT. 2004 18 (2006), http://pubs.usgs.gov/of/2006/1393/pdf/ofr20061393.pdf.

8. ENVIRONMENTAL PROTECTION AGENCY, INTERNATIONAL WORKSHOP ON ENDOCRINE DISRUPTORS (Jan. 23-24, 1997), http://epa.gov/endocrine/Pubs/smithrep.html; *See also* HOULIHAN et al., BODY BURDEN *supra* note 4, at 25-39; Noah Sachs, *Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals*, 24 COLUM. J. ENVTL. L. 289, 295 (1999).

9. Breast Cancer Fund, *State of the Evidence 2008: The Connection Between Breast Cancer and the Environment*, http://www.breastcancerfund.org/site/pp.asp?c=kwKXLdPaE&b=206137 (last visited Feb. 25, 2009).

10. American Cancer Society, *What are the Key Statistics About Prostrate Cancer?*, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_prostate_cancer_36.asp?sitearea= (last visited Feb. 15, 2009).

sition for the disease.[11] Prostate cancer rates have more than doubled in a generation, rising 4.4 percent a year between 1973 and 1992.[12] The incidence has declined since 1992, but it is still 2.5 times its 1973 rate.[13] Prostate cancer is the most common cancer among U.S. men, and the second most lethal.[14]

Exposure to endocrine disrupting phthalates is an issue of increasing concern. In 2003, the CDC confirmed widespread contamination, finding phthalates in virtually every person tested and the highest levels in children and women of reproductive age.[15] The biologically active metabolites of DEHP, BBP, and DBP, which are used in children's toys, were highest among children.[16] However, according to the CDC's most recent report in 2005, phthalates are found in virtually 100% of the population.[17] Phthalates have been linked to early puberty in girls, premature delivery, impaired sperm quality and sperm damage, testosterone production, and testicular cancer.[18] Phthalates have also been linked to the feminization of boys. A recent government-funded study by Dr. Shanna Swan, a professor of obstetrics and gynecology at the University of Rochester, correlated prenatal phthalate exposure with a shortened anogenital distance (AGD) in male babies.[19] The higher the levels of phtha-

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11. Breast Cancer Fund *State of the Evidence 2006: What is the Connection between Breast Cancer and the Environment*, http://www.breastcancerfund.org/site/pp.asp?c=kwKXLdPaE&b=1370047 (last visited Feb. 15, 2009).

12. HOULIHAN ET AL., BODY BURDEN *supra* note 4, at 29 (Part of this increase can be explained by better detection, but increased incidence has also been accompanied by an increase in mortality - which better detection cannot explain).

13. *Id.*

14. *Id.* at 30.

15. Env't Cal. Phtalates Overivew, https://www.environmentcalifornia.org/environmental-health/stop-toxic-toys/phthalates (last visited Feb. 25, 2009) (citing U.S. Centers for Disease Control and Prevention. 2003. Second National Report on Human Exposure to Environmental Chemicals. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Environmental Health, Division of Laboratory Sciences).

16. *Id.*

17. *Id.* (citing U.S. Centers for Disease Control and Prevention. 2005. Third National Report on Human Exposure to Environmental Chemicals. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Environmental Health, Division of Laboratory Sciences).

18. *Id.*

19. Shanna H. Swan, *Decrease in Anogenital Distance among Male Infants with Prenatal Phthalate Exposure*, 113 ENVTL HEALTH PERSP. Issue No. 8, Aug. 2005, at 1056-61, *available at* http://www.ehponline.org/members/2005/8100/8100.pdf.

lates in the mother during pregnancy, the more likely the researchers were to find the shortened AGD.[20] When this occurred, the boys were more likely to have incomplete testicular descent and smaller penises. The changes occurred at phthalate levels that have been measured in about one quarter of women in the United States.[21] Bans for phthalates in products intended for children exist in European nations and Japan. Austria, Denmark, Finland, France, Germany, Greece, Norway, and Sweden have all adopted bans.[22] In 2005, the European Parliament made permanent an earlier temporary emergency ban in place since the 1990s.[23] Several other nations, including Argentina, Fiji, Mexico, and Japan have banned the use of phthalates in toys and products intended for use by children.[24]

Another chemical receiving particular attention is bisphenol-A (BPA). BPA is used in the production of epoxy resins and polycarbonate plastic, food and drink packaging, and resins used as lacquers to coat metal products such as food cans, bottle tops, and water supply pipes.[25] Human's are exposed to BPA at levels that cause problems in wildlife and laboratory animals, and scientists have concluded that there is a great cause for concern with regard to the potential for similar adverse effects in humans.[26] An expert panel sponsored in 2006 by the National Institutes of Health, the U.S. EPA, and Commonweal (a non-profit health and environmental research group) explained that recent trends in human diseases relate to adverse effects observed in experimental animals exposed to low doses of BPA. As specific examples, the panel noted: the increase in prostate and breast cancer, uro-genital abnormalities in male babies, a decline in semen quality in men, early onset of puberty in girls,

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20. *Id.*

21. *Id.*

22. Assemb. B. 1108, 2007 Cal. State Leg., (Cal. 2007), Bill Analysis, Senate Envtl. Quality Comm. at 4, *available at* http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1101-1150/ab_1108_cfa_20070712_131934_sen_floor.html (to add Chapter 11 (commencing with § 108935) to Part 3 of Division 104 of the Health and Safety Code, relating to product safety).

23. *Id.*

24. *Id.*

25. S.F., CAL., ORDINANCE NO. 120-06 (2006).

26. Frederick S. vom Saal et al., *Chapel Hill Bisphenol A Expert Panel Consensus Statement: Integration of Mechanisms, Effects in Animals and Potential to Impact Human Health at Current Levels of Exposure*, 24 REPROD. TOXICOLOGY 131 (2007) *available at* http://www.environmentalhealthnews.org/newscience/2007/2007-0801bpaconsensus.pdf.

metabolic disorders including insulin resistant (type 2) diabetes and obesity, and neurobehavioral problems such as attention deficit hyperactivity disorder (ADHD).[27] The panel also expressed concern that fetuses and children may be particularly susceptible to BPA exposure and that irreversible developmental effects may not become apparent until long after the exposure.[28]

Addressing widespread issues of chemical exposure in the United States is difficult under the current toxic regulatory regime. With the exception of manufacturers of pharmaceuticals, pesticides, and food contact substances, manufacturers of most chemical substances in consumer products are not required to do any toxicity testing before selling their products to the public. Chemical regulation in consumer products is delayed or indefinitely deferred as consumers bear the risk until harm is well established and an effort is undertaken to review the chemical or the product. This system puts a considerable burden on governmental and also non-governmental entities. Adding to the complexity, the post-market regulatory system is fragmented with separate federal agencies responsible for addressing toxins in different types of products. Although the same chemical may be contaminating our bodies from different sources of exposure, there is no one regulatory authority that comprehensively considers the question of cumulative exposure. Different divisions of the Food and Drug Administration, operating under different enabling legislation, are responsible for food contaminants, drug ingredients, medical devices, and cosmetics.[29] Toys are under the regulatory authority of the Consumer Product Safety Commission.[30]

Following Europe's lead, advocacy groups in the U.S. have been working to improve toy and cosmetic regulation. In 2005, the State of California adopted the California Cosmetics Act, S.B. 484 (2005), sponsored by the National Environmental Trust, Breast Cancer Action, and Breast Cancer Fund, and supported by 42 other public health, environmental, and civil rights advocacy groups. In passing this legislation, the State identified inadequate federal regulation and recent testing of cosmetic products in the United States and the

27. *Id.* § 4.1.4.

28. *Id.*

29. *See* Food and Drug Administration, www.fda.gov./default.htm; *see also* 21 U.S.C.§ 341 et seq. (food); 21 U.S.C. §351 et seq. (drugs and devices); 21 U.S.C. § 361 (cosmetics).

30. Federal Hazardous Substance Act, 15 U.S.C.A. § 1261; Consumer Product Safety Act, 15 U.S.C.A §2501.

European Union, identifying substances known or suspected to cause cancer and reproductive toxicity, including chemicals not identified as ingredients on the product's label.[31] The California Cosmetics Act requires manufacturers of cosmetic products to provide the state with a list of its products that contain chemicals identified as causing cancer or reproductive toxicity. The Act authorizes an investigation of these cosmetic products, provides authority to require manufacturers to submit health effects data,[32] and to regulate worker safety.

In 2006, the City of San Francisco adopted the first law in the U.S. to restrict BPA and phthalates in children's toys. The Healthy Products Healthy Children ordinance banned the manufacture, sale, and distribution of child care articles and toys intended for use by children under age three containing bisphenol-A (BPA) and six phthalates.[33] Bisphenol-A, and phthalates and are used in many products designed for children, including but not limited to toys, pacifiers, baby bottles and teethers.[34] Implementation of the ordinance was temporarily suspended and the BPA portion removed following a lawsuit alleging that the city was preempted by state and federal law from engaging in this type of regulation.[35] San Francisco later suspended its ordinance due to legislative action at the state level.[36] In 2007, California adopted AB 1108 prohibiting, after January 1, 2009, the manufacture, sale, or distribution in commerce of certain toys and child care articles if those products contain types of phthalates in concentrations exceeding 1/10 of 1%.[37] Legislative efforts

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31. CAL. HEALTH & SAFETY CODE § 111791 (West 2006).

32. *Id.* §111792.5.

33. S.F., CAL., ORDINANCE NO. 120-06 (2006) (banning the phthalates DEHP, DBP, BBP in concentrations exceeding 0.1 percent in any toy or child care product, and DINP, DIDP, and DnOP in concentrations exceeding 0.1 percent in any toy or child care article intended for use by a child under three years if the product can be placed in the child's mouth).

34. *Id.*

35. Board of Supervisors, City & County of San Francisco, Apr. 17, 2007 Agenda, *available at* http://www.sfgov.org/site/bdsupvrs_page.asp?id=58837.

36. S.F., CAL., HEALTH CODE art. 34, § 34.10 (2008) (suspending the ordinance, but committing to continue a testing program).

37. CAL. HEALTH & SAFETY CODE §§ 108935-39 (West 2007) (prior to amended on Apr. 25, 2007, the bill also included a prohibition on BPA. *See* Official Cal. Legislative Information, http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1101-1150/ab_1108_bill_20070425_amended_asm_v98.html. Another bill currently in the Cal. Leg., S.B. 1713, introduced on Feb. 22, 2008, to amend §§ 108937 and 108939 of the Health and Safety Code would expand the restrictions and requirements for phthalates in toys to apply also to BPA).

focused on both BPA and phthalates are underway in several states and at the federal level.[38] Congress recently banned children's toy or child care articles that contain specified concentrations of specified phthalates.[39]

These recent legislative efforts have worked around, instead of through, our current regulatory system for consumer product regulation. Our existing system is deeply flawed, and this post-market chemical-by-chemical approach to regulation is a long and burdensome process, which leaves consumers unprotected in the interim. There are too many chemicals of potential concern for us to continue in this fashion. Serious questions of safety concerning other chemicals on the market, as well as questions of safety about nanoparticles, are coming to the forefront.[40] Given the thousands of untested chemicals on the market, we must move for more comprehensive reform. The EPA reports that insufficient scientific data are available for most of the estimated 87,000 chemicals produced today to allow for an evaluation of endocrine associated risks.[41] EPA is currently developing an Endocrine Disruptor Screening Program (EDSP),[42] but any results that may affect the consumer are far in the

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38. E-mail from Margie Kelly, SAFER, to Rachael Rawlins (May 2, 2008) (on file with author); *see also* Ban Poisonous Additives Act of 2008, H.R. 6228, 110th Congress (would amend the Federal Food, Drug, and Cosmetic Act to deem to be adulterated a food in a container that is composed, in whole or in part, of bisphenol A or that can release bisphenol A into food); The BPA-Free Kids Act of 2008, S. 2928, 110th Congress (would ban BPA in children's products); *Senate Panel Takes On Plastics Additives in Consumer Products*, E&E DAILY, May 12, 2008, http://www.cancerpreventionsociety.org/ (last visited Feb. 25, 2009).

39. 15 U.S.C.A. § 2057 (2008).

40. Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349 (2007); Carl F. Cranor, *Do you Want to Bet your Children's Health on Post-Market Harm Principles? An Argument for a Trespass or Permission Model for Regulating Toxicants*, 19 VILL. ENVTL. L. J. 251 (2008) (including a discussion of particular risk to fetuses and infants and identifying risks of PBDE's, a class of flame retardants that have been used extensively in consumer products since the 1960's); *see also* Assemb. B. 706, 2007 Cal. State Leg., (Cal. 2007) (which would have revised and extend the findings relating to fire retardants, and would require all seating, bedding, and furniture products to comply with certain requirements, including restrictions on brominated fire retardants or chlorinated fire retardants).

41. Endocrine Disruptor Screening Program, http://www.epa.gov/scipoly/oscpendo/index.htm (follow "Priority Setting Activities" hyperlink) (last visited Feb. 27, 2009) [hereinafter *EDSP*].

42. *Id.; see also* 21 U.S.C.A. § 346a(p) (West 2008) (Congress passed the Food Quality Protection Act in 1996, requiring that EPA initiate EDSP to screen

future. The program was created by the Food Quality Protection Act in 1996 with deadlines for the EPA to develop screening procedures within two years (by mid 1998) and to implement the program within three years (by mid 1999). Even after having been spurred by a lawsuit for failing to meet statutory deadlines,[43] EPA did not publish its final approach for selecting the initial 50 to 100 chemicals for Tier 1 Screening until 2005.[44] In June 2007, EPA announced a draft list that includes 73 chemicals to be screened under Tier 1 of the program. In December 2007, EPA announced the draft policies and procedures. [45] Once identified and tested, the chemicals will remain on the market unless regulated under existing laws or new laws are adopted.

II. FEDERAL REGULATION OF COSMETIC PRODUCTS IS LARGELY ILLUSORY

Cosmetics are regulated by the federal Food and Drug Administration (FDA) under the Sherman Food, Drug and Cosmetic Act (FDCA).[46] Section 201(i) of the FFDCA defines a cosmetic as an article (excluding soap) intended to be rubbed, poured, sprinkled, sprayed on, introduced into, or otherwise applied to the human body

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pesticide chemicals and environmental contaminants for their potential to affect the endocrine systems of humans and wildlife. § 408 (p) of the Federal Food, Drug, and Cosmetics Act (FFDCA) mandated EPA to "to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effects as [EPA] may designate"); *EDSP*; Chemical Selection Approach for Initial Round of Screening, 70 Fed. Reg. 56,449, 56,463 (Sept. 27, 2005) (Over the past few years, EPA has been working to develop a priority setting approach. In 2002, EPA published a chemical selection approach for comment, and has now published a final approach for selecting the initial 50 to 100 chemicals for Tier 1 Screening in Sept. 2005).

43. Settlement Agreement Between Plaintiffs and EPA, 5-7 (2001), http://www.epa.gov/endo/pubs/settlement.pdf (In 1999 Natural Resources Defense Council; The Breast Cancer Fund; CALPRIG Charitable Trust; Pesticide Watch Education Fund; Pesticide Action Network; San Francisco By Area Physicians for Social Responsibility; and United Farm Workers of America, and AFL-CIO filed a complaint in the US District Court for the Northern District of California (Case No. C-99-3701 CAL) against the US EPA. A Settlement Agreement with EPA committing to "use best efforts" to meet specified deadlines was signed Jan. 9, 2001).

44. *EDSP, supra* note 41.

45. *Id.*

46. Codified at 21 U.S.C.§301 et seq.

or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles.[47] "Cosmetics" include skin-care creams, lotions, hairsprays, perfumes, lipsticks, fingernail polishes, eye and facial makeup, permanent waves, hair colors, deodorants, baby products (e.g., baby powder, baby oil, wipes), bath oils, bubble baths, and mouthwashes.[48] Regulation of these products is minimal. Except for color additives,[49] the FDA does not require pre-market safety testing, review, or approval of chemicals in cosmetic products before they are sold to the public.[50] The FDA has no authority to require manufacturers to file health and safety data on cosmetic ingredients or to order a recall of a dangerous cosmetic product.[51] The Federal statute does prohibit the adulteration[52] or misbranding[53] of any cosmetic in interstate commerce, and products that contain a "poisonous or deleterious substance which may render it injurious" pursuant to customary use;[54] or a "filthy, putrid, or decomposed substance."[55] However, these terms are not clearly defined and, because the FDCA does not require cosmetic manufacturers to submit any pre-market information to the agency,[56] it has little information upon which to take regulatory action.

Federal regulation does require that every ingredient in a cosmetic product and every finished cosmetic product be adequately substan-

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47. 21 U.S.C.A. § 321(i) (West 2007). However, sunscreen is generally regulated as a drug. 21 C.F.R. § 700.35 (2008).

48. DEPT. OF HEALTH & HUMAN SERVICES, NANOTECHNOLOGY: A REPORT OF THE U.S. FOOD AND DRUG ADMINISTRATION NANOTECHNOLOGY TASK FORCE, July 25, 2007 at 27, *available at* http://www.fda.gov/nanotechnology/taskforce/report2007.pdf.

49. *Id.* at 26 ("FDA regulates color additives under §§ 201(t) and 721 of the FFDCA. Generally under these statutory provisions, any substance capable of imparting color to any food, drug, cosmetic, or medical device, or the human body is a color additive that requires premarket approval by FDA in the form of a regulation listing (i.e., approving) the color additive for its intended uses.").

50. Cal. Safe Cosmetics Act of 2005, CAL. HEALTH & SAFETY CODE § 111791(1)(b) (West 2006) (identifying problems with federal regulation).

51. *Id.* § 111791(1)(c).

52. 21 U.S.C.A. § 361 (West 2008).

53. *Id.* § 362.

54. *Id.* § 361(a).

55. *Id.* § 361(b).

56. 21 C.F.R. §§ 710, 720, 730 (2008) (voluntary regulations requesting registration but no toxicity information).

tiated for safety prior to marketing,[57] but, in practice, this requirement has proven meaningless. The regulations state that any ingredient or product whose safety has not been adequately substantiated prior to marketing is misbranded unless it displays a warning statement declaring, "the safety of this product has not been determined."[58] However, the FDA has not defined "safe," nor established minimum testing requirements.[59] There is no requirement that industry report the basis for its conclusion that a product is "safe." The cosmetic industry has established a panel, a nongovernmental body funded by the industry's main trade association, called the Cosmetic Ingredient Review (CIR).[60] However, CIR has reviewed only 11 percent of the 10,500 ingredients that FDA has documented in personal care products.[61] Through its own analysis, the Environmental Working Group (EWG),[62] a non-profit research organization, found that products are on the market that violate the CIR's own safe use recommendations to manufacturers, and that contain ingredients that the CIR reviewed but found specifically lacked the data needed to substantiate safety.[63] None of these products contained a warning label.[64] In a review of 20,000 product labels in 2004 and 2005 the

57. *Id.* § 740.10(a).

58. *Id.*

59. *See* Envtl. Working Group [hereinafter *EWG*], Cosmetic Safety Database, *Consumer Update – FDA Admits Inability to Ensure the Safety of Personal Care Products*, http://www.cosmeticsdatabase.com/research/fdafails.php?nothanks=1 (last visited Feb. 27, 2009) [hereinafter *Cosmetic Safety Database*].

60. *Id. See also* CAL. HEALTH & SAFETY CODE § 111793.5 (West 2006).

61. *Cosmetic Safety Database*, *supra* note 59, (study based on a 2004 analysis of the 2003 CIR Compendium by the *EWG*).

62. E-mail from Bill Walker, Vice President/West Coast, *EWG* & EWG Action Fund, to Rachel Rawlins, Adjunct Professor, University of Texas at Austin School of Architecture (May 23, 2008) (on file with author) (*EWG* is a non-profit research organization with a team or scientists, computer programmers and media strategists. EWG has 33 employees, and gets almost all of its money from charitable foundations that make grants in support of their work. A small amount comes from contributions by individuals and a very small amount from companies. The EWG's 2005 budget was 3.7 million); *see also* ENVTL. WORKING GROUP, ANNUAL REPORT (2005), www.ewg.org/files/EWG-AR2005.pdf; Campaign for Safe Cosmetics, Contact Us, http://www.safecosmetics.org/contact/ (last visited Oct. 12, 2008).

63. *Cosmetic Safety Database*, *supra* note 59 (study based on a 2004 analysis of the 2003 CIR Compendium by the *EWG*). *See also* CAL. HEALTH & SAFETY § 111793.5(a)(2) (West 2006) (citing the 2004 analysis of the 2003 CIR Compendium by the EWG).

64. *See Cosmetic Safety Database*, *supra* note 59.

EWG did not find a single warning. In fact, warning statements are rare, possibly nonexistent, on cosmetic products.[65] Yet, in response to a petition by the EWG, the FDA has refused to take enforcement action, stating that the industry panel recommendations are insufficient evidence to determine if ingredients are safe and that it lacks sufficient information to determine whether or not the ingredients were adequately substantiated for safety.[66]

Only 11 percent of the ingredients used in cosmetic products have been tested for safety,[67] and many existing known carcinogens and endocrine disruptors have been found in cosmetic products. An EWG study found that 80 percent of all cosmetic products may be contaminated with one or more recognized cosmetic impurities that are linked to cancer and other health concerns and often readily penetrate the skin.[68] Although the FDA has taken the position that the concentrations are not at levels to be a cause for concern,[69] researchers found one carcinogen, 1, 4 Dioxane, in 57% of all baby soaps and 34% of all baby lotions.[70] Another study found endocrine

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65. *Id.*

66. *See id.* (In June 2004, the EWG submitted a cosmetic safety petition to the Food and Drug Administration challenging the claim that products were substantiated for safety and requesting a warning label for products containing ingredients that were contraindicated for the product use (for example, skin creams with ingredients for which the industry review panel concluded the ingredient should not contact the skin) and products containing ingredients that the industry panel concluded lacked the safety data needed to support a finding of safety. In the FDA's September 2005 response to this petition, the agency replied that it could not take action against these products, because it lacked the information to determine whether or not the ingredients were adequately substantiated for safety, or were causing acute injury. The FDA took the position that the industry panel recommendations were not sufficient evidence to determine if ingredients are safe).

67. BREAST CANCER FUND, STATE OF THE EVIDENCE: THE CONNECTION BETWEEN BREAST CANCER AND THE ENVIRONMENT 79 (Janet Gray ed., 5th ed. 2008) *available at* http://www.breastcancerfund.org/site/pp.asp?c=kwKXLdPaE&b=206137 (follow "Download PDF" hyperlink) [hereinafter *State of the Evidence 2008*].

68. *EWG, EWG Research Shows 22 Percent of all Cosmetics may be Contaminated with Cancer-causing Impurities*, Feb. 8, 2007, http://www.ewg.org/node/21286 (last visited Feb. 26, 2009) (finding that 22 percent of all products may be contaminated with 1,4-dioxane, but also discussing broader contamination with other toxins).

69. U.S. Food and Drug Admin., Center for Food, Safety & Applied Nutrition, *1,4-Dioxane*, July 3, 2007, http://www.cfsan.fda.gov/~dms/cosdiox.html (last visited Feb. 26, 2009) [hereinafter *Center for Food, Safety & Applied Nutrition*].

70. *EWG, supra* note 68.

disrupting chemicals phthalates in more than 70% of health and beauty products tested, including popular brands of shampoo, deodorant, hair mouse, face lotion and every single fragrance tested.[71] A study in Europe found phthalates in nearly 80% of products.[72]

In the FDA's own study, a survey of 48 consumer cosmetic products, including hair care products, deodorants, lotions and creams, nail products, fragrances, and body washes, most products were found to contain at least one phthalate ester.[73] However, based on the available exposure and toxicity data, the FDA concluded that there is insufficient data to conclude that a human health hazard exists from exposure to phthalate esters from cosmetic products.[74] The FDA explains that, although the CDC survey report in 2001 noted elevated levels of phthalates excreted by women of child-bearing age, neither it nor the other data reviewed by FDA established an association between the use of phthalates in cosmetic products and a health risk.[75] The FDA dismissed an article from the American Academy of Pediatrics that reported that infants exposed to infant care products, specifically baby shampoos, baby lotions, and baby powder, showed increased levels of phthalate metabolites in their urine.[76] Researchers found a strong association between several phthalates and infant care products that are applied dermally and therefore concluded that this is a major source and route of exposure for infant phthalate exposure. Nevertheless, the FDA explained that it did not establish an association between these findings and any health effects, and that the levels of phthalates (if any) in the infant care products were not determined.[77]

We know that phthalate exposure has been correlated with premature breast development, sperm damage in men and, changes in the

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71. JANE HOULIHAN ET AL., NOT TOO PRETTY: PHTHALATES, BEAUTY PRODUCTS & THE FDA 5 (2002), http://www.safecosmetics.org/docUploads/NotTooPretty_r51.pdf.

72. JOSEPH DIGANGI, & HELENA NORIN, PRETTY NASTY – PHTHALATES IN EUROPEAN COSMETIC PRODUCTS 6 (2002), http://www.safecosmetics.org/docUploads/Prettynasty.pdf (last visited Feb. 26, 2009).

73. *See* FDA, Center for Food, Safety & Applied Nutrition, *Phthalates and Cosmetic Products* (Feb. 7, 2008), http://vm.cfsan.fda.gov/~dms/cos-phth.html. (last visited Feb. 26, 2009).

74. *Id.*

75. *Id.*

76. *Id.* (citing Sheela Sathyanarayana et al., *Baby Care Products: Possible Sources of Infant Phthalate Exposure*, 121 PEDIATRICS 260 (2008)).

77. *Id.*

anatomy and size of genitalia in male babies.[78] We also know that phthalates disrupt sexual development in male rates, resulting in undescended testicles and reduced testosterone production, and can cause reproductive and developmental toxicity, including adverse effects on the developing skeletal system in rats.[79] We know that the U.S. population is contaminated with phthalates,[80] and that health affects are likely to also occur in humans.[81] What we don't know is the exact extent to which cosmetics products are contributing to the phthalate contamination of people. Historically, diet has been considered the major source of phthalate exposure in the general population, but all sources, pathways, and their relative contributions to human exposures are not well understood.[82] Cosmetics, and other products may result in significant but poorly quantified human exposures to dibutyl phthalate, diethyl phthalate, or dimethyl phthalate.[83] Significant data gaps make it difficult to identify with certainty, the various sources, exposure pathways and their relative contributions to phthalates exposure levels in the general population.[84]

The FDA did not eliminate the possibility that cosmetic products pose a significant human health risk. [85] However, the FDA made it clear that it is looking for "compelling evidence" before it will take action to protect consumers for the uncertain risk posed by phthalates.[86] Under this system, not only must the consumer bear the risk pending development of further data, but that risk is not disclosed. Current labeling requirements are inadequate to inform the consumer as to the risk posed by phthalates or other potentially toxic ingredients. FDA requires an ingredient declaration on the cosmetic products sold at the retail level to consumers,[87] labels are generally re-

78. James Bothwell, *Toy Story: Timeout for Phthalates*, 39 MCGEORGE L. REV. 551, 557-60 (2008) (summarizing evidence on phthalates).

79. *Id.*

80. *See supra* note 15.

81. *Center for Food, Safety & Applied Nutrition, supra* note 69.

82. *See* Ted Schettler, *Human Exposure to Phthalates Via Consumer Products*, 29 INT'L J. ANDROLOGY 134 (2006).

83. *Id.*

84. *Id.* at 137.

85. *See* J.C. Hubinger & D.C. Havery, *Analysis of Consumer Cosmetic Products for Phthalate Esters*, 57 J. OF THE SOC'Y OF COSMETIC CHEMISTS 127 (2006), abstract *available at* http://www.ncbi.nlm.nih.gov/pubmed/16688376.

86. *Center for Food, Safety & Applied Nutrition, supra* note 69.

87. 15 U.S.C.S. § 1454(c) (2008).

quired to include ingredient lists,[88] and may be unlawful if the label or container is false or misleading.[89] However, federal law exempts chemicals that qualify as trade secret and those used as fragrances or flavoring from being identified as ingredients on the labels of cosmetic products.[90] Laboratory analyses of cosmetic products sold in California found products that contain substances known to or likely to cause cancer or reproductive toxicity and not identified as an ingredient on the product's label.[91] Further, the labeling requirements do not apply to products used exclusively by professionals (i.e., in salons).[92] However, even if ingredient labeling was complete, it would still be inadequate to inform the consumer as to the risk posed by the chemicals identified. That this information is desired by the consumer is reflected in the fact that EWG's cosmetic safety database, Skin Deep,[93] gets one million product searches per month.[94] The database matches ingredients in more than 25,000 products against 50 toxicity and regulatory databases.[95] After entering the name of a product, the website system will identify ingredients, provide basic toxicity information and a product rating on a 1-10 scale for safety. On the website, the EWG asks and answers the

88. *See Center for Food, Safety and Applied Nutrition, Cosmetic Labeling: An Overview*, http://www.cfsan.fda.gov/~dms/cos-lab4.html (last visited Feb. 26, 2009) (noting the FDA regulates cosmetic labeling under the authority of both the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). If the product is sold on a retail basis to consumers, even it is labeled "For professional use only" or words to that effect, the ingredients must appear on an information panel, in descending order of predominance); *see also* 21 U.S.C.S. § 362(b) (2008); 21 C.F.R. § 701.3 (2008).

89. 21 U.S.C.S. § 362(a) (2008).

90. *See* 15 U.S.C. § 1454(c)(3)(B) (2008) ("nothing . . . shall be deemed to require that any trade secret be divulged"); *see also* 21 C.F.R. § 701.3(a) (2008) (The label on each package of a cosmetic shall bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. In lieu of the declaration of the name of a confidential ingredient, the phrase "and other ingredients" may be used at the end of the ingredient declaration); S.B. 484, § 1(g), 2005 Leg., (Cal. 2005).

91. S.B. 484, § 1(g), 2005 Leg., (Cal. 2005).

92. 15 U.S.C.S. § 1459(a) (2008) (definition of consumer commodity); *see also Center for Food, Safety and Applied Nutrition, Phthalates and Cosmetic Products*, http://vm.cfsan.fda.gov/~dms/cos-phth.html (last visited Feb. 26, 2009).

93. *See generally, Cosmetic Safety Database, supra* note 59, http://www.cosmeticsdatabase.com/ (last visited Feb. 26, 2009).

94. STACY MALKAN, NOT JUST A PRETTY FACE, THE UGLY SIDE OF THE BEAUTY INDUSTRY 64 (New Society Publishers 2007).

95. *Cosmetic Safety Database*, supra note 59.

question as to why a small nonprofit took on such a big project. Their answer: "[b]ecause the FDA doesn't require companies to test their own products for safety."[96]

III. HISTORY OF INACTION AT THE FEDERAL LEVEL

The lax state of federal cosmetics regulations is particularly troublesome given that problems were identified almost 30 years ago in a report by the 1978 General Accounting Office which recommended that the FDA be given greater authority to regulate cosmetic safety:[97]

> Cosmetics are being marketed in the United States which may pose a serious hazard to health. Some contain toxic ingredients which may cause cancer, birth defects or other chronic toxic effects and contain contaminants known to cause cancer in animals because exposure to these ingredients can occur through skin absorption and inhalation as well as oral ingestion. It is important that the hazards posed by them be carefully assessed.[98]

The report listed 125 ingredients used in cosmetics suspected of causing cancer, 25 ingredients suspected of causing birth defects, and 20 items suspected of adversely affecting the nervous system.[99] Almost 20 years later, responding to a bill intended to preempt state regulations dealing with cosmetic safety, Senator Kennedy referred to the 1978 report and pointed out that federal attention to cosmetic safety remained wholly inadequate. He reported that less than 30 FDA employees regulate the $20 billion cosmetics industry, and only 2 employees actually regulate cosmetic packaging and labeling.[100] He also cited a 1988 National Institute of Occupational Safety and Health at NIH report to a congressional subcommittee that analyzed 2,983 substances in cosmetics and found 884 cosmetic

96. *Id.*
97. 143 Cong. Rec. S8878, 8884 (Sept. 8, 1997) (statement of Sen. Kennedy).
98. *Id.*
99. 143 Cong. Rec. S9133, 9147 (Sept. 11, 1997) (statement of Sen. Kennedy).
100. 143 Cong. Rec. S8878, 8883 (Sept. 8, 1997); 143 Cong. Rec. S9133, 9150 (Sept. 11, 1997).

ingredients had been reported to the Government as toxic substances.[101]

In more recent years, the political climate has not improved. The Bush administration spent considerable time and effort working on behalf of the Chemical Industry. According to a U.S. House of Representatives special interest case study, the Administration mounted a campaign to block the efforts of the European Union to regulate chemical companies. [102] The chemical and related manufacturing sector provided $21,027,663 in campaign contributions in the 2000, 2002, and 2004 election cycles. Of this amount $16,543,081 was provided to Republicans, and $912,207 was given to George W. Bush.[103] Meanwhile, the Office of Cosmetics and Colors which regulates toxins in cosmetic products has continued to have capacity problems. Tooting a 2007 increase in funding, Pamela Bailey, President and CEO of the Cosmetic, Toiletry and Fragrance Association recently stated "our strong partnership with the FDA has been put at risk because the Office of Cosmetics and Colors has shrunk to an insufficient level."[104] Given that the increase in funding, reported at $2 million, came on the heals of the FDA's Nanotechnology Task Force Report, which expressed concern over the agency's ability to deal with the added complexity of nanotechnology,[105] serious questions as to capacity remain.

IV. CALIFORNIA'S SAFE COSMETICS ACT, A STEP IN THE RIGHT DIRECTION

The California Cosmetics Act requires manufacturers of cosmetic products to provide the state with a list of products that contain

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101. 143 Cong. Rec. S8846 (Sept. 5, 1997) (statement of Sen. Kennedy).

102. U.S. HOUSE OF REP. ON GOV'T REFORM – MINORITY STAFF SPECIAL INVESTIGATIONS DIV. FOR REP. HENRY A. WAXMAN, A SPECIAL INTEREST CASE STUDY, THE CHEMICAL INDUSTRY, THE BUSH ADMINISTRATION, AND EUROPEAN EFFORTS TO REGULATE CHEMICALS (Apr. 1, 2004), *available at* http://oversight.house.gov/documents/20040817125807-75305.pdf.

103. *Id.* at 3 (citing Center for Responsive Politics, *Chemical & Related Manufacturing: Long-Term Contribution Trends*).

104. Skin Inc., *CTFA Applauds Increased Funding for FDA Office of Cosmetics and Colors*, Aug. 14, 2007, http://www.skininc.com/skinscience/ingredients/9154396.html (last visited Feb. 26, 2009).

105. FDA, NANOTECHNOLOGY TASK FORCE REPORT (July 2007), http://www.fda.gov/nanotechnology/ (last visited Feb. 26, 2009).

chemicals substances that are known or "reasonably anticipated" to be a human carcinogen as well substances that have "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.[106] This list must include chemicals that are contained in the product for purposes of fragrance or flavoring, and those identified by the phrase "and other ingredients" and determined to be trade secret.[107] The Act authorizes an investigation of these cosmetic products and provides authority to require manufacturers to submit health effects data.[108] In cases where the state determines that products contain ingredients that the CIR has found are not safe for the specific use indicated on the product, it requires referral of the findings to the Attorney General and the FDA for possible enforcement under the federal Food, Drug and Cosmetic Act.[109] It also requires that chemicals which are potentially toxic be regulated for worker safety unless there is an affirmative written finding that regulation is not necessary.[110]

Except as it may work in conjunction with the Federal law, and California's proposition 65, the Act does not provide any immediate protection for consumers. Proposition 65,[111] adopted by California voters in 1986, requires warning labels on consumer products that contain certain chemicals identified by various international, federal, and state entities as either carcinogens or reproductive toxicants. The list of regulated chemicals under Proposition 65 (about 700 chemicals are listed),[112] is more limited than the chemicals that will be identified under the California Cosmetics Act. Proposition 65's warning requirement does not apply to chemicals only "reasonably anticipated" to cause cancer for which reporting and testing may be required under the Cosmetics Act, or those with only "some" evi-

106. CAL. HEALTH & SAFETY CODE § 111791.5(b)(4) (West 2006).
107. *Id.* § 111792(a).
108. *Id.* § 111792.5.
109. *Id.* § 111793.5(3).
110. *Id.*
111. CAL. HEALTH & SAFETY CODE § 25249.5 et seq. (West 2006).
112. STATE OF CAL. ENVTL PROTECTION AGENCY, OFFICE OF ENVTL HEALTH AND HAZARD ASSESSMENT, SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986, CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY (Sept. 12, 2008), http://www.oehha.ca.gov/prop65/prop65_list/files/P65single091208.pdf (last visited Feb. 26, 2009); *see also* 27 Cal. Code of Reg. § 2700.

dence adverse developmental, or reproductive toxicity. For chemicals to be added to the Proposition 65 list they must be have been "clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity," identified by an authoritative body "as causing" cancer or reproductive toxicity, or already required by the state or federal government to be labeled or identified as "causing" cancer or reproductive toxicity.[113] California has now listed four phthalates on the Proposition 65 list. One phthalate, Di(2-ethylhexyl)phthalate (DEHP), a "known carcinogen," has been on California's list since January 1988, and three more "known to cause reproductive toxicity," butyl benzyl phthalate (BBP), di-n-butyl phthalate (DBP), and di-n-hexyl phthalate (DnHP) were added in December 2005.[114] The possibility of listing BPA is under consideration.[115]

Given the national effect of California's Proposition 65, other states will likely benefit from California's effort even if they do not adopt programs of their own.[116] Proposition 65 has been credited

113. CAL. HEALTH & SAFETY CODE § 25249.8 (warnings are required unless the chemical is present in the product below a level that poses "no significant risk" that is a level that causes no more than one excess lifetime case of cancer per 100,000 exposed individuals, and, for reproductive toxicants, 1/1000th of the highest level at which the chemical has been shown to have no observable reproductive effect. *Id.* § 25249.10. If a chemical is present in a product, the burden is on industry to show that it does not exceed the allowable level. *Id.*

114. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, PROPOSITION 65 – CHANGES TO THE P-65 LIST (Dec. 12, 2005), http://www.oehha.org/prop65/prop65_list/120205list.html (last visited Feb. 26, 2009) (chemicals become "listed" based on a formal identification by an authoritative body, in this case the National Toxicology Program Center for Evaluation of Risks to Human Reproduction (NTP-CERHR). Butyl benzyl phthalate (CAS No. 85-68-7), di-n-butyl phthalate (CAS No. 84-74-2), and di-n-hexyl phthalate (CAS No. 84-75-3) met the criteria for reproductive toxicity for both males and females as well as developmental toxicity as established under OEHHA).

115. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, ANNOUNCEMENT OF CHEMICALS SELECTED BY OEHHA FOR CONSIDERATION FOR LISTING BY THE DEVELOPMENTAL AND REPRODUCTIVE TOXICANT IDENTIFICATION COMMITTEE AND REQUEST FOR RELEVANT INFORMATION ON THE DEVELOPMENTAL AND REPRODUCTIVE TOXICITY OF THESE CHEMICALS: BISPHENOL A (Mar. 11, 2008), http://www.oehha.ca.gov/prop65/CRNR_notices/state_listing/data_callin/extend031108.html (last visited Feb. 26, 2009).

116. Other states must consider additional preemption issues. Except for State requirements adopted by a State public initiative or referendum enacted prior to Sept. 1, 1997 (that is, Proposition 65), and those specifically approved after application by the State, states are preempted from creating labeling and packaging for cosmetic products that are different from or in addition to, or not otherwise identi-

with stimulating significant consumer-product reformulation which, in some cases, has been close to industry-wide with a nationwide affect.[117] However, Proposition 65 does not fully resolve the issue of consumer notification because of the limited class of chemicals to which it applies and deficiencies in the allowable warning statements. Unless there is certainty as to a chemical's harmful effects, there is no law, state or federal, that requires consumer warnings. Even for those chemicals where warning labels are required by Proposition 65, consumers are often left in the dark. The regulations establish "safe harbor" warning messages which have been used on virtually all consumer product warnings. The safe harbor message for consumer products states: "Warning: This product contains a chemical known to the State of California to cause cancer birth defects or other reproductive harm."[118] The warning statement informs individuals only that the product contains a chemical, not that use of the product will expose them to a listed chemical. It leaves recipients unsure about whether there is an exposure, the identity of the chemical, and the source of the exposure.[119]

V. EUROPE'S LEAD, A MORE PRECAUTIONARY APPROACH

In 2004, the European Parliament prohibited the use in cosmetics of certain chemicals that cause cancer, reproductive harm, or mutagenicity. The substances are classified based on their intrinsic properties without taking into account exposure. It is not necessary to determine the exact contribution of cosmetic products to exposure, or how much of a toxin might be considered "safe." The directive prohibits the sale of personal care products that contain any of the 1,100 carcinogens, mutagens or reproductive toxins classified as toxicants by the directive,[120] including di-methyl phthalate (DMP),

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cal to Federal standards. 21 U.S.C.S. § 379 (2008). The preemption provision on "packaging and labeling" specifically includes any State requirements relating to public information or any other form of public communication. *Id.* According to discussions on the Senate Floor, the provision was not intended to block any State from otherwise exercising its police powers against unsafe cosmetic products. 143 Cong. Reg. S8880 (Sept. 8, 1997) (statement of Sen. Jeffords).

117. Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 341 (1996).

118. Cal. Code Regs. Tit. 26, 22-12601(b)(4)(A)-(B)(1995).

119. Rechtschaffen, *supra* note 117, at 326.

120. STATE OF THE EVIDENCE 2008, *supra* note 67.

benzylbutl phthalate (BBP); di-(2ethylhexyl) phthalate (DEHP).[121] The law creates three levels of certainty that the chemical harms human health: known, probable and possible.[122] The ban is absolute for chemicals that fall in categories 1 and 2. For category 3, it is conditional: a manufacturer may use the chemicals only if the Scientific Committee finds the substances to be safe for use in cosmetics.[123] The law also allows for some degree of risk assessment for the presence of trace substances which are unavoidable and do not cause damage to human health.[124] For example, traces of phthalates that may leach unintentionally into cosmetic products through contact with other products, materials or containers during production or storage are allowed if they do not cause damage to human health.[125]

Europe is currently considering a legislative proposal for change to their cosmetic regulation.[126] The proposal would allow, subject to rigid conditions, the use of a risk management regime that would consider exposure and actual use of the substance and allow category 1 and 2 substances if they are determined to be safe by the Scientific

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121. EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION, SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS, OPINION ON PHTHALATES IN COSMETIC PRODUCTS (Mar. 21, 2007), *available at* http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_106.pdf.

122. COMMISSION OF THE EUROPEAN COMMUNITIES, WORKING PAPER: IMPACT ASSESSMENT REPORT ON SIMPLIFICATION OF THE "COSMETICS DIRECTIVE" 16, COM (May 2, 2008) *available at* http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/sec/2008/0117/COM_SEC(2008)0117_EN.pdf.

123. Council Directive 76/768/EEC, art. 4b, 1976 O.J. (L 262) *available at* http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1976/L/01976L0768-20060809-en.pdf ("The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. . . . A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.").

124. EUROPEAN COMMISSION, OPINION ON PHTHALATES IN COSMETIC PRODUCTS, *supra* note 117, at 6 (citing the Cosmetic Directive (76/768/EC)) ("The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2" (must not cause damage to human health)).

125. *Id.*

126. COMMISSION OF THE EUROPEAN COMMUNITIES, *supra* note 122, at 5; European Parliament, The Legislative Observatory, *Impact Assessment* http://www.europarl.europa.eu/oeil/OpenDetailFiche.do?ficheId=1445&language=en (last visited Feb. 27, 2009).

Committee for Consumer Products.[127] The change is proposed as an exception to the principal rule of a ban.[128] The legislative impact assessment report explains that because the automatic ban does not consider exposure and actual use of the substance, it can lead to situations of incoherence between different legislative regimes for different products. As an example, the report discusses the possibility that Ethanol would be banned for use in consumer products (i.e. perfume), but not in food and beverages.

The legislative proposal would also create a notification requirement and establish clear minimum safety standards for the cosmetic safety assessments that are required before a product is placed on the market.[129] Pre-market regulatory approval would not be required, but industry would be required to actively report serious undesirable effects.[130] The report explains this approach of reviewing products as a whole would complement the ingredient-by-ingredient approach which does not take into account interactions between ingredients.[131] The assessment of individual substances also ties up considerable regulatory resources.[132] The impact assessment further explains that that there are safety-challenges lying ahead in the fast moving cosmetic sector and the regulation of individual substances is too slow to ensure safety. The EU industry places approximately 60,000 new cosmetic formulations on the EU market every year.[133] The time between identification of a substance which poses a risk, evaluation of the risk, regulation through technical adaptation of the Cosmetics Directive and actual changes in the composition of the product sold to the consumer is very long (approximately five years).[134] The Scientific Committee for Consumer Products already has an enormous

127. European Parliament, *supra* note 122.

128. *Id.* ("Additional safeguards shall ensure that risk-based regulation of these substances would be the exception to the principal rule of a ban.").

129. *Id.*

130. COMMISSION OF THE EUROPEAN COMMUNITIES, Commission Staff Working Paper, Executive Summary, *Impact Assessment Report on Simplification of the "Cosmetics Directive"* (2008) at 3 *available at* http://www.uni-mannheim.de/edz/pdf/sek/ 2008/sek-2008-0118-en.pdf; Commission of the European Communities, *supra* note 122, at 38.

131. COMMISSION OF THE EUROPEAN COMMUNITIES, *supra* note 122, at 38.

132. *Id.* at 36.

133. *Id.* at 35.

134. *Id.* at 33.

backlog, with almost 100 opinions on the safety of individual substances pending.[135]

VI. POST MARKET FEDERAL REGULATION OF TOYS ALSO BURDENS THE CONSUMER WITH POTENTIALLY SERIOUS UNDISCLOSED RISK

Toys, like cosmetics, are non-essential consumer products where leaching chemical constituents may potentially affect a vulnerable population. As with cosmetics, consumer product safety review is generally limited to post-market review on a product by product basis with the difficult burden of proof as to toxicity and exposure on the government. Safety considerations are also complicated by the potential for multiple sources of exposure to the same chemical, and possible unknown toxic synergistic effects between chemicals as they commingle in the blood stream. As currently drafted, the Consumer Product Safety Act (CPSA)[136] and the Federal Hazardous Substances Act (FHSA)[137] have not been effective as vehicles for regulating carcinogen, mutagens or reproductive toxins. The CPSC has identified relatively few banned hazardous substances, its list of banned toys and articles intended for use by children is short, and its safety standards generally focus on such products with more obvious hazards such as matchbooks, bicycle helmets, and swimming pool slides.[138] Under the FHSA, the CPSC has authority to ban or regulate substances that are hazardous and that may cause substantial injury or illness.[139] Under the CPSA, the CPSC may ban products that create an "unreasonable risk of injury," when "no feasible consumer product safety standard" can adequately address that risk.[140] Both the FHSA and the CPSA, however, impose significant procedural and evidentiary burdens that require a high level of proof and

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135. *Id.* at 37.

136. 15 U.S.C.A. § 2501 (West 2008) (note that the FHSA and the CPSA specifically exclude cosmetics from their regulatory reach. § 1261; § 2052(a)(1)).

137. § 1261.

138. James Bothwell, *Toy Story: Timeout for Phthalates*, 39 MCGEORGE L. REV. 551, 565 (2008) (citing Banned Toys and Other Banned Articles Intended for Use by Children, 16 C.F.R. § 1500.18 (2007); Safety Standard for Matchbooks, 16 C.F.R. pt. 1202 (2007); Safety Standard for Bicycle Helmets, 16 C.F.R. pt. 1203 (2007); Safety Standard for Swimming Pool Slides, 16 C.F.R. pt. 1207 (2007)).

139. 15 U.S.C.A. § 1261(f)(1) (defining "hazardous substance"); § 1261(q) (defining "banned hazardous substance").

140. § 2057.

certainty before action may be taken to protect the unknowing consumer from the risk of carcinogens, mutagens and reproductive toxins.

Under the FHSA, the CPSC may ban toxic substances which have the capacity to produce personal injury or illness through ingestion, inhalation, or absorption through the body surface.[141] "Toxic" substances include known or probable human carcinogens, human neurotoxins, and human developmental or reproductive toxicants.[142] However, the regulations exclude from the definition of "toxic" those substances that are only "possible" carcinogens, human neurotoxins, and human developmental or reproductive toxicants.[143] In the absence of human data, agents with "limited" evidence of carcinogenicity from animal studies fall into this category.[144] The CPSC explains that "[t]his does not imply that the substances are or are not carcinogens, only that the evidence is too uncertain to provide for a determination."[145] The burden of proof is on the CPSC to demonstrate by "substantial evidence" that a substance is a known or probable carcinogen, human neurotoxin, or human developmental or reproductive toxin.[146] Before a toxic substance may be banned, the FHSA also requires an elaborate rule making process with a formal hearing applying the rules of evidence and the right to confront and cross-examine witnesses.[147] The CPSC must include in its review an analysis of the nature of the risk of injury, regulatory alternatives, reasons why existing and proposed standards are inadequate, a description of the potential benefits and potential costs, an identification of those likely to receive the benefits and bear the costs.[148] Further, before the Commission can adopt a regulation, it must also

141. § 1261(g) (defining toxic).

142. 16 C.F.R. § 1500.3(c)(ii) (2008).

143. *Id. See also* 16 C.F.R. § 1500.135 (2008) (in defining "possible human developmental toxicant," the CPSC does note that "it believes that data from well planned animal studies are important to consider even though they may provide only limited evidence of developmental toxicity." § 1500.135(c)(iii). However, the significance of this statement is unclear as only known and probable human developmental or reproductive toxicants are within the definition of toxic for the purposes of regulation).

144. 16 C.F.R. § 1500.135(a)(3) (2008).

145. *Id.*

146. 15 U.S.C.A. § 1262(a)(2) (requiring compliance with 21 U.S.C.A. § 371(f)).

147. Gulf S. Insulation v. Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1149-50 (5th Cir. 1983) (citing 15 U.S.C.A. § 1262(a)(2)).

148. 15 U.S.C.A. §§ 1262(h)-(i).

make a finding that a voluntary standard would be inadequate, and that the regulation imposes the least burdensome requirement which prevents or adequately reduces the risk of injury.[149]

Under the Consumer Product Safety Act (CPSA), the Commission has the authority to enact performance requirements, warnings or instruction,[150] and product bans,[151] but again only after if it makes affirmative findings, supported by substantial evidence.[152] Before proceeding under the CPSA, the Commission must first find that the risk could not be regulated sufficiently under the FHSA or that it is in the public interest to proceed under the CPSA rather than the FHSA.[153] It must also bear the burden of proof to establish the hazard and the likelihood of its reduction at reasonable cost. It must be able to prove that the rule is reasonably necessary to eliminate or reduce an "unreasonable risk of injury," that the rule imposes "the least burdensome requirement" which prevents or adequately reduces the risk of injury, and that the benefits expected from the rule bear a "reasonable relationship to its costs."[154] The inquiry as to whether the potential effects are "unreasonable" involves a balancing test. The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation imposes upon manufacturers and consumers.[155] Although the rulemaking process is less formal under

149. § 1261(i)(2).

150. § 2056.

151. § 2057.

152. § 2060(c).

153. Gulf S. Insulation v. Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1149-50 (5th Cir. 1983); *but see* Edward M. Fox, Note and Comment, *Urea Formaldehyde Foam Insulation: Defusing a Timebomb*, 11 AM. J.L. & MED. 81 (1985) (questioning whether the Fifth Circuit was correct in its interpretation of § 2079(d)).

154. 15 U.S.C.A. § 2058(f)(3).

155. D.D. Bean & Sons Co. v. Consumer Prod. Safety Comm'n, 574 F.2d 643, 649 (1st Cir. 1978) (citing Aqua Slide ' N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831, 838-39 (5th Cir. 1978)); *see also*, Forester v. Consumer Prod. Safety, 559 F.2d 774, 786 n.14 (D.C. Cir. 1977) (clarifying the meaning of "unreasonable" in 15 U.S.C.A. § 1261(s) in the definition of "mechanical hazard" explaining the requirement that the risk be "unreasonable" necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers).

the CPSA than the FHSA,[156] the burden of proof is still substantial. Further, the Commission is again required to rely upon voluntary consumer product safety standards whenever compliance with voluntary standards would eliminate or adequately reduce the risk of injury.[157]

As discussed above, under both the FHSA and the CPSA, the CPSC must be able to support their findings as to toxicity with substantial evidence. Although it is not entirely clear whether the "substantial evidence" standard is actually stricter than the typical "arbitrary and capricious" standard of review of agency actions, some courts have found the standard more demanding.[158] In *Gulf S. Insulation v. Consumer Prod. Safety Comm'n*,[159] in striking down a consumer product safety rule banning Urea-Formaldehyde Foam Insulation (UFFI), the court found that "[C]ongress put the substantial evidence test in the statute because it wanted the courts to scrutinize the Commission's actions more closely than an 'arbitrary and capricious' standard would allow."[160] The *Gulf South Insulation* case exposes the burden on the CPSA and the relative risk allocation between industry and the consumer. In that case, the court held that the agency had failed to meet the burden of proof as to both acute irritant effects and carcinogenicity of UFFI. UFFI is a thermal insulation building material used that emits formaldehyde. The levels are highest for several months after installation, and then decrease gradually over a several-year period, eventually approaching ambient levels.[161] Following the results of a Chemical Industry Institute for Toxicology study linking formaldehyde exposure at high levels to nasal cancer in rats, the agency established

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156. *Gulf S. Insulation*, 701 F.2d at 1149-50 (the rulemaking procedures mandated by The Consumer Product Safety Act, specifically 15 U.S.C.A. § 2057, and the Federal Hazardous Substances Act, 15 U.S.C.A. §§ 1261-1276, differ substantially. The Consumer Product Safety Act provides for an informal rulemaking. 15 U.S.C.A. § 2057. In contrast, the Federal Hazardous Substances Act requires a formal hearing, complete with rules of evidence and the right to confront and cross-examine witnesses. 15 U.S.C.A. § 1262(a)(2)).

157. 15 U.S.C.A. §§ 2056(b), 2058(d) (West 2008).

158. Holly E. Petitt, Comment, *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, 425 (2000) (citations omitted).

159. 701 F.2d 1137.

160. *Id.* at 1142.

161. *Id.* at 1140.

the Federal Panel on Formaldehyde, a group of sixteen scientists from various government agencies, to evaluate the Chemical Institute findings. The panel concluded that the Chemical Institute study was valid and that formaldehyde should be presumed to pose a carcinogenic risk to humans. However, in the face of conflicting evidence submitted by the defendants and noting the element of doubt with respect to formaldehyde levels, the court reasoned that finding could not "authenticate the use of the study's results, and only those results, to predict exactly the cancer risk UFFI poses to man."[162] Although the court agreed with the agency that the epidemiologic studies cited by the industry do not demonstrate conclusively that formaldehyde poses no cancer risk to man, it concluded that the commission failed to satisfy the substantial evidence test.[163] In 1995, long after the conclusion of this failed agency effort at regulation, the International Agency for Research on Cancer (IARC) concluded that formaldehyde is a probable human carcinogen. In a reevaluation of existing data in June 2004, the IARC reclassified formaldehyde as a known human carcinogen.[164] It is not possible to know if this case would have been resolved differently if this information had been known previously, but it is clear that burden of uncertainty weighed in favor of industry.

Under the FHSA, in addition to proving toxicity, the CPSA still must also show that the product may cause substantial injury as used by the consumer. There must be the potential that persons are exposed to the substance, that the substance can enter the body, and that there is a significant risk of an adverse health effect associated with the customary handling, and use of the substance.[165] Under the agency's guidelines, existence of an adverse health effect means that such exposure is above the "acceptable daily intake" (ADI).[166] Although the regulations do provide for a margin of safety, determining the acceptable daily intake is rife with uncertainty.[167] Adding to

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162. *Id.* at 1146.

163. *Id.* at 1147.

164. National Cancer Institute, Formaldehyde and Cancer: Questions and Answers, http://www.cancer.gov/cancertopics/factsheet/risk/formaldehyde (last visited Feb. 27, 2009).

165. Hazardous Substances and Articles; Admin. and Enforcement Regulations, 16 C.F.R. § 1500.135(d) (2008).

166. 16 C.F.R. § 1500.135(d)(4).

167. 16 C.F.R. § 1500.135(d)(4) (For carcinogens the ADI is that exposure of a toxin that is estimated to lead to a lifetime excess risk of one in a million. The regulations state that due to the difficulties in using a numerical risk assessment

that uncertainty is the uncertainty of actual exposure levels. The CPSC's decision on phthalates reflects the type of considerations that may come into play in this approach. In 1998, the National Environmental Trust and 11 other organizations petitioned the CPSC to initiate a rulemaking to ban PVC from all toys and products intended for children five years of age and under and issue a national advisory on the health risks allegedly associated with PVC toys and products.[168] The Commission convened a Chronic Hazard Advisory Panel to assess the health risks of exposure to diisononyl phthalate (DINP), the plasticizer most commonly used in flexible vinyl toys.[169] The Panel reviewed and commissioned studies measuring migration of phthalates and estimating the time children spent mouthing products containing phthalates.[170] It issued its final report to the CPSC in June 2001.[171] It determined an "acceptable" daily intake of DINP, found that a child would have to mouth DINP-plasticized toys for 75 minutes or more per day in order to pose a possible risk, and that children do not mouth these toys for such extensive periods. The Commissioners denied the petition for rulemaking on February 26, 2003 finding that "[f]or the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury,"[172] and noting that a survey of toys mouthed by children under the age of three shows that not all soft plastic toys contain DINP.[173] This conclusion avoids consideration of the possibility of multiple sources of

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method to determine risk for neurotoxicological or developmental/reproductive toxicants, the Commission is using a safety factor of ten from the lowest no observed effect level (NOEL) if the hazard is ascertained from human data, and 100 from the NOEL if the hazard is ascertained from animal data. If no NOEL can be determined, a safety factor of 100 will be applied to the lowest observed effect level (LOEL) where the hazard is ascertained with human data, and a safety factor of one thousand from the LOEL where the hazard is ascertained with animal data). *See also*, Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 119 (1988).

168. *See* Toy Indus. Ass'n, Inc., v. City and County of San Francisco, N.D. Cal., case no. 06 7111, Complaint for Declaratory Judgment and Injunctive Relief, at 8, citing Petition NO. HP 99-01.

169. *Id.* at 7, 14.

170. *Id.* at 10.

171. *Id.* at 12.

172. *Id.* at 17 (citing Letter from Todd Stevenson, Secretary, CPSC to Jeffrey Becker Wise, Policy Director, Nat'l Envtl. Trust, citing a 2001 finding, and additional studies).

173. *Id.*

exposure, the need to protect those children who may not behave like the majority, and whether the value of these products is "worth" the risk.

VII. HISTORY OF INACTION, AGAIN

As far back as 1977, the CPSC recognized that we need a product assessment scheme for carcinogens.[174] At that time, CPSC proposed a "Cancer Policy" that called for classification of chemicals into four categories based on the type of scientific data suggesting cancer-causing potential: Category A was to include those substances for which there are data from either human studies or long-term animal testing; Category B was to include those substances for which there are only data from short- term *in-vitro* studies; Category C substances were to include those for which there is only limited evidence of a cancer risk, as well as chemicals belonging to classes or families of chemicals known to cause cancer; and Category D was to include substances previously classified by CPSC into one of the other three classes but for which new data do not support the original indication of potential carcinogenicity.[175]

> CPSC's policy is that it should not permit known carcinogens to be intentionally added to consumer products if they can be absorbed, inhaled or ingested into the human system. Substances in Category A which can enter the human system will probably be banned. Substances in Categories B and C will be tested further. Pending test completion, CPSC may require point-of-sale warnings, labeling or mandatory record-keeping by manufacturers and distributors. CPSC will not take any regulatory action on substances in Category D but will continue to monitor any new information.

At the time of publication of this policy, CPSC had taken action against four potential carcinogens: aerosols containing the chemical vinyl chloride, the flame-retardant chemical TRIS in children's

174. Press Release, U.S. Consumer Prod. Safety Comm'n, CPSC Adopts Cancer Policy (June 8, 1978), *available at* http://www.cpsc.gov/CPSCPUB/PREREL/prhtml78/78044.html.

175. *Id.*

sleepwear, and artificial ashes and patching compounds containing asbestos. Consumer products containing benzene had been proposed to be banned.[176] That same year, 1977, Consumer Product Safety Commission (CPSC) Chairman S. John Byington speaking before a group of medical alumni, Byington said:

> The nation must reach agreement on the validity of certain screening procedures for carcinogens, as well as premarket testing and analysis of scientific and socio-economic trade-offs. More importantly, there must be leadership not only within the government but also among the American people to give this problem the priority attention it deserves.[177]

No significant progress has been made to date. The Commission's 2005 staff of 446 was less than half its size in 1980,[178] and its regulatory list of banned hazardous substances remains short with restrictions on chemical compounds concerning only carbon tetrachloride, sodium and/or potassium hydroxide in liquid drain cleaners, soluble cyanide salts, lead compounds, asbestos, and vinyl chloride.[179] The Commission's workforce, as reported in 2007, had shrunk fifteen percent since 2004, and, according to one of its commissioners, it was in the midst of a dramatic "downsizing and dismantling" in 2007.[180]

This year, with the recently enacted CPSC Reform Act[181] there is a change in direction. The CPSC Reform Act will give the Commission a significant boost in funding and additional statutory

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176. *Id.*

177. Press Release, U.S. Consumer Prod. Safety Comm'n, CPSC Chairman Calls on Medical Profession To Support Nat'l Policy on Carcinogen (May 11, 1977), *available at* http://www.cpsc.gov/CPSCPUB/PREREL/prhtml77/77047.html.

178. Albert Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 369 (2007), (citing SUSAN DUDLEY & MELINDA WARREN, UPWARD TREND IN REGULATION CONTINUES: AN ANALYSIS OF THE U.S. BUDGET FOR FISCAL YEARS 2005 AND 2006 21 tbl. A-3 (George Mason Univ., Wash. Univ.) (2005).

179. 16 C.F.R. § 1500.17.

180. James Bothswell, *Toy Story: Timeout for Phthalates*, 39 MCGEORGE L. REV. 551, 565 (2008) (citations omitted).

181. Consumer Product Safety Improvement Act of 2008, H.R. 4040, 110th Cong. (2nd Sess. 2008).

authority. The legislation addresses a broad range of issues, [182] however, it does not address the problems fundamental to toxic substance regulation. The legislation will increase the Commission's budget which will rise from its current $80 million to $118 million starting in fiscal 2010, and growing to $136 million over five years.[183] It will also require the CPSC, subject to the availability of appropriations, to increase by at least 500 the number of its full-time employees and by at least 50 the number of its port-of-entry and overseas production facility inspectors.[184] Along with this considerable increase, Congress recognized the need for mandatory third party testing for children's products.[185] However, the new testing rules apply only where there is already a Consumer Product Safety Commission rule, ban, standard, or regulation already in place.[186] Congress also moved to enact a direct statutory ban on phthalates in children's products and child care articles,[187] but made no structural changes to regulatory system for reviewing other toxins in child care or other consumer products generally.

VIII. THE FEDERAL REGULATORY SYSTEM FOR CHEMICAL REGULATION GENERALLY, THE TOXIC SUBSTANCE CONTROL ACT IS UNQUESTIONABLY INADEQUATE

Toxic Substances Control Act (TSCA)[188] was enacted by Congress in 1976 to "regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on

182. *Id.* (Among other provisions, it will reduce the permissible levels of lead found in children's products, require third-party testing of certain types of children's products, establish a publicly available and searchable database on the safety of consumer products, provide whistleblower protection for industry employees, and increase the maximum civil penalty for the violation of consumer product safety standards).

183. Georgina Coolidge, *Bush signs consumer bill to cut lead in toys*, REUTERS, Aug. 15, 2008, http://www.boston.com/news/nation/washington/articles/2008/08/15/bush_signs_consumer_bill_to_cut_lead_in_toys/ (last visited Feb. 27, 2009); H.R. 4040 § 201.

184. H.R. 4040, CRS Summary.

185. H.R. 4040 § 40.

186. *Id.* § 102.

187. *Id.*

188. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601-2692 (1988 & Supp. V 1993)) (regulations promulgated pursuant to the Act are found at 40 C.F.R. Parts 702 through 775).

certain chemical substances."[189] For "chemical substances" within TSCA's regulatory reach, but also possibly regulated by other statutes, EPA must also first make a determination that it is in the public interest to protect against a risk under TSCA as opposed to under another Federal law (or laws) that it administers.[190] TSCA's regulatory reach is also restricted with the specific exclusion of certain chemical substances, including cosmetics and components of cosmetics.[191] TSCA regulates the manufacture, use, and disposal of other chemicals that pose a significant risk of injury to the environment and human health. However, TSCA creates such burdensome factual and evidentiary requirements that it has proven largely ineffective.

Under TSCA, chemical companies must only notify EPA of their intent to manufacture or import new chemicals and to provide any testing, environmental and health effects data that is available.[192] However, EPA estimates that most pre-manufacture notices do not include test data of any kind, and only about 15 percent include health or safety test data – such as acute toxicity of skin and eye irritation data.[193] Chemical companies are not required to develop and submit toxicity information to EPA unless the agency first promulgates a testing rule.[194] Except for chemicals produced in high volumes and posing a substantial risk of exposure,[195] TSCA provides the EPA with authority to impose testing requirements on chemicals only if the EPA can demonstrate by substantial evidence that the

189. *Id.*

190. 15 U.S.C.S. § 2605(C) ("In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act (15 U.S.C.S. §§ 2601 *et seq.*) and under such law (or laws), and (iii) the relative efficiency of actions under this Act [15 U.S.C.S. §§ 2601 et seq.] and under such law (or laws) to protect against such risk of injury").

191. 15 U.S.C. § 2602(2)(B)(vi); 21 U.S.C.S. § 321 (defining cosmetics).

192. 15 U.S.C. § 2604(d)(1)(B).

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

194. 15 U.S.C.S. § 2603 (2000).

195. 15 U.S.C. § 2603(a)(1)(B); *see also* High Productive Volume (HPV) Challenge, http://www.epa.gov/HPV/ (last visited Feb. 27, 2009) (involving voluntary agreements between the EPA and manufacturers to test chemicals produced in high volumes).

existing data are "insufficient" to assess the chemical and the EPA has a "more than theoretical" basis to suspect that the chemical "may present" a risk or hazard.[196] Finalizing test rules can take 2 to 10 years and require the expenditure of substantial resources.[197] The costly and time consuming burden of obtaining data is on EPA, not the chemical companies.[198] EPA assesses production volume and exposure using the pre-manufacture notices; however, chemical company estimates of a production volume and anticipated uses do not generally have to be amended accept in the few cases where EPA promulgates a rule determining that a use of a chemical constitutes a significant new use.[199] EPA has authority to promulgate rules which require chemical companies to submit lists or copies of any *existing* health and safety rules to EPA.[200] Chemical companies must also to report any information to EPA that reasonably supports a conclusion that a chemical presents a substantial risk of injury to health or the environment.[201] However, EPA has required testing of fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979.[202]

After obtaining test data, TSCA places the burden of proof on EPA to show that a chemical poses an "unreasonable risk" before EPA can act to regulate its production or use.[203] The substantial evidence rule applies.[204] The test here is the same as that under the FHSA. The requirement that the risk be "unreasonable" involves a balancing test. "The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, off-

196. Chemical Mfrs. Ass'n v. U.S. E.P.A., 859 F.2d 977 (D.C. Cir. 1988) (Upholding a test rule and finding that, under § 4 of Toxic Substances Control Act (15 U.S.C.S. § 2603), EPA is empowered to issue test rule on health grounds where it finds "more-than-theoretical" basis for suspecting that chemical substance in question presents unreasonable risk of injury to health, considering the toxicity of the substance and human exposure).

197. General Acct. Office, Chemical Regulation, Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals, G.A.O. 07-825 (2007) at 9 (estimates by officials responsible for implementing TSCA).

198. *Id.*

199. Statement of John B. Stephenson, *supra* note 193, at 3; *see also* 15 U.S.C. § 2604(a)(2); 40 C.F.R. § 721 pt. E.

200. 15 U.S.C.S. § 2607(d) (2008).

201. *Id.*

202. Statement of John B. Stephenson, *supra* note 193, summary of findings.

203. 15 U.S.C.S. § 2605 (2008).

204. Corrosion Proof Fittings v. E.P.A., 947 F.2d 1201, 1213 (5th Cir. 1991).

sets the harm the regulation itself imposes upon manufacturers and consumers."[205] EPA must also choose the least burdensome requirement that will protect adequately against the risk.[206]

EPA's failed attempt to ban asbestos, a known carcinogen, exposes the difficulty of satisfying the statutory prerequisites. In *Corrosion Proof Fittings v. Environmental Protection Agency*,[207] the Fifth Circuit vacated EPA's asbestos rule due to insufficient data and calculations, as well as the difficulty of according weight to "unquantifiable" benefits.[208] The court required both costs and benefits to be discounted, including benefits measured in terms of human lives saved, and faulted EPA for equating the time of exposure with the time of latent injury.[209] The court also found that EPA failed to measure the costs and benefits over a long enough time frame. EPA's quantitative analysis spanned only 13 years, leaving unquantified the cost of injury to young workers who will still be at risk more than thirty years after EPA's analysis period had ended.[210] Among other deficiencies, EPA was also faulted for failing adequately consider improvements in the workplace, and to meet its obligation to calculate how many lives a less burdensome regulation would save, and at what cost.[211] Of most concern to the Court was EPA's failure to adequately evaluate less burdensome alternatives.[212] Also important was its failure to adequately evaluate substitute products.[213] Although unable to fully quantify the risks of possible alternatives,[214] EPA had concluded that substitute fibers appear to pose less hazard than this known carcinogen, that years would likely pass before experimental toxicological data are available to quantify or adequately evaluate the possible health effects of

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205. *Id.* at 1222.

206. 15 U.S.C.S. § 2605 (2008).

207. *Corrosion Proof Fittings*, 947 F.2d at 1201.

208. *See* Andrew Hanan, Note and Comment, *Pushing the Environmental Regulatory Focus a Step Back: Controlling the Introduction of New Chemicals Under the Toxic Substances Control Act*, 18 AM. J. L. & MED. 395, 415 (1992) (detailed analysis of decision).

209. *Corrosion Proof Fittings*, 947 F.2d at 1218.

210. *Id.* at 1218-19.

211. *Id.* at 1215.

212. *Id.* at 1229.

213. *Id.* at 1230.

214. Hanan, *supra* note 208, at 413 (citing 54 Fed. Reg. 29,481 (1989)) ("Regulatory decisions about asbestos which poses well-recognized, serious risks, should not be delayed until the risks of all replacement materials are fully quantified.").

substitutes, that it would take even longer to confirm any hazards, the risks that would need to be evaluated are themselves evolving as the industry is creating new substitutes, and the risks associated with other fibers are easier to control because the diameter size can be controlled.[215] Although noting that EPA did not have a duty to affirmatively seek out and test all possible substitutes, the court concluded that substitutes identified by interested parties that may present significant risks must be fully evaluated.[216] The EPA's effort failed under the substantial evidence test.

One commentator remarked: *[i]t is entirely possible that, at one level of practical scientific investigation, a reasonable conclusion could be drawn that a risk exists and is potentially large. To go to the next level of scientific investigation and actually calculate these risks with precision, however, may be completely impractical.*"[217] EPA reports that TSCA's legal standards for demonstrating unreasonable risk are so high that they have generally discouraged EPA from using its authorities to ban or restrict the manufacture or use of existing chemicals.[218] Since TSCA was enacted in 1976, EPA has issued regulations under the act to ban or limit the production of only five existing chemicals or groups of chemicals.[219]

IX. EUROPE'S LEAD, AGAIN A MORE PRECAUTIONARY APPROACH

The EU has recently revised its chemical control policy to create a single system for the regulation of new and existing chemicals through legislation known as Registration, Evaluation, and Authorization of Chemicals (REACH).[220] Reach is based on the principle that chemical companies – manufacturers, importers, and other entities in the supply chain – should ensure that the chemicals they manufacture, place on the market, or use, do not adversely affect

215. *Id.* at 413-14 (citing 54 Fed. Reg. 29, 483).

216. *Corrosion Proof Fittings*, 947 F.2d at 1230.

217. Hanan, *supra* note 208, at 416.

218. Statement of John B. Stephenson, *supra* note 193, summary of findings.

219. *Id.* at 2-3 (noting that TSCA's approach to trade secrets is also problematic. According to EPA officials, about 95% of the pre-manufacture notices for new chemicals contain some information claimed as confidential); *Id.* at 26-27 (stating TSCA restricts EPA's ability to share confidential information even with state officials or with officials of foreign governments. EPA may challenge confidentiality claims, but doing so is resource intensive.).

220. *Id.*

human health or the environment.[221] Under REACH, chemical companies must obtain authorization to use chemicals that are listed as chemicals of very high concern. Generally, to obtain such authorization, chemical companies need to demonstrate that they can adequately control risks posed by the chemical or otherwise ensure that the chemical is used safely. Information requirements with registration will vary according to the production volume and suspected toxicity of the chemical.[222] The application for authorization must also include an analysis of the technical and economic feasibility of using safer substitutes.[223] The EU is generally required to grant an authorization if the applicant meets the burden of demonstrating that the risks from the manufacture, use or disposal of the chemical can be adequately controlled. However, for certain very bioaccumulative chemicals and certain other chemicals that are carcinogens or reproductive toxins, the chemical company must demonstrate that the social and economic benefits outweigh the risks to receive approval.[224] REACH also places substantial restrictions on the types of data that chemical companies may claim as confidential,[225] and provides procedures for placing restrictions on chemicals that pose an unacceptable risk to health or the environment.[226]

Some of the information developed under REACH may be required to be disclosed to the EPA under the Toxic Substances Control Act (TSCA). There is significant concentration and integration between the European and U.S. markets with the nine top chemical companies based in the U.S.[227] In 2006, U.S. chemical exports to Europe were valued at over $45 billion, and imports from Europe were valued at over $79 billion.[228] However, if chemical companies initiate new chemicals in the U.S. before Europe, TSCA does not necessarily require submission of data later submitted to the EU.[229] Pre-manufacture notices of new chemicals must only submit available data. However, TSCA does require that chemical companies report any information to EPA that reasonably supports a con-

221. *Id.* at 18.
222. *Id.* at 15.
223. *Id.* at 23.
224. *Id.* at 23-24.
225. *Id.* at 27.
226. *Id.* at 24.
227. Michael McCoy et al., *Facts and Figures of the Chemical Industry*, 85 CHEMICAL & ENGINEERING NEWS 27 (2007).
228. *Id.*
229. 15 U.S.C.S. § 2604(d)(B) (2008).

clusion that a chemical presents a "substantial risk" of injury to health or the environment.[230]

X. TSCA, EXISTING PROPOSALS FOR REFORM

As recognized in recent reports from the General Accounting Office, TOSCA would require major changes to become effective to protect against the risks of toxic chemicals.[231] The GAO's proposed reforms are consistent with the recent legislative action in the European Union. In its August 2007 report, the GAO suggested that Congress consider revising TSCA to place more of the burden on industry to demonstrate that new and existing chemicals are safe, and to set specific deadlines or targets for the review of existing chemicals.[232] The GAO suggested that some of the burden could be shifted by requiring industry to test new chemicals based on substantial production volume and the necessity for testing, and to notify EPA of significant increases in production, releases, and exposures or of significant changes in manufacturing processes and uses after new chemicals are marketed.[233]

The GAO report does not specifically address the issue of consumer warnings, or any possible expansion of TSCA that might include coverage for cosmetic products. Other issues that have been discussed for recommended reform include a clarification of concerns and priorities under the act to guide both the EPA and the courts, a standard that the social benefits of a given chemical must significantly outweigh its potential risk to both human health and the environment in order for production to be approved, and substitution

230. 15 U.S.C. § 2607(e).

231. Statement of John B. Stephenson, *supra* note 193, summary of findings.

232. Comparison of U.S. and Recently Enacted European Union Approaches to Prot. against the Risks of Toxic Chemicals, *supra* note 197, at 42-43.

233. *Id.* (The report also suggested that Congress take action to limit confidentiality claims by clarifying that health and safety data cannot be claimed as confidential business information, requiring substantiation of confidentiality claims, limiting the length of time for which information may be claimed as confidential without reaffirming the need the confidentiality, establishing penalties for false filing of confidentiality claims, and authorizing state and foreign governments to have access to confidential business information where they have a legitimate need and can adequately protect against unauthorized disclosure).

of the arbitrary and capricious standard of review for the substantial evidence test.[234]

On May 20, 2008, the Kid-Safe Chemicals Act[235] was introduced in the House. If ultimately passed, it would amend TSCA to reduce exposure of children, workers, and consumers to toxic chemical substances. The proposed legislation is premised on the finding that "a fundamental overhaul of chemical management in the United States is needed to build a nontoxic environment for the children of the United States."[236] However, the legislation as currently proposed does not amend the definition of chemical substances regulated under TSCA and thus would not apply to cosmetic products, or components of those products. The proposal establishes safety standards and requires the review of existing chemicals on a priority basis.[237] The proposal places the burden of proof on industry to establish that the chemical substance meets the safety standard.[238] Industry would also be required to submit and update all reasonably available information.[239] No new chemical substances would be allowed to be distributed in commerce unless the government determines that the manufacturer of the chemical substance has established that the chemical substance meets the safety standard.[240]

XI. NON-ESSENTIAL CONSUMER PRODUCTS, A CASE FOR CHANGE: A LOW RISK THRESHOLD, INDEPENDENT TESTING, AND DISCLOSURE

In the context of nonessential consumer products where vulnerable populations are exposed to unknown risks, the procedural and evidentiary standards are excessive, and the threshold for risk is unreasonably high. The recent decision in Congress, voting in favor

234. Hanan, *supra* note 208, at 416-17 (also proposing mandatory testing of all new chemicals that contain a potential risk to human health and the environment. If a new chemical, presented to EPA in a PMN, is suspected of having any potential deleterious effect on human health or the environment from its intended or possible uses, EPA should require adequate testing. EPA should vary the testing standards to match the potential risk foreseen).

235. Kid-Safe Chemicals Act of 2008, H.R. 6100, 110th Cong. (2008).

236. *Id.* at § 2.

237. *Id.* at § 501(4), (5).

238. *Id.* at § 502.

239. *See* CRS summary on Kid-Safe Chemicals Act of 2008, H.R. 6100, 110th Cong. (2008) http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR06100:@@@D&summ2=m& (last visited Feb. 27, 2009).

240. *Id.*

of a statute directly banning phthalates in children's products and child care articles,[241] bypasses the procedural and evidentiary hurdles, but only for phthalates, and only for certain products. This is important legislation, but phthalates are not the only chemicals potentially affecting our children, and this legislation does not address the issue of phthalates from other sources, including cosmetic products. A statutory approach requiring congressional action to regulate toxins in consumer products on a chemical by chemical basis is ultimately ineffective given the size of the toxic universe and the possibility of multiple sources of exposure. As discussed above, there are an estimated 87,000 chemicals awaiting an evaluation of endocrine associated risks.[242] We have no system in place to monitor which of these chemicals are making their way into our children's toys and cosmetic products or their potential hazard. As one commentator reflected:

> [C]itizens are experimental subjects in that de factor they become one of the main testing grounds for the toxicity of products, but without having authorized or consented to the exposures. Moreover, to the degree that actual practice requires that human harm must be scientifically demonstrated before regulatory action is justified and exposures reduced or eliminated, citizens are guinea pigs in the more robust sense.[243]

In this post-market regulatory system, it is our children who must bear the cost of uncertainty until and unless it is resolved.

Proving toxicity and exposure is a difficult process. Animal studies may take up to 7 years.[244] There may be questions as to the

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241. CPSC Reform Act (Engrossed Amendment as Agreed to by Senate), H.R.4040, 110th Cong. (2d Sess. 2008) http://thomas.loc.gov/cgi-bin/query/F?c110:5:./temp/~c110oTnEDz:e144115: (last visited Feb. 27, 2009).

242. U.S. E.P.A., Endocrine Disruptor Screening Program, http://www.epa.gov/scipoly/oscpendo/pubs/prioritysetting/index.htm (last visited Feb. 27, 2009).

243. Carl F. Cranor, *Symposium: Do You Want To Bet Your Children's Health On Post-Market Harm Principles? An Argument For A Trespass Or Permission Model For Regulating Toxicants*, 19 VILL. ENVTL. L.J. 251, 313 (2008).

244. *Id.* at 283 (citing Carl F. Cranor, *Toxic Torts: Science, Law and the Possibility of Justice* 96-97 (Cambridge Univ. Press, 2006) (providing description of different types of epidemiological studies)). *See also* Kenneth J. Rothman & Sander Greenland, *Modern Epidemiology* 73-74, (Lippincott Williams & Wilkins 2d ed. 1998) (discussing different types of epidemiological studies).

comparability of exposure levels, and the comparative sensitivity of animals and humans. It is difficult, if not impossible, to use observations of dose-response correlations in animals to determine at what level of exposure a person may be affected.[245] There is also the difficult issue of possible multiple sources of exposure and the potential interaction of different chemicals as they mix into the pool of contaminated human blood. Even when some segment of the human population has been exposed to a potentially toxic substance, epidemiologists may be unable to determine cause and effect relationships due to other factors that can adversely affect an individual's health. Endocrine disrupting chemicals in particular are hard to evaluate and animal studies may not be able to capture behavior changes, intergenerational effects, or other subtle or difficult to identify risks. The science related to measuring and demonstrating endocrine disruption is relatively new and validated testing methods are still being developed. Endocrine disrupting chemicals defy the rules of classic toxicology.[246] They have been identified as having an unusual U-Shaped dose response curve where negative health effects increase as the dosage increases, but above a certain dose, the effects diminish, possibly due to an overloading of the hormonal system that causes it to "shut off," effectively reducing or preventing the dysfunction.[247] Further these chemicals can have opposite effects at different stages of an organism's development, and there may be no threshold effect, that is most hormones in the blood stream occur in dilute concentrations and even very dilute levels of endocrine disrupting chemicals can prove dangerous.[248] The low dose problem makes it difficult to set permissible exposures, and risk assessment is complicated by the fact that fertility or reproductive disorders are much more difficult to detect in laboratory animals than cancerous tumors.[249] Further, because endocrine disrupting chemicals are thought to have synergistic effects, chemical-by-

245. Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. REG. 89, 119 (1988).

246. Jason M. Vogel, *Tunnel Vision: The Regulation of Endocrine Disruptors*, 37 POL'Y SCI. 277, 281-82 (2004), *available at* http://www.springerlink.com/content/q45q1618427p/?p=fd36e7ab7be0403c907e6d4eed45392d&pi=14.

247. *Id.*

248. *Id.*

249. Noah Sachs, *Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals*, 24 COLUM. J. ENVTL. L. 289, 317 (1999).

chemical screening might be inadequate.[250] Also complicated, is the possibility of intergenerational effects. Diethylstilbestrol (DES), a synthetic estrogen given to pregnant woman in the early 1970's damaged the children's reproductive system and caused vaginal cancer later in lives of the children.[251]

The controversy over BPA is informative as to the difficulty of regulating endocrine disrupting chemicals and the importance of clear standards and independent testing. Approved as a food contact substance,[252] BPA has received more consideration than many other chemicals in the marketplace, yet politics, risk thresholds, and uncertainty have kept it on the market. The FDA has issued regulations approving, for food-contact uses, several polymers (such as polycarbonate) and other substances made with BPA.[253] Before new food additives are placed on the market, a company must first prove to the FDA that the food additive is safe for human consumption at the intended level of use.[254] According to the legislative history, the relevant standard is one of "reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal."[255] In this case, however, even when working with this relatively conservative standard, the relevant question may be: whose scientists?

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250. *Id.*

251. U.S. E.P.A., Endocrine Disruptor Screening Program, *What Are Endocrine Disruptors?*, http://www.epa.gov/endo/pubs/edspoverview/whatare.htm (last visited Feb. 27, 2009).

252. *See generally* 21 U.S.C.S. §§ 301-399 (2008); 21 U.S.C.S. § 321(s) (2008) ("The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use).").

253. Citikids Baby News, Inc. v. City of San Francisco, No. CGC-06-457303, at 9 (Cal. App. Dep't Super. Ct. filed Oct. 25, 2006) (Application for Preliminary Injunction) [hereinafter *Citikids*] ("BPA has the chemical name 4,4'-isopropylidenediphenol. It is identified in various forms and for different uses as an approved direct and indirect food additive." (citing 21 C.F.R. §§172.105(a), 175.105, 175.300, 175.380, 177.1440, 177.1555, 177.1580, 177.1585, 177.1595, 177.1655, 177.2280, 177.2420, 177.2600, and 21 C.F.R. §178.2010)).

254. 21 U.S.C.S. § 348 (2008).

255. Report of the Senate Committee on Labor and Public Welfare, S. Rep. No. 2422, 1958 U.S.C.C.A.N. 5300., 5301; *see also* 21 C.F.R. section 170.3(i).

In the case of BPA, industry has been accused of manufacturing doubt as to its risk for some time.[256] "A 2005 analysis of the BPA literature revealed a clear pattern of bias in reporting results: the funding source often determined the findings. Of 115 studies on health effects of BPA, 94 government-funded studies conducted in academic laboratories in Japan, Europe, and the United States found adverse effects at low dose exposure. None of these studies funded by industry reported adverse effects."[257] Responding to an inquiry from a California Assemblyman in 2005, the FDA wrote:

> FDA is aware of several reports stating that bisphenol-A has estrogenic activity and that, in spite of evidence that bisphenol-A is harmless when consumed by animals in amounts far (orders of magnitude) higher than humans would consumer, such estrogenic activity persists at very low doses. However, other reports appear to dispute any reason to expect harm at the low exposures that humans experience. FDA continues to closely follow the research in this area. However, based on all the evidence available at this time, FDA sees no reason to change its long-held position that current uses with food are safe.[258]

In 2006, the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (CERHR) published a draft advisory panel report that was heavily criticized by scientists for having failed to include important studies, and inappropriately discounting the value of others.[259] The report was allegedly written largely by an outside consultant hired by the National Institute of Health (NIH) who was fired in 2007 after public disclosure of its conflicts of interest with the regulated industry.[260] Yet, still in February 2008, the FDA was relying on only two studies, both sponsored by the American Plastics Council to base its decision as to the

256. *See* BREAST CANCER FUND, STATE OF THE EVIDENCE (2008), *supra* note 67, at 52.

257. *Id.*

258. *Citikids*, *supra* note 253, at 10 (citing letters from FDA (Apr. 6, 2005 & Nov. 28, 2005)).

259. Jane Houlihan et al., *Timeline: BPA from Invention to Phase-Out*, ENVTL. WORKING GROUP, Apr. 2008, http://www.ewg.org/reports/bpatimeline (citing NAT'L TOXICOLOGY PROGRAM, DRAFT EXPERT PANEL REPORT (2006), http://cerhr.niehs.nih.gov/chemicals/bisphenol/Bispehnol_A_Draft_Report.pdf).

260. *Id.*

safety of BPA.[261] FDA has held to this position despite the 2007 report released from a panel sponsored by the National Institute of Environmental Health Sciences (NIEHS), a division of the National Institutes of Health (NIH).[262] The panel, composed primarily of academic investigators specialized in BPA research concluded that the "wide range of adverse effects of low doses of BPA in laboratory animals [within the range of human exposure] exposed both during development and in adulthood is a great cause for concern with regard to the potential for similar adverse effects in humans."[263] The panel explained that "BPA alters 'epigenetic programming' of genes in experimental animals and wildlife.... These organizational effects...persist into adulthood, long after the period of exposure has ended. Specifically, prenatal and/or neonatal exposure to low doses of BPA results in organizational changes in the prostate, breast, testis, mammary glands, body size, brain structure and chemistry, and behavior of laboratory animals."[264]

Following the release of a new National Toxicology Program report, Representative John Dingell, Chairman of the Committee on Energy and Commerce, called on FDA to reconsider the safety of BPA in products for infants and children.[265] In its draft report released in Spring 2008, the National Toxicology Program concluded:

> The scientific evidence that supports a conclusion of *some* concern for exposures in fetuses, infants, and children comes from a number of laboratory animal studies reporting that "low" level exposure to bisphenol A during development can cause changes in behavior and the brain, prostate gland, mammary gland, and the age at which females attain puberty. These studies only provide limited evidence for adverse effects on development and more research is needed to better understand their implications for human health. However, because these effects

261. *Id.* (citing letter from Steven R. Mason, Acting Assistant Commissioner for Legislation, to Congressman John D. Dingell, Chairman of Committee on Energy & Commerce (Feb. 25, 2008), *available at* http://energycommerce.house.gov/Investigations/Bisphenol.022508.respto011708.HHS.ltr.pdf).

262. Frederick S. vom Saal et al., *supra* note 26.

263. *Id.* at 136.

264. *Id.* at 134.

265. Committee on Energy and Commerce, News Release, May 6, 2008, *available at* http://energycommerce.house.gov/Press_110/110nr277.shtml.

> in animals occur at bisphenol A exposure levels similar to those experienced by humans, the possibility that bisphenol A may alter human development cannot be dismissed.[266]

Despite this finding that there is cause for concern, on August 15, 2008, FDA issued a draft assessment reaffirming its finding as to the safety of BPA for use as a "food additive."[267] Whether this will be the final position of the government on this matter is unclear at this point. The ongoing nature of controversy is reflected in the Washington Post's recent reporting that this finding stands in contrast more than 100 studies performed by government scientists and university laboratories finding health concerns associated with BPA.[268]

Without a clear and conservative definition of "safe," and adequate testing and labeling standards, the U.S. regulatory system is creating an unacceptable burden on the unknowing consumer. In the context of non-essential consumer products where there is a significant potential for a toxic exposure, some cause for concern ought to be enough to restrict use of the chemical pending further study as to its safety. Testing standards are especially important in face of the current disincentives for industry to engage in testing considering, cost, time, and potential litigation and reporting requirements.[269] The long delay from exposure to injury and the difficulty of linking latent adverse effects with the product and its manufacturer create a situation where the market is not likely to discriminate between a tested and an untested product.[270] We must also require that the testing be done by independent companies. Congress, in the recent CPSC Reform Act,[271] recognized this need for mandatory third party

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266. NATIONAL TOXICOLOGY PROGRAM, DRAFT NTP BRIEF ON BISPHENOL A, 37 (2008), *available at* http://energycommerce.house.gov/Press_110/Draft NTPBriefonBPA.041408.report.pdf.

267. Christopher Lee, *FDA Draft Report: No Risk from BPA in Food Containers*, WASH. POST, Aug. 16, 2008, at A02 (citing NATIONAL TOXICOLOGY PROGRAM, DRAFT NTP BRIEF ON BISPHENOL A (2008)).

268. *Id.* (noting "studies linking the chemical to prostate and breast cancers, diabetes, behavioral disorders such as hyperactivity and reproductive problems in lab animals").

269. *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 784-88 (1997).

270. *Id.* at 784.

271. *See* CPSC Reform Act (Engrossed Amendment as Agreed to by Senate), H.R.4040, 110th Cong. (2d Sess. 2008).

testing for children's products, but as discussed above, only in the limited context where there is a Consumer Product Safety Commission rule, ban, standard, or regulation already in place.[272] We must now expand this standard.

When people are making choices to buy nonessential consumer products, they are weighing the cost in dollars and the benefit of the product. Any health risk hidden in the equation is not being balanced by the consumer. In the case of cosmetics, in addition to a direct risk to children from the use of these products, the risks may also be disproportionately born by women of child bearing age and thereby pose a risk to fetuses and nursing infants. In the case of toys and child care articles, there is no doubt that the risk is disproportionately born by children. Consumers should not unknowingly be subjected to chemical contamination from such products. It is wrong and misleading to market products for children without disclosing the possibility of toxic exposure to carcinogens, mutagens and endocrine disrupting chemicals. Where there is cause for concern, we should take regulatory action. Given the difficulty of evaluating toxicity, and the capacity of industry to manufacture uncertainty, the threshold for acceptable risk must be low, independent testing required, and any remaining risk clearly disclosed. As one commentator suggested, chemical invasions of our blood should perhaps be considered a wrong, a "trespass" (regardless of whether they pose a "risk"), with any resulting risks or harms viewed as additional wrongs.[273]

XII. CONCLUSION – POLICY RECOMMENDATIONS

It is clear that our system needs a major overhaul, and there are economic benefits to achieving some consistency with the European approach. According to the impact assessment on the European proposal, overall costs for duplication of effort if cosmetic products are developed for both the US and EU markets are 25% higher than for developing products for only one of these markets. These costs mount disproportionately if reformulation of a complex formula is

272. *See id.* at § 10.

273. *See* Cranor, *supra* note 243, at 252.

required.[274] Undoubtedly similar considerations apply to toys and child care articles. We should develop our regulatory system with an eye toward achieving some consistency. At the forefront, TSCA should be amended to require premarket testing and review of new chemicals, and testing of existing chemicals on a priority basis as now required by Europe's REACH legislation. Since this effort is already underway in Europe, the legislation should be drafted so as to require review and sharing of information between Europe and the USA. TSCA must also be extended to include coverage of chemicals that will be used as components of cosmetic products. Data gathered through this premarket testing program could be used to establish a database that could later be used to help inform decisions under the CPSA, the FHSA and the Cosmetic Act. These acts must be amended to evaluate chemicals in products that may not yet have been evaluated under an amended TSCA and to allow for a consideration of the value of the consumer product to the consumer in relation to the risk it poses.

The European ban for identified, known and probable carcinogens in cosmetic products should be generally replicated and extended to include toys and child care articles in addition to cosmetics. The current European proposal with the possibility for exceptions does not seem unreasonable, as long as those exceptions do not override the overall scheme, and the burden of proof is on the manufacturer. As discussed in the European risk assessment, a ban may lead to inconsistencies in regulatory regimes for different products. However, we should not allow a toxin in a cosmetic product just because it has not yet been banned under another regulatory regime. There may also be arguments for a different regulatory standard where product availability is important. In the context of toys and cosmetic products, the risk threshold should be low, commensurate with the societal value of the product, and the vulnerable populations potentially affected.

As is currently proposed in Europe, we also must ensure that there are clear standards as to required safety assessments, and a clear definition of what will be considered "safe." The safety evaluation should take into consideration only health, independent of any consideration of cost to industry. Cost-benefit analysis here, where the

274. *See* COMMISSION OF THE EUROPEAN COMMUNITIES, WORKING PAPER: IMPACT ASSESSMENT REPORT ON SIMPLIFICATION OF THE "COSMETICS DIRECTIVE" supra note 122, at 16.

human and societal cost is so difficult to evaluate and quantify, favors industry while unfairly burdening future generations. The "unreasonableness" balancing test under the CPSA and TSCA, which weighs the cost to industry, may find some justification in the context of regulating consumer products that serve important functions in our society, but it is generally inappropriate in the context of toys and cosmetics. Where we are talking about nonessential products, we are talking about an industrial activity that we don't need. We should not look at this as a loss, but as an opportunity to redirect industry to create nontoxic alternatives, to shift resources into another area that would be more socially productive. Given the possibility for new formulations and products, it would take a crystal ball to know whether there would in the end be any significant cost to society in terms of jobs or economic loss following the banning of hazardous substances in nonessential products. At a minimum, consumers must be informed of any risk so that they may make their purchasing decisions accordingly. Given rising cancer rates and other health concerns, we should, at a minimum, have the choice to reduce our chemical blood burden and that of our children where it is relatively easy to do so.

Following the European approach to cosmetic regulation (with the proposed amendment to the absolute ban for category 1 and 2 chemicals), we should consider a conditional ban on known, probable, and also possible human carcinogens, human neurotoxins, and human developmental or reproductive toxins in children's toys, childcare articles, and cosmetics that may be absorbed, inhaled or ingested, unless the government can make an affirmative finding of safety. If the government must find support for an affirmative finding of safety before allowing the product on the market, the substantial evidence rule would work in favor of consumer protection. In the absence of substantial evidence as to safety, we should remove the chemicals from the market. Given the difficulty of establishing acceptable daily intake, and evaluating all sources of exposure, and the importance of protecting all children (including those who may mouth toys more than others), we should consider a higher threshold, a presumption against a finding of safety for known and probable carcinogens, mutagens and endocrine disrupting chemicals. Proof should be required beyond a reasonable doubt. In cases where only "possible" carcinogens, mutagens and endocrine disrupting chemicals may be absorbed, inhaled or ingested, we could remove the presumption against a finding of safety, but still require "reasonable certainty" that there is "no cause for concern." In such cases,

we should not equate this finding with one of safety, but recognize the uncertain nature of the risk. Where there is a potential exposure to possible carcinogens, mutagens and reproductive toxins, we should require a finding that the societal value of the product to the consumer exceeds the potential risk. In the end, however, the choice should be that of the consumer. In all cases, there should be full disclosure of potential exposure to any chemicals that may cause cancer, reproductive harm, or mutagenicity, including all known, probable and possible carcinogens and endocrine disrupting chemicals. This notice should apply where there is a potential for exposure, regardless of any findings as to safety. We should reject the uninformative type of generic warning. The notice should provide information to the consumer that, in using the product, potentially toxic chemicals may be ingested, inhaled or absorbed (as the case may be) and increase the risk of cancer, reproductive harm or mutagenicity. The warning should be explicit as to any risk to children and woman of child bearing age.

In the interest of the consumer, we should consider a substantial pre-market review process with independent testing required. The European proposal for cosmetic regulation with a pre-market toxicity assessment requirement, coupled with the possibility of post-market enforcement is an interesting proposal. This would perhaps operate similarly to our tax system where review is threatened, but not guaranteed. Success may depend on the resources committed to the program. However, given the obvious superiority from the standpoint of consumer protection of a premarket approval process, this possibility should be more closely evaluated. In rejecting a formal premarket approval scheme for cosmetics, the EU legislative report explains that the disproportionate risk posed by cosmetic products does not justify such a regulatory approach given the following factors: cosmetic products are not intended to be ingested, inhaled or injected, a premarket approval system would be highly burdensome both for regulators and the industry considering the 60,000 new product formulations a year on the EU market; it would be a hindrance to innovation and to new products entering the market; and this approach would run counter to other international regulatory systems.[275] However, even though cosmetics are not ingested, inhaled or injected, they may be absorbed into the body. We should not so quickly dismiss the uncertain risk of nonessential products;

275. *Id.* at 35.

indeed the very purpose of the regulatory scheme is to evaluate that risk. We must also consider the other side of the equation. Cosmetic products and toys may pose a lesser risk that some other products like food contact substances, but they may also be less important products. In reducing our risk to chemical exposure, we must ask whether the product is important enough to risk its potential contribution to our chemical burden and that of our children.

The cost to industry may not be extreme. The European cosmetic proposal discussed the fact that REACH is going to ease access to information on chemicals as 70% of all cosmetic ingredients are going to be affected by its registration/information obligation as they are produced in quantities greater than 1 ton per year.[276] To further reduce the regulatory burden, we could consider the possibility of creating an abbreviated process for the review of new formulations that include chemicals or mixtures that have already been subject to review. Although the European cosmetic legislative impact assessment notes that there are 60,000 new cosmetic formulations a year, it does not disclose the extent to which they differ. Safety determinations could perhaps be split into different levels of review as appropriate. A very basic or "minimal" level of research might consist of one or more short-term laboratory tests designed to determine if a product is likely to constitute a serious hazard.[277] Consideration should be given to EPA's Endocrine Disruptor Screening Program which uses a tiered approach for determining whether a substance may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, androgen, or thyroid hormones. The program includes standards for Tier 1 Screening, Tier 2 Testing, and hazard assessment.[278] EPA has recognized the importance of reviewing chemicals in establishing this program. However, without shifting more of the burden to industry to complete the review and analysis of suspected endocrine disrupting chemicals, we are moving forward at a snail's pace. In all fairness to the next generation, we

276. *Id.* at 43-44.

277. *See* Wagner, *supra* note 269, at 780-82 (noting the availability of testing standards that have already been created by governmental bodies); *see also*, Meghan E. Gallagher, *Toxicity Testing Requirements, Methods and Proposed Alternatives*, 26 ENVIRONS ENVTL. L. & POL'Y J. 253 (2003).

278. U.S. EPA, Endocrine Disruptor Screening Program, EDSP Phases, http://www.epa.gov/endo/pubs/edspoverview/components.htm#1 (last visited Feb. 27, 2009).

must move for reform to shift the burden away from the unknowing consumer to the industry profiting from the uncertainty.